Leading learning and skills

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Analysis of Skills Needs in Life Sciences Sector in Merseyside & Halton

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1. Executive Summary

The UK life science industry is the largest in Europe, second only to the United States. In Merseyside and Halton this sector represents a significant knowledge base, with over 80 companies employing approximately 5,000 people.

Operational skill requirements are a moving target, with new technologies presenting a constant challenge to companies to meet the ever increasing demand of changing manufacturing processes. In order to become competitive, the technical skills within the industry need to be regularly reviewed and updated to ensure the workforce is skilled appropriately. These skills are utilised by biotechnology, pharmaceutical and biopharmaceutical companies. Without this capability, there is a serious deficit in appropriate recruitment and retention as is highlighted by a national report, published in 2005 by the Association of the British Pharmaceutical Industry (abpi), emphasising the difficulty in recruiting good candidates in manufacturing disciplines.

To address this issue within Merseyside and Halton, a number of key stakeholder organisations agreed to specific actions required to raise life sciences' manufacturing skills capability.

MerseyBIO – the organisation responsible for leading the development of the sector in the area – commissioned this work to :

a) identify current competence in technical manufacturing skills;

b) highlight the future importance of these skills according to the industry;

c) map existing availability of specialist training to help address any gaps in these skills.

The research involved 33 companies in total, which amounts to 42.8% of all of those based in Merseyside and Halton and represents 2,895 employees. Of the 33 companies involved in total, 24 took part in the full survey and 9 companies responded to a condensed version of the questionnaire.

This work was approached through initial desk research to identify existing information on skills issues and to draw up a list of technical skills relevant to the sector. Companies were asked to rate the current level of competence in each skill between 1 and 10, with 10 being perfectly skilled.

A mean score was derived for each skill to allow for detailed analysis of the exact current skills requirements. Individuals were also asked to state how important they perceived each skill would be in the future. Mean importance was then analysed for each skill and mapped against the mean score.

The mean was a useful way of highlighting the average scores according to responses. As the analysis dealt with a relatively small number of responses (24 companies) it has been difficult to derive any meaningful analysis on the distribution of results. However, the median was also established for each skill to highlight any skew. In the majority of cases, the median did not differ significantly from the mean.

The work involved company employees who have an overview of staff competence and also an understanding of the likely implications of any skills gaps. Training managers and Directors in smaller companies were also consulted.

A score of 7.00 was set at the level for which employers consider skills to be satisfactory in meeting their business requirements. Skills where the mean score was lower than this have been highlighted as areas of concern. Some of these skills are also considered to be increasingly important for the future. These skills have been highlighted as 'actionable' in that they are a priority for future development. They are presented in scatter diagrams for each level of staff in the main report: front line/operational staff; technical/supervisory staff; and managerial staff.

A number of companies also answered additional questions on their use of training and any issues experienced in accessing appropriate provision, particularly training sourced from external organisations.

Results

The interviews identified 98 skills for front line/operational staff, 51 for technical/supervisory staff and 29 skills for managerial staff (see appendices for list of skills).

Companies' Responses

The greatest proportion of skills gaps is evident for technical/supervisory staff. A total of 43.1% of the 51 skills are currently scored at a mean of below 7.00. 29.4% of all 51 skills are critical and require action, in that they will also be of significant future importance to the industry. When additional 'borderline' skills are considered, this figure rises to 37.3%.

These areas of concern are mainly related to: use of Statistical Process Control; identifying and addressing skills needs of staff; understanding of environmental considerations; regulation and validation

A quarter of the 98 skills used by front line/operational staff are also in need of development and 17.3% of these are actionable and critical (rising to one-third of skills if those borderline are included). These include understanding of the requirements of Good Manufacturing Practice and Good Laboratory Practice. Setting up and operating automated equipment and controlling process automation are also issues. Competence in effective virus growth and fermentation is also a concern.

According to responses from the 24 companies involved in the research, managerial staff are already skilled to a satisfactory level or above. Only two skills are considered to be in need of further action in terms of appropriate training. Measuring line efficiency and improving overall equipment effectiveness are both an issue. Managers also need to improve their understanding of potential hazards with airflow and filter sizes and the legislation regarding waste routes and environmental impact.

It is important to consider that managers have in most cases been commenting on their own skills and their colleagues at a similar level. Because of this, the overall proportion of skills that already meet business requirements should be treated with some caution.

Many areas of quality and regulation are currently a concern for life sciences companies in Merseyside and Halton. Quality issues are partly addressed by training appropriate staff in-house, which is the preferred method of training. Training on regulation requires external resourcing.

A number of factors are driving the sector nationally as well as regionally and at sub-regional level. These include: developments in automation and technology; increase in market competition; and changes in demand for products.

Despite concerns around the use of automation being expressed by companies, training in this area has been very low over the past 12 months, with just 4.9% of businesses training their staff in this area. Companies tend not to use structured training plans but do use training when the need arises and where time permits. Time and cost were highlighted by half of all companies involved in this research as issues for accessing and using training.

Surprisingly, half of the companies surveyed also deliver training to other companies in Merseyside and Halton. All of those consulted expressed that they have specialist knowledge that they could share with other businesses in the country. This includes knowledge in manufacturing processes and the production of specific products. However, funding would need to be made available to cover the release of staff to work with other companies.

Training provision

A number of local universities and private specialist providers offer a range of specialist skills development courses to companies within the sector. However, a few of the skills identified as areas of concern in this research do not appear to be covered very well by existing local provision. These include: process automation and use of Statistical Process Control (SPC); reviewing and making judgements on the effectiveness of processes; writing reports; environmental considerations; and conducting in-house inspections.

Companies' preferred methods of training include full-time courses attended through provision off-site and training delivered 'on the job', conducted a few days a week. Awareness and competence in regulation needs to be learned through work-based practice to ensure that these skills are fully developed.

Three quarters of the technical manufacturing skills required by life sciences companies are currently at a level that meets business requirements.

The remaining gaps including those for the future could be addressed through short vocational courses or more focussed job shadowing offered by Universities and other providers.

Immediate action is needed to ensure tailored training is in place locally to help companies address the needs identified. However, before this can be done, work is required to ascertain how they can best be supported in accessing such provision, both in terms of investing in training and in releasing staff where required. Companies also need to be made aware of the opportunities available to them.

A series of key recommendations have been made to help achieve this. These will involve input from a range of partners, including: the LSC, JET South Liverpool, life sciences companies, and providers of training.

The recommendations are :

- **Canvas local life sciences companies to quantify demand to help derive the scale of training required in Merseyside and Halton - through courses in priority areas such as process automation and use of Statistical Process Control.**
- **Consult with the local provider network – including the Universities – on their capacity to offer tailored training that addresses skills gaps in key areas.**
- **Ascertain where specific training may need to be introduced and whether the skills need can be targeted through short courses.**
- **Consult further with companies regarding their preferred methods of training and establish their awareness of any financial support available to them.**
- **Investigate the availability of financial resources to cover release of staff from companies to allow for the sharing of expertise with other businesses in the area.**
- **Sector Skills Councils, the LSC, JET and the Regional Skills Partnership should work to develop unitised and/or more flexible modes of learning for staff – this work should inform finalisation of the Sector Skills Agreements.**
- **Set in place targets for providers to ensure training is developed in line with standards - where this is funded by the LSC - and also request evidence that knowledge has been transferred to individuals.**
- **Consider separate focussed discussions with Universities to establish how modules can include a greater number of work related elements, delivered in a form that is of practical value to companies.**
- **Re-use skills scoring questionnaires with companies every 18 months to help benchmark any changes in the level of skill.**

Acknowledgements

Pye Tait Limited would like to thank the project Steering Group for their guidance in designing and completing the research. In addition, the team would like to thank the life sciences companies in Merseyside and Halton that contributed to this work.

The information presented in this report is the result of discussions with 33 companies and does not necessarily represent the views of all companies in the area.

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2. Introduction

2.1 Introduction

This report presents detail on the existing skills levels of staff working within life sciences companies in Merseyside and Halton. **MerseyBIO** – the organisation responsible for leading the development of the sector in the area – commissioned this work to help it:

a) identify current competence in technical manufacturing skills; and

b) map existing availability of specialist training to help address any gaps in these skills

MerseyBIO intends to use this detailed evidence base as a means of ensuring that there is a systematic programme of training available locally. This will be achieved in partnership with key bodies such as the Learning and Skills Council (LSC) for Greater Merseyside.

It is important to note that this work has focused on manufacturing skills only and excludes management development and leadership.

The Merseyside and Halton life sciences cluster consists of over 80 companies employing approximately 5,000 people with a further 2,000 employed in the science base of the region's universities, hospitals and research institutes.

The region is recognised as one of Europe's leading locations for biomanufacturing and more people in Merseyside go to work to produce biopharmaceuticals for a global marketplace than anywhere else in Europe.

In 2005, a study was commissioned by MerseyBIO, the Learning and Skills Council for Greater Merseyside and JET South Liverpool, into the skills needs requirements and gaps in training provision of the life science manufacturing sector in Merseyside and Halton.

This report provides a summary of the study and will be of interest and use to the sector itself as well as those concerned with meeting the training needs of the sector, including HE and FE Institutions.

The ability to recruit and retain staff is a notable feature of a successful life sciences cluster. In 2002, the Life Sciences Sector Steering Group for Merseyside identified the need for life science specific skills across different professional levels in the region. In particular, it was recognised that there was a growing demand and need for manufacturing skills consistent with the growing manufacturing capability. This was currently not being addressed by existing initiatives or providers of training and there was a real concern that this could jeopardise the future growth of the sector.

Whilst some specialist training had been introduced by the larger manufacturing companies in the region this was not available to smaller companies or individuals.

In order to ascertain the current and future needs requirements and the gaps in provision, a detailed skills capability and skills needs map of the sector, with a particular focus on manufacturing, was undertaken.

This report provides detail on the existing skills levels of staff working within life sciences companies in Merseyside and Halton. It highlights the current skills training and identifies both current and future skills gaps that will impact adversely on the sector. In particular, it identifies current competences in technical manufacturing skills and maps existing availability of current specialist training to help address any gaps in these skills.

The ultimate objective of this report is to provide partners with the information needed to develop and implement a systematic and comprehensive manufacturing training programme capable of addressing the current and future needs of the life science companies and organisations in the region.

It is important to note that this study has focused on manufacturing skills only and excludes management development and leadership.

2.2 Life Sciences

Industry Snapshot

The UK life science industry is the largest in Europe, second only to the United States, and accounts for one third of Europe's early-stage life science companies. The sector employs people in highly skilled, high value-adding jobs at every level and the gdp impact of jobs in the sector is calculated to be 3.5 times that of jobs in the general economy.

The life science industry is of critical importance to UK national economic and scientific strategies, and represents one of the most important emerging markets of the 21st century.

Merseyside and Halton

Merseyside and Halton possess a significant cluster of life science companies encompassing a number of different business areas including biopharmaceutical and pharmaceutical manufacture, diagnostics, clinical foods and nutraceuticals.

Liverpool is recognised as one of Europe's leading location for biomanufacturing: a fact reflected by the cluster of biomanufacturing companies in the Speke area, including global companies such as Novartis Vaccines (formerly Chiron Vaccines), Eli Lilly & Co Ltd and MedImmune.

Novatis Vaccines (formerly Chiron Vaccines) specialises in manufacturing vaccines and employs approximately 650 staff at its site in Speke.

Eli Lilly & Co. manufactures medical drugs and vaccines primarily for animals. It employs approximately 515 staff at its site in Speke.

MedImmune manufactures vaccines and employs approximately 160 staff.

Such is the confidence in Liverpool's expertise in biomanufacturing that in 2006 the National Biomanufacturing Centre opened in Speke. This 4100m^2 facility is being supported through a £34 million investment, and has been assisted by the North West Regional Development Agency. It provides the facilities for carrying through a product from concept to manufacture, and is aimed at smaller companies which struggle to pay for contracting out such services. An Access Fund is also available to help Small and Medium Sized Enterprises (SMEs) to purchase services in biomanufacturing. Essentially, this will support the sector by 'speeding up' the journey from research to full scale manufacture and commercial exploitation.

Examples of other major life sciences companies in Merseyside are:

Unilever on the Wirral employ approximately 900 staff. This site deals mainly with knowledge and new product development.

SHS International specialise in the manufacture and development of clinical foods. They employ approximately 350 staff at their site in Liverpool.

Life Sciences Sector Development

MerseyBIO is the Life Sciences Sector Development Organisation for Merseyside. It was established to help stimulate business growth in the life sciences sector by providing specialist advice and support to companies in Merseyside. This is achieved through a number of different, but related, activities:

- Technology transfer and commercialisation support
- Start-up and incubation
- Facilities
- Support to the local life sciences business community
- Bringing together local companies and academics to create thriving networks
- Promoting Merseyside as a life sciences region beyond Merseyside, the North West and the UK

MerseyBIO is developing growth opportunities in the sector, thereby driving forward the prosperity of the life sciences industry in Merseyside. Addressing skills requirements and gaps in training provision is an essential component in the success of the sector.

The Merseyside Life Sciences cluster also involves the following organisations:

- University of Liverpool
- Liverpool School of Tropical Medicine
- Liverpool John Moores University
- Royal Liverpool University Hospital

- Liverpool Science Park
- Estuary Commerce Park, Speke
- National Biomanufacturing Centre
- Clatterbridge Centre for Oncology/Clatterbridge Cancer Research Trust
- University Hospital Aintree
- Royal Liverpool Children's Hospital
- Cardiothoracic Centre Liverpool – NHS Trust/Broadgreen Hospital
- Liverpool Women's Hospital NHS Trust
- University of Liverpool Cancer Research Centre
- Partnership for Learning

Manufacturing within Life Sciences

The Life Science sector is concerned with the development of products and services derived from the study of living systems or the use of living systems in research, development and manufacturing.

A number of labels are used (sometimes interchangeably) to describe the industry or its components, including: 'biotechnology; 'bioscience'; 'pharmaceutical'; 'diagnostics'; 'healthcare'; 'medical technology'; 'life science'. There is no Standard Industry Classification ('SIC') code for the industry.

Although there are potential applications for markets such as environment and agriculture the main drivers in the life science industry relate to its importance to human health and well-being. There remain significant unmet medical needs which the sector has the potential to address, not only improving human health but also the economics of preventative medicine and treatment of illness. The developed world's changing population demographics together with lifestyle-related medical interventions and the disease burden in the developing world present major challenges and opportunities for innovators and companies alike.

The life science industry sector has the potential to enable:

- earlier identification of disease and susceptibility to disease;
- development of targeted drugs with higher efficacy and improved safety;
- faster and more precise detection of pathogens;
- disease prevention and eradication through vaccine development;
- new modes of treatment for 'untreatable' conditions through regenerative medicine, engineered tissue and stem cell therapies;
- faster development of new medicines.

Manufacturing Skills

Manufacturing within life sciences covers a number of different areas of a company's functions including:

- development of diagnostic tools
- research and development (pre and post clinical trials)
- primary manufacture
- secondary manufacture
- engineering of relevant equipment
- underpinning requirements for quality control, regulatory compliance and health and safety requirements

Manufacturing skills are required in a number of different processes undertaken by biotechnology, pharmaceutical, and biopharmaceutical companies.

Research has recently been undertaken by The Association of the British Pharmaceutical Industry (abpi) on the skills landscape in the UK pharmaceutical and biopharmaceutical industries. The results of this research were published in the 2005 report, '*Sustaining the Skills Pipeline'*.

One of the trends that the abpi report highlighted was that life sciences companies are currently experiencing difficulty in recruiting good candidates into the manufacturing disciplines. This was put down to public perceptions of the industry and a lack of awareness of the careers available. These recruitment difficulties subsequently make it all the more important for the existing workforce to continually develop their skills, knowledge and expertise.

'Drug discovery factories' - specialist pharmaceutical screening facilities - have stimulated a significant increase in identifying the number of lead products taken forward for pre-clinical and clinical trials. This transformation has been brought about by the use of high-throughput technologies and automation. This 24 hour production has replaced laborious or time-consuming manual processes, reducing costs and greatly increasing throughput. However this requires new skills to be learnt and applied in the workplace.

New and emerging technologies applied to clinical problems such as gene array, nanotechnology, combinatorial chemistry, structural genomics, proteomics, informatics and computational biology are all leading to discovery of evermore potentially valuable clinical targets for drug development programmes that enhance the study and treatment of diseases.

2.3 Aim

The aim of this work undertaken by Pye Tait Limited on behalf of **MerseyBIO** was to investigate manufacturing skills requirements. By reviewing the current skills levels and addressing training needs within the life science sector, areas for future development will be highlighted in order to ensure that this highly skilled workforce continues to grow and develop. This will ensure Merseyside and Halton sustain its global competitive edge in life sciences manufacturing.

2.4 Methodology

The research requirements of **MerseyBIO** and its partners - Learning and Skills Council (LSC) Greater Merseyside and JET South Liverpool - have been met using the following methodology.

2.4.1 Desk research and examination of learning provision

Desk research

The main priorities here were to highlight what information already existed on issues with the current state of skills at national, regional and local level. The necessary starting point was to conduct a desk-based review of all data available via the Internet and hard copies of reports and other documents.

Specialist learning provision

Although the main focus of this work was to identify skills issues according to companies themselves, this needed to be considered alongside the current supply of training that may help to address any gaps.

At this initial stage, a list of providers known to offer relevant specialist training was obtained from the project Steering Group. This list was then enhanced as the research progressed, as additional information was provided by life sciences companies.

Designing the consultation with companies

Involvement of life sciences companies has been the main priority for this work.

The project Steering Group required very specific information on exact skills needs. For example, rather than finding out about the level of competence in using technology, greater detail was required to highlight the exact issues, such as: controlling process automation and setting up automated inspections.

There were also a number of other considerations:

1. the need to obtain very detailed scores for each skill from companies;

2. the requirement for more qualitative feedback on the use of training and any issues with availability;

3. to minimise the subjectivity of responses.

Previous work undertaken by Pye Tait has been very successful in developing this detailed set of skills and asking companies to score the extent to which staff are currently skilled in these areas.

Drafting a list of technical manufacturing skills

It was critical to develop an initial list of the technical manufacturing skills that are relevant to the sector. Skills were drafted for each of the three standard levels of staff: front line/operational; technical/supervisory; and managerial.

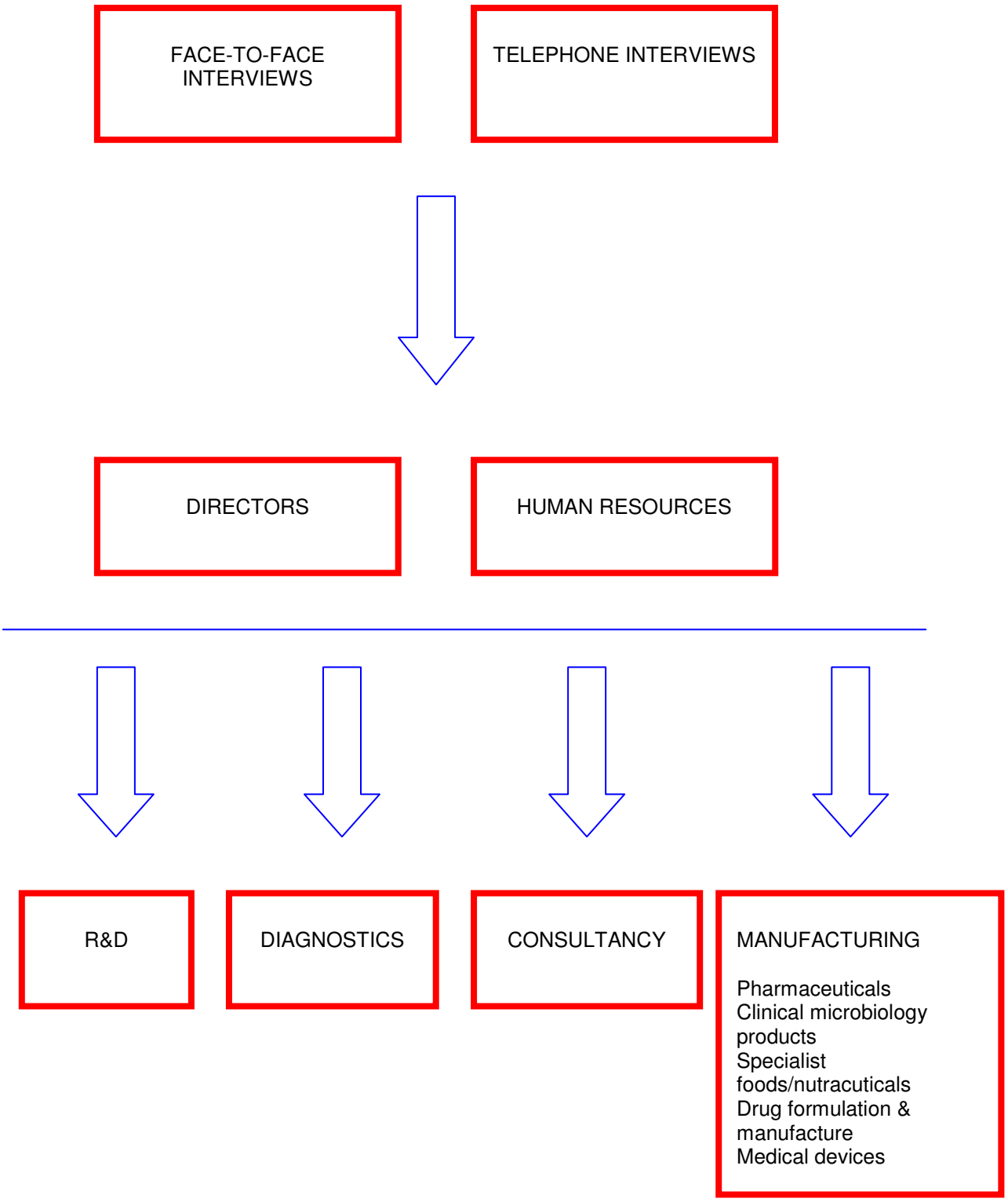
This exercise required considerable time, attention and reflection to ensure that the skills for each level of staff were entirely relevant and well defined. To meet this requirement, Pye Tait enlisted assistance of a specialist consultant with expert knowledge of the life sciences sector. The skills were drafted in consultation with this specialist and the project Steering Group.

A separate questionnaire was then designed for managing directors and human resources managers who had some additional time to comment on their use of training. This script was also used as the main focus for face-to-face discussions.

The research aimed to involve staff who have a view of the competence of employees within the company. It was important that these individuals were also aware of the implications of any skills gaps on the development of the company, considering factors driving the sector, use of training and how they could be supported with addressing these issues. Individuals working as training managers or in human resources were consulted in larger companies. For the smaller companies in Merseyside and Halton, these tended to be Directors.

Refer to figure 1 which illustrates the approaches taken to consult with companies to assist with the research design and to gather data. This figure also outlines the level and role of staff who were interviewed during the skills scoring exercise and types of companies involved in the research.

Figure 1: Consulting with Companies



2.4.2 Survey of technical skills needs

The list of technical manufacturing skills, once agreed with the project Steering Group, was then incorporated into a questionnaire which was tested with seven companies.

A rating system was used of 1 to 10, with 1 as not at all skilled and 10 as perfect. Again this approach has been used in previous studies and the system of 1 to 10 works well for respondents as it is easy for them to identify where to score skills they feel are currently poor.

The full survey phase involved 24 companies in the skills scoring.

Part two of the questionnaire enabled the honing down of the skills issues by establishing:

- factors driving skills needs
- use of training
- perceived barriers to accessing development
- how specialist knowledge could be shared within the sector.

Encouraging involvement

Initially, some difficulties were experienced in engaging companies in the research. This was mainly because of the time constraints placed on companies to ensure their work is completed and therefore, there was little time spare to assist with this study. To further support involvement in the research, Pye Tait worked with the project Steering Group to:

- Set up project web pages

Web pages were set up by Pye Tait specifically to give companies an alternative means of scoring current skills needs and indicating future requirements. These asked companies to provide their perceptions on 10-15 headline skills which are central to manufacturing.

- Promote the work at one of **MerseyBIO**'s networking evenings

Pye Tait also attended one of these evening meetings in October 2005 to meet with companies and encourage participation in the survey.

Brief telephone discussions with training providers

As discussed, it was important for the work to also identify the scope and suitability of training available to life sciences companies in Merseyside and Halton. The research team conducted brief discussions with training providers over the telephone to establish the range of technical and other skills training available. This informed development of a master list of training available (refer to appendix D).

2.4.3 Analysis of skills and training requirements

Scoring skills data

For each skill, a mean score has been derived from all companies that responded. These scores have been provided for each level of staff.

It bears repeating that these scores represent the employer or company's assessment of the current level of skill of their staff, at a given level of staff and for a specific, defined skill.

The analysis dealt with a relatively small number of responses (24 companies), which renders robust and detailed statistical interpretation impossible. All of the results from the quantitative analysis have, therefore, been handled with this constraint in mind, using straightforward summary measurements such as the mean and median of the scores.

The mean provides a simple summary of the scoring for each skill while comparing this to the median permits the reader to gain a rough idea of the distribution.

The data are not sufficiently extensive as to allow any of the more sophisticated measures of skewness to be used (or, at least, to carry any reliable meaning).

For practically all skills, the median did not differ significantly from the mean. This data is highlighted in Appendix B.

Future skills

For each skill, companies were also asked to indicate whether this would become more important to the sector in five years time. From these responses, a separate mean score was developed to represent the future importance of each skill.

In this way, Pye Tait was able to arrive at two separate mean scores for each detailed skill relevant to the sector. The first was essentially an expert (ie employer's) view of the level of that skill in the existing workforce; the second their assessment of how important that particular skill would be to the company in the future.

The scores for the current skill level and the mean importance of each skill were then mapped against each other on a scatter diagram. These are included for each level of staff in the main body of this report.

Actionable Skills

Having gained an idea of the level of skill in the current workforce and of employers' views of the future importance of those skills, the next stage in the analysis was to develop a method for ascertaining for what exact skills the sector needed to take action and what the priority of that action was.

In effect, Pye Tait needed to identify at what level employers feel that skills are satisfactory in meeting their business requirements. While a score of ten out of ten would be extremely desirable in an ideal world, all employers operate on a more practical definition of what is acceptable in a workforce.

The level clearly differs from company to company and – depending on its priority – probably from skill to skill, but, for the sector as a whole, one could either take an arbitrary point below which a given skill was in need of remedial action (for example, any skill falling below the mean for the sector as a whole), or one could ask employers as a whole what they felt the "satisfactory" level was. For this purpose, the Steering Group (composed of senior and experienced practitioners) was selected as a proxy for the industry as a whole.

The project Steering Group agreed that **7 could be considered to be the level at which skills are considered to meet business requirements**. This report highlights where the mean scores are currently below this level and therefore, identifies areas of concern.

On each diagram, attention is focused on the bottom right quadrant which contains:

Skills that are currently below 7 AND that will increase significantly in importance in the future

It is these skills that need to be prioritised to ensure the sector in Merseyside and Halton is able to strengthen and compete effectively.

Within the report, skills that have a mean score of 7 or above are discussed as meeting or exceeding the required level.

Mean scores presented in the scatter diagrams in the report have been normalised. This is to provide ease of reference when comparing the diagrams for each level of staff. Diagrams representing the actual mean scores are included in Appendix A.

Review of additional feedback from companies

Qualitative responses have been reviewed to pull out the key messages such as those regarding the factors driving changes in requirements for skills. Detail has also been obtained on concerns for companies and the sector as a whole in accessing the most appropriate provision to help address gaps.

2.5 Profile of Respondents

In total, the research involved 33 life sciences companies. These account for 42.8% of all those based in Merseyside and Halton. Twenty four commented on the current levels of individual skills where relevant. A further nine companies provided more detailed feedback on drivers and use of training during face-to-face interviews.

Findings highlighted in this report represent 2,895 employees in Merseyside and Halton.

The majority of manufacturing companies that participated in the research were those that employed a total of 21 staff or more.

Refer to figure 2 for a breakdown of activity by size of company.

Figure 2: Company Size by Type of Activity

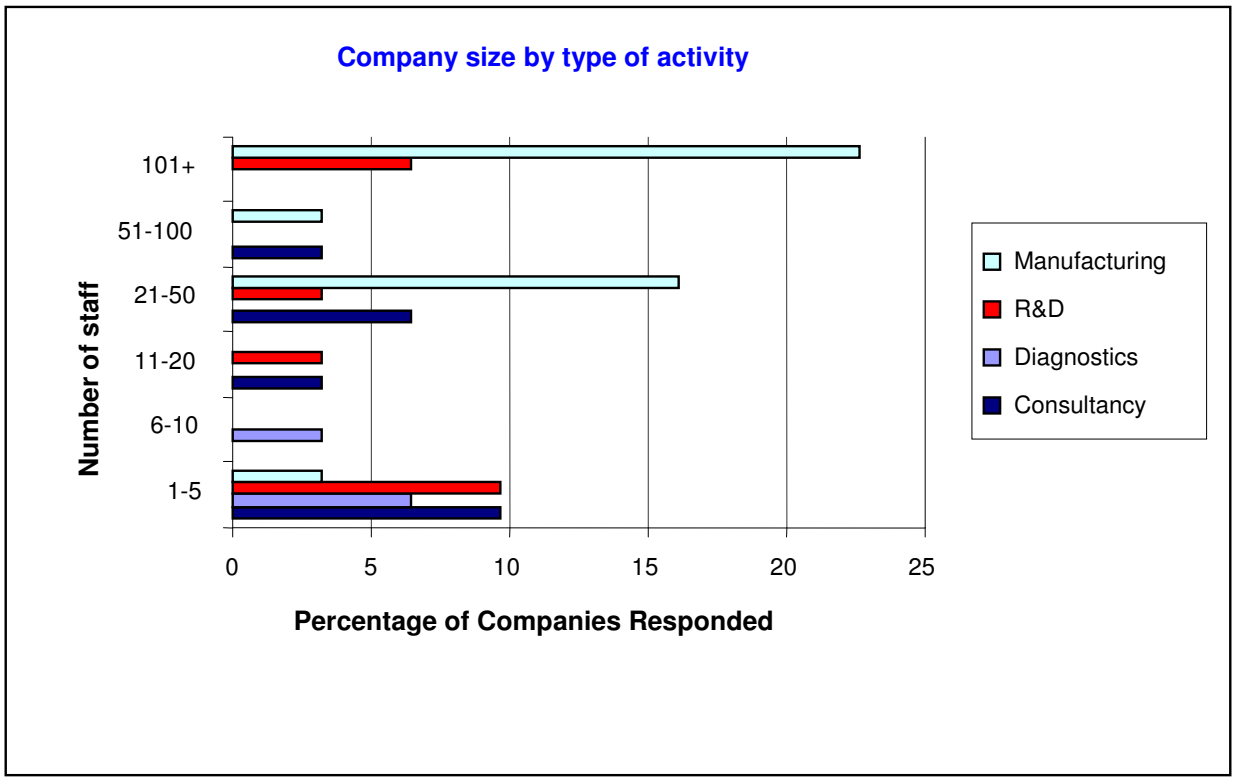


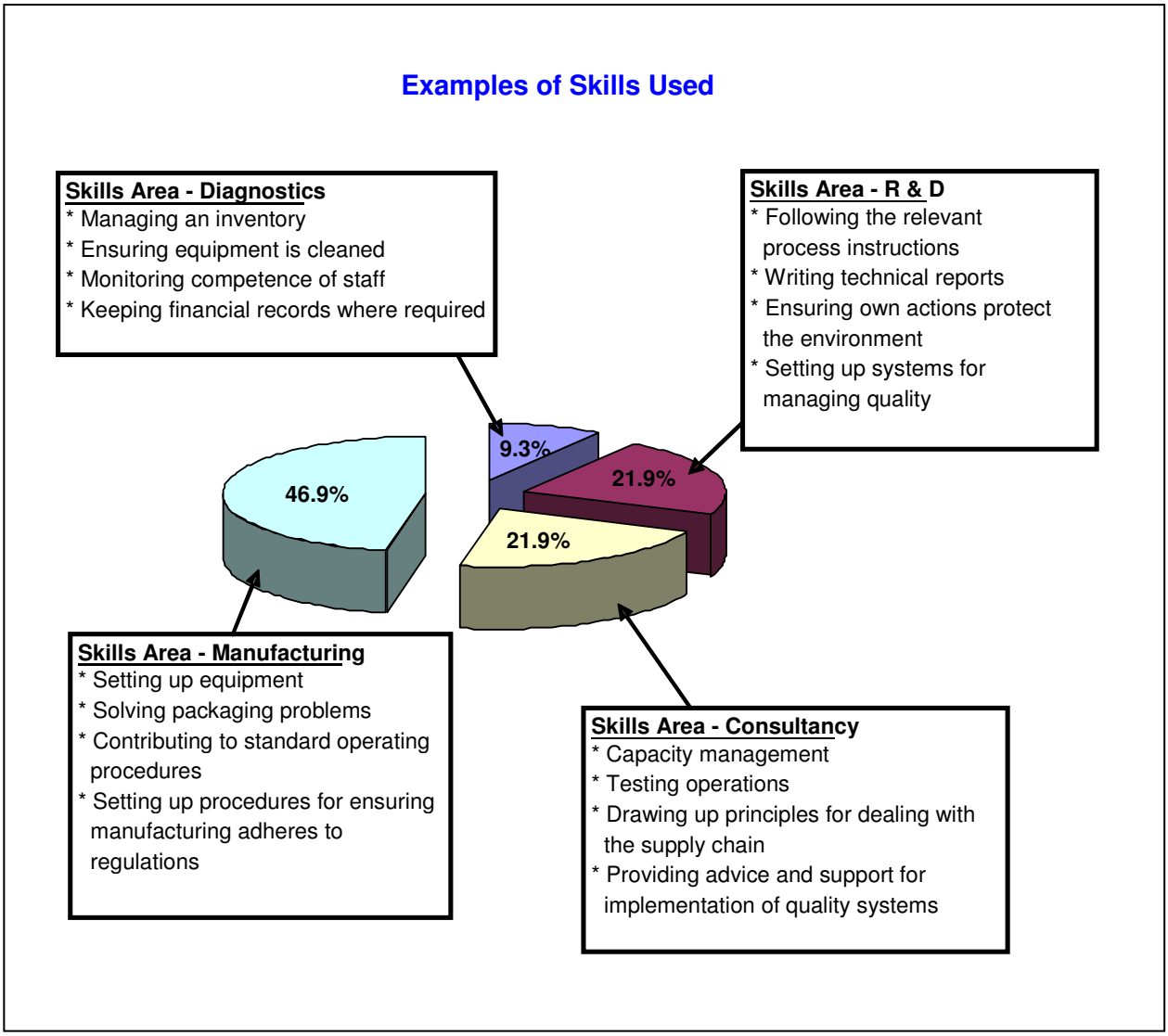
Figure 2 illustrates how, not surprisingly, those involved in R&D and diagnostics tend to employ a smaller number of workers. Companies offering consultancy also operate from a small base of 10 or less staff. Manufacturing companies taking part in the research are clearly the larger companies with over one-fifth of these employing over 100 staff.

Companies were asked about their main areas of business. These are summarised in figure 3, with examples of relevant skills used according to the type of business.

The dominance of manufacturing companies is illustrated in figure 3 where skills that are commonly used are for example, setting up equipment and solving packaging problems. Consultancy and R&D companies each equate to just over one-fifth of the sample involved in this research, these areas utilising such skills as testing operations and writing technical reports.

Details of the areas of business across the four main types of company are provided below.

Figure 3: Profile of Respondents



- Manufacturing

  Nearly half of life sciences companies surveyed are involved in manufacturing – either primary, secondary or both. The majority are involved in more than one area of business. Areas of manufacturing include:

  - Pharmaceuticals
  - Clinical microbiology products
  - Specialist foods/nutraceuticals
  - Drug formulation and manufacture
  - Medical device companies

- R&D

  Some companies offering manufacturing or diagnostic testing are also involved in R&D activities to inform product development.

- Diagnostic testing

  9.3% of responses indicated they provide diagnostic testing. For these companies, this tended to be the sole product or service they market to customers. Although some R&D is involved, manufacturing is not.

  Services provided cover DNA profiling and In Vitro Diagnostics (IVD) blood testing – knowledge and technology that is accessed by clients who need faster results than those offered through public healthcare.

- Consultancy

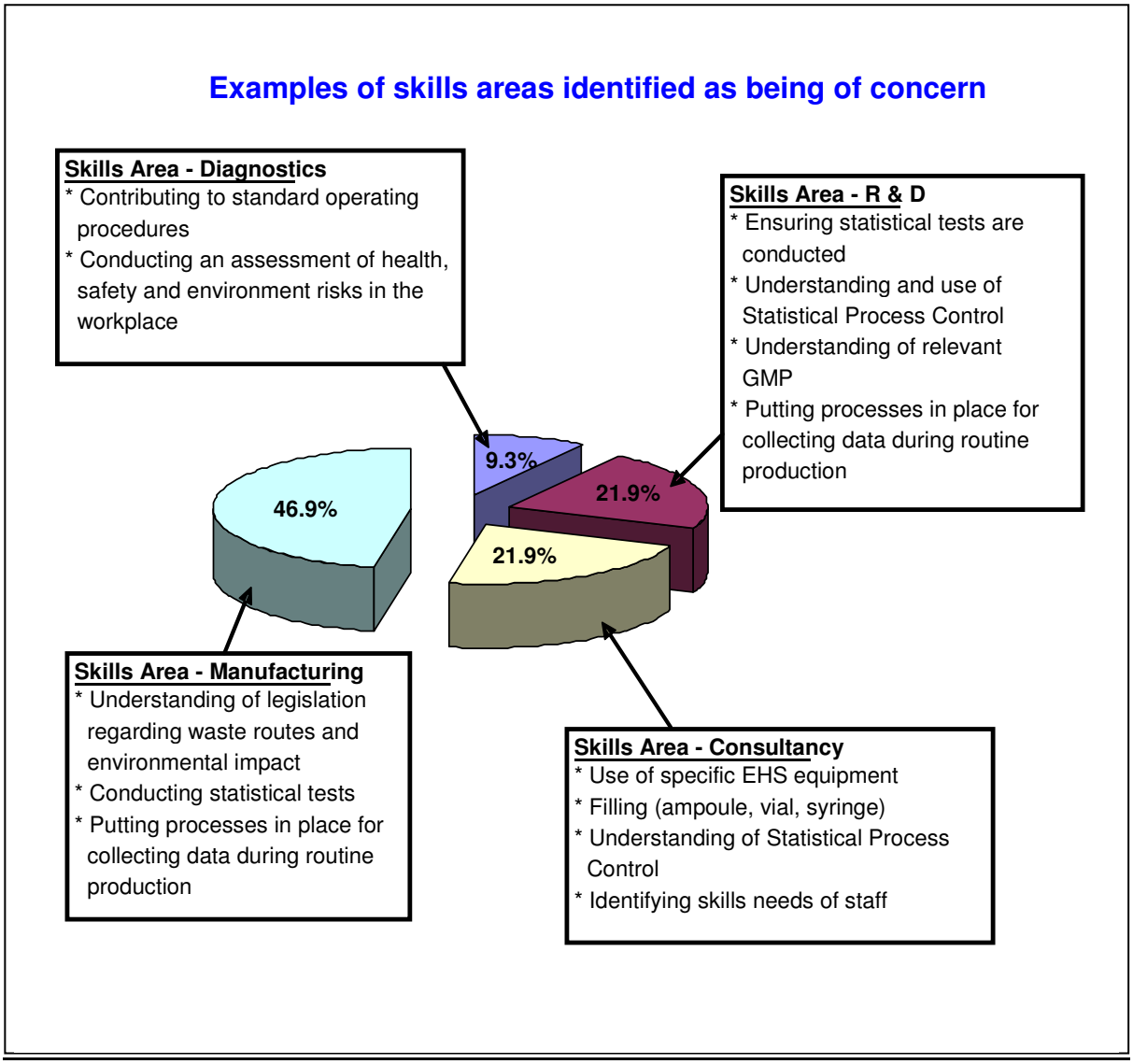
  20% of companies involved in the research provide consultancy to the industry as part of their activities.

  In some cases, companies initially started out in raising awareness of health and safety regulations and quality guidelines as well as providing training in the local area. Consultancy includes:

  - Conception and design to product realisation
  - Analytical testing
  - Compound safety

  Turning to look at the types of company and their respective areas of concern in relation to skills (refer to figure 4), for manufacturing companies, among others, understanding of legislation regarding waste routes and environmental impact, is identified as a concern. See figure 4 for examples of the main skills areas of concern, by type of company.

Figure 4: Profile of Respondents and Examples of Skills of Concern



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3. Results: Front Line/Operational Staff

3.1 Methodology

Scoring skills data

For each skill, a mean score has been derived from all companies that responded. These scores have been provided for each level of staff.

It bears repeating that these scores represent the employer or company's assessment of the current level of skill of their staff, at a given level of staff and for a specific, defined skill.

The analysis dealt with a relatively small number of responses (24 companies), which renders robust and detailed statistical interpretation impossible. All of the results from the quantitative analysis have, therefore, been handled with this constraint in mind, using straightforward summary measurements such as the mean and median of the scores.

The mean provides a simple summary of the scoring for each skill while comparison to the median permits the reader to gain a rough idea of the distribution.

The data are not sufficiently extensive as to allow any of the more sophisticated measures of skewness to be used (or, at least, to carry any reliable meaning).

For practically all skills, the median did not differ significantly from the mean. This data is highlighted in Appendix B.

Future skills

For each skill, companies were also asked to indicate whether this would become more important to the sector in five years time. From these responses, a separate mean score was developed to represent the future importance of each skill.

In this way, Pye Tait was able to arrive at two separate mean scores for each detailed skill relevant to the sector. The first was essentially an expert (ie employer's) view of the level of that skill in the existing workforce; the second their assessment of how important that particular skill would be to the company in the future.

The scores for the current skill level and the mean importance of each skill were then mapped against each other on a scatter diagram. These are included for each level of staff in the main body of this report.

Actionable Skills

Having gained an idea of the level of skill in the current workforce and of employers' views of the future importance of those skills, the next stage in the analysis was to develop a method for ascertaining on which exact skills the sector needed to take action and what the priority of that action was.

7 or above = satisfactory Below 7 = requires action

In effect, Pye Tait needed to identify at what level employers feel that skills are satisfactory in meeting their business requirements. While a score of ten out of ten would be extremely desirable in an ideal world, all employers operate on a more practical definition of what is acceptable in a workforce.

The level clearly differs from company to company and – depending on its priority – probably from skill to skill, but, for the sector as a whole, one could either take an arbitrary point below which a given skill was in need of remedial action (for example, any skill falling below the mean for the sector as a whole), or one could ask employers as a whole what they felt the "satisfactory" level was. For this purpose, the Steering Group (composed of senior and experienced practitioners) was selected as a proxy for the industry as a whole.

The project Steering Group agreed that **7 could be considered to be the level at which skills are considered to meet business requirements and for the purpose of this report is equivalent to satisfactory**. This report highlights where the mean scores are currently below this level and therefore, identifies areas of concern.

On each diagram, attention is focused on the bottom right quadrant which contains:

Skills that are currently below 7 AND that will increase significantly in importance in the future

It is these skills that need to be prioritised to ensure the sector in Merseyside and Halton is able to strengthen and compete effectively.

Within the report, skills that have a mean score of 7 or above are discussed as meeting or exceeding the required level.

Mean scores presented in the scatter diagrams in the report have been normalised. This is to provide ease of reference when comparing the diagrams for each level of staff. Diagrams representing the actual mean scores are included in Appendix A.

7 or above – skill is satisfactory
Below 7 – skill requires action

3.2 Summary

- There were 98 skills identified for front line/operational staff.
- 74.5% of skills required by front line/operational staff are currently at a satisfactory level according to life sciences companies involved in the research
- Individuals' understanding of relevant Good Manufacturing Practice (GMP) and ability to conduct checks against this, was perceived to be good for the manufacture of proteins
- Staff were also scored at a high level for collation and checking of materials from the supply chain, preparing materials and use of additional chemicals to create a chemical reaction

- Other good skills are filling and packaging, confirming components and products and calibration of sensors/gauges and chart recorders

- One-third of skills are of concern and also have been identified as likely to increase in importance in the next five years – these are 'actionable' skills (these include borderline actionable skills)

- Just over half of these actionable skills relate primarily to regulation but also to quality

- A good level of understanding and also the ability to adhere to regulations such as GMP, GLP and FDA guidelines are absolutely crucial in making sure companies stand up to scrutiny and avoid variation or revocation of their licences

3.3 Satisfactory Skills

73 of the 98 relevant skills required by front line/operational staff are well developed – scoring at 7.00 or above.

In summary, these cover:

- literacy and numeracy
- collation and checking of materials from the supply chain
- preparing materials
- use of additional chemicals to create a chemical reaction
- filling and packaging
- confirming components and products
- calibration of sensors/gauges and chart recorders
- understanding of relevant GMP and checking against this in manufacturing proteins

- **Literacy and numeracy**

Staff are already skilled to a good level in basic comprehension of literacy and in conducting calculations. These scored an average of 8.55 and 8.41 out of 10.

- **Collation and checking of materials from the supply chain**

Appropriate checking of orders is important for companies to ensure they have the right amount of materials for R&D and manufacture.

Companies stated that front line/operational staff are already competent in checking that the materials provided are as requested. They can also manage data on the materials and equipment ordered and keep track of what is outstanding. This is done effectively through collating orders and checking against the inventory.

Crucial to effective checking is also an understanding of how to manage the shelf life of materials, which is another area that is already completed satisfactorily.

Staff are also able to check and control the temperature and humidity of storage conditions for materials.

7 or above = satisfactory Below 7 = requires action

- **Preparing materials**

  In terms of R&D, one particular skill is at a very good level. This is the preparation of laboratory materials, equipment and resources. Clearly this is key in setting up facilities for effective practice.

- **Creating a chemical reaction**

  According to employers, staff are good at using additional chemicals in primary manufacture to create an exothermic or endothermic chemical reaction. This needs to be done in a carefully controlled environment with due consideration to health and safety.

- **Filling and packaging**

  As part of secondary manufacture, front line/operational staff are required to conduct filling in an ampoule, vial or syringe. These then need to be packaged into secure containers. This is one of the areas that is already at a satisfactory level.

- **Confirming components and products**

  Individuals also demonstrate a competence in confirming components that are used and also the final products. This is an important area of quality assurance and it is encouraging that this is not an area of concern.

- **Checking quality of diagnostic kits**

  Companies that use diagnostic kits were clear that staff already possess competence in checking these effectively.

- **Calibration of sensors/gauges and chart recorders**

  This skill is required to make sure that equipment is set up, programmed and calibrated to a specification to make sure that various processes are conducted in the right way.

- **Understanding relevant GMP (manufacturing proteins)**
- **Conducting checks against GMP (manufacturing proteins)**

  The two skills above were scored at an excellent level - an average of 9 out of 10 in terms of awareness of processes used in manufacturing proteins.

  Understanding of relevant Good Manufacturing Practice (GMP) is critical for life sciences companies as this ensures they are signed up to good practice and are able to avoid any issues during inspection. Knowing what is involved is not enough. Individual staff need to conduct checks where relevant on a regular basis to support this.

- **Dealing with the supply chain**

  Seven of the skills required for packaging are already at a satisfactory level. These include managing an inventory which is an important part of checking and reviewing stock. Staff also need to develop and communicate a plan for production.

  This involves managing the capacity available to record and store materials. Companies are clear that this is done well. Stock levels are also reviewed on a regular basis.

  Materials are also labelled effectively and handled with the required care.

- **Sampling (raw) materials**

  Front line/operational staff are well versed in the requirements of sampling materials, including raw materials, as part of R&D activities.

- **Setting up and operating equipment**

  Staff can also set up the necessary equipment for primary manufacture. In addition, there is a good level of understanding of how to operate equipment during secondary processes.

- **Ensuring the security of materials, including when on pallets**
- **Quarantining materials**

  These skills are required to ensure effective storage of raw and other materials. Quarantining of materials is particularly important to avoid cross contamination.

- **Managing the line**

  Companies stated that individuals are competent in dealing with the manufacturing line. They are scored at satisfactory level for removing the product(s) from the line, cleaning the line, preparing it for the next operation and loading the line.

- **Packaging during secondary manufacture**

  It is important that the product is marked and distributed safely. This area appears to be sufficiently covered by existing skills. Individuals can conduct overlabelling, batch number and expiry dating effectively.

  They can also operate and clean packaging machines as well as carton the product and insert leaflets.

  The remainder of the satisfactory skills associated with manufacture are highlighted in the table below.

7 or above = satisfactory Below 7 = requires action

Table 1: Other Satisfactory Skills

Primary manufacture	Secondary manufacture	Regulation	Engineering
Cleaning and preparing vessels	Loading the line	Dealing with unusual occurrences (regulation)	Understanding of how to monitor/analyse efficiency of equipment
Charging vessels (manually or through a vacuum)	Use of purified water, sterile water, water for injection, steam clean		Maintenance of purified water, sterile water, water for injection and steam clean generation facilities
Use of specific EHS equipment e.g. respirators, spillage, dust extraction	Overwrapping as part of packaging		Maintenance of sterilisers and autoclaves
Understanding of filtration	Palletising the packaged product		
Milling and grinding materials to correct particle size as part of preparation			

- **Quality functions**

  Staff know how to follow the relevant process instructions. They also know how to control, monitor and adjust the operation.

  Other sufficient areas comprise washing in-between batches and products to remove impurities and carry over. Staff can sample and undertake in-process control measurements and tests as well as use autoclaves and sterilisers.

- **Regulation**

  Individuals can follow detailed process instructions and keep the relevant associated records. Crucially, they also comply with organisational safety requirements.

  One area of this includes the safe transportation of chemicals and by products.

- **ICT**

ICT is at a satisfactory level for front line/operational staff, scoring 7.00.

Competence in use of computers and automation forms a crucial part of the skills base in the sector. As stated in MerseyBroadband's report on the use of ICT in life sciences:

'The growth in biotechnology companies accompanies and runs parallel to developments in ICT and computer science. Advances in processing power and increased memory…has enabled biotechnologies to excel'[1].

Important areas include statistical analysis and use of programme automation, especially in computer systems validation.

- **Improving your own performance**

This also received a mean score of 7.00. The ability of staff to continuously review and act on their own ability to perform certain functions is a key skill that is integral to all working practices. Clearly this is of critical importance when, for example, considering the need to monitor and evaluate quality processes and ensure effective validation techniques.

- **Communication, team working and problem solving**

These are central to effective manufacturing within a safe environment. Good communication and team working between operatives ensures there is a constant flow of information on what is currently going on.

Part of this process is the identification of issues as they arise. However, staff also need to be able to address these appropriately.

3.4 Gaps

3.4.1 Actionable Skills

Figure 6 (refer to page 34), highlights the 'normalised' scores for all the skills required of front line/operational staff. The lower-right quadrant contains those that have been rated at less than 7.00 out of 10 for skills levels and are considered by companies to be of increasing importance for the future.

These skills should be prioritised for future development to help ensure life sciences companies on Merseyside are best placed to grow and compete effectively.

Analysis of skills scores and future importance of skills

All companies gave scores for each defined skill per level of staff. This represented their assessment of the level of skill held by their staff (low to highly skilled). A mean score was then derived for each skill.

[1] MerseyBroadband (2005) 'The Benefits of Broadband and ICT to Life Sciences on Merseyside', p.3.

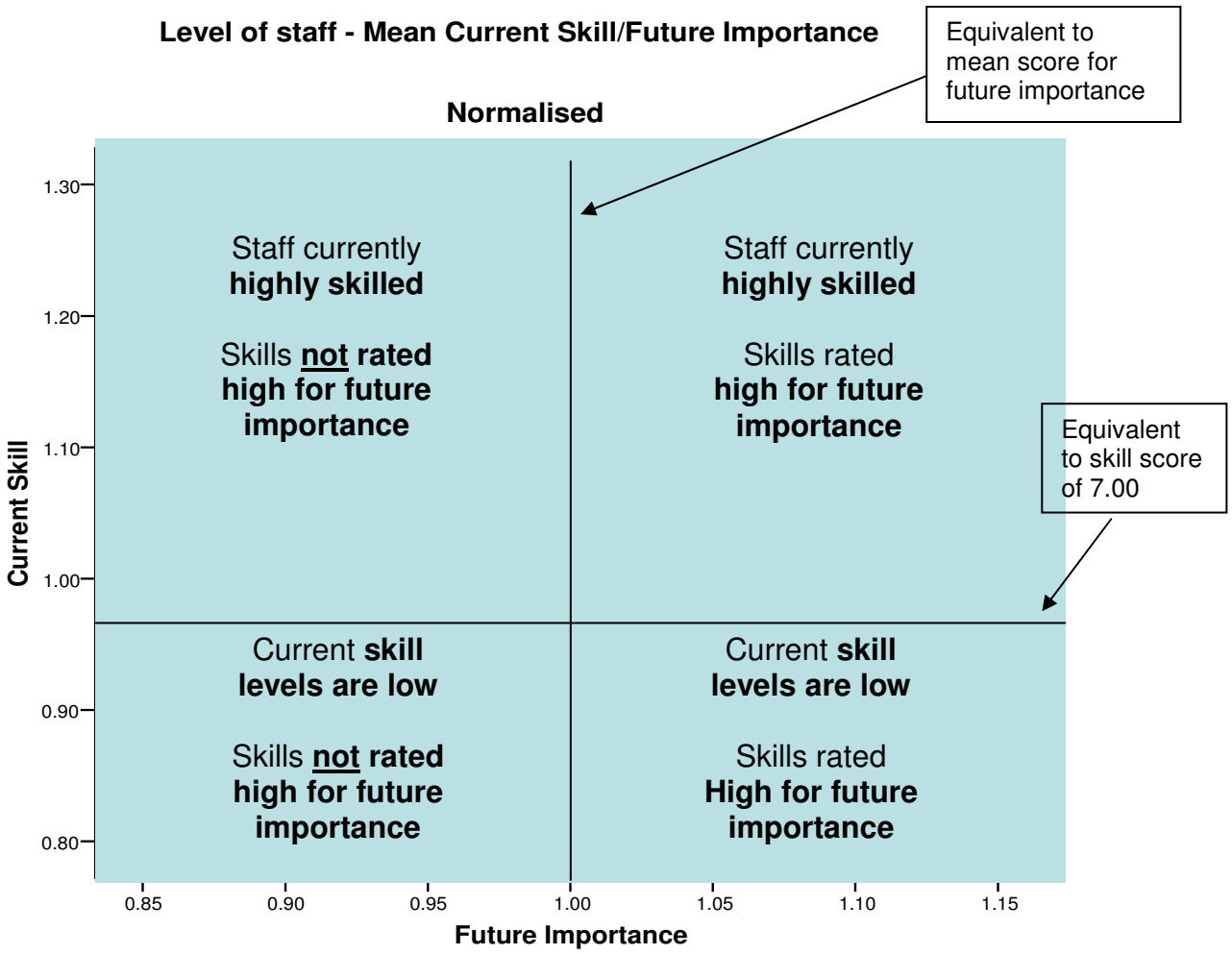
7 or above = satisfactory Below 7 = requires action

Companies also gave an indication as to whether each defined skill per level of staff would become more important (the same or less important) for the sector over the next five years.

To ascertain the critical skills where action is required to raise skill levels in the sector, the mean score for each skill was mapped against its mean score for future importance. The outcome of this mapping exercise is presented in scatter diagrams.

Normalised scores for skills and future importance were used for the scatter diagrams to allow comparison across levels of staff. Each score has been divided by the overall mean for all skills for this level of staff. 1.00 represents this overall mean score. The scatter diagrams of normalised scores are presented in the main body of this report. The nominal scores achieved are presented on scatter diagrams in the appendices to the report.

Figure 5: Example Scatter Diagram



7 or above = satisfactory Below 7 = requires action

Once all scores are plotted on the scatter diagram, identifying those which should be prioritised for future development becomes a relatively simple task. See the example above which illustrates the definition of each quadrant where scores could fall.

The position of each defined skill when its mean current skill score and future importance score are mapped against each other, determines whether this skill should be a priority for future skills development for the sector.

Each quadrant on the scatter diagram represents the current level of skill and future importance of skills.

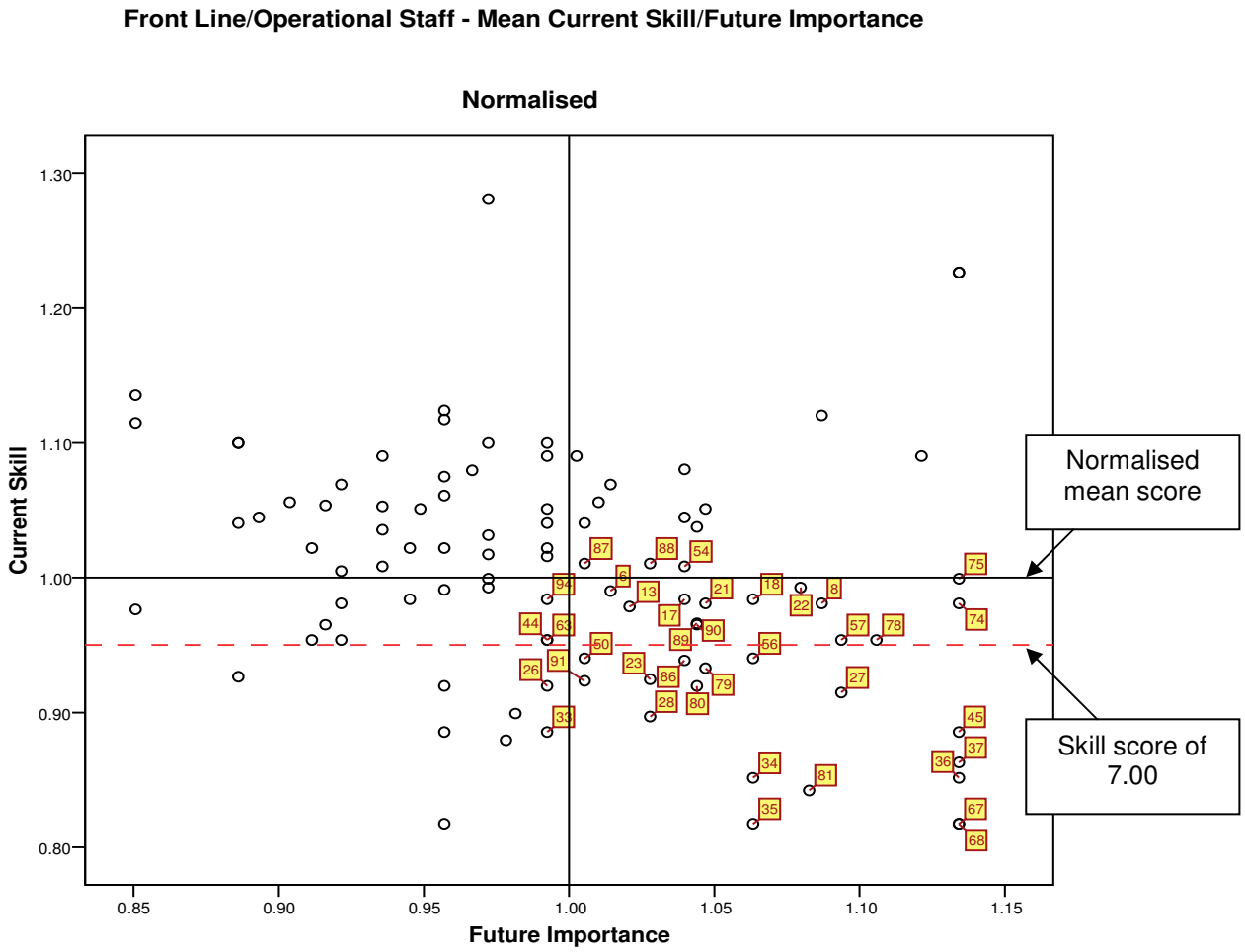
The Project Steering Group agreed that a current skill score of 7.00 could be considered to be the satisfactory level at which skills are considered to meet business requirements. Scores below this level are therefore areas of concern.

An average is taken for the mean score for future importance, for each skill, anything above this average is considered to be significant in terms of future skills development.

Critical skills which require action are those which score low on current skill levels and score high for future importance to the sector. These are represented in the lower-right quadrant where the mean current skill score is below a score of 7.00 and where future importance score is greater than the mean score for that skill.

7 or above = satisfactory Below 7 = requires action

Figure 6: Front line/Operational Staff: Actionable Skills



Refer to the lower-right quadrant of the scatter diagram above to identify skills that have scored below the satisfactory level (7.00) in current skill level and high in future importance (above average). These are detailed below.

Those skills falling directly into the area of the diagram which represent critical skills requiring action (below a skill score of 7.00 and higher than average score for future importance), account for just over 17% of all skills for front line/operational staff.

However, there are a number of skills which are identified as 'borderline actionable skills'. These fall just outside the critical area but due to their borderline position, should also be considered for future development.

Combining the actionable and borderline skills, accounts for over one-third of all the required skills at 33.7%. A large proportion of these (51.5%) are concerned with regulation mainly, but also quality.

7 or above = satisfactory Below 7 = requires action

Actionable Skills

23	Cleaning equipment
27	Understanding of relevant Good Laboratory Practice/Good Clinical Practice (R&D)
28	Conducting checks against GLP/GCP (R&D)
34	Incubating a virus
35	Harvesting a virus
36	Potential inactivation of a virus
37	Protein separation
45	Fermentation
50	Controlling process automation
56	Understanding of relevant GMP (secondary manufacture)
67	Understanding of relevant GMP (secondary manufacture)
68	Conducting checks against GMP (packaging)
79	Understanding of FDA requirements, Material Resources Planning
80	Awareness of European guidelines about distribution and CE marking
81	Complying with FDA requirements for GMP
86	Monitoring of air standards and air pressure for validation/routine production
91	Executing validation protocols

Borderline Actionable Skills

6	Resource management
8	Understanding of how to classify materials according to GMP (production planning and ordering materials)
13	Segregating materials (warehousing)
17	Understanding of relevant GMP (warehousing)
18	Conducting checks against GMP (warehousing)
21	Testing operations
22	Testing materials
33	Inoculation
44	Separating and disposing of processing materials, by products and waste
57	Conducting checks against GMP (secondary manufacture)
63	Checking the weight of the product
74	Operating/setting up automated inspections
75	Carrying out environmental monitoring – air, water and surface sampling
78	Understanding of European GMP standards
89	Setting up automated systems to conduct validation/rejecting or accepting product during routine production
90	Reviewing effectiveness of such systems

The following table (table 2), highlights the **process skills** for front line/operational staff that currently have a mean score below 7.00 but are also considered by employers to be of increasing importance in the future.

Table 2: Front line/Operational Staff - 'Actionable' Process Skills

Preparation	Control	Completion
6: Resource management **13**: Segregating materials **23**:Cleaning equipment **74**: Operating/setting up automated inspections **89**: Setting up automated systems to conduct validation	**21**: Testing operations **22**: Testing materials **34**: Incubating a virus **35**: Harvesting a virus **36**: Potential inactivation of a virus **37**: Protein separation **45**: Fermentation **50**: Controlling process automation **57**: Conducting checks against GMP **74**: Operating/setting up automated inspections	**26**: Control of inventory/stock **23**: Cleaning equipment **44**: Separating/disposing of processing materials, by products and waste

- **Resource management**

  As well as managing an inventory, individuals in these roles are also required to identify and address any issues with the supply. This is crucial for making sure companies have the specified materials and equipment in order to conduct R&D and to manufacture.

- **Segregating materials**

  In storing materials, front line/operational staff must have sufficient knowledge on how to separate these out to store them safely, preventing any damage or critical situations.

- **Testing operations and materials**

  An important part of R&D is the testing of operations and materials to ensure that these are fit to specification and effective in producing the intended product.

- **Setting up and operating automated equipment**

  Staff need to be able to put in place equipment for automating inspections. This involves not only the knowledge in how to set these up but also the ability to use this effectively. Individuals should also know how to conduct automated inspections specifically for the purposes of validation.

  In addition, skills are needed in the set up and use of PLC controllers.

  Currently these skills are nearly developed but still have some way to go to being at the right level.

7 or above = satisfactory Below 7 = requires action

- **Controlling process automation**

  Companies that conduct secondary manufacture felt more development is needed in process automation, specifically in controlling this.

- **Virus growth**

  Four out of the five skills required for effective virus growth need to be strengthened. These relate to incubating and harvesting a virus. There is also a need to be able to conduct inactivation of a virus and protein separation.

- **Fermentation**

  Fermentation is the process by which the living cell is able to obtain energy through the breakdown of glucose and other simple sugar molecules without requiring oxygen.

  This is a highly skilled process that requires a good understanding and awareness of the different steps involved.

- **Cleaning equipment**

  The ability to clean relevant equipment is a key part of ensuring effective operations in R&D. Employers consulted for the research were clear that this area needs to be strengthened.

- **Separating and disposing of processing materials, by products and waste**

  When preparing materials in primary manufacture it is important that these are separated from processing materials. Further work is needed to ensure front line/operational staff are able to do this effectively.

  High standards in quality and regulation form the basis for effective manufacturing. These are essential for all aspects of the process covering preparation, control and completion.

- **Good Manufacturing Practice**

  Understanding of Good Manufacturing Practice (GMP) and being able to implement checks on this is a core function required of front line/operational staff. Limited comprehension could result in the variation or revocation of a company's licence to manufacture medicinal products.

  Good Manufacturing Practice (GMP) is about both product and quality control and can be defined as:

  'That part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use[2]'.

2 http://www.emea.eu.int/Inspections/GMPhome.html

Products must be produced in line with the marketing authorisation or product specification.

Employees working at different stages in the manufacturing process need to have a very clear understanding of the requirements of the GMP and be able to apply this knowledge effectively.

Inspections are carried out by the Medicines and Healthcare products Regulatory Agency (MHRA) every two years. Failure to address identified deficiencies can result in changes to the licence or this being withdrawn entirely.

- **Good Laboratory Practice**

This code of practice serves as a guide to companies to prevent and control exposure to laboratory chemicals. It covers responsibility for: assessing, planning and carrying out a process; safe storage of chemicals; emergency procedures; and the ultimate disposal of all substances involved.

Staff need to strengthen their ability to conduct checks against these measures during routine production.

3.4.2 Other Gaps

A smaller number of skills where competence is currently low – 7.1% of all skills are not considered to be of importance in the future. However, these still need to be addressed to make sure companies are able to operate effectively in the here and now.

- **Control of inventory/stock (R&D)**

Staff need to know how to monitor and control the inventory and stock required for R&D. Companies have identified that this particular skill needs to be developed further.

- **Conducting statistical tests**
- **Status labelling**

The majority of skills required of front line/operational staff in R&D are already at a satisfactory level or higher. However, companies stated that individuals are less competent in conducting statistical tests. In addition, they would benefit from further development in status labelling.

- **Understanding of financial regulations**

Further development is also needed in understanding what financial regulations are in place and what information needs to be collected and monitored to help ensure adherence to these.

- **Primary manufacture**

Most of the other under-developed skills are concerned with primary manufacture. These include:

7 or above = satisfactory Below 7 = requires action

- Inoculation as part of virus growth
- Understanding of how to convert base into salt and then back again as part of purification
- Understanding of crystallisation

Cross-cutting themes

Areas of concern in quality and regulation are highlighted below. These are referred to as 'cross cutting themes' because they underpin all elements of dealing with the supply chain and R&D, as well as manufacturing. These are skills required across all levels of staff.

Cross-Cutting Themes
89: Setting up automated systems to conduct validation **91**: Executing validation protocols **87**: Testing of filters for validation **74**: Operating/setting up automated inspections **50**: Controlling process automation **94:** Understanding of how to monitor/analyse efficiency of equipment **56**: Understanding of relevant GMP (secondary manufacture) **8:** Understanding of how to classify materials according to GMP **81**: Complying with FDA requirements for GMP **79**: Understanding of FDA requirements, Material Resources Planning **75**: Carrying out environmental monitoring – air, water and surface sampling **80**: Awareness of European guidelines about distribution and CE marking **28**: Conducting checks against GLP/GCP (R&D)

4. Results: Technical/Supervisory Staff

4.1 Methodology

Scoring skills data

For each skill, a mean score has been derived from all companies that responded. These scores have been provided for each level of staff.

It bears repeating that these scores represent the employer or company's assessment of the current level of skill of their staff, at a given level of staff and for a specific, defined skill.

The analysis dealt with a relatively small number of responses (24 companies), which renders robust and detailed statistical interpretation impossible. All of the results from the quantitative analysis have, therefore, been handled with this constraint in mind, using straightforward summary measurements such as the mean and median of the scores.

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Future skills

For each skill, companies were also asked to indicate whether this would become more important to the sector in five years time. From these responses, a separate mean score was developed to represent the future importance of each skill.

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The scores for the current skill level and the mean importance of each skill were then mapped against each other on a scatter diagram. These are included for each level of staff in the main body of this report.

Actionable Skills

Having gained an idea of the level of skill in the current workforce and of employers' views of the future importance of those skills, the next stage in the analysis was to develop a method for ascertaining on which exact skills the sector needed to take action and what the priority of that action was.

7 or above = satisfactory Below 7 = requires action

In effect, Pye Tait needed to identify at what level employers feel that skills are satisfactory in meeting their business requirements. While a score of ten out of ten would be extremely desirable in an ideal world, all employers operate on a more practical definition of what is acceptable in a workforce.

The level clearly differs from company to company and – depending on its priority – probably from skill to skill, but, for the sector as a whole, one could either take an arbitrary point below which a given skill was in need of remedial action (for example, any skill falling below the mean for the sector as a whole), or one could ask employers as a whole what they felt the "satisfactory" level was. For this purpose, the Steering Group (composed of senior and experienced practitioners) was selected as a proxy for the industry as a whole.

The project Steering Group agreed that **7 could be considered to be the level at which skills are considered to meet business requirements**. This report highlights where the mean scores are currently below this level and therefore, identifies areas of concern.

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Skills that are currently below 7 AND that will increase significantly in importance in the future

It is these skills that need to be prioritised to ensure the sector in Merseyside and Halton is able to strengthen and compete effectively.

Within the report, skills that have a mean score of 7.00 or above are discussed as meeting or exceeding the required level.

Mean scores presented in the scatter diagrams in the report have been normalised. This is to provide ease of reference when comparing the diagrams for each level of staff. Diagrams representing the actual mean scores are included in Appendix A.

4.2 Summary

- There were 51 skills identified for technical and supervisory staff.
- In total, 56.9% of skills required of technical/supervisory staff are already satisfactory
- However, this means that over **40% of the skills required by these staff are in need of development**
- The majority – **68.2% - of skills gaps are expected to increase in importance** over the next five years
- Technical/Supervisory staff are the only level of staff to receive mean scores under 6 out of 10 for some skills. This is the case for four skills. These are concerned with;
    - Monitoring data
    - Understanding environmental considerations in packaging
    - Understanding the use of Statistical Process Control (SPC)
    - Monitoring the use of SPC techniques during routine production

7 or above = satisfactory Below 7 = requires action

4.3 Satisfactory Skills

Just over half (56.9%) of the 51 skills identified as of relevance to supervisory staff are already at a satisfactory level.

- **Dealing with the supply chain**

Supervisory staff are able to work effectively within a supply chain where required by companies. As with front line/operational staff, those in a supervisory role are competent in ensuring materials have been provided to specification.

- **Using equipment**

They also know how to ensure equipment is cleaned effectively. In addition, staff are perceived to be effective in inspecting machinery. They also understand how to use critical equipment controls.

Individuals also know how to conduct statistical tests.

- **Monitoring and assessing data**
- **Inspecting third party contractors**

The monitoring and assessment of data is a critical part of process control. Supervisory staff already do this well. They can also inspect third party contractors involved in supply and distribution.

- **Approving component/material specifications**

One of the key roles required of technical staff is to approve specifications for the use of specific components and materials for R&D and manufacture.

This competence already exists at a sufficient level to allow companies to be confident that this is being done effectively.

- **Supervising and coaching staff**

Supervisory staff are competent in supporting colleagues at the same level and also those in a front line/operational role in ensuring that tasks are completed effectively.

- **Contributing to procedures**

Staff can also participate effectively by inputting into the development of standard operating procedures. In addition, they can contribute towards the maintenance of product quality. They can also propose legitimate operations to control parameters.

- **Identifying and resolving problems**

Also satisfactory are skills in solving process problems. Controlling emergencies and critical situations is a very important aspect of a

7 or above = satisfactory Below 7 = requires action

supervisor's role. Companies are confident that individuals are already competent at this, both in terms of controlling contamination and also accidents and incidents.

- **Health and safety**

  Staff are able to monitor and maintain health and safety systems.

- **Quality**

  Furthermore individuals are also well placed to provide advice and support for the implementation of quality systems. They can sign off and verify actions concerning quality.

  Staff can also conduct ongoing tests throughout each process to assess product quality according to GMP.

- **Regulation**

  Companies require technical/supervisory staff to keep up to date with requirements of regulatory bodies such as the FDA and also GMP guidelines. They keep up to date with industry standards for validation processes.

  They also sufficiently understand the legislation in packaging and the hazards of warehousing and distribution. They can also ensure their own actions protect the environment.

  Monitoring and analysis of the efficiency of equipment is at a satisfactory level and staff are also competent in measuring Overall Equipment Effectiveness (OEE).

4.4 Gaps

4.4.1 Actionable Skills

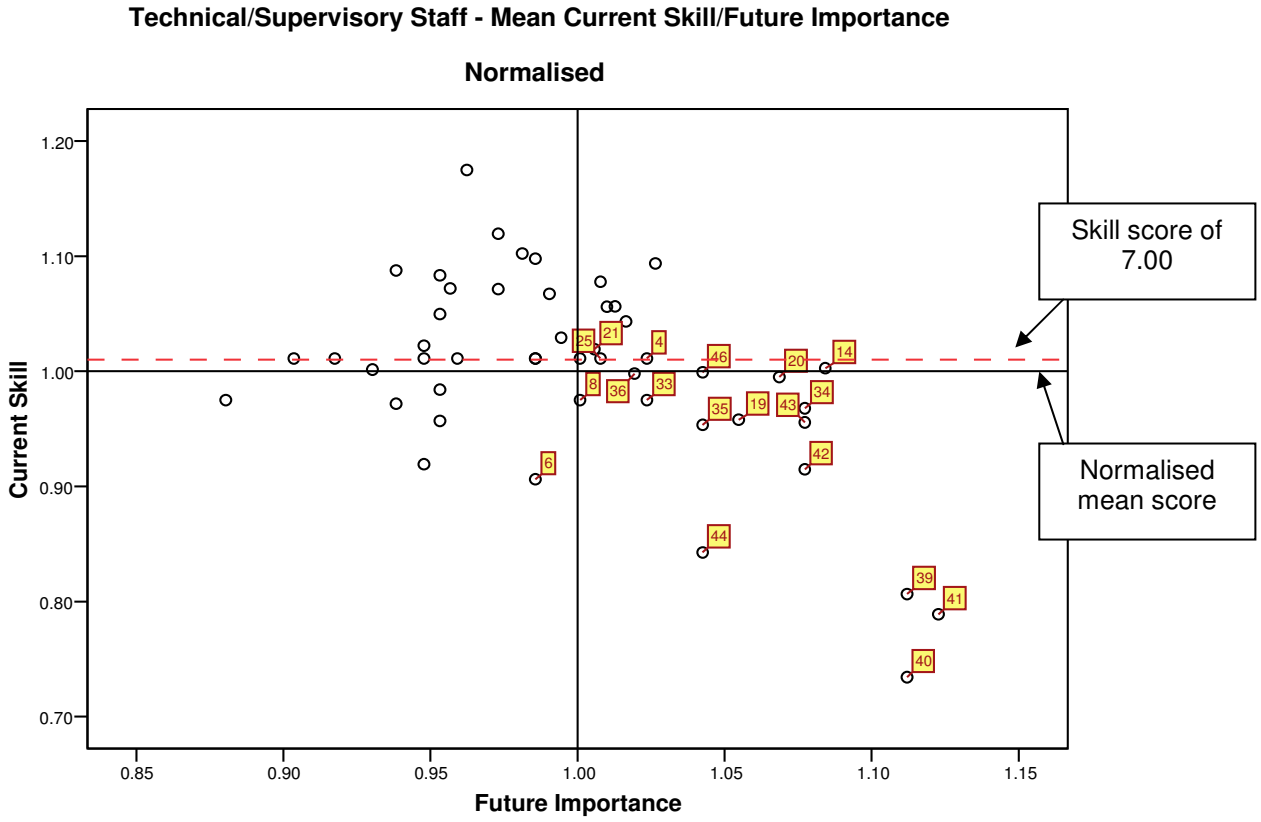
The following diagram highlights the 'normalised' scores for all the skills required of technical/supervisory staff. The lower-right quadrant highlights those skills that have been rated at less than 7.00 out of 10 and are considered by companies to be of increasing importance.

It is important to note that 68.2% of the skills gaps identified for supervisory staff are expected to become more crucial for the sector. This figure represents those skills falling below a satisfactory level (below 7.00) and above the mean for future importance.

Figure 7 illustrates how for technical/supervisory staff, there are a number of scores which fall very low on the skills level scale (therefore not satisfactory) and significantly high in terms of future importance to the sector. These are in particular, understanding environmental considerations in packaging, understanding the use of SPC, and monitoring use of SPC techniques during routine production.

7 or above = satisfactory Below 7 = requires action

Figure7: Technical/Supervisory Staff: Actionable Skills



Refer to the lower- right quadrant of the scatter diagram above to identify skills that have scored below the satisfactory level (7.00) in current skill level and high in future importance (above average). These are detailed below.

Actionable Skills

8	Solving packaging problems
14	Responding to poor performance in the team
19	Writing technical reports
20	Identifying skills needs of staff
33	Setting the parameters for process validation
34	Defining which processes impact on product quality and need validating
35	Assessing effectiveness of personnel in validating equipment and environment
36	Planning timescales for revalidation
39	Understanding environmental considerations in packaging
40	Understanding and use of Statistical Process Control (SPC)
41	Monitoring use of SPC techniques during routine production
42	Putting processes in place for collecting data during routine production
43	Collecting data during routine production
44	Monitoring data (including looking for deviations and trends in performance)
46	Inspecting machinery provided by third parties

7 or above = satisfactory Below 7 = requires action

Borderline Actionable Skills

4	Ensuring statistical tests are conducted
6	Allocating personnel to maintain processing
21	Supervising and coaching staff
25	Controlling emergencies and critical situations (contamination control)

- **Solving packaging problems**

  When receiving deliveries, supervisory staff are required to address any issues with how materials have been packaged during secondary manufacture.

- **Collecting data during routine production**

  Two skills were highlighted here as likely to increase in importance in the next five years. These are the setting up of processes for collecting data as well as gathering information. As an important part of the quality process, it is crucial that this is done well.

- **Inspecting machinery provided by third parties**

  This is required to ensure companies' adherence to regulations and to avoid any issues with equipment. Staff need to be able to do this effectively on a regular basis.

- **Process validation**

  Process validation is a requirement of the Current Good Manufacturing Practices (GMP) Regulations for Finished Pharmaceuticals, 21 CFR Parts 210 and 211, and of the Good Manufacturing Practice Regulations for Medical Devices, 21 CFR Part 820.

  It involves a number of different elements:

  -installation qualification
  -process performance qualification
  -prospective validation
  -retrospective validation
  -providing documented evidence of validation
  -setting validation protocol[3]

  Setting the parameters for process validation is a key part of making sure companies are aware of what needs to be checked. This involves defining which processes could impact on the quality of the production and will need to be validated as a result.

  As indicated, supervisory staff also need to be able to set out timescales for when these processes need to be revalidated.

[3] http://www.fda.gov/cder/guidance/pv.htm

- **Assessing effectiveness of staff and responding to issues**

  Three out of the four skills related to ensuring the effectiveness of skills must be developed further. Less than satisfactory scores were given for identifying the skills needs of staff and responding to poor performance in the team. It is crucial that those in a supervisory position are able to recognise and act on skills issues as these arise to help avoid any critical situations in manufacturing.

  In addition, companies stated that individuals need to be trained further in assessing the effectiveness of personnel in validating equipment and the environment. Seeing as validation and regulation in general is so fundamental to the success of companies, this area also needs to be prioritised.

- **Writing technical reports**

  Individuals are also required to write clear and accurate reports on the processes undertaken; results of these; and how any critical situations have been addressed. This is a requirement of GMP including reporting on process validation.

  An additional four skills are currently poor, scored at below 6 out of 10. These are concerned with understanding and use of Statistical Process Control (SPC), monitoring use of SPC techniques during routine production, monitoring data and environmental considerations in packaging.

- **Monitoring data**

  Staff are required to monitor process data on a regular basis. This includes looking for any deviations and identifying trends in performance that need to be recorded.

- **Understanding environmental considerations in packaging**

  Efficient packaging of products demands understanding of how this can best be achieved to avoid any contamination or disposal that will be harmful to the environment.

- **Use of Statistical Process Control**

  Statistical Process Control is the application of statistical methods to identify and control the special cause of variation in a process. This can be conducted using methodology guidelines such as Six Sigma.

  Currently, individuals do not have satisfactory knowledge of how to use this approach or how to monitor use of these techniques during routine production. These areas must be developed further to ensure these activities are conducted effectively.

4.4.2 Other Gaps

Additional skills have been rated less than 7.00 out of 10 by companies and are not likely to grow in importance according to life sciences companies. However, it is crucial that these are addressed now to help the sector to continue to develop.

- **Allocating personnel to maintain processing**
- **Allocating personnel to maintain line efficiency**

  This may be an issue with identifying the most appropriate staff for these purposes or development may be needed in giving out the right instructions to make sure these individuals are aware of these responsibilities.

- **Conducting an assessment of quality risks in the workplace (HACCP)**

  Technical/supervisory staff are not fully competent in conducting assessments of health, safety and environment risks in the workplace.

- **Defining the process limits for equipment (eg: using guidance such as Six Sigma)**

  Setting process limits is central to ensuring the most effective and accurate use of equipment in manufacturing. This is also needs to be done well to ensure adherence with regulation.

- **Confirming production and completing process paperwork**

  Companies also felt that staff at this level need to further develop their skills in confirming production and also in producing the relevant paperwork that accompanies this.

- **Inspecting purified/sterile water, water for injection and steam clean facilities**
- **Inspecting sterilisers and autoclaves**

  Two of the main responsibilities for inspection are checking purified and sterile water and that used for injection and steam clean, as well as sterilisers and autoclaves. Technical/Supervisory staff need to know how to conduct this task and ensure this is done on a regular basis. Currently this is not carried out to a satisfactory level.

5. Results: Managerial Staff

5.1 Methodology

Scoring skills data

For each skill, a mean score has been derived from all companies that responded. These scores have been provided for each level of staff.

It bears repeating that these scores represent the employer or company's assessment of the current level of skill of their staff, at a given level of staff and for a specific, defined skill.

The analysis dealt with a relatively small number of responses (24 companies), which renders robust and detailed statistical interpretation impossible. All of the results from the quantitative analysis have, therefore, been handled with this constraint in mind, using straightforward summary measurements such as the mean and median of the scores.

The mean provides a simple summary of the scoring for each skill while comparison to the median permits the reader to gain a rough idea of the distribution.

The data are not sufficiently extensive as to allow any of the more sophisticated measures of skewness to be used (or, at least, to carry any reliable meaning).

For practically all skills, the median did not differ significantly from the mean. This data is highlighted in Appendix B.

Future skills

For each skill, companies were also asked to indicate whether this would become more important to the sector in five years time. From these responses, a separate mean score was developed to represent the future importance of each skill.

In this way, Pye Tait was able to arrive at two separate mean scores for each detailed skill relevant to the sector. The first was essentially an expert (ie employer's) view of the level of that skill in the existing workforce; the second their assessment of how important that particular skill would be to the company in the future.

The scores for the current skill level and the mean importance of each skill were then mapped against each other on a scatter diagram. These are included for each level of staff in the main body of this report.

Actionable skills

Having gained an idea of the level of skill in the current workforce and of employers' views of the future importance of those skills, the next stage in the analysis was to develop a method for ascertaining on which exact skills the sector needed to take action and what the priority of that action was.

7 or above = satisfactory Below 7 = requires action

In effect, Pye Tait needed to identify at what level employers feel that skills are satisfactory in meeting their business requirements. While a score of ten out of ten would be extremely desirable in an ideal world, all employers operate on a more practical definition of what is acceptable in a workforce.

The level clearly differs from company to company and – depending on its priority – probably from skill to skill, but, for the sector as a whole, one could either take an arbitrary point below which a given skill was in need of remedial action (for example, any skill falling below the mean for the sector as a whole), or one could ask employers as a whole what they felt the "satisfactory" level was. For this purpose, the Steering Group (composed of senior and experienced practitioners) was selected as a proxy for the industry as a whole.

The project Steering Group agreed that **7 could be considered to be the level at which skills are considered to meet business requirements**. This report highlights where the mean skills scores are currently below this level and therefore, identifies areas of concern.

On each diagram, attention is focused on the lower-right quadrant which contains:

Skills that are currently below 7 AND that will increase significantly in importance in the future

It is these skills that need to be prioritised to ensure the sector in Merseyside and Halton is able to strengthen and compete effectively.

Within the report, skills that have a mean score of 7.00 or above are discussed as meeting or exceeding the required level.

Mean scores presented in the scatter diagrams in the report have been normalised. This is to provide ease of reference when comparing the diagrams for each level of staff. Diagrams representing the actual mean scores are included in Appendix A.

5.2 Summary

- There were 29 skills identified for managerial staff.
- Managerial staff are already skilled to a satisfactory level in 93.1% of all relevant skills
- Gaps are only evident in measuring line efficiency and improving Overall Equipment Effectiveness (OEE) and understanding of potential hazards with airflow and filter sizes

5.3 Satisfactory Skills

However, it is important to consider that managers have in most cases been commenting on their own skills and those of colleagues at a similar level. Because of this subjectivity, the overall proportion of skills that already meet business requirements should be treated with some caution.

7 or above = satisfactory Below 7 = requires action

- **Understanding of regulations for gowning and gloving**
- **Ensuring staff are qualified in gowning and gloving**

Managerial staff must possess a good understanding of regulations for gowning and gloving during processes. In addition, they need to be able to ensure all relevant staff are qualified in these procedures.

- **Keeping financial records where required**
- **Confirming production and complete process paperwork**

Companies stated that those at a managerial level are very competent in keeping financial records. They also confirm production and can complete process paperwork to requirements.

- **Understanding and setting up procedures for adhering to regulation**

A number of skills required in adhering to regulation are already very good. Firstly, staff have a good understanding of the legal and ethical requirements involved in manufacturing. They also ensure systems are in place for ongoing checks against GMP guidelines. They are also able to ensure staff are aware of regulations for working in aseptic operations.

They can also set up equipment and facilities and oversee the cleaning of these.

- **Understanding of microbiology (aseptic)**

Where required, individuals have a satisfactory understanding of the use of microbiology in aseptic conditions. This is important for preventing the infection of workers and contamination of the material under process.

Staff understand the different steps required to ensure conditions are aseptic.

- **Setting up systems for managing quality**
- **Overseeing rollout and maintenance of quality procedures**

It is also very positive that managerial staff are already competent in setting up systems for implementing and managing quality control processes. They can also effectively oversee and steer rollout of these procedures.

- **Understanding the role of the Qualified Person (QP) status**

A Qualified Person (QP) is responsible for certifying medicinal products for release.

Although only a few individuals at a company may have QP status, it is critical that managers are aware of their role and how this contributes to ensuring adherence to regulations.

7 or above = satisfactory Below 7 = requires action

- **Auditing effectiveness of manufacturing processes**

  This is central for manufacturing companies in being able to conduct informed reviews of what is working and what may be causing issues within processes.

- **Understanding of legislation regarding waste routes and environmental impact**
- **Ensuring ongoing sampling of environment including air, water and surface**

  Managers' understanding of the impact waste routes can have on the environment is sufficient. Individuals also know how to make sure the company is being responsible in continuously sampling the environment.

- **Identifying and reviewing skills needs of staff**
- **Monitoring and evaluating the effectiveness of training for staff**
- **Monitoring competence of staff**

  In contrast with supervisory staff, identifying and reviewing the effectiveness of staff is satisfactory. Managers are able to firstly highlight where further development is required. They can also regularly monitor and evaluate how competences may have changed, particularly after completing training.

- **Setting up, reviewing and addressing procedure issues against regulation**

  Three skills associated with regulation are also satisfactory. These include setting up procedures for ensuring manufacturing activity adheres to all relevant guidelines. In addition, managers are competent in recording trends and improving processes in line with these.

  Effective troubleshooting is also very important, particularly with regard to validation protocols in order to optimise performance.

- **Understanding of legislation regarding waste routes and environmental impact**
- **Ensuring ongoing sampling of environment including air, water and surface**

  Managerial staff already possess a good level of understanding of the regulations in terms of waste routes and the potential environmental impact of these. They also know how to ensure the continuous sampling of the environment.

- **Ensuring statistical tests are conducted**

  Another role of managers is to ensure that statistical tests are conducted. This already takes place and companies do not have any concerns about this.

- **Ensuring equipment is cleaned**

  Managers are aware of agreed responsibilities of various staff for cleaning equipment.

7 or above = satisfactory Below 7 = requires action

- **Troubleshooting issues with validation protocols and optimising performance**

  Crucially, managers know how to react to any problems that emerge from the design and implementation of protocols for validation. They also know how to optimise performance.

- **Writing reports and maximising performance**

  Companies are satisfied with managers' ability to write reports – both technical reports on quality issues and those on the use and effectiveness of validation techniques.

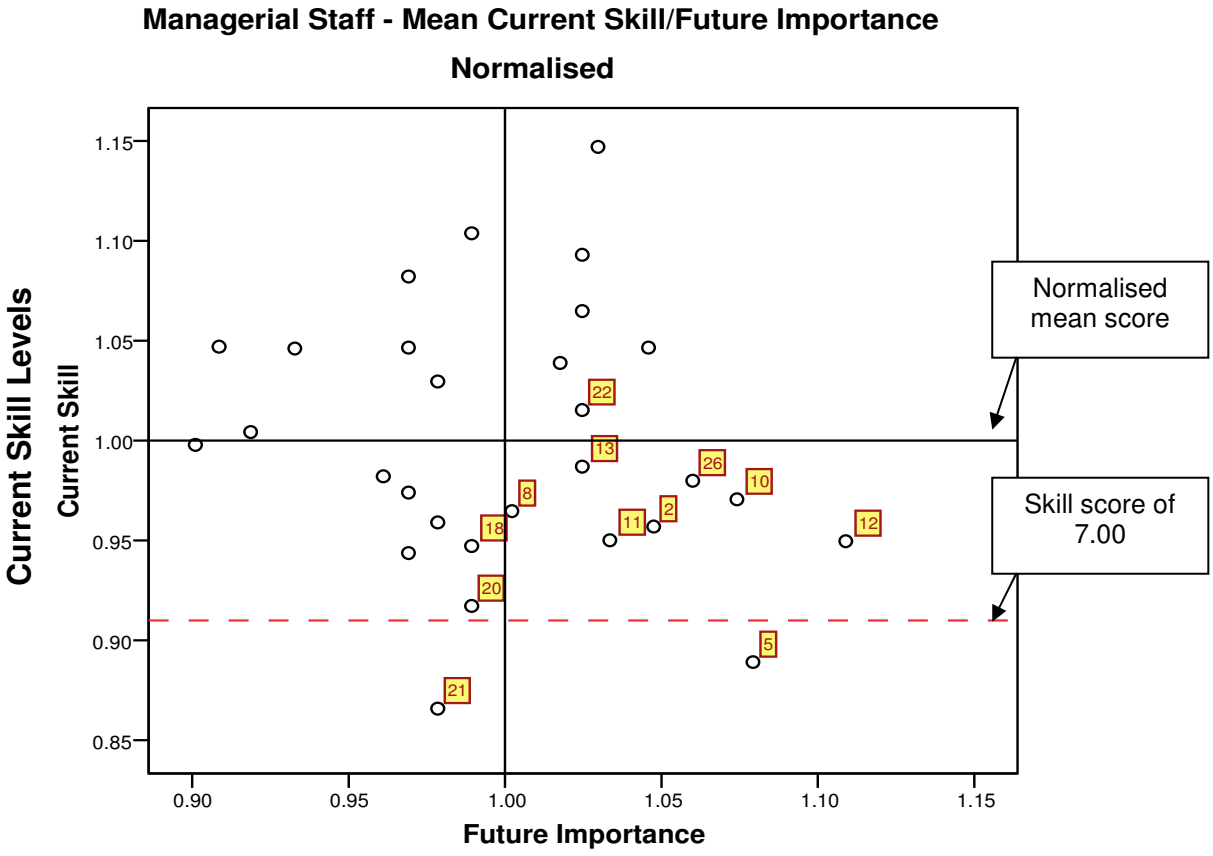
  Staff also know how to make sure performance is maximised as much as possible.

5.4 Gaps

5.4.1 Actionable Skills

The following diagram highlights the 'normalised' scores for all the skills required of managerial staff. The lower-right hand quadrant highlights those skills that have been rated at less than 7.00 out of 10 and are considered by companies to be of increasing importance.

Figure 8: Managerial Staff: Actionable Skills



7 or above = satisfactory Below 7 = requires action

Refer to the bottom right quadrant of the scatter diagram above to identify skills that have scored below the satisfactory level (7.00) in current skill level and high in future importance (above average). These are detailed below.

The majority of skills fall above the satisfactory skills level of 7.00. Just one of the skills required by managerial staff needs to be prioritised for further action. There is one additional skill which although it does score sufficiently on future importance and is therefore not critical, it is still perceived to currently be insufficiently developed and is therefore highlighted as a borderline actionable skill.

Actionable Skills

5	Measuring line efficiency and improving OEE

Borderline Actionable Skills

20	Understanding the legislation regarding waste routes and environmental impact
21	Understanding the potential hazards with airflow and filter sizes

- **Measuring line efficiency and improving OEE**

  Although those in a supervisory role are able to measure Overall Equipment Effectiveness (OEE) effectively, companies are concerned about the ability of managers to conduct this.

5.4.2 Other Gaps

- **Understanding of potential hazards with airflow and filter sizes**

  The level of understanding of potential hazards with airflow and filter sizes needs to be addressed (as shown by a less than satisfactory skill score). This also applies to understanding of the financial regulations to which companies are subjected.

PRIORITISING SKILLS FOR DEVELOPMENT

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6. Prioritising Skills for Development

6.1 Summary of Gaps

This survey has focused on a significant body of skills – 178 in all, covering three levels of staff. Data presented in the previous three sections have indicated that just under **one third of these are currently of concern for companies in Merseyside and Halton,** with 18.5% of all skills being critical requiring skill development to meet future requirements. 27.5% of all these skills are not as developed as companies need them to be.

Nearly two thirds (61.1%) of these areas of concern are expected to increase in importance over the next five years.

The table below shows that technical/supervisory staff have the greatest proportion of gaps to all skills, followed by front line/operational staff.

Individuals commenting on the skills of staff tended to be those in a management role, covering roles such as Managing Director and HR Manager. It is likely therefore that managers have been commenting on their own skills and those of colleagues at their level and the relatively low number of gaps, as illustrated in the table, should be treated with caution.

Table 3: Summary of gaps by level of staff

Level of staff	Actionable Skills		Borderline Skills		TOTAL gaps	
	Number	%	Number	%	Number	% ALL skills
Front line/operational	17	17.3	16	16.3	33	**33.7**
Technical/supervisory	15	31.3	4	7.8	19	**37.3**
Managerial	1	3.4	2	6.9	3	**10.3**

6.2 Considerations

It is necessary to focus in on the gaps identified to consider which may need to be prioritised considering the current and future drivers for the sector, nationally as well as in the region and at local level.

➢ Developments in automation and technology

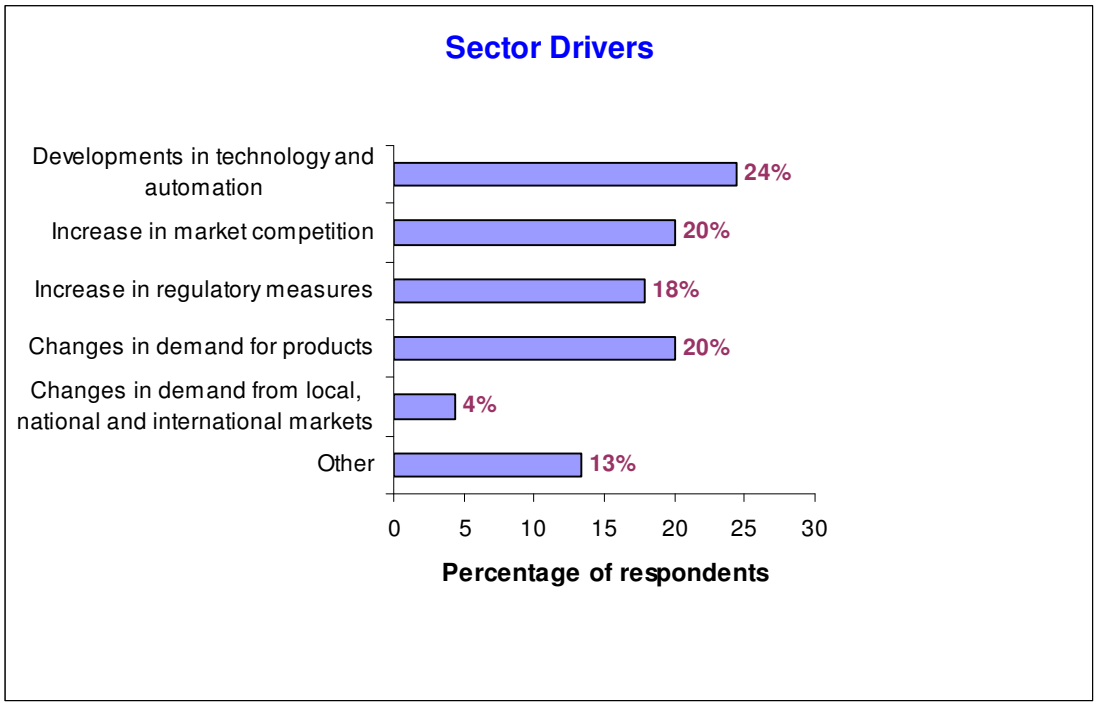
Nearly one quarter of companies that responded to the survey stated that advances in technology have changed requirements for the skills base. Staff at all levels are increasingly required to hold a more sophisticated range of competences in operating equipment.

This reflects an issue at national level. The recent abpi report on 'Sustaining the Skills Pipeline', outlines the increasing complexity of manufacturing control that is in turn raising the demand for more specific skills in this area.

'The increasing complexity of manufacturing control systems and scientific equipment for R&D is raising the level of skill required…[it is] already difficult to recruit and the level of skills/sophistication is expected to increase[4]*'…*

Companies were asked about their perception of which issues drive growth of their company. A summary of their perceived sector drivers is illustrated in figure 9 below.

Figure 9: Sector drivers



[4] abpi (2005) 'Sustaining the Skills Pipeline in the Pharmaceutical and Biopharmaceutical Industries', p.18.

- **Increase in market competition and changes in demand for products**

  As with many industries, competitiveness for markets is a key consideration when strengthening in certain areas or developing new products. Quite a few life sciences on Merseyside are fairly embryonic and have been based on identified niche markets. One example is the fast-tracking of DNA profiling for clients to inform proceedings regarding paternity.

  Customers are also demanding faster results. Knowledge and scientific awareness are forcing changes in demand for products, such as understanding of the human genome.

6.3 Priorities

Summary of Priorities

This section draws out those **'actionable' skills** that **need to be prioritised** by the companies themselves. The table below highlights related skills that are an issue for one or more levels of staff. Clearly these signify gaps across the workforce and should benefit first from the targeting of any specific training.

In addition, the demand for some of these has been underlined further through comments made in more detailed discussions with companies. A few of the skills have been mentioned as one of the top three skills that will become more important in the next five years during face-to-face interviews. **These areas are marked in bold** (table 4).

Table 4: Process

Front line/operational	Supervisory	Managerial
1. Process automation and Statistical Process Control (SPC)		
Setting up and operating automated inspections Controlling process automation	Understanding use of SPC Monitoring use of SPC techniques	
2. Reviewing process effectiveness		
Understanding of how to monitor/analyse efficiency of equipment	Collecting data during routine production Monitoring data	

3. Identifying and reviewing skills needs of staff		
	Identifying skills needs of staff Assessing effectiveness of personnel in validating equipment and environment Responding to poor performance in the team	

Other increasingly important skills mentioned by companies tended to relate to their specific products and services. Examples included:

- Late stage variance
- Segmentation
- Purified antibody production
- Interfacing and IT solutions
- Molecular diagnostics

6.4 Quality and Regulation

Some areas of quality and regulation are a real concern for companies and especially for staff working in front line/operational roles. In fact, these account for half of actionable skills gaps at 51.5%.

All of these need to be prioritised, considering the very real and significant impact of these gaps could have on the effective operation of the sector on Merseyside and Halton.

However, it is useful to highlight those areas that are an issue across more than one level of staff (table 5).

Table 5: Quality and regulation

Quality

Front line/operational	**Supervisory**	**Managerial**
1.Environmental considerations		
Carrying out environmental monitoring – air, water and surface sampling	Understanding environmental considerations in packaging	

Regulation

Front line/operational	Supervisory	Managerial
2. Understanding of relevant GMP in secondary manufacture and conducting checks against this		
Understanding of relevant GMP Conducting checks against GMP Complying with FDA requirements for GMP		

3. Validation		
Executing validation protocols Testing of filters for validation	Assessing effectiveness of personnel in validating equipment and environment Setting the parameters for process validation	

4. In-house inspection		
Operating/setting up automated inspections	Inspecting machinery provided by third parties	

USE OF TRAINING

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7. Use of Training

Twenty five companies commented on: their use of training, preferred methods of accessing development for their staff; and any barriers in accessing these.

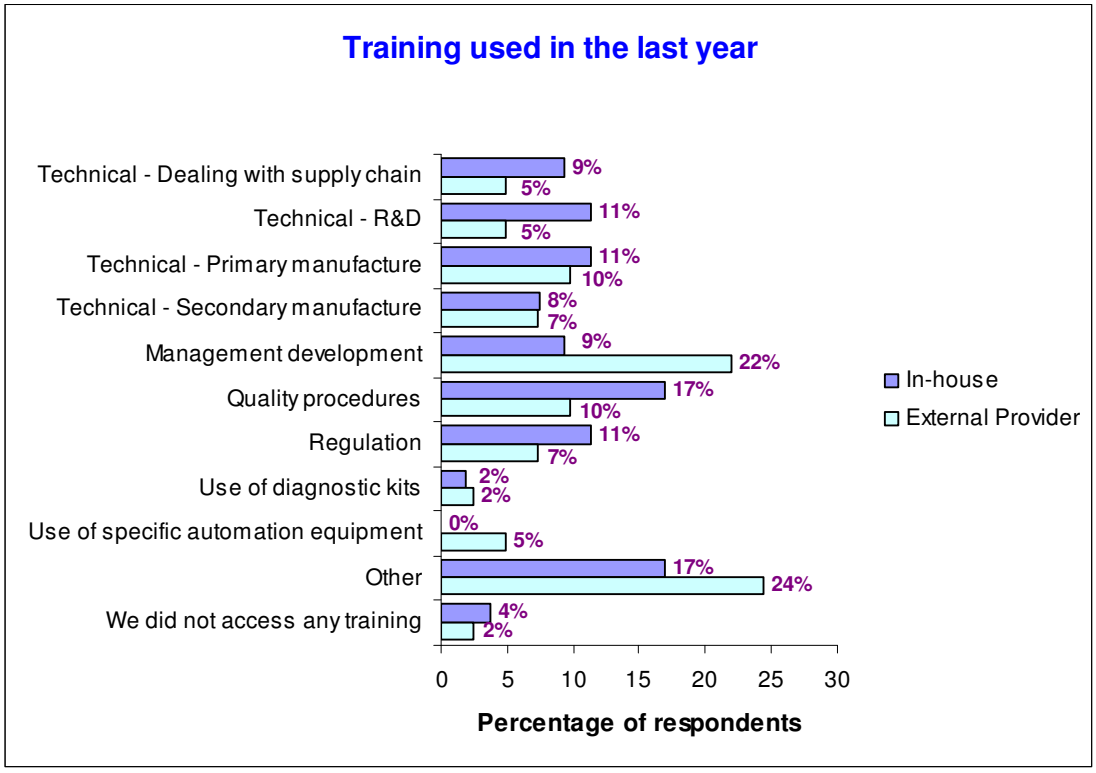
7.1 Use of Training

Quality procedures training has been the most popular development delivered in-house in the last twelve months (figure 10). Other areas accessed by more than 10% of the companies consulted include: regulation; technical skills for primary manufacture; and technical skills used in R&D.

Many of the responses indicated under 'other' relate to areas of regulation such as dealing with hazardous waste and maintaining a clean room.

22% of companies have also sourced management development training from external providers.

Figure 10: Training used in last twelve months



Despite the use of automation being a significant area that needs to be developed further in Merseyside and Halton, use of this training has been low – by only 4.9% of companies.

Table 6: Factors considered in prioritising training for staff

Factors	Percentage of respondents
Those skills required which directly affect quality of the product	19.1%
Those skills required which impact on company adherence to regulations	23.4%
Relative training costs	19.1%
Release of staff required	12.8%
Other	25.5%

Any impact of skills development on the companies' ability to adhere to regulations such as GMP and GLP is a significant factor in deciding what training will be prioritised. This is reinforced by comments from companies:

> *"Anything to do with health and safety directly related to our obligation as a company is prioritised".*
>
> *"Firstly we consider safety requirements".*
>
> *"Product safety is key in its relevance to GMP…"*

Likely improvements on the quality of the product being produced is also important. However, the cost of training is also an important consideration.

Comments made under 'other' mainly, again, relate to adherence to regulations. Commercial drivers were also mentioned.

Companies were clear that they tend not to use structured training plans but that staff are sent on provision when the need arises. Certain staff can be prioritised depending on how central the skills need is to their role.

> *"There is no structured plan and as need arises people are sent on courses".*
>
> *"There is no training plan so if training is required in house it would just get done – for external training requests are put in and each case is considered separately".*
>
> *"Training is prioritised according to the role of the member of staff…its necessity is considered".*

One third of companies evaluate the effectiveness of any training undertaken by discussing impact in staff development reviews. This usually involves focusing on progress against individual training plans.

A smaller proportion of 10.3%, consult with individuals' supervisors or line managers to ascertain how successful training has been.

Companies were also asked about any issues they faced in accessing the required development for their staff.

Half of all respondents indicated that the cost of training or the time and money lost in releasing staff is a real barrier.

This is a serious issue that needs to be addressed and will involve tying in with work by relevant Sector Skills Councils and the Regional Skills Partnership in offering support to companies to avoid these problems.

Perhaps more significant is the view from nearly 15% of companies that there is a lack of the relevant training available in Merseyside and Halton. In addition, 17% feel there is insufficient detail available locally on what can be accessed.

Table 7: Barriers to accessing training

Barrier	Percentage of respondents
Cost of training required	25.7%
Time and money lost in releasing staff	25.7%
Lack of information on relevant specialist training available	17.1%
Lack of required training within the local area	14.3%
Lack of specialised training to meet need in the UK	2.9%
Other	14.3%

7.2 Availability of Training

7.2.1 In-house Capabilities

A few companies do provide training for their own staff. This tends to be on specific induction procedures and operations concerning the individual business and its product(s).

Two of the largest local employers are partners in 'Partnership for Learning' – a training and business resource specific to the local area. In these instances a great deal of training provision is offered in-house and expertise is also provided to other companies.

Provision to other companies

Half of manufacturing companies consulted provide training or other development activities to others in the area.

These include companies that provide consultancy services to the sector such as Eden Biodesign and Safebridge Europe Limited. They also offer training, such as quality assurance.

All companies involved in the research feel they have specialist knowledge they can share to benefit others. This ranges from competence in manufacturing processes to skills in producing certain products eg; through freeze drying to bacterial endo toxin testing. Analytical skills and business excellence models were also mentioned.

In most cases, companies would be willing to work with others in the sector to transfer these skills if funding was available to cover the release of their staff. It was stressed that a number of different methods should be used to disseminate this knowledge through non-traditional forms of training. For example, networking events and workshops are considered a good means of sharing information. Methods that include the use of case studies and more specific vocational seminars were also thought to be useful. Comments have been made around the tendency for training to be very formalised and classroom based – especially in academic settings.

7.2.2 External Provisions

A range of training is available from companies based locally; regionally; UK-wide and also those with an international coverage. These are mainly vocational qualifications ranging from Foundation Degrees to Higher National Certificates. NVQs are also on offer. There are also a wide range of academic courses available locally in the North West, supplying many new staff in Merseyside and Halton.

Specialist areas

Universities

A number of universities in the North West provide relevant training at undergraduate and postgraduate level. These include: Liverpool University; Liverpool Hope University; Liverpool John Moore's University; and the University of Manchester. Specialist areas include:

- Microbiology of food and drinking water
- Molecular biology (with genetics)
- Immunology basic terms and techniques
- Basic microbiology for infection control
- Consultancy and lab services
- Pharmacokinetics
- Pharmacovigilance
- Clinical lab support
- Biomedical sciences
- Biotechnology
- Forensic science
- Medical biochemistry
- Industrial pharmaceutical science
- Pharmaceutical and biological chemistry
- Clinical pharmacy
- Oncology pharmacy practice
- Chemical engineering
- Chemical technology
- Chemical practice
- Virology

Other providers

A number of professional bodies and private training providers offer a range of specialist training for life sciences companies. The areas covered are summarised below.

Table 8: Specialist training available in Merseyside and Halton

Preparation	Control	Completion
Supply chain logistics	Clinical statistics	Pharmaceutical packaging
Inventory control and management	Analysis and testing (including chemical analysis)	
Clinical trials	Stability testing	
Cleaning	Cryogenic application	
Engineering	Statistical quality control	
Clean room design	Specialist gases	
	Pharmaceutical water systems	
	Autoclaves/sterilisers	
	Aseptic manufacture	
	Toxicology	

Quality and regulation	
Computer systems validation	Statistical quality control
Financial management	GMP
Information Technology	Health and safety (HSE)
Human resources	Management development
HVAC awareness	Risk management
FDA regulation and inspection	Qualified Person (QP)
Water validation	Validation

Generally training is provided according to specific industry standards. These include:

- Chartered Institute of Purchasing
- GMP guidelines
- British Standards Institute
- HGM20 and ISOEN285 for sterilisation
- IBMS
- APMG
- Institute of Leadership and Management
- NVQs

However, this does appear to be dependent in some cases as to whether the employer requests the use of guidelines.

There is less evidence of providers using specific measures to ensure the appropriate knowledge has been transferred to companies. In most cases, the fact that staff have undertaken development based on industry standards is used as an indicator of success.

According to providers, the majority of courses are developed as requested by employers. However, it is not clear how they ensure that they are continuously reviewing the needs of employers. Nor is it obvious the degree to which the sector is aware of the flexibility of training.

There is limited evidence on to what extent plans are in place to develop or introduce new provision to meet the requirements of the industry locally.

Coverage

There are a number of skills areas where further training is required that do not appear to currently be available.

Although training is on offer for computer systems validation, this does not seem to cover **process automation and use of SPC**.

Analysis is covered in training available locally but this may not sufficiently cover identification and monitoring of data as required to **review and make judgements on the effectiveness of processes**.

Writing reports, environmental considerations and in-house inspection also do not appear to be included.

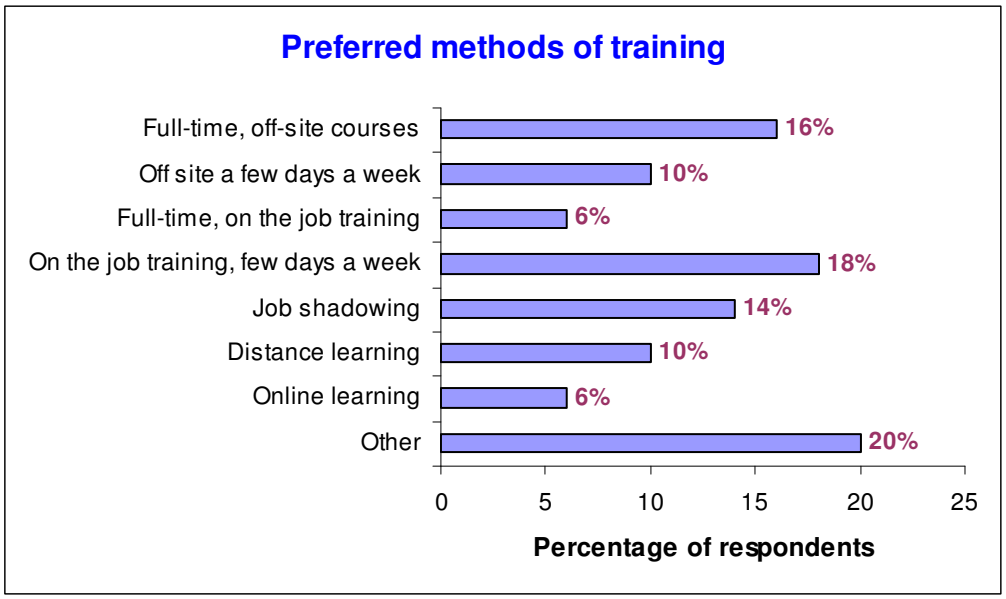
As many providers offer tailored support it is important that this report is followed by further consultation with them regarding what they may be able to offer to help address these gaps.

7.3 Methods of Delivering Training

Companies involved in the research were asked to comment on the methods of delivery they prefer when accessing training.

Opinion is divided here mainly between full-time courses attending provision off site and 'on the job' training conducted a few days a week.

Figure 11: Preferred methods of training



Methods of training mentioned under 'other' also related to provision full-time off site and that delivered 'on the job'.

There appears to be a demand for **greater availability of training** for very specialist skills in a **vocational format** to 'top up' academic training

Employers have been very clear that the only way in which awareness and competence in regulation and other areas can be fully accomplished, is through learning 'on-the-job'.

> *"There is a huge demand for vocational qualifications to help individuals understand process control and other regulatory matters".*
>
> *"Universities are not in touch with the very specialist skills needed".*
>
> Life sciences companies

CONCLUSIONS AND RECOMMENDATIONS

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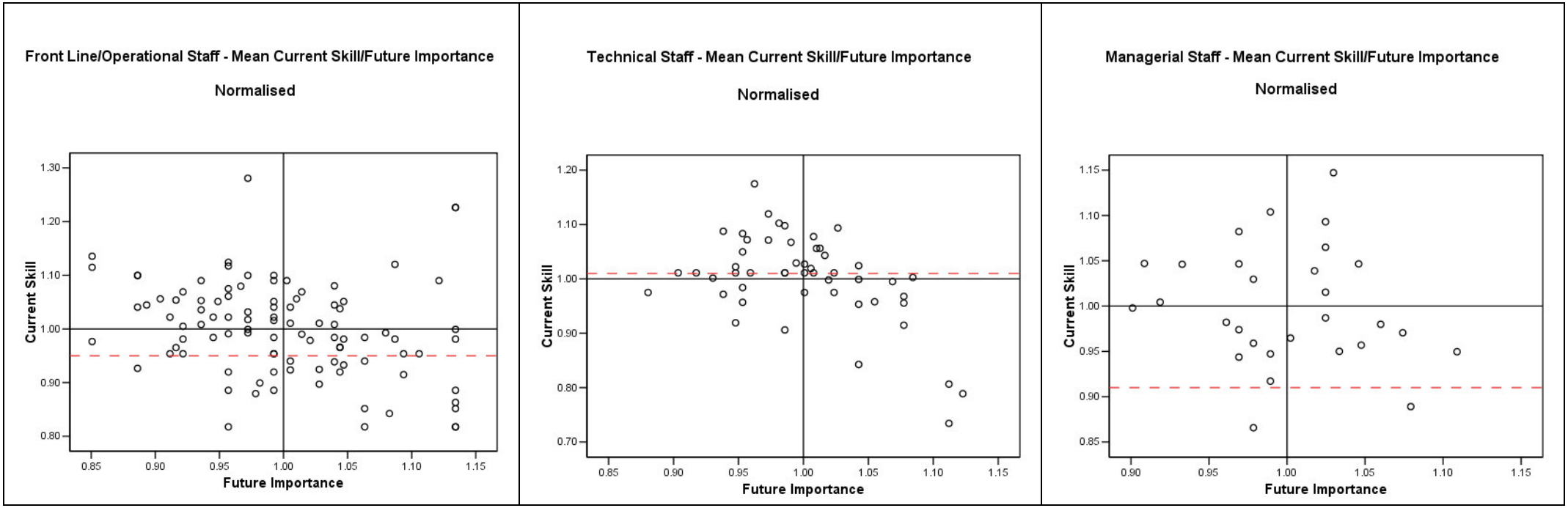
8. Conclusions and Recommendations

8.1 Conclusions

The sector is diverse in Merseyside, both in terms of the range of services and products provided, but also the various stages in development, ranging from their first year of operation to well established global enterprises. Despite these differences there are some clear, cross-cutting skills that can affect everyone, particularly those impacting on quality and adherence to regulation. Figure 12 allows comparison of distribution of skills scores across all staff.

Figure 12: Distribution of Mean Scores for all levels of staff



The scatter diagrams presented above, illustrate the distribution of 'normalised' scores for each level of staff. The purpose of this is to highlight how these distributions look when compared with one another. As before, the skills below a satisfactory level (below a score of seven), fall below the dotted line on the diagrams and skills regarded as important for future development, are located to the right of the average score of future importance (above the normalised 1.00). Although there are far more skills located in the lower-right quadrant for front line/operational staff, the chart for technical/supervisory staff clearly shows that companies have provided lower scores for this level of staff compared to other levels.

According to the respondents this indicates, that in their perception, the biggest gaps are for technical/supervisory staff.

When considering the results for each level of staff, a number of conclusions can be made as follows:

- **Three quarters of the technical manufacturing skills** used by life sciences companies are already at a **satisfactory level**.
- Companies have been clear about existing competence in: **dealing with the supply chain; identifying and resolving problems; and health and safety**. A few areas of **quality and regulation** are also satisfactory such as washing in-between batches and products to remove impurities and carry over.
- Proportionally there are **more significant skills gaps for technical/supervisory staff**.
- However, **front line/operational staff** also lack a similar number of both general and very specific technical competences required for effective manufacturing.
- Approximately **half of actionable skills for front line/operational staff relate primarily to regulation** but also to quality.
- **Process automation and use of SPC does not appear to be covered by existing provision.**
- **The ability to review and make judgements** on the effectiveness of processes also needs to be developed within companies.
- **Writing reports, environmental considerations and in-house inspection** also do not appear to be included within what is available.
- Many of the **skills gaps could be addressed through short vocational courses** offered by the Universities or other providers or more focused job-shadowing.
- Companies believe that **awareness of specific regulation issues and highly specialised technical skills can only be learned through doing**.

8.2 Recommendations

In order for the sector to grow and compete effectively in Merseyside and Halton, in the North West and nationally and internationally, immediate action is needed to:

a) ensure tailored training is in place locally to help companies address the needs identified;

b) identify how employers can best be supported in accessing this provision - in terms of financial investment and release of staff where required; and

c) ensure they are aware of these opportunities.

A series of recommendations are outlined on the following page to help ensure this becomes a reality.

Recommendations

Timescales:

Short-term	up to 6 months
Medium-term	6 to 12 months
Longer-term	beyond 12 months

Recommendation	Partners responsible	Timescale
❖ **Canvas local life sciences companies to quantify demand to help derive the scale of training required in Merseyside and Halton - through courses in priority areas such as process automation and use of SPC**	Life sciences companies, LSC, JET, MerseyBIO*	Short-term
❖ **Consult with the local provider network – including the Universities – on their capacity to offer tailored training that addresses skills gaps in key areas**	LSC, JET, Partnership for Learning, Universities, other training providers, HEIs, MerseyBIO*	Short-term
❖ **Ascertain where specific training may need to be introduced and whether the skills need can be targeted through short courses**	Sector Skills Councils, LSC, JET, Regional Skills Partnership, MerseyBIO*	Short-term
❖ **Consult further with companies regarding their preferred methods of training and establish their awareness of any financial support available to them**	LSC, MerseyBIO*	Short-term
❖ **Investigate the availability of financial resources to cover release of staff from companies to allow for the sharing of expertise with other companies in the area**	LSC, employers, MerseyBIO*	Short-term

❖ **MerseyBIO should work with the relevant Sector Skills Councils, the LSC, JET and the Regional Skills Partnership to develop unitised and/or more flexible modes of learning for staff – this work should inform finalisation of the Sector Skills Agreements**	MerseyBIO*, Sector Skills Councils, LSC, JET, Regional Skills Partnership	Short-term
❖ **Set in place targets for providers to ensure training is developed in line with standards - where this is funded by the LSC and also request evidence that knowledge has been transferred to individuals**	MerseyBIO*, LSC	Medium-term
❖ **Consider separate focused discussions with Universities to establish how modules can include a greater number of work related elements, delivered in a form that is useful for companies**	MerseyBIO*, Universities	Medium-term
❖ **Reuse skills scoring questionnaires with companies every 18 months to help benchmark any changes in the level of skill**	MerseyBIO*, LSC	Longer-term

** MerseyBIO facilitates and supports companies and is not is a position to lead on these actions*

Actions

As LSC and Jet South Liverpool have both been closely involved with Skills Survey from its inception the following actions based on the recommendations have been put in place by Greater Merseyside LSC and Jet South Liverpool.

LSC Programmes

Programme Title	Overview	Available
Skillworks	Demand-led training programme for Small and Medium Enterprises (SMEs) in Objective 1 area of Greater Merseyside utilising European Social Funding. Eligible businesses may receive a contribution of up to 60% towards the cost of training required. Opportunity to access support through a number of training providers who deliver the programme on behalf of the Learning & Skills Council (LSC).	Now
Train to Gain	National LSC programme which provides free impartial and independent advice for businesses provided by Skills Brokers. Working closely with each individual Employer, the Train to Gain Skills Broker will provide support to: **1) Identify the skills each business needs** A free review and analysis of the business to assess what skills the business has and identify what it might need in the future. **2) Pinpoint the right training** Based on the skills analysis the Skills Broker will provide recommendations to help each Employer: • Identify the type of training which would best meet the skills needs identified. • Select the most appropriate Training Providers. • Choose how and when the training is delivered. • Determine which qualifications employees will benefit from most. **3) Agree a tailored training package** The Employer, Skills Broker and Training Provider agree a training package to meet the needs identified. **4) Find available funding** The Skills Broker can recommend the best ways of funding the training, explaining all the options available including:	August 2006

	• Free training to help employees gain their first full Level 2 qualification and Skills for Life first numeracy and literacy qualification. This includes all training toward 5 GCSE at Grade C or above, NVQ Level 2 or equivalent (such as Skills for Life programmes) and a wide range of other training for low-skilled staff. • Wage compensation for companies with less than 50 employees. • Funded programmes including Apprenticeships and Advanced Apprenticeships, NVQ Level 3 and above, such as higher education. **5) Review The Progress The Employer Is Making** The Skills Broker will provide continual support to the Employer to review how the training is progressing and assistance to address any additional needs which may arise.	
Skillworks for the Bio-technology Sector	Dedicated demand-led training programme utilising European Social Funding for the Life-Sciences Sector to access. Under the programme all businesses, regardless of size, will potentially be able to receive a contribution towards the cost of training, which is not already funded through Train to Gain or other public programmes. Employers will only be able to access the programme via the Train to Gain Skills Broker.	August 2006
Skills Passports	Skills Passports offer opportunity for sector specific re-training and it proposed they include • To achieve sector-wide consensus on competencies • Three basic elements – generic , sector specific and soft skills • An element of verification • Experiential learning as well as qualification	September 2006
	The Qualifications & Curriculum Authority (QCA) is looking at sector qualification reform, to design, create & implement vocational qualifications.	
	DfES are currently working with Sector Skills Development Agency, Sector Skills Councils and Key Stake holders including Jet South Liverpool to develop and promote Skills Passports.	
	The LSC are looking to introduce a Unique Learner Number and Learner Registration Service, along with a set of core common data definitions and a UK register of learning providers, as soon as possible. A controlled two year testing and trial phase is due to start in September 2006. The LSC are looking to introduce a Unique Learner Number and Learner Registration Service, along with a set of core common data definitions and a UK register of learning providers, as soon as possible.	

APPENDICES

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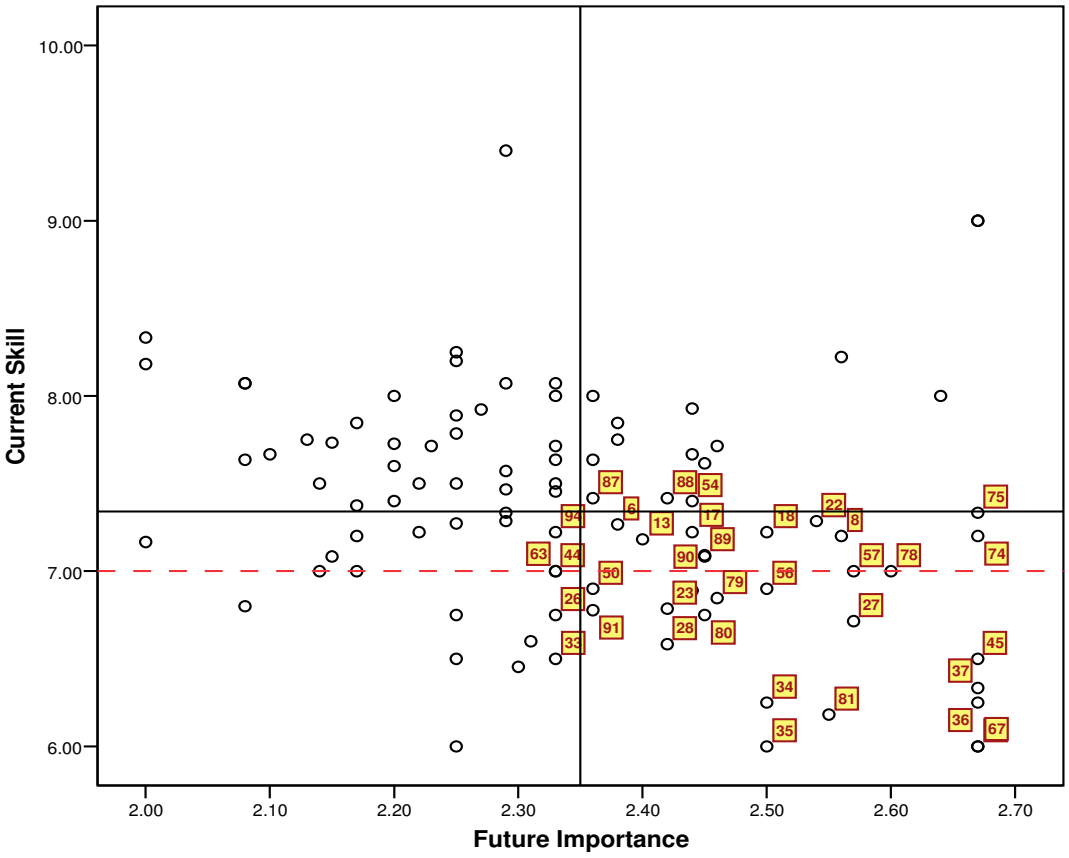
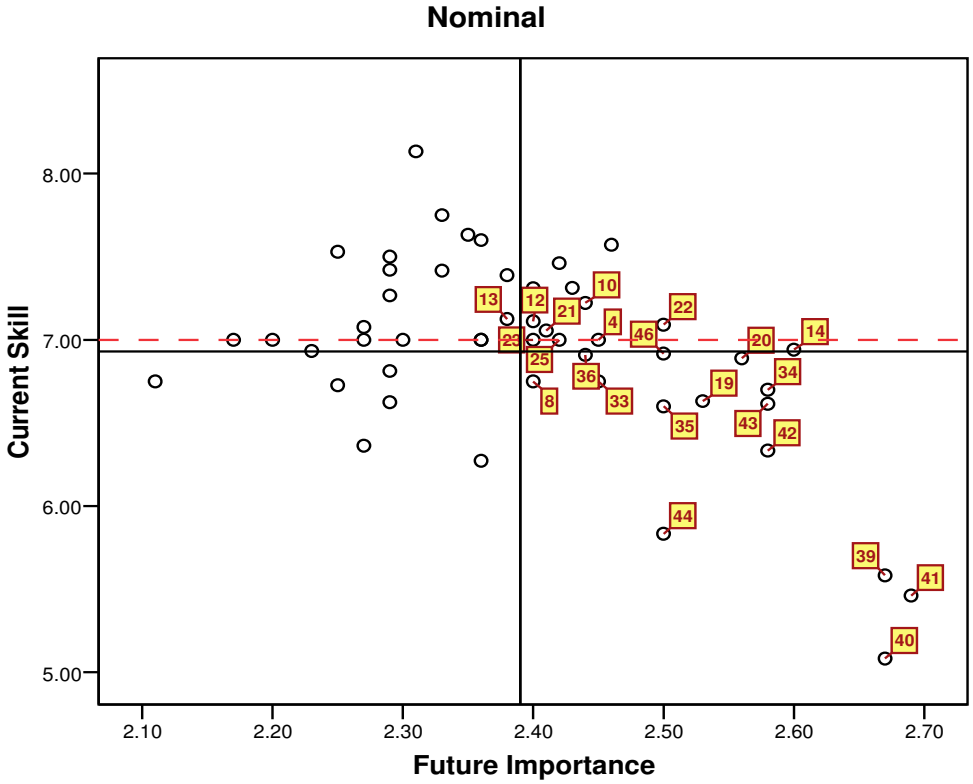
Appendix A: Absolute Scores - Scatter Diagrams

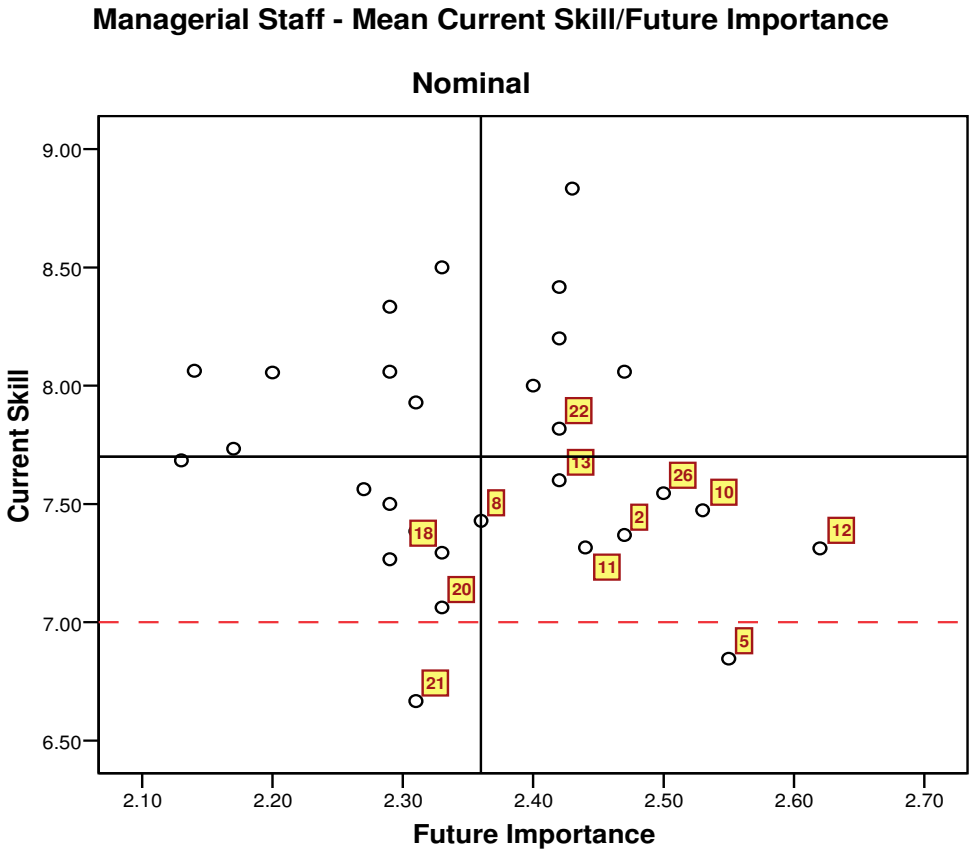
Front Line/Operational Staff - Mean Current Skill/Future Importance

Nominal



Technical/Supervisory Staff - Mean Current Skill/Future Importance




Managerial Staff - Mean Current Skill/Future Importance
Nominal
Current Skill
9.00
8.50
8.00
7.50
7.00
6.50
2.10
2.20
2.30
2.40
2.50
2.60
2.70
Future Importance
22
13
26
10
8
2
18
12
11
20
5
21

Appendix B: Mean and Median Skills Scores

Mean and Median Scores

1.Front Line/Operational Staff

Skill	Mean	Median
A) *Production planning and ordering materials and components*		
1. Managing an inventory	7.73	8
2. Checking materials have been provided to 'fit for purpose' specification	8.07	8
3. Developing and communicating a production plan	7.79	8
4. Managing data about materials/equipment ordered	8.07	8
5. Capacity management	7.47	8
6. Resource management	7.27	8
B) Receiving deliveries		
7. Collating orders and checking against inventory	8.07	8
8. Understanding of how to classify materials according to GMP	7.2	8
9. Understanding of how to manage the shelf life of materials	8.25	8
10. Reviewing stock levels on a regular basis	7.71	8
C) Warehousing		
11. Checking and controlling the temperature and humidity storage conditions for materials	8.18	8
12. Status labelling	7.92	8
13.Segregating materials	7.18	8
14. Ensuring the security of materials, including when on pallets	7.4	8
15. Handling materials with required care	7.85	8
16. Quarantining materials	7.5	8
17. Understanding of relevant GMP	7.22	8
18. Conducting checks against GMP	7.22	8
R & D (pre and post clinical trials)		
19. Prepare laboratory materials, equipment and resources	8.07	8.5
20. Sampling (raw) materials	7.62	8
21. Testing operations	7.2	8
22. Testing materials	7.29	8
23. Cleaning equipment	6.79	7
24. Conducting statistical tests	6.6	7
25. Status labelling	6.45	7
26. Control of inventory/stock	6.75	7.5
27. Understanding of relevant Good Laboratory Practice/Good Clinical Practice	6.71	7.5
28. Conducting checks against GLP/GCP	6.58	7.5
Primary manufacture		
29. Cleaning and preparing vessels	7.67	9
30. Charging vessels (manually or through a vacuum)	7.27	9
31. Setting up equipment	7.73	8
32. Use of specific EHS equipment e.g. respirators, spillage, dust extraction	7.08	8.5

D) Virus growth		
33. Inoculation	6.5	7.5
34. Incubating a virus	6.25	7.5
35. Harvesting a virus	6	7
36. Potential inactivation of a virus	6.25	7
37. Protein separation	6.33	8
E) Purification		
38. Understanding of how to load equipment with input chemicals	7.57	9
39. Understanding of how to convert base to salt and then back again	6	8
40. Understanding of crystallisation	6.75	8
41. Understanding of filtration	7.6	9
F) Chemical synthesis		
42. Using additional chemicals to create a chemical reaction	8.33	9
G) Preparation		
43. Milling and grinding materials to correct particle size	7.2	7
44. Separating and disposing of processing materials, by products and waste	7	7
H) Manufacturing proteins		
45. Fermentation	6.5	6.5
46. Understanding relevant GMP	9	9
47. Conducting checks against GMP	9	9
Secondary manufacture		
48. Understanding how to operate equipment	7.64	8
49. Filling (eg: ampoule/vial/syringe) and packaging into secure containers	8.2	8
50. Controlling process automation	6.9	7.5
51. Loading the line	7.22	8
52. Removing product from the line	7.64	8
53. Cleaning the line/facility	7.45	8
54. Preparing for next operation	7.4	7.5
55. Use of purified water, sterile water, water for injection, clean steam	7.75	8
56. Understanding of relevant GMP	6.9	7.5
57. Conducting checks against GMP	7	8
I) Packaging		
58. Loading the line	7.5	7.5
59. Overlabelling/batch number and expiry dating	7.89	8
60. Operating packaging machines	7.75	8
61. Cleaning packaging machines	7.5	7
62. Cartoning and leaflet insertion	7.71	8
63. Checking the weight of the product	7	8
64. Overwrapping	7.17	7.5
65. Casing the product	7	8
66. Palletising the packaged product	7.29	8
67. Understanding of relevant GMP	6	6
68. Conducting checks against GMP	6	6
Quality procedures		
69. Checking quality of diagnostic kits	9.4	9
70. Following the relevant process instructions	7.85	8
71. Controlling, monitoring and adjusting the process operation	7.71	8

72. Washing in-between batches/products to remove impurities /carry over	7.67	8.5
73. Sampling and undertaking in-process control measurements and tests	8	8.5
74. Operating/setting up automated inspections	7.2	8.5
75. Carrying out environmental monitoring – air, water and surface sampling	7.33	8
76. Use of autoclaves and sterilisers	7.38	8
77. Confirming components and products meet inspection criteria	8.22	9
Regulation		
78. Understanding of European GMP standards	7	7.5
79. Understanding of FDA requirements, Material Resources Planning	6.85	7
80. Awareness of European guidelines about distribution and CE marking	6.75	7
81. Complying with FDA requirements for GMP	6.18	6
82. Complying with organisational safety requirements	8	8
83. Dealing with unusual occurrences	7.33	7
84. Following detailed process instructions and associated record keeping	8	8
85. Movement of chemicals and other by products in a safe manner	7.93	8
86. Monitoring of air standards and air pressure for validation/routine production	6.89	7
87. Testing of filters for validation /during routine production	7.42	8
88. Testing and challenging equipment during routine production	7.42	7.5
89. Setting up automated systems to conduct validation/rejecting or accepting product during routine production	7.09	8
90. Reviewing effectiveness of such systems	7.08	8
91. Executing validation protocols	6.78	8
92. Understanding of financial regulations	6.8	7.5
93. Keeping financial records where required	7.64	8
Engineering		
94. Understanding of how to monitor/analyse efficiency of equipment	7.22	8
95. Maintenance of purified water, sterile water, water for injection and clean steam generation facilities	7	8
96. Maintenance of sterilisers and autoclaves	6.5	7.5
97. Calibration of sensors/gauges and chart recorders	8	7.5
98. Setting up and use of PLC controllers	7.5	7.5

2. Technical/Supervisory Staff

Skill	Mean	Median
1.Working effectively within a supply chain	7.31	7
2. Ensuring materials have been provided to specification/fit for purpose	7.75	8
3. Ensuring equipment is cleaned	8.13	8
4. Ensuring statistical tests are conducted	7	8
5. Inspecting equipment	7.6	8
6. Allocating personnel to maintain processing	6.27	7
7. Approving component/material specifications	7	7
8. Solving packaging problems	6.75	7
9. Allocating personnel to maintain line efficiency	6.36	7
10. Conducting an assessment of health, safety and environment risks in the workplace	7.22	8
11. Conducting an assessment of quality risks in the workplace (HACCP)	6.81	8
12. Contributing to standard operating procedures	7.11	8
13. Contributing towards the maintenance of product quality	7.13	8
14. Responding to poor performance in the team	6.94	7
15. Providing advice and support for implementation of quality systems	7.39	8
16. Signing off and verifying quality actions	7.53	7
17. Solving process problems	7.63	8
18. Monitoring and assessing data	7.42	8
19. Writing technical reports	6.63	7
20. Identifying skills needs of staff	6.89	7
21. Supervising and coaching staff	7.06	7
22. Inspecting third party contractors	7.09	7
23. Understanding of critical equipment controls	7	7.5
24. Confirming production and completing process paperwork	6.93	8
25. Controlling emergencies and critical situations (contamination control)	7	8
26. Controlling emergencies and critical situations (Accidents and incidents)	7.5	8
27. Ensuring own actions protect the environment	7.27	8
28. Keeping up to date with requirements of regulatory bodies (eg: EU GMP)	7.57	8
29. Conducting ongoing tests throughout each process product quality according to GMP	7	8
30. Proposing legitimate operations control parameters	7.46	7
31. Monitoring and maintaining health and safety systems	7	7
32. Keeping up to date with industry standards for validation processes	7	8
33. Setting the parameters for process validation	6.75	8
34. Defining which processes impact on product quality and need validating	6.7	7
35. Assessing effectiveness of personnel in validating equipment and environment	6.6	7.5
36. Planning timescales for revalidation	6.91	8
37. Understanding legislation in packaging	7.42	7
38. Understanding the hazards of warehousing and distribution	7.08	7

39. Understanding environmental considerations in packaging	5.58	7
40. Understanding and use of Statistical Process Control (SPC)	5.08	6.5
41. Monitoring use of SPC techniques during routine production	5.46	5.5
42. Putting processes in place for collecting data during routine production	6.33	5
43. Collecting data during routine production	6.62	7
44. Monitoring data (including looking for deviations and trends in performance)	5.83	7
45. Defining the process limits for equipment (eg: using guidance such as Six Sigma)	6.73	6.5
46. Inspecting machinery provided by third parties	6.92	7
47. Monitoring and analysing efficiency of equipment and measuring overall equipment effectiveness (OEE)	7	7
48. Inspecting purified/sterile water, water for injection and clean steam facilities	6.63	7
49. Inspecting sterilisers and autoclaves	6.75	7
50. Understanding of financial regulations	7	7
51. Keeping financial records where required	7.31	7

3. Managerial Staff

Skill	Mean	Median
1. Ensuring equipment is cleaned	7.68	8
2. Ensuring statistical tests are conducted	7.37	8
3. Overseeing setting up/cleaning of equipment and facilities	8.06	9
4. Understanding of microbiology (aseptic)	7.73	8
5. Measuring line efficiency and improving OEE	6.85	8
6. Setting up systems for managing quality	8.06	8
7. Overseeing rollout and maintenance of quality procedures	8.06	8
8. Auditing effectiveness of manufacturing processes	7.43	8
9. Writing and assessing technical reports on quality issues	7.50	8
10. Monitoring competence of staff	7.47	7
11. Identifying skills needs of staff	7.32	7
12. Monitoring and evaluation the effectiveness of training for staff	7.31	7
13. Setting up procedures for ensuring manufacturing adheres to regulations	7.60	8
14. Confirming production and complete process paperwork	8.20	8
15. Ensuring systems in place for ongoing checks of GMP	8.00	8.5
16. Understanding of legal and ethical requirements	8.06	8.5
17. Identifying issues with validation protocols and optimising performance	7.56	8
18. Troubleshooting such issues	7.29	8
19. Writing reports on use and effectiveness of validation techniques	7.27	7
20. Understanding of legislation regarding waste routes and environmental impact	7.06	7.5
21. Understanding of potential hazards with airflow and filter sizes	6.67	7
22. Ensuring ongoing sampling of environment including air ,water and surface	7.82	8
23. Understanding of regulations for gowning and gloving	8.50	9
24. Ensuring staff are qualified in gowning and gloving	8.42	9
25. Ensuring staff are aware of regulations for working in aseptic operations	8.83	9
26. Recording trends and process improvement against regulations	7.55	7
27. Understanding the role of the Qualified Person (QP)	7.93	9
28. Understanding of financial regulations	7.38	8
29. Keeping financial records where required	8.33	9

Appendix C: Mean Skills Scores and Mean Importance

Mean Skills and Mean Importance

1.Front Line/Operational Staff

Skill	Mean	Future Importance
Supply Chain		
A) *Production planning and ordering materials and components*		
1. Managing an inventory	7.73	2.15
2. Checking materials have been provided to 'fit for purpose' specification	8.07	2.29
3. Developing and communicating a production plan	7.79	2.25
4. Managing data about materials/equipment ordered	8.07	2.08
5. Capacity management	7.47	2.29
6. Resource management	7.27	2.38
B) Receiving deliveries		
7. Collating orders and checking against inventory	8.07	2.08
8. Understanding of how to classify materials according to GMP	7.2	2.56
9. Understanding of how to manage the shelf life of materials	8.25	2.25
10.Reviewing stock levels on a regular basis	7.71	2.23
C) Warehousing		
11. Checking and controlling the temperature and humidity storage conditions for materials	8.18	2
12. Status labelling	7.92	2.27
13. Segregating materials	7.18	2.4
14. Ensuring the security of materials, including when on pallets	7.4	2.2
15. Handling materials with required care	7.85	2.17
16. Quarantining materials	7.5	2.22
17. Understanding of relevant GMP	7.22	2.44
18. Conducting checks against GMP	7.22	2.5
R & D (pre and post clinical trials)		
19. Prepare laboratory materials, equipment and resources	8.07	2.33
20. Sampling (raw) materials	7.62	2.45
21. Testing operations	7.2	2.46
22.Testing materials	7.29	2.54
23. Cleaning equipment	6.79	2.42
24. Conducting statistical tests	6.6	2.31
25. Status labelling	6.45	2.3
26. Control of inventory/stock	6.75	2.33
27. Understanding of relevant Good Laboratory Practice/Good Clinical Practice	6.71	2.57
28. Conducting checks against GLP/GCP	6.58	2.42

Primary manufacture		
29. Cleaning and preparing vessels	7.67	2.1
30. Charging vessels (manually or through a vacuum)	7.27	2.25
31. Setting up equipment	7.73	2.2
32. Use of specific EHS equipment e.g. respirators, spillage, dust extraction	7.08	2.15
D) Virus growth		
33. Inoculation	6.5	2.33
34. Incubating a virus	6.25	2.5
35. Harvesting a virus	6	2.5
36. Potential inactivation of a virus	6.25	2.67
37. Protein separation	6.33	2.67
E) Purification		
38. Understanding of how to load equipment with input chemicals	7.57	2.29
39. Understanding of how to convert base to salt and then back again	6	2.25
40. Understanding of crystallisation	6.75	2.25
41. Understanding of filtration	7.6	2.2
F) Chemical synthesis		
42. Using additional chemicals to create a chemical reaction	8.33	2
G) Preparation		
43. Milling and grinding materials to correct particle size	7.2	2.17
44. Separating and disposing of processing materials, by products and waste	7	2.33
H) Manufacturing proteins		
45. Fermentation	6.5	2.67
46. Understanding relevant GMP	9	2.67
47. Conducting checks against GMP	9	2.67
Secondary manufacture		
48. Understanding how to operate equipment	7.64	2.33
49. Filling (eg: ampoule/vial/syringe) and packaging into secure containers	8.2	2.25
50. Controlling process automation	6.9	2.36
51. Loading the line	7.22	2.22
52. Removing product from the line	7.64	2.36
53. Cleaning the line/facility	7.45	2.33
54. Preparing for next operation	7.4	2.44
55. Use of purified water, sterile water, water for injection, clean steam	7.75	2.38
56. Understanding of relevant GMP	6.9	2.5
57. Conducting checks against GMP	7	2.57
I) Packaging		
58. Loading the line	7.5	2.14
59. Overlabelling/batch number and expiry dating	7.89	2.25

60. Operating packaging machines	7.75	2.13
61. Cleaning packaging machines	7.5	2.25
62. Cartoning and leaflet insertion	7.71	2.33
63. Checking the weight of the product	7	2.33
64. Overwrapping	7.17	2
65. Casing the product	7	2.17
66. Palletising the packaged product	7.29	2.29
67. Understanding of relevant GMP	6	2.67
68. Conducting checks against GMP	6	2.67
Quality procedures		
69. Checking quality of diagnostic kits	9.4	2.29
70. Following the relevant process instructions	7.85	2.38
71. Controlling, monitoring and adjusting the process operation	7.71	2.46
72. Washing in-between batches/products to remove impurities /carry over	7.67	2.44
73. Sampling and undertaking in-process control measurements and tests	8	2.64
74. Operating/setting up automated inspections	7.2	2.67
75. Carrying out environmental monitoring – air, water and surface sampling	7.33	2.67
76. Use of autoclaves and sterilisers	7.38	2.17
77. Confirming components and products meet inspection criteria	8.22	2.56
Regulation		
78. Understanding of European GMP standards	7	2.6
79. Understanding of FDA requirements, Material Resources Planning	6.85	2.46
80. Awareness of European guidelines about distribution and CE marking	6.75	2.45
81. Complying with FDA requirements for GMP	6.18	2.55
82. Complying with organisational safety requirements	8	2.36
83. Dealing with unusual occurrences	7.33	2.29
84. Following detailed process instructions and associated record keeping	8	2.33
85. Movement of chemicals and other by products in a safe manner	7.93	2.44
86. Monitoring of air standards and air pressure for validation/routine production	6.89	2.44
87. Testing of filters for validation /during routine production	7.42	2.36
88. Testing and challenging equipment during routine production	7.42	2.42
89. Setting up automated systems to conduct validation/rejecting or accepting product during routine production	7.09	2.45
90. Reviewing effectiveness of such systems	7.08	2.45
91. Executing validation protocols	6.78	2.36

92. Understanding of financial regulations	6.8	2.08
93. Keeping financial records where required	7.64	2.08
Engineering		
94. Understanding of how to monitor/analyse efficiency of equipment	7.22	2.33
95. Maintenance of purified water, sterile water, water for injection and clean steam generation facilities	7	2.14
96. Maintenance of sterilisers and autoclaves	6.5	2.25
97. Calibration of sensors/gauges and chart recorders	8	2.2
98. Setting up and use of PLC controllers	7.5	2.33

2. Technical/Supervisory Staff

Skill	Mean	Future Importance
1. Working effectively within a supply chain	7.31	2.43
2. Ensuring materials have been provided to specification/fit for purpose	7.75	2.33
3. Ensuring equipment is cleaned	8.13	2.31
4. Ensuring statistical tests are conducted	7	2.45
5. Inspecting equipment	7.6	2.36
6. Allocating personnel to maintain processing	6.27	2.36
7. Approving component/material specifications	7	2.27
8. Solving packaging problems	6.75	2.4
9. Allocating personnel to maintain line efficiency	6.36	2.27
10. Conducting an assessment of health, safety and environment risks in the workplace	7.22	2.44
11. Conducting an assessment of quality risks in the workplace (HACCP)	6.81	2.29
12. Contributing to standard operating procedures	7.11	2.4
13. Contributing towards the maintenance of product quality	7.13	2.38
14. Responding to poor performance in the team	6.94	2.6
15. Providing advice and support for implementation of quality systems	7.39	2.38
16. Signing off and verifying quality actions	7.53	2.25
17. Solving process problems	7.63	2.35
18. Monitoring and assessing data	7.42	2.29
19. Writing technical reports	6.63	2.53
20. Identifying skills needs of staff	6.89	2.56
21. Supervising and coaching staff	7.06	2.41
22. Inspecting third party contractors	7.09	2.5
23. Understanding of critical equipment controls	7	2.4
24. Confirming production and completing process paperwork	6.93	2.23
25. Controlling emergencies and critical situations (contamination control)	7	2.42
26. Controlling emergencies and critical situations (Accidents and incidents)	7.5	2.29
27. Ensuring own actions protect the environment	7.27	2.29
28. Keeping up to date with requirements of regulatory bodies (eg: EU GMP)	7.57	2.46

29. Conducting ongoing tests throughout each process product quality according to GMP	7	2.3
30. Proposing legitimate operations control parameters	7.46	2.42
31. Monitoring and maintaining health and safety systems	7	2.36
32. Keeping up to date with industry standards for validation processes	7	2.36
33. Setting the parameters for process validation	6.75	2.45
34. Defining which processes impact on product quality and need validating	6.7	2.58
35. Assessing effectiveness of personnel in validating equipment and environment	6.6	2.5
36. Planning timescales for revalidation	6.91	2.44
37. Understanding legislation in packaging	7.42	2.33
38. Understanding the hazards of warehousing and distribution	7.08	2.27
39. Understanding environmental considerations in packaging	5.58	2.67
40. Understanding and use of Statistical Process Control (SPC)	5.08	2.67
41. Monitoring use of SPC techniques during routine production	5.46	2.69
42. Putting processes in place for collecting data during routine production	6.33	2.58
43. Collecting data during routine production	6.62	2.58
44. Monitoring data (including looking for deviations and trends in performance)	5.83	2.5
45. Defining the process limits for equipment (eg: using guidance such as Six Sigma)	6.73	2.25
46. Inspecting machinery provided by third parties	6.92	2.5
47. Monitoring and analysing efficiency of equipment and measuring overall equipment effectiveness (OEE)	7	2.17
48. Inspecting purified/sterile water, water for injection and clean steam facilities	6.63	2.29
49. Inspecting sterilisers and autoclaves	6.75	2.11
50. Understanding of financial regulations	7	2.2
51. Keeping financial records where required	7.31	2.4

3. Managerial Staff

Skill	Mean	Future Importance
1. Ensuring equipment is cleaned	7.68	2.13
2. Ensuring statistical tests are conducted	7.37	2.47
3. Overseeing setting up/cleaning of equipment and facilities	8.06	2.20
4. Understanding of microbiology (aseptic)	7.73	2.17
5. Measuring line efficiency and improving OEE	6.85	2.55
6. Setting up systems for managing quality	8.06	2.47
7. Overseeing rollout and maintenance of quality procedures	8.06	2.29
8. Auditing effectiveness of manufacturing processes	7.43	2.36
9. Writing and assessing technical reports on quality issues	7.50	2.29
10. Monitoring competence of staff	7.47	2.53
11. Identifying skills needs of staff	7.32	2.44
12. Monitoring and evaluation the effectiveness of training for staff	7.31	2.62
13. Setting up procedures for ensuring manufacturing adheres to regulations	7.60	2.42
14. Confirming production and complete process paperwork	8.20	2.42
15. Ensuring systems in place for ongoing checks of GMP	8.00	2.40
16. Understanding of legal and ethical requirements	8.06	2.14
17. Identifying issues with validation protocols and optimising performance	7.56	2.27
18. Troubleshooting such issues	7.29	2.33
19. Writing reports on use and effectiveness of validation techniques	7.27	2.29
20. Understanding of legislation regarding waste routes and environmental impact	7.06	2.33
21. Understanding of potential hazards with airflow and filter sizes	6.67	2.31
22. Ensuring ongoing sampling of environment including air ,water and surface	7.82	2.42
23. Understanding of regulations for gowning and gloving	8.50	2.33
24. Ensuring staff are qualified in gowning and gloving	8.42	2.42
25. Ensuring staff are aware of regulations for working in aseptic operations	8.83	2.43
26. Recording trends and process improvement against regulations	7.55	2.50
27. Understanding the role of the Qualified Person (QP)	7.93	2.31
28. Understanding of financial regulations	7.38	2.31
29. Keeping financial records where required	8.33	2.29

Appendix D: Summary of Training Provision

Provider Name	Provision	Location/Spread
Adair Leadership Foundation	Management Development MBA Pharmaceutical: 4 day course	London
AstraZeneca	Apprenticeships in Pharmaceutical sector	Cheshire
BBC Learning	Management Development bespoke	Online
BioTech Manchester	Support environment for biotechnology companies excellent biotechnology links with Manchester Uni, Salford, Bolton, Victoria Uni, Manchester Met	Manchester
Brathay	Management Development, diagnostic consultancy, bespoke courses	Cumbria
Capita	Management Development, bespoke, in house training	London, Birmingham
Charles River UK Ltd	Technical - Egg School, software, validation packages, Bio-medical research current trends, lab animal care & use	Worldwide, Europe, USA, Loughborough
Chartered Institute of Personnel/Development	Management Development	London
Chartered Institute of Purchasing & Supply	Purchasing	Uk, Zambia, Botswana
City College Brighton & Hove	Engineering, Manufacturing engineering first and national diploma	Brighton, Hove
Clemortan Consultancy	Management Development	Glasgow
Commercial Language Training	Language	Derbyshire
Cranfield School of Management	Management Development	
Croner Training	Management Development, health & safety, train the trainer	London
cse demos	Management Development	London
Datrix Training Ltd	IT	Lancashire, Leeds, Manchester, Liverpool, Preston & on site
David Begg Associates	GMP, Pharmaceutical audits, Emulation & processing, good management ,active pharmaceutical ingredients, tablets manufacture, pharmaceutical packaging, Validation, computer validation, clinical trials, analysis & testing, a-z pharmaceutical water systems.	UK Manchester, York, Windsor & Ireland Cork, Dublin
Department of Immunology, University of Liverpool	MSC in Human Immunity	Liverpool
Euro Language Link Limited	Language	Manchester
Eurosource	Management Development	Staffordshire
Edge Hill College	BSC (Hons) Clinical Practice,	Lancashire
Eversheds	HR	UK, Asia, Middle East, Europe, America
Fielden-Cegos	Management Development trainer, purchasing supply, e-learning	Manchester
FT Knowledge	Various, financial management accounting, e-learning, risk management	Online, UK
Gas Safe Consultants Ltd	HSE, industrial, lab, medica, cryogenic application, specialist gases	Cheshire
Hemsley Fraser	Management Development	Plymouth

Honeyman	Technical ,Process & cleaning validation, laboratory, engineering practices, good manufacturing.	On site, hotel based across Europe
IIR Limited	Technical Medical Writing clinical statistics, stability testing pharmaceutical products, regulatory affairs for biotechnology, toxicology, pharmaceutical licensing, computer software validations, lab equipment, water validation, fast track guide to pharmaceutical industry, R&D clinical, R&D discovery and development, manufacturing, pharmaconvigilance regulatory affairs	Durham
IMS	Management Development and Consulting, Health economics and outcomes	imshealth.com
Incomes Data Services Limited	HR - Management Dev employment law	London
Industrial Training & Consultancy Services	Engineering introduction to automation and control systems	Northamptonshire
Institute of Operations Management	Management Development	Warwick
JSB Training & Development	Management Development	London, Scotland, on site
Kays Medical	HSE, safety of medicine and first aid	Liverpool, on site
Kepner Tragoe	Management Development	Windsor, UK, Ireland, International
Keyturn Training	Management Development	Midlands
Learn Direct at PfL	Various, SEMTA	Liverpool, on site, online, across UK
Liverpool Hope University	Combined honours degree human biology	Liverpool
Liverpool John Moores University	Biochemistry &microbiology applied, biomedical sciences, biotechnology, forensic science, molecular biology with genetics, medical biochemistry, bio chemistry & forensic science, pharmacy BSc Hons, industrial pharmaceutical science, pharmaceutical & biological chemistry, pharmaceutical science &clinical research, medicinal chemistry, Pharmacy, MSC Clinical research, MSc, Pg Dip Cert Clinical Pharmacy, CPD oncology pharmacy practice, CPD Supplementary prescribing, virology	Liverpool
Liverpool School of Tropical Medicine	Masters of tropical Medicine, MSc biology and control of parasites and disease vectors, diploma in medical micro biology, postgraduate biology and control of parasites and disease vectors, post-grad medical microbiology, short accredited course laboratory diagnosis of malaria, diagnostic parasitology	Liverpool
Learning Tree International	IT	London, Edinburgh
Management Centre Forum	Management Development	London, Europe
Management Forum	Management Development	Surrey, e learning
Manufacturing Institute	Various, Inventory control and management, operations personnel managing and developing op personnel training, supply chain logistics and management training	

New Horizons Computer Learning		UK, Yorkshire, Manchester, Birmingham, Bristol Nottingham, London
New Horizons Training (TTE)	Technical, Pharmaceutical, process operator, management, H&S	On site, UK
Oak Tree Management & Training Ltd	Various	UK, Leeds, Manchester, Bristol
Oliver Wight	Management Development	UK
Partnership for Learning	Various, computer systems validation workshop, GMP. Validation workshop seminar, HVAC awareness, HVAC for managers, Freeze drying, Autoclave/sterilisation, gas chromatography, systems sampling, assembly disassembly of aseptic pipe work. GMP for operators inspection and the operators, introduction, personal health and hygiene. GMP for managers. Introduction, licensing and regulations. Miscellaneous Clean room awareness, GMP for engineers, GMP for lab staff, GMP for warehouse and distribution staff.	Liverpool
Paterson Institute for Cancer Research	Provides postgraduate students and clinical research fellows the opportunity to study for cancer-related M.Phil, M.D. and Ph.D. degrees by research	Manchester
Pharmaceutical Training International	Technical Medical Writing, clinical statistics ,stability testing pharmaceutical products, regulatory affairs for biotechnology, toxicology, pharmaceutical licensing, computer software validations, lab equipment, water validation, fast track guide to pharmaceutical industry.	London
Phillips Export Training	Export, basics of exporting, basics of importing, letters of credit bill of exchange	Liverpool Warrington
Pivotal Training	Management Dev - HSE	
Polymath Training Limited	HSE, waste management, risk assessment, manual handling, first aid, gas testing, basic mechanical maintenance.	Cheshire
Professional Automation Support Services	Engineering	Crewe or in house
Purchasing Management Services	Purchasing	York or in house
Quality Partnership	Technical, quality function deployment, advanced statistical quality control	Cheshire
Remarc Technologies Training	IT	St Helens
Roffey Park Institute	Management Development	West Sussex
Rostrum	Management, statisions & programmers, regulatory affairs professional, medical writers, drug safety professional, clinical trail support, business skills development, pharma skills diploma	London, UK
Royal Society of Chemistry	Technical essential skills management workshops and courses. Long distance learning Msc Chemical technology, MA chemical analysis, NVQ or SVQ.	

RSSL Pharma	Technical, gclp, process, cleaning, computer systems validation, packaging gmp, gmp for lab staff, basic microbiology, pharmaceutical supplier standards, water systems, clean room design and aseptic manufacture, FDA regulation & inspection. QP training	Reading
St Helens College	Further Education, Chemical handling horticulture, HNC applied chemistry, Btec applied science, sciences laboratory & associated technical activities& industrial sciences, foundation degree microbiology, w/e unit forensic science	St Helens
Statistics for Industry	Statistics	
TMI	People & Org Development	
UK e-Universities Worldwide Ltd	e-learning	
University of Hertfordshire	short bio medical courses public health microbiology of food and drinking water, Molecular Biology short courses Introduction to bio information, Immunology basic terms and techniques, basic microbiology for infection control, MSc /pgdip/pg cert pharmacovigilance, e-learning cds an introduction to molecular biology, pharmacokinetics. Consultancy and lab services, Bio deterioration Centre	University Hertfordshire
University of Liverpool	Microbial technology, genetics, microbiology, pharmacology, tropical disease biology.	Liverpool
University of Manchester	Degree programmes: Biological Sciences with a Foundation Year, Anatomical Sciences, Biochemistry, Biology, Biological and Computing, Science (Bioinformatics), Biology with Palaeontology, Biology with Science and Society, Biomedical Sciences, Biotechnology (Enterprise), Cell Biology, Genetics, Life Sciences, Medical Biochemistry, Microbiology, Molecular Biology, Neuroscience, Pharmacology, Physiology, Pharmacology and Physiology, Plant Science, Psychology and Neuroscience, Zoology.	Manchester
Vision in Business	Various	
Wirral Metropolitan College	Further Education, NVQ 1, 2, 3 & 4 lab & associated technical activities, NVQ 2 clinical lab support, NVQ 3 lab technician in education, process plant ops level 1&2,sqa higher national certificate chemical engineering	Wirral Met

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