



Project Overview: January 2007- June 2008

The Pharmaceuticals Education Council (PEC), was established in October 2003 as a critical component of the Pharmaceuticals Industry Action Agenda (PIAA). Its aim was to investigate pharmaceutical workforce needs, assess skills gaps and work with federal and state governments and tertiary institutions to ensure that the Australian education system produces the personnel with the right skills for this knowledge-based industry. The PEC identified that there was a need for a significant increase in the availability of skilled and trained scientific and business personnel to work in the biopharmaceutical industry¹. As a result, the Commonwealth funded a research project to establish why this is occurring and how best to ameliorate the situation. This overview provides details of this project and its findings.

The project comprised three phases which ran from July 1, 2007 to June 30, 2008, which are briefly described below. A full copy of each of these reports is available at www.pharmacouncil.com.au/news_pdfs.

Phase One

Phase One focussed on carrying out a survey of skills gaps, which was completed by companies and individuals in the biopharmaceutical sector, academia, venture capitalists and government representatives involved in health, innovation and state development.

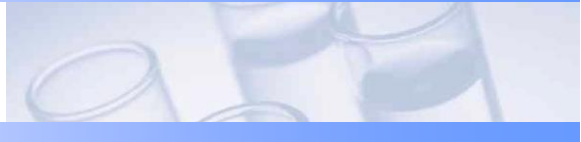
To assist in developing the survey, a national and international literature review was carried out. This included a web search and analysis of reports from fifteen companies/ educational institutions/ government departments about their view of skills needs and shortages in the biopharmaceutical industry. The findings from this literature review were that:

- universities do not generally understand industry needs
- industry is fragmented and is not coordinating the development of solutions
- students generally do not have all the necessary work skills when they leave university
- smaller companies have more challenges in attracting and retaining staff
- academic and industry interests are not always aligned.

Using these themes as guiding principles, a survey tool was designed. Part A of the survey focussed on identifying gaps in specific skills and functional areas and determining the reasons for these gaps. It used the pharmaceutical industry value chain as its basis, that is, the phases from drug discovery through to commercialisation, registration and marketing. Part B used an open questionnaire format, asking questions about type of business, size of company, expectations about revenue growth, barriers to revenue growth and R&D expenditure. A copy of the survey can be found in the Phase One report.

The survey was distributed electronically (using an online research company) to individuals and

¹ Throughout this paper, "biopharmaceutical" is used to refer to both pharmaceutical and biopharmaceutical companies, including large multinationals, national businesses and small and medium enterprises, including early stage, pre-revenue companies.



industry associations during May and June 2007.

98 respondents from 59 different organisations completed the survey, with a good cross section of 20 large companies, 26 mid-sized companies and 13 smaller companies i.e. with fewer than 20 employees. The majority of respondents were from medium to large research based organisations and biopharmaceutical companies, and all areas of the value chain from basic research to late stage commercialisation activities were represented.

The survey results showed that the main reason for the skills gaps, averaged across all functions and skills areas, for all respondents irrespective of type of business or size, was match of new graduates with job requirement (“job readiness”). Whilst this was the only reason given by large companies, small to medium enterprises (SMEs) provided a number of additional concerns regarding skills gaps, listed in order of importance:

- availability of up-skilling programmes both in-house and external
- career paths in-house
- anticipated long term availability of qualified staff
- availability of qualified staff within Australia.

Overall, it was clear that job readiness was a significant issue for all involved, as it was the only factor consistently scoring a high rating across all functional skills areas, particularly in research, clinical development, regulatory and reimbursement.



The survey also highlighted other individual areas where the skills gaps were greatest, as outlined in the table below.

Value Chain Phase	Skills Gap
Basic research & proof of concept	<ul style="list-style-type: none"> • SMEs had greatest skills gaps in this area. • Large companies identified skills gaps specifically in pre-clinical toxicology
Clinical development	<p>All aspects of clinical development rated as having high skills gaps with the greatest gaps identified in:</p> <ul style="list-style-type: none"> • investigator brochure preparation • clinical trial design • biostatistics
Manufacturing and quality assurance	<p>The greatest gaps were identified in:</p> <ul style="list-style-type: none"> • scale-up of biologicals • scale-up of NCEs • packaging design
Regulatory	<p>Large companies specifically reported skills gaps in:</p> <ul style="list-style-type: none"> • preparation of internationally acceptable non-clinical IND and CTX submissions
Reimbursement	<p>SMEs reported significant skills gaps in:</p> <ul style="list-style-type: none"> • reimbursement/pharmacoeconomics
Strategic commercialisation	<p>Identified as more of a problem for SMEs than large companies particularly in the areas of:</p> <ul style="list-style-type: none"> • intellectual property, licensing and patenting
Business and management	<ul style="list-style-type: none"> • Despite previous work indicating that this was likely to be a large skills gap area, the survey did not reflect this

The survey also revealed that, while there were a wide range of *ad hoc* training and collaboration initiatives underway, each had been arranged by individual organisations, and there was no industry-wide, formal, planned response to addressing skills gaps.

Phase Two

Phase Two aimed to establish how to close the skills gaps across the value chain (which had been identified in the Phase One survey) and what was considered necessary to make graduates ‘job ready’. Questions to be answered here included:

- “is job readiness solely about on-the-job training or should industry have a role in developing the educational content of certain undergraduate or postgraduate courses?” and
- “which technical / functional areas should take priority?”



To achieve this aim, members of the PEC Steering Committee approached State Government departments in New South Wales, Queensland, South Australia and Victoria, to host a series of consultation workshops held with:

- respondents to the Phase One survey
- industry association members of Medicines Australia, AusBiotech, ARCS, AAMRI, ACRP, ASCEPT
- university academics and TAFE lecturers of relevant courses
- individuals invited by the respective State Government Departments.

Three 'strawman' models of potential solutions were developed by the Committee to stimulate discussion at the workshops. The findings from Phase One were also discussed with workshop participants.

At every workshop, each one of the three strawman models was discussed in separate breakout groups. Through the consultation forums, it became clear that there are a number of separate initiatives underway, led either by State Government Departments as part of their education and training strategies for the future, or by academics seeking alternatives to traditional training supply solutions.

From our Phase One questionnaire and subsequent workshops held during Phase two, the skills gaps identified could be broadly categorised into three areas:

1. Lack of understanding of the biopharmaceutical industry sector, in terms of:
 - general knowledge of the sector
 - career opportunities
 - scope of work
2. Lack of ability to undertake specific tasks:
 - turn raw materials into a product
 - specific practical skills, including proof of concept; fermentation; pre-clinical toxicology, medicinal and synthetic chemistry; instrument management; stability testing
 - reimbursement
 - basic research skills
 - QA and regulatory affairs
 - clinical development
 - IP and commercialisation
 - Project management
3. Lack of ability to work effectively in the biopharmaceutical industry sector:
 - timelines/work smart tools
 - job readiness
 - resilience and initiative
 - attention to detail
 - ability to come to conclusions
 - ability to develop a clear statement of purpose
 - presentation and communication skills



- ability to handle electronic data.

Phase Two also involved gathering information on any current courses that already provided some degree of industry focused tertiary education. As there was no pre-existing comprehensive database of courses, the project had to gather the information bottom-up, with the possibility of some data gaps existing. However, this review and categorisation of courses showed that there were only a few specific courses focused on preparing individuals for employment in the pharmaceutical industry. In addition there appeared to be very few targeted IP and commercialisation courses.

Workshop participants agreed that there were likely to be a number of barriers which would impact successful implementation of initiatives to address these issues. Three in particular were discussed:

1. Nature / size of the pharmaceutical industry in Australia
2. Culture of industry vs academia
3. Funding /tax issues.

It would therefore be necessary for any recommendations to take these into account.

Overall from the work undertaken in Phases One and Two, the PEC Steering Committee concluded that:

- there is a low awareness of career opportunities in the biopharmaceutical industry
- there is a lack of understanding of the biopharmaceutical industry sector amongst key stakeholders
- there are many courses (current and planned) which are relevant to the biopharmaceutical industry but the absence of a coordinated approach means that they are difficult to identify. While a few courses are targeted at industry needs, there is no consistent approach to meeting current and future industry needs
- graduates lack the ability to undertake specific role-related tasks within biopharmaceutical organisations.
- there is insufficient industry involvement in developing the content and delivery of relevant courses
- there is insufficient opportunity for students to gain relevant work experience during their studies
- government sponsorship is seen as an important enabler of collaborative training initiatives between industry and academia.

Phase Three

Phase Three focussed on reviewing and testing the possible solutions for closing the skills gaps which had been identified in Phases One and Two. This involved two areas:



- A. A desk-based literature search on supply and demand for graduates with skills in areas of relevance to this project, to ensure that any recommendations made by the Committee did not result in an oversupply of graduates
- Existing literature was reviewed to determine trends in supply of graduates and their entry into careers in the biopharmaceutical industry. Quantitative data was sought on science graduate numbers, to compare supply with industry demand
- B. Consultation with key opinion leaders from industry and industry recruiters. In particular, this phase sought input from chief executives and scientific officers of SMEs, as they had not been well represented in Phases One and Two. This involved interviews with:
- key opinion leaders from 18 Australian owned SME biopharmaceutical companies, to identify their perspectives including views on jobs growth in the sector. A job survey was also completed by many of these leaders.
 - five sector specific recruiters to understand their views on supply and demand of employees in the biopharmaceutical industry

Key findings

In summary, the outputs of these two steps were the findings that:

- Industry's capacity to employ people is likely to significantly increase over the next five years
- Finding people with adequate skills and experience in Australia particularly at senior levels is a real challenge
- There are a number of common views held by recruiters and the industry executives but there were different perceptions about where the specific skills gaps lie, perhaps reflecting that needs differ among for example: diagnostic, vaccines, protein and small molecule companies. There is a strong view that there is an insufficient number of job ready graduates. In specific post graduate areas, including synthetic chemistry, biochemistry and pharmacology -particularly with drug discovery and pre-clinical development experience – it is more difficult to find Australian-trained graduates
- Companies are willing to contribute resources and collaborate with other firms to address these issues, and to develop solutions, (in some cases only with non-competing companies and in other cases with non-disclosure agreements in place first) and are willing to contribute towards training in the form of developing course curricula, lecturing, marking exams and providing internships
- Overall, any recommendation resulting in an increased uptake and completion of biopharmaceutical related courses is unlikely to result in an oversupply of specific skills.



Strategic recommendations

As a result of the overall findings from Phases One, Two and Three, which have been summarised in this overview, the Committee developed seven detailed strategic recommendations which would form the basis of an implementation plan. These recommendations cover a broad scope, largely due to the wide scale of the project being undertaken and are described below:

1. Establish a national strategic framework for the future development of a biopharmaceutical industry training system.
2. Establish a Federal Government- funded Coordinating Body (CB) which represents the industry, academic and government sectors to develop and oversee the implementation of the national strategic framework. Such a group would play a pivotal role in championing the national biopharmaceutical industry training system by ensuring that the needs of the industry are being met by courses of international standard, which are producing graduates with skills readily accepted by the national and international biopharmaceutical industry. One of its early tasks will be to recommend short term solutions to fill the immediate skills gaps. Another task would be to encourage and enable industry/ government partnerships around specific skills needs such as pharmacoeconomics. Government instrumentalities such as the Therapeutic Goods Administration (TGA) and the Department of Health and Ageing have as much interest in addressing these skills gaps as does industry.
3. Within the existing training system, the CB should work with industry and academia to give a tick of approval to those courses which structure and manage work experience placements of students at companies. Information about these courses will be available on various websites including industry associations (as determined by the CB). A performance measurement framework will need to be put in place to facilitate new entrants and exit of non-performers.
4. Provide Government- funded incentives to companies who take on students for work experience placements - a type of apprenticeship or internship model and/ or taxation breaks for companies for training. The placement programme should be linked to achievement of agreed core content.
5. Provide Government-funded incentives to universities:
 - a. a “job relevance premium” incentive to develop and deliver industry relevant education and training courses in areas of high need, for example, by:
 - i. integrating specific and practical biopharmaceutical industry skill components into existing courses such as pharmaceutical science, medicinal chemistry and chemical engineering
 - ii. offering specific elective units related to biopharmaceutical industry needs, for example:
 - pharmacoeconomics and commercialisation in commerce/economics courses
 - clinical development, regulatory affairs and pharmaceutical quality assurance in relevant courses including: medical science, pharmacology, pharmaceutical science and pharmacy courses



- intellectual property management, commercialisation and project management electives in the above-mentioned courses
 - formulation chemistry and engineering in pharmacy and chemical engineering courses (which already occurs with the double degrees e.g. BE/BPharmSc)
- iii. offering the specific elective units listed above as postgraduate diploma, masters or honours courses for biopharmaceutical science and commerce/economics graduates to enable upskilling of current graduates
 - b. an “expert usage premium” for involving industry experts to teach modules.
6. Raise awareness of the biopharmaceutical industry as an option for new graduates by for example:
 - a. introducing university career days in concert with industry
 - b. conducting pre-graduation employment interviews similar to those currently run by the law, accounting and mining industries
 - c. developing a career choice/guidance section on relevant industry websites.
 7. Develop strategies to encourage seamless movement between industry and academia for example by:
 - a. funding adjunct teaching positions for industry experts,
 - b. providing mentorship opportunities for industry-experienced senior academics
 - c. introducing career exchange options between industry and academia, facilitated by Government direct or indirect incentives to reduce current financial barriers and
 - d. introducing an “expert usage premium” for involving industry experts to teach modules at university.

Further detail on each of these recommendations can be found in the Phase Three report.

Implementation Plan

The final step in Phase Three was to develop an implementation plan setting out main tasks, responsibilities and timeframe for consideration. It should be noted that it will be a significant challenge to negotiate the fine line between competition and cooperation that will allow companies and training providers to work together to construct an effective and enduring skills supply system. It will also be important to be able to demonstrate to employers, training institutions and governments that the economic, commercial and social returns will fully justify the investment entailed.