

A Survey of Workforce Skills and Capacity

in the Medical Technology, Biotechnology, Pharmaceutical and Digital Health (MTP) Sector

0 C T O B E R 2 0 2 0

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Report creation led by:





MONASH SUSTAINABLE DEVELOPMENT INSTITUTE



Cross-industry project team:







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Executive Summary

Executive Summary

Australia's medical technology, biotechnology, pharmaceutical and digital health sector supports approximately 70,000 Australian jobs and contributed more than \$5 billion in Gross Value Added (GVA) to the Australian economy in 2019. Its future is dependent on the skills of its workforce.

To better understand the sector's workforce needs and skills gaps, an online survey of human resource (HR) professionals and managers with hiring responsibilities in the sector was developed in consultation with MTPConnect and a cross-industry project team, including AusBiotech, ANDHealth, Medical Technology Association of Australia and Medicines Australia.

This report identifies current, emerging and future skills gaps that need to be addressed in order to drive growth in the Australian MTP sector.



Key findings: Business Skills and Commercial Expertise

When all respondents were asked about the top three areas where skill will be needed in the future, open-text responses across all sectors most often related to 'management', 'development', 'regulatory' and 'clinical'. In relation to specific business skills, the area of greatest concern was 'Global experience' (65% rated as major concern or concern), however in general most respondents were concerned with the level of skill across most business areas.

Overall, commercialisation expertise were seen as less of a concern than business skills, however there were a number of specific skills for which the majority of respondents had some level of concern. These included 'Regulatory requirements – local and global' (54% rated as major concern or concern) and 'Translational understanding' (52%).

A common theme for both business and commercialisation expertise was that identified concerns were mostly related to mid- and senior level recruits, rather than entry level.



Key findings: Regulation and Quality

Skills related to Regulation and Quality were rated as high or medium priority areas by the majority of eligible respondents, with the highest priority area being 'Regulatory affairs' (75% rated this as high or medium priority). This was also one of the areas highlighted most often as having a problem with both the number and quality of candidates. Most eligible respondents also believed that recruitment within all Regulation and Quality skill areas would become more difficult in the future.



Key findings: Clinical (including trials)

Almost all respondents (94%) who recruit in 'Clinical pharmacology/translational medicine' rated the area as either high or medium priority. Respondents recognised that there was also a problem with the number and quality of candidates in this area across all levels and almost all eligible respondents believed it would become more difficult to recruit for this area in the future.



Key findings: Biological Sciences & Technologies

The skills most often flagged as high priorities were 'Pharmacology' (50% of respondents) and 'Biopharmaceuticals/biologics' (48%). Respondents also typically believed there was a problem with the number and quality of candidates with these skills. Similarly, both skills were rated by most eligible respondents as areas that would become difficult to recruit for in the future.

Key findings: Informatics, Computation, Mathematical and Statistics

'Pharmacokinetic/Pharmacodynamic' and 'Cyber security' were skills rated by all respondents as high or medium priorities. These areas were also flagged as problematic in terms of the number and quality of candidates, with almost all respondents believing that the skills would become difficult to recruit for in the future. Conversely, over half the respondents rated several skills as areas in which there was no problem with the number or quality of candidates. These included '3D printing' (71% no problem with number, 71% no problem with quality), 'Computer science' (62%, 62%) and 'Data management' (58%, 63%)



Key findings: Chemical Science

Chemical Sciences was one of the least represented areas in the survey. However, of those who recruit in this area, every skill was rated as medium or high priority by the majority of respondents. The skills most frequently highlighted as problematic in terms of the number and quality of candidates were 'Chemical biology' (84% of respondents considered this a medium or high priority), 'Process chemistry' (80%) and 'Nanotechnology' (80%). The skill most often rated as difficult to recruit for in the future in terms of number of candidates was 'Process chemistry' (only 20% rated number of candidates as 'no problem'). The skill considered most problematic in terms of quality of candidates was 'Medicinal and synthetic organic chemistry' (only 27% rated quality of candidates as 'no problem').

In addition to the specific skills in the survey, respondents also raised some other areas of concern, often related to real-world industry and international experience. These included digital skills, intellectual property, manufacturing and research skills, as well as certain 'soft skills' such as teamwork, collaboration and problem solving. The importance of experience was also reiterated in the final survey question which asked respondents to provide any additional comments, with several respondents noting that there is less of a 'skills gap' and more of an 'experience gap' across the sector.

Introduction and Aims

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Introduction and Aims

The objective of this report is to identify the current, emerging and future skills gaps that need to be addressed in order to drive growth in the Australian medical technology, biotechnology, pharmaceutical and digital health (MTP) sector. MTPConnect collaborated with AusBiotech, Medicines Australia, Medical Technology Association of Australia and Australia's National Digital Health Initiative, ANDHealth, on this project.

Some gaps between the skills required and those that exist are already known and are the subject of education programs already in place. However, although there has been some exploration of workforce skills and capacity in some parts of the MTP sector, a sector-wide formal analysis of gaps and needs has been lacking.

This project was modelled on a survey undertaken by the Association of the British Pharmaceutical Industry (ABPI). The original survey format used by ABPI was modified to suit the objectives of the current research.

The aim of the current survey was to understand perceptions of skills gaps from managers with hiring responsibilities and HR Professionals. This sampling frame was chosen because these groups are best placed to understand workforce skills and capacity within their sector. It is acknowledged that this sampling frame is small by definition, compared to the size of the actual MTP workforce. This places limitations on interpretation of results, as detailed statistical analysis is not valid. A larger survey, for example inviting members of the workforce to self-rate their knowledge and skills, could enable more robust statistical testing but was beyond the scope of this project.



Methodology

Methodology

An online survey was used to collect insights.

Key organisational contacts approached eligible organisations within the MTP sector, and known to their organisation, and invited relevant staff within their organisation (organisational hiring managers or H.R. professionals) to participate in the survey. The anticipated response rate, based on knowledge of the number of eligible people within the sector, was between 50-250 individuals.

Because MTPConnect provides funding through open calls to this sector, the survey was entirely voluntary and anonymous so that responses could not be linked to any past, current or potential future funding calls made by MTPConnect. BehaviourWorks Australia, an applied research unit based at Monash University, was engaged to undertake the data collection and analysis. Ethics approval to conduct the survey has been received by the Monash University Human Research Ethics Committee (#24116).

The survey was split into six overarching areas to measure respondents' impressions of workforce skills across:

- 1. Biological sciences and technologies;
- 2. Chemical sciences;
- 3. Clinical (including trials);
- 4. Informatics, computation, mathematical and statistics;
- 5. Regulation and quality; and
- 6. Business skills and commercialisation expertise.

For the first five sections, respondents were asked to comment on skill areas relevant to their work. Each survey section initially asked respondents to select all the areas that they are involved with in their recruitment. Next, for each skill area selected respondents were asked to indicate:

- a) If there was a problem with the **number** of candidates in the area;
- b) At which levels did the problem with the **number** of candidates exist entry level / junior, mid- level, senior;
- c) If there was a problem with the **quality** of candidates in the area;
- d) At which levels did the problem with the quality of candidates exist entry level / junior, mid- level, senior;
- e) If recruitment in the area was expected to become more difficult in the future; and
- f) How much of a priority was recruitment in the area (low, medium, or high).

For the final section, all respondents were asked to provide their general impressions about core competencies and anticipated needs in the future. This included:

- Their level of concern across a list of 11 business skills;
- At which levels they were concerned, if applicable entry level / junior, mid-level, senior;
- Their level of concern across a list of 15 commercialisation skills;
- At which levels they were concerned, if applicable entry level / junior, mid-level, senior;
- If they had any other areas of concern;
- · If it was company policy that candidates have a degree, or are experience and transferrable skills considered;
- The anticipated top three areas in which skills will be needed in 2030; and
- If they had any additional comments.

For a copy of the questionnaire, see Appendix A.

Findings and Discussion

Findings and Discussion

Survey Sample Characteristics

In total 121 respondents completed the survey between 11 June and 5 July 2020. Participating organisations represent the following sectors:



A further 15 respondents indicated that they worked in another sector (e.g. research, clinical, education) and were deemed eligible to complete the survey. Respondents also represented a range of organisation types, most often private companies of varying sizes – see Figure 1 below.

Figure 1. Number of respondents from each organisation type



Business Skills And Commercialisation Expertise

All respondents were asked to provide their general impressions about core competencies and anticipated skill needs in the future. These were grouped into two broad skillsets – business skills and commercialisation expertise.

Business skills

Three in ten of the 121 survey respondents believed that the overall level of 'Global experience' was a major concern with an additional one in three believing it was a concern. Overall, at least half of respondents were concerned with the level of skill across most business areas, with the exception of 'Fund raising capability', 'Corporate governance understanding' and 'Marketing'. However, while 'Fund raising capability' was not applicable for one third of respondents, it was still a concern for two thirds of those who responded. Likewise for 'Corporate governance understanding' and 'Marketing', over half of those for which this skill was relevant had a concern.

Figure 2. Overall impressions of business skills (percentage of all respondents)



■ Major concern ■ Concern ■ Not a problem ■ N/A

Most companies in Australia are start-ups and thus need to employ people with experience that can 'hit the ground running', thus making it difficult for graduates to get a foot in the door because management need to spend time on training.



[survey respondent]

Those respondents who believed there was a concern with each business skill were then asked to nominate the level at which their concern applied. Among eligible respondents, at least four in five were concerned at the senior level for 'Fund raising capability', and at the mid-level for 'Project planning and management', 'Budget development and financial analysis', 'Communication and presentation to key stakeholders – oral and written', and 'Negotiation and persuasion ability'.

Figure 3. Percentage of concerned respondents' level of concern for business skills

■ Entry level ■ Mid-level ■ Senior level ■ N/A

Clarity of vision for the business 42% Project planning and management 49% Budget development and financial analysis 44% Corporate governance understanding 45% Fund raising capability 44% Communication and presentation 58 (of both science and business) to key stakeholders - oral and written Negotiation and persuasion ability 519 Marketing 47% Leadership and decision making 29% Risk assessment & mitigation 44% Global experience 529



Commercialisation expertise

Across the 15 commercialisation skill areas, 'Regulatory requirements – local and global' and 'Translational understanding' were selected by over one in four respondents as areas of major concern. Around half of respondents did not believe there was a problem with 'Stakeholder management' and 'Budget development and management.'

Figure 4. Percentage of all respondents' overall impressions of commercialisation expertise

	Major conce	ern Concern	Not a proble	m N/A		
	0%	20% 40%	60%	8	0%	100%
Investor communication	18%	17%	24%		40%	
Commercial judgment	19%	36%		30%		16%
Opportunity/Unmet need identification	19%	38%		27%		16%
Intellectual property strategy and management	15%	26%	4	1%		18%
Business development plan	19%	30%		44%		7%
Stakeholder management	14%	27%		50%		9%
Project planning and management	15% 40% 40		%	5%		
Budget development and management	13%	13% 31% 50%			6%	
Market analysis – local and global	17%	40%		29%		14%
Regulatory requirements – local and global	28%	26	5%	35%		12%
Funding track record – local and international	18% 26% 24%		31%			
Sales	11%	22%	36%		31%	
Strategic partnerships and networking	16%	33%		40%		11%
Translational understanding	26% 26% 23%		25	25%		
Training (individuals and groups)	16%	30%		44%		11%



Among respondents who were concerned with each commercialisation skill, at least three in four believed the problem was at the senior level for 'Investor communication' and around four in five believed the problem was at the mid-level for 'Project planning and management' and 'Regulatory requirements – local and global'.

■ Entry level ■ Mid-level ■ Senior level ■ N/A

Figure 5. Percentage of all respondents' overall impressions of commercialisation expertise

Investor communication Commercial judgment Opportunity/Unmet need identification Intellectual property strategy and management Business development plan Stakeholder management Project planning and management Budget development and management Market analysis – local and global Regulatory requirements – local and global Funding track record – local and international Sales

Strategic partnersnips and networking Translational understanding Training (individuals and groups)

47%		72%				77%		
41%		71%			55%	<mark>2</mark> %	6	
46%		74%			58	%	1%	
43%		78%			6	1%	<mark>2</mark> %	
41%		76%			54%			
58%			76%			46%	<mark>2</mark> %	
52%		8	2%		3	6% 3	%	
45%		70%		4	5%	<mark>2</mark> %		
38%		78%			55%		<mark>4%</mark>	
45%		82%				68%		<mark>2</mark> %
33%		59%		65%		11%		
43%		58%		50%		13%		
36%		78%			61%			
49%		799	%			52%	5%	
60%	6	-	71%			56%		7%

Regulation and Quality

Figure 6, presents the number of respondents involved in recruitment within Regulation and Quality. Overall n=79 (65%) selected at least one Regulation and Quality area, most commonly 'Regulatory affairs' and 'Quality assurance'.





Around one in three respondents rated 'Regulatory affairs' as a high-priority area. Half of eligible respondents rated 'Medical device safety monitoring' as a medium priority and around two in five rated 'Quality assurance', 'Quality control' and 'Pharmacovigilance' as low priorities.

Figure 7. Recruitment priority level in **Regulation and Quality** (percentage of eligible respondents)

	■Low 0%	Medium 20%	High 409	% 60%	80%	6	100%
Pharmacovigilance	e l	39%		39%		22%	
Medical device safety monitoring	9	29%		50%		21%	
Quality assurance	ssurance 43%			31%		26%	
Quality contro		39%		34%		26%	
Cleanroom	ר 🗌 ר	31%		44%		25%	
Regulatory affairs	6 🗾	25%		39%	36	5%	
Government affairs	6	30%		40%		30%	

Within Regulation and Quality, more than half of eligible respondents believed there was <u>no problem</u> with the number of candidates in 'Quality assurance' and 'Quality control'. Around three quarters of respondents who recruit in the areas of 'Medical device safety monitoring' and 'Regulatory affairs' believed that there was a problem, most often at mid- and senior levels.

Figure 8. Problem with the number of candidates in Regulation and Quality (percentage of eligible respondents)



At least half of eligible respondents in Regulation and Quality believed that there was a problem with the quality of candidates across all skill areas. 'Regulatory affairs', 'Government affairs' and 'Medical device safety monitoring' were most frequently rated as problem areas, often at mid- and senior levels.

Figure 9. Percentage of eligible respondents who believe there is a problem with the **quality** of candidates in **Regulation and Quality** recruitment area



At least half of eligible respondents believed that all areas within Regulation and Quality would become more difficult to recruit in the future. The areas identified most often were 'Regulatory affairs', 'Government affairs' and 'Medical device safety monitoring'.

Figure 10. Recruitment will become more difficult in the future – **Regulation and Quality** (percentage of eligible respondents)

Pharmacovigilance Medical device safety monitoring Quality assurance Quality control Cleanroom Regulatory affairs Government affairs



Clinical (Including Trials)

Figure 11, presents the number of respondents involved in recruitment within Clinical (including trials). Of the 121 survey respondents, n=69 (57%) selected at least one Clinical area, most commonly 'Clinical research operations' and 'Clinical trial design (incl. novel trial design)'.

Questions relating to skills areas which were selected by less than five respondents ('Clinical pathology') are not presented in the remainder of this report due to insufficient sample size.

Figure 11. Involved in Clinical recruitment (number of respondents)



Almost two in three eligible respondents rated 'Clinical pharmacology/translational medicine' as a high priority area. Whereas two in five eligible respondents rated 'Registered nurses', 'Medically qualified clinicians', and 'Clinical trial design' as low priority areas.

Figure 12. Recruitment priority level in Clinical (percentage of eligible respondents)



Within Clinical, around half or more of eligible respondents believed there was a problem with the number of candidates all areas. Almost all respondents who recruited in the area of 'Clinical pharmacology/translational medicine' believed that there was a problem – most often at mid- and senior levels.

Figure 13. Problem with the number of candidates in Clinical (percentage of eligible respondents)



Regarding the quality of candidates within Clinical, three in five eligible respondents believed there was <u>no problem</u> for 'Registered nurses' and 'Medically qualified clinicians' whereas most respondents in 'Clinical pharmacology/translational medicine' and 'Clinical research operations' believed that there was a problem, most often at mid-level.

Figure 14. Problem with the **quality** of candidates in **Clinical** (percentage of eligible respondents)



At least half or more of eligible respondents believed that each Clinical area would become more difficult to recruit in the future, with the exception of 'Registered nurses'. The area identified most often was 'Clinical pharmacology/translational medicine,' selected by almost all eligible respondents.

Figure 15. Recruitment will become more difficult in the future – **Clinical** (percentage of eligible respondents)



Biological Sciences and Technologies

As shown in Figure 16 n=85 (70%) of respondents indicated that they were involved in recruitment in at least one Biological Sciences and Technologies area. The most common skills represented in the survey were: 'Medical technology', 'Biotechnology', and 'Biopharmaceuticals/biologics'.

Questions relating to skill areas which were selected by less than five respondents ('Metabonomics', 'Physiology', 'Proteomics', and 'Structural biology') are not presented in the remainder of this report due to insufficient sample size.





Within the Biological Sciences and Technologies, around half of eligible respondents rated 'Pharmacology' and 'Biopharmaceuticals/biologics' as high priority areas. More than half of eligible respondents rated 'Animal technology', 'Drug metabolism and ADME' and 'Toxicology' as medium priorities and almost two-thirds rated 'Histology' as a low priority area.



Figure 17. Recruitment priority level in Biological Sciences and Technologies (percentage of eligible respondents)

When asked if there was a problem with the number of candidates, over half of eligible respondents believed there was no problem for 'Molecular biology', 'Lab technician', 'Biochemistry', 'Microbiology' and 'Histology'. Most eligible respondents believed that there was a problem with the number of candidates in 'Biopharmaceuticals/biologics' and 'Drug metabolism and ADME', most often at mid- and senior levels.

Figure 18. Problem with the number of candidates in Biological Sciences and Technologies (percentage of eligible respondents)



Regarding the quality of candidates, 'Histology', 'Microbiology', and 'Toxicology' respondents had the highest proportion who believed there was no problem. Whereas 'Molecular/translational toxicology', 'Medical technology', 'Genomics', and 'Animal technology' had the highest proportion who believed there was a problem – most often at mid- and senior levels.

Figure 19. Problem with the quality of candidates in Biological Sciences and Technologies (percentage of eligible respondents)



When asked about whether recruitment would become more difficult in the future, at least half of eligible respondents anticipated future problems for all areas except for 'Lab technician', 'Histology', Microbiology' and Molecular biology'. 'Toxicology' and 'Biopharmaceuticals/biologics' were identified most often as areas which would become more difficult to recruit for in the future.

Figure 20. Recruitment will become more difficult in the future – **Biological Sciences and Technologies** (percentage of eligible respondents)



Informatics, Computation, Mathematical and Statistics

As shown in Figure 21, n=75 (62%) of survey respondents recruit in at least one area within Informatics, Computation, Mathematical and Statistics. The most common areas represented in the survey were: 'Data management', 'Data science', 'Engineering', and 'Health economics and outcomes (includes market access)'.

Questions relating to skills areas which were selected by less than five respondents ('Chemoinformatics', 'Chemometrics', 'Computational chemistry' and 'Physiological modelling') are not presented in the remainder of this report due to insufficient sample size.



Figure 21. Involved in Informatics, Computation, Mathematical and Statistics (number of respondents)

Within Informatics, Computation, Mathematical and Statistics, at least half of eligible respondents rated 'Health informatics' and 'Epidemiology and pharmacoepidemiology' as high priorities. In addition, all eligible respondents rated 'Pharmacokinetic/Pharmacodynamic' and 'Cyber security' as either high or medium priorities.

	Low	Medium	High			
	0%	20%	40%	60%	80%	100%
Automation	23	3%		54%		23%
Biomedical imaging		29%	29%		43%	
Bioinformatics/ Computational systems biology	6%		56%		38%	
Computational science	18%		45%		36%	
Computer science	2	38%		31%	31	.%
Data management		42%		38%		21%
Data science	9	38%		29%	339	6
Epidemiology and pharmacoepidemiology	17%		33%	50%		
Engineering	21	%	38%		42%	
Health economics and outcomes (includes market access)	8%		46%		46%	
Health informatics	2	5%	19%		56%	
Pharmacokinetic/ Pharmacodynamic modelling			67%		339	6
Statistics	;	45%		35%		20%
Cyber security	y 60%			40%		
3D printing		57	7%	149	6 2	9%

Figure 22. Recruitment priority level in Informatics, Computation, Mathematical and Statistics (percentage of eligible respondents)

More than half of eligible Informatics, Computation, Mathematical and Statistics respondents believed there was no problem with the number of candidates in '3D printing,' 'Engineering', 'Computer science' and 'Data management'. Almost all respondents who recruit in the areas of 'Pharmacokinetic/Pharmacodynamic' modelling, 'Health informatics' and 'Bioinformatics/ Computational systems biology' believed that there was a problem with the number of candidates, most often at mid- and senior levels.

Figure 23. Problem with the number of candidates in **Informatics, Computation, Mathematical and Statistics** (percentage of eligible respondents)



The skills most likely to not have a problem with the quality of candidates within Informatics, Computation, Mathematical and Statistics were '3D printing', 'Statistics', 'Computer science' and 'Data management'. Most respondents who recruit in the areas of 'Cyber security' and 'Health informatics' believed that there was a problem with the quality of candidates, most often at low and mid-levels.

Figure 24. Problem with the quality of candidates in **Informatics**, **Computation**, **Mathematical and Statistics** (percentage of eligible respondents)



At least half of eligible respondents believed that each Informatics, Computation, Mathematical and Statistics area would become more difficult to recruit in the future, with the exception of 'Statistics', 'Computer Science', 'Automation' and 'Engineering'. The areas identified as difficult by nine in ten respondents were 'Bioinformatics/Computational systems biology' and 'Health economics and outcomes (includes market access)'.

Figure 25. Recruitment will become more difficult in the future – **Informatics, Computation, Mathematical and Statistics** (percentage of eligible respondents)



Chemical Sciences

Figure 26 presents the number of respondents involved in recruitment within Chemical Sciences. Only n=34 (28%) of survey respondents selected at least one Chemical Sciences area. The most common areas selected were 'Analytical chemistry/biochemistry' and 'Protein & peptide chemistry'.

Questions relating to skills areas which were selected by less than five respondents ('Physical chemistry') are not presented in the remainder of this report due to insufficient sample size.

Figure 26. Involved in Chemical Sciences recruitment (number of respondents)



Across the Chemical Sciences, around half of eligible respondents rated each area as a medium priority. Around one in three eligible respondents rated 'Process chemistry' and 'Protein & peptide chemistry' as high priorities, whereas around one in three rated 'Materials science' and 'Medicinal and synthetic organic chemistry' as low priorities.

Figure 27. Recruitment priority level in Chemical Sciences (percentage of eligible respondents)

	Low 0%	Medium 20%	■ High 40%	60%	80%	100%
Analytical chemistry/biochemistry		26%		53%		21%
Chemical biology	17%	0	6	7%		17%
Materials science		29%		57%		14%
Medicinal and synthetic organic chemistry		33% 53%		53%		13%
Nanotechnology	20	%		70%		10%
Process chemistry	20	%	50%		30	%
Protein & peptide chemistry	22	2%	44%		33%	6

In the areas in which I recruit (mostly chemistry graduates, typically without post graduate qualifications) there is a massive over-supply of applicants. Unfortunately, the fresh graduates from Australian Universities tend to lack appropriate practical and theoretical knowledge. The Australian-trained staff that we recruit tend to be older, with several years of industry experience, and the more recent graduates tend to be a mixture of locally & overseas-trained scientists.

[survey respondent]

Within Chemical Sciences, most eligible respondents in 'Materials science' believed there was no problem with the number of candidates, while most respondents in 'Chemical biology' and 'Process chemistry' believed that there was a problem with the number of candidates, split across entry, mid-, and senior levels.



Figure 28. Problem with the number of candidates in Chemical Sciences (percentage of eligible respondents)

Most eligible Chemical Sciences respondents in 'Materials science' believed there was no problem with the quality of candidates. In contrast, most respondents in 'Medicinal and synthetic organic chemistry' believed that there was a problem, across entry, mid-, and senior levels.

Figure 29. Problem with the quality of candidates in Chemical Sciences (percentage of eligible respondents)



The majority of eligible respondents believed that 'Process chemistry,' 'Chemical Biology,' 'Protein & peptide chemistry' and 'Medicinal and synthetic organic chemistry' were areas which would become more difficult to recruit in the future.

Figure 30. Recruitment will become more difficult in the future – Chemical Sciences (percentage of eligible respondents)



Additional Insights

At the end of the survey, respondents were asked to provide additional insights on other areas of concern, necessity of holding a degree, predictions for the top three recruitment areas for 2030 and anything else they would like to mention.

Other areas of concern

In response to the open-text question regarding additional areas of concern which were not already covered in the survey, 52 respondents provided an additional comment. Of those, a number of responses reflected skills already measured in the survey. The verbatim responses to this question are provided in Appendix B.

One of the new areas raised by respondents most often was the issue of "experience." Rather than skill-specific concerns, several respondents mentioned concerns with real-world experience in industry or internationally – e.g. "Major concern about lack of international experience within industry".

Another area which was raised by multiple respondents related to "digital skills." This included references to digital marketing and digital capabilities more broadly e.g. "Digital marketing and Digital capability across all roles".

"Intellectual property (IP)" was also raised by several respondents as an area of concern. Specifically, respondents mentioned IP valuation, translation, management and strategy e.g. "Intellectual property valuation, particularly at early stages post discovery".

Similarly, "Manufacturing" was mentioned by some respondents in relation to "high end international healthcare grade manufacturing", "Practical, hands on training in emerging manufacturing sectors", "Local manufacturing capacity" and "Understanding the manufacturing and translation process".

Several respondents also raised issues in relation to "research skills". Specifically, these related to research translation (e.g. "Identification of translational health research/technology opportunities, particularly in the engineering space") and scientific skills in general (e.g. "The basic scientific skills are lacking - too much emphasis on what results a machine can spit out, rather than an ability to interpret the results and recognise if they are wrong").

Several "soft skills" were also mentioned frequently by respondents including teamwork, collaboration, problem solving, critical thinking, 'big picture' thinking and client acumen.

A degree is great (and in most cases are a minimum requirement), but practical hands on training for the manufacturing of next-gen pharmaceuticals is non-existent.

[survey respondent]

Top three areas where skills will be needed in 2030

The penultimate survey question asked respondents to predict the top three areas where skills would be needed in 2030. Figure 30 provides a visual summary of the most common words mentioned according to the sector(s) in which respondents recruit: Medical technology (n=44 valid responses), Pharmaceutical (n=30 valid responses), Biotechnology (n=38 valid responses), and Digital health (n=15 valid responses).

As highlighted below, across all four areas 'management', 'development', 'regulatory', and 'clinical' were mentioned most often (between 18 and 22 times across the 93 respondents who provided a response). A full list of verbatim responses is provided at Appendix C.

Figure 31. Word cloud: most common words for skill areas needed in 2030 - by sector



Degree versus transferable experience and skills

Next, respondents were asked to explain if it was company policy that candidates have a degree or if experience and transferable skills are considered when recruiting.

Three in ten respondents indicated that candidates must have a degree, while just over half indicated that experience and transferable skills were also considered. Just over one in ten described 'something else'. When prompted to explain, the other responses most often related to either 'a combination' of the two options or respondents clarified that 'it depends on the role/position'.

Figure 32. Company policy that candidates have a degree or are experience and transferable skills taken into account (percentage of respondents)



Additional comments

The final survey question provided respondents with an opportunity to provide any additional comments. Thirty respondents provided additional comments.

Several of those who provided an additional comment used the space to elaborate on their response to the previous question regarding whether candidates must have a degree or whether experience is considered. For example, "preference is to have a degree, but experience and transferable skills can be an option too". Others used the space to emphasise other concerns they had regarding an experience gap – e.g. "I don't think Australia has a large skills gap, especially not in a time of growing unemployment. What we do have in an experience gap - and that comes because we've allowed technology-based industries to decline over time..." and "In the areas in which I recruit (mostly chemistry graduates, typically without post graduate qualifications) there is a massive over-supply of applicants. Unfortunately, the fresh graduates from Australian Universities tend to lack appropriate practical and theoretical knowledge".

A small number of respondents also provided feedback on the survey and research process. Some noted that the data may not reflect skills gaps accurately due to surveying HR and recruitment professionals e.g. "Many questions were beyond the technical scope of my understanding, as a HR professional, I always undertake recruiting with a technical expert, therefore I do not need to understand all of the medical terminology, this has affected my responses in the questionnaire". Others felt the survey was biased towards university/research and 'classroom topics' with less attention paid to other areas such as manufacturing and industry placements.

Appendix A Questionnaire

Appendix A – Questionnaire

Survey Landing Page

Welcome to the MTP workforce skills survey. Before you continue, please read the information below.

We are inviting hiring managers and HR professionals whose role involves recruitment in the medtech, pharma, biotech and digital health sectors to take this survey. The aim of the survey is to identify the current, emerging, and future skills gaps our sector is facing and that need to be addressed in order to drive greater growth in the Australian sector.

The survey is expected to take 10 – 15 minutes, and focuses on skills required for roles in the medtech, biotech, pharmaceutical and digital health sectors. You are able to skip over areas that are not applicable to you. We recognise that due to the COVID-19 crisis, your organisation is unlikely to be operating in the usual manner at this time. Please answer the questions assuming 'business as usual' – that is, based on your experiences before any changes to your role or your company's hiring plans as a result of the COVID-19 crisis.

The survey and analysis is funded by MTPConnect, who set up a cross-industry project team involving AusBiotech, ANDHealth, Medical Technology Association of Australia and Medicines Australia to develop the project. The final report will be hosted and shared by these organisations by the end of 2020.

Anonymity and confidentiality are guaranteed; only de-identified and collated data will be released. Your participation is completely voluntary. If you agree to take part, you can withdraw from the survey at any time before the end. If you choose to withdraw your answers will not be used. Please note that:

- Because it is anonymous, your survey data, and whether or not you choose to participate, cannot be known by your employer or others in your workplace.
- MTPConnect provides funding through open calls to this sector. Because this survey is entirely voluntary and anonymous, it cannot be linked to any past, current or potential future funding calls made by MTPConnect.

BehaviourWorks Australia, an applied research unit based at Monash University, is undertaking the data analysis and ethics approval to conduct the survey has been received by the Monash University Human Research Ethics Committee. The survey data will be held for at least five years on a secure Monash University network that has access limited to the research staff. The data may be retained and used by the research team for comparative purposes in the future.

If you have any concerns or complaints about the project, you can contact the Executive Officer of the Monash University Human Research Ethics Committee using the details below:

Project number: 24116 Executive Officer Monash University Human Research Ethics Committee (MUHREC) Room 111, Building 3e Research Office Monash University VIC 3800 Tel: +61 3 9905 2052 Email: muhrec@monash.edu

Section A: About Your Work

*(ALL)

Int1. First, we'd like to know about the work you do.

*(ALL)

A1: Are you an organisational hiring manager or Human Resources professional whose role involves recruitment in the Australian medtech, pharma, biotech or digital health sector?

1. YES

2. NO

{If NO – Thank you for your interest, however we are only surveying people who are organisational hiring managers or Human Resources professionals whose role involves recruitment in the MedTech and Pharma sector. If this is not you, please forward the survey link to the appropriate person within your organisation - END SURVEY}

*(ALL – MULTIPLE RESPONSE)

A2: In which part of the sector do you work?

Select all that apply

- 1. Medical technology
- 2. Pharmaceutical
- 3. Biotechnology
- 4. Digital Health

*(ALL)

A3: And what type of organisation do you work in?s

- 1. Small company (includes start ups) (1-50)
- 2. Medium company (51-100)
- 3. Large company (100+)
- 4. University
- 5. Medical Research Institute
- 6. Hospital
- 7. Government department
- 8. Co-operative Research Centre
- 9. Contract research organisation
- 10. Research Service provider
- 11. Consultant
- 12. Professional Advisor
- 13. Other

Int2. The following sections ask about the areas you are involved in. For each area we would like to know your impression of workforce skills. We are interested in your impressions **for all areas that you are involved in.** This means that if you are involved in one area you will only be asked one set of questions, but if you are involved in six areas you will be asked a similar set of questions six times.

NOTE: We recognise that due to the COVID-19 crisis, your organisation is unlikely to be operating in the usual manner at this time. **Please answer the questions assuming 'business as usual' – that is, based on your experiences before any changes to your role as a result of the COVID-19 crisis.**

Section B: Impressions of Workforce Skills in Biological Sciences and Technologies

*(ALL - MANDATORY, MULTIPLE RESPONSE)

B1: Within the Biological Sciences & Technologies, select all the specific areas in the list below that you are involved with in your recruitment.

Skill	Definition (rollover text)
1. Animal technology	Animal technicians are responsible for the day to day welfare of the animals used in in vivo research work. Tasks range from general animal care and husbandry to monitoring the health and development of the animals and ensuring environmental conditions are correct. Qualified animal technicians conduct technical procedures such as administering medicines and collecting clinical data as part of experimental protocols. Additionally, animal technicians are responsible for preparation of samples for pathology and administration of euthanasia.
2. Biochemistry	Biochemists study chemical processes in living organisms, looking at the structure and function of biomolecules such as proteins and DNA.
3. Biopharmaceuticals/ biologics	Biopharmaceuticals are medicinal compounds produced in cells, usually in bio- fermenters, and purified using a range of upstream and downstream processes to produce purified drug substance. Critical skills involved are cell and fermenter sciences, protein purification, various separation and analysis techniques. Biopharmaceuticals are growing rapidly in importance in the pharmaceutical industry and include vaccines, medicines and diagnostic tests.
4. Biotechnology	Biotechnology is the combination of biological and microbiological sciences and protein engineering to discover and optimise biologic drug candidates to be medicines or to use biological molecules to perform specific processes to enable their discovery. Use of stem cell biology tools and technologies to assemble biologically relevant, predictive assays and cell models. Bringing cell therapy tools and technologies into clinical practice.
5. Drug metabolism and ADME	This is the study of how the body affects a drug following its administration, through the rate and extent of absorption, distribution, metabolism and excretion (ADME). A good understanding of pharmacokinetics (PK) is crucial to the understanding of whether or not a drug will be safe for use in humans and gives information about dose size and frequency.
6. Genomics	Genomics is a discipline where techniques to sequence, assemble and analyse genomes are used to establish their structure and function.
7. Histology	Histology is a discipline where daily, routine, and specialised histology techniques and procedures are performed for the benefit of a range of disciplines. Histologists can acquire specialist disease expertise.
8. Immunology	Knowledge of the human immune system is incorporated into a broad range of roles within the sector.
9. Lab technician	Operational knowledge of the common equipment and methods
10. Medical technology	Medical technology (MedTech) refers to medical devices and diagnostics, including in vitro diagnostics (IVDs). The Therapeutic Goods Administration (TGA) describes medical devices as having therapeutic benefits, which either affect the body in a physical way or are used to measure or monitor functions of the body. Examples of medical devices include artificial hips, blood pressure monitors and orthodontics.

Skill	Definition (rollover text)
11. Metabonomics	Metabonomics looks at changes in the metabolites present in a cell or organism and can be used to determine the toxicity of potential new drug targets.
12. Microbiology	The study of microscopic organisms. It includes the sub-disciplines of virology, mycology, parasitology, and bacteriology.
13. Molecular biology	Molecular biology is the study of biology at a molecular level, particularly looking at the way in which various systems within a cell interact and how they are regulated.
14. Molecular/translational toxicology	Molecular and translational toxicologists study the adverse effects that drugs can have on living organisms, from the level of molecules and cells to whole organs. Their work increases the understanding of the safety of a drug before it is trialled in humans. This discipline does not include animal based toxicology.
15. Pharmacology	Pharmacology is the study of how medicines interact with cells and tissues, with the aim of predicting what effects a medicine might have in humans
16. Physiology	Physiology is the study of the physical, chemical and biochemical properties of the functions of living organisms.
17. Proteomics	This is the large-scale study of the structure and function of proteins. Proteomics can be used to identify new biomarkers of disease as well as potential new drugs and drug targets.
18. Regenerative medicine/ Stem cell biology	Regenerative medicine is a branch of translational research in tissue engineering and molecular biology which deals with the process of replacing, engineering or regenerating human or animal cells, tissues or organs to restore or establish normal function.
19. Structural biology	This involves the determination of the molecular structure of biological macromolecules, especially proteins and nucleic acids, as well as the structure of compounds complexed to these macromolecules. This information can be used in compound design by medicinal and computational chemists, as well as in developing an understanding of the relationship between structure and biological function.
20. Toxicology	Toxicologists study the adverse effects of chemicals on living organisms. Compounds that have the potential to become medicines are assessed for toxicity in both in vitro and in vivo experiments that are required by law for preclinical studies.
21. None of the above	[EXCLUSIVE GO TO C1]



*(ALL)

B1e: Is recruitment for this area expected to become more difficult in future?

- 1. Yes
- 2. No

*(ALL)

B1f: How much of a priority is recruitment in this area?

- Low priority an area to watch
 Medium priority requires action
- 3. High priority requires immediate action

Section C: Impressions of Workforce Skills in Chemical Sciences

*(ALL – MANDATORY, MULTIPLE RESPONSE)

C1: Within the Chemical Sciences, select all the specific areas in the list below that you are involved in with your recruitment:

Skill	Definition (rollover text)
1. Analytical chemistry/ biochemistry	Analytical chemists/biochemists work at every stage of development of a medicine, from confirming the structure of a compound that has been made for the first time, to checking the purity of a batch of medicine that is about to be released for sale. Analytical chemists/biochemists may be involved in investigating biological targets, using biophysical techniques to screen and validate targets and studying how molecular properties affect biological activity. Analytical chemists/biochemists also develop techniques for biomarker identification and detection and probe design (mass spectrometry, PET, SPECT, MRI, labelling) and may have broader understanding to translate analytical results into practical outcomes and solutions to the problems being solved or assessed.
2. Chemical biology	Chemical biology uses chemical techniques and tools, and compounds synthesised by chemists, to understand the biological processes that cause disease.
3. Materials science	Materials science is an interdisciplinary field which deals with the discovery and design of new materials to meet a specific need.
4. Medicinal and synthetic organic chemistry	Synthetic chemists are involved in making chemical compounds, which are then tested for their potential as new medicines. Medicinal chemists are involved in the design of these compounds. Peptide chemists use synthetic organic chemistry techniques to make, purify and analyse compounds for use as medicines. In medicinal chemistry various techniques are used to design and predict the activity of compounds at a biological target such as a receptor or enzyme, as well as its likely pharmacokinetic profile and safety properties. In many organisations chemists perform the role of both synthetic and medicinal chemist at the same time.
5. Nanotechnology	Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modelling, and manipulating matter at 1-100 nanometer scale.
6 Physical chemistry	Physical chemists generate high quality physicochemical property data on compounds. Structural chemists try to elucidate the structures and shapes of molecules.
7. Process chemistry	Process chemists design suitable chemical syntheses for the large scale preparation of molecules that are being progressed to advanced clinical studies as potential drugs. For approved drugs, process chemists will have devised the synthetic route that will be used in commercial manufacture
8. Protein & peptide chemistry	Protein and peptide chemists are very important within the chemical science areas, though invariably work in multidisciplinary groups. Protein and peptide chemists develop and execute analytical methods alongside characterisation of techniques and development and validation of methodologies. It also includes expression of recombinant proteins and peptides for both research and commercial purposes
9. None of the above	[EXCLUSIVE GO TO D1]



- Low priority an area to watch
 Medium priority requires action
- 3. High priority requires immediate action

Section D: Impressions of Workforce Skills In Clinical (Including Trials)

*(ALL – MANDATORY, MULTIPLE RESPONSE)

D1: Within Clinical (including trials), select all the specific areas in the list below that you are involved in with your recruitment:

Skill	Definition (rollover text)
1. Clinical pathology	Clinical pathology is the study of the nature of disease and the structural and functional changes it causes. In industry pathologists work to establish disease models to assess potential therapies, and to characterise the structural changes in the disease state that occur in response to medicines.
2. Clinical trial design (incl. novel trial design)	Application of clinical trial guidelines and regulatory requirements for clinical trial design. Includes, levels of evidence, hypothesis generation and may include novel trial design (e.g adaptive design and human challenge model)
3. Clinical pharmacology/ translational medicine	Clinical pharmacology is the study of drugs and their clinical use. Clinical pharmacologists carry out work involving the analysis of the effects of medicines on people within clinical trial studies. Translational Medicine is a discipline that aims to bridge the divide between basic scientific research and patient care through translating scientific discoveries into real therapies (also known as "bench to bedside"). This section is to include: Clinical Pharmacology Scientists (non-medical); Physician Pharmacologists; Pharmacometricians (modellers).
4. Clinical research operations	This discipline involves working operationally in the field of clinical research trials, to ensure correct set-up monitoring and close-down of clinical trials. This includes developing protocols, identifying trial sites/locations, setting-up and monitoring trial progress, ensuring complete documentation throughout the trial and resolving any issues that arise with a view to high quality data being obtained in a timely fashion. Job titles include Project/Study Managers, Clinical Research Associates (CRAs) and Clinical Trial Assistants (CTAs).
5. Medically qualified clinicians	There are many areas where doctors play an important part within the sector, including clinical development, regulatory affairs, drug safety, and clinical pharmacology. They have a key role in supporting clinical research and clinical trials.
6. Registered nurses	This section includes Healthcare practitioners and Nurses. There are numerous and diverse job roles within the sector for those with nursing experience who can apply knowledge of healthcare or healthcare systems – such roles for example, can be within Pharmacovigilance, Drug Safety disciplines, education roles.
7. None of the above	[EXCLUSIVE GO TO E1]



- 2. Medium priority requires action
- 3. High priority requires immediate action

Section F: Impressions Of Workforce Skills In Informatics, Computation, Mathematical And Statistics

*(ALL - MANDATORY, MULTIPLE RESPONSE)

F1: Within Informatics, Computation, Mathematical and Statistics, select all the specific areas in the list below that you are involved in with your work:

Skill	Definition (rollover text)
1. Automation	Laboratory automation is a multi-disciplinary strategy to research, develop, optimize and capitalise on technologies in the laboratory that enable new and improved processes.
2. Biomedical imaging	Biomedical imaging is increasingly used as a non-invasive technique during preclinical studies and clinical. Imaging techniques can also provide data on biomarkers of disease.
3. Bioinformatics/ Computational systems biology	Systems biology integrates experimental and computational research to better understand complex biological processes. Bioinformatics and computational systems biology use statistical techniques, including Bayesian methods, to interpret large sets of biological data.
4. Chemoinformatics	Chemoinformatics involves the application of computational techniques to existing datasets to address a range of chemical problems. Chemoinformatics toolkits allow virtual screening, chemical database mining and structure-activity studies.
5. Chemometrics	Chemometrics is the science of extracting information from chemical systems by data- driven means using methods such as multivariate statistics, applied mathematics and computer science, in order to address problems in chemistry, biochemistry, medicine, biology and chemical engineering.
6. Computational chemistry	This discipline involves the use of computational approaches in drug design and in lead identification. The properties of molecules and target proteins are modelled to predict and gain insight into how these will interact. Computational chemists often work with structural chemists who in turn try to elucidate the structures and shapes of molecules, protein targets and protein-molecule complexes.
7. Computational science	Computational Scientists use mathematical modelling techniques along with information from published literature to build hypotheses. The use of computational science allows large data sets to be collected and analysed quickly.
8. Computer science	Computer Scientists play a vital role within areas of software development, app development, AI and coding.
9. Data management	Broadly this involves the development, execution and supervision of plans, policies, programmes and practices that control, protect, deliver and enhance the value of data and information assets.
10. Data science	The process of analysing data to find correlations or patterns in large sets of data, possibly from multiple sources.
11. Epidemiology and pharmacoepidemiology	Epidemiology is the study of health and disease conditions in a defined population to identify patterns. Pharmacoepidemiology uses these techniques to study the uses and effects of medicines in large, well defined, populations.
12. Engineering	Utilising scientific understanding to invent, design, or build, or solve problems. Wide applicability.

Skill	Definition (rollover text)
13. Health economics and outcomes (includes market access)	Health economics is a branch of economics concerned with issues relating to the allocation of health and healthcare. Health economists study factors that affect the supply and demand for healthcare and the market equilibrium, and look at healthcare system design and reform as well as aspects of financing, expenditure and purchasing.
14. Health informatics	Health informatics deals with the resources, devices, and methods required to optimise the acquisition, storage, linkage, retrieval, and use of health-related data to improve health care outcomes and optimise the development and use.
15. Pharmacokinetic/ Pharmacodynamic modelling	Pharmacokinetics (PK) focuses on how the body processes a drug, resulting in a drug concentration. Pharmacodynamics (PD) is concerned with how the drug acts on the body, resulting in a measurable drug effect. Through PK/PD modelling and simulation, which combines the two disciplines, pharmaceutical scientists acquire an earlier understanding of the link between drug and response, and can better characterise a drug's absorption, distribution, and elimination properties.
16. Physiological modelling	Modelling and simulation involves integration of data on physicochemical properties, pharmacokinetics, pharmacodynamics, formulation and safety.
17. Statistics	Statisticians are a fundamental part of a development project team across the whole lifecycle of a product - from laboratory work through to trials in humans (clinical trials) and finally to manufacturing and marketing.
18. Cyber security	Collection of tools, technologies, processes and practices that can be used to protect networks, computers and data from unauthorised access or attack
19. 3D printing	Process through which a three-dimensional solid object, virtually of any shape, is generated starting from a digital model.
20. None of the above	[EXCLUSIVE GO TO G1]

Impressions of Workforce Skills in Question Loop

*(IF F1=1-18 - LOOP for F1_1 through F1_18)

F1a: Thinking about {INSERT F1 area}, is there a problem with the number of candidates in this area?

1. Yes

2. No

*(IF F1a=1 - MULTIPLE RESPONSE)

F1b: At which levels is there a problem with the number of candidates? Tick all that apply

- 1. Entry level / junior
- 2. Mid-level
- 3. Senior level

*(ALL)

F1c: Is there a problem with the quality of candidates in this area?

- 1. Yes
- 2. No

*(IF F1c=1 - MULTIPLE RESPONSE)

F1d: At which levels is there a problem with the quality of candidates? Tick all that apply

- 1. Entry level / junior
- 2. Mid-level
- 3. Senior level

*(ALL)

F1e: Is recruitment for this area expected to become more difficult in future?

- 1. Yes
- 2. No

*(ALL)

F1f: How much of a priority is recruitment in this area?

- 1. Low priority an area to watch
- 2. Medium priority requires action
- 3. High priority requires immediate action

Section G: Impressions of Workforce Skills in Regulation And Quality

*(ALL – MANDATORY, MULTIPLE RESPONSE)

G1: Within Regulation & Quality, select all the specific areas in the list below that you are involved in with your work:

Skill	Definition (rollover text)	
1. Pharmacovigilance	Pharmacovigilance is the process of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medicines, to ensure that drugs on the market are safe for patients, and to identify new hazards associated with the medication.	
2. Medical device safety monitoring	Involves process of evaluating reported adverse events, disseminating information that could be used to prevent or minimise the consequences of adverse events, and modifying the medical device or removing the medical device from the market, where appropriate.	
3. Quality assurance	Quality needs to be built into the product and all processes related to its manufacture and transport to the final site of administration. GLP, GCP and GMP guidelines ensure that appropriate standards are adhered to.	
4. Quality control	Process through which a business seeks to ensure that product quality is maintained or improved	
5. Cleanroom	Standards, practices and procedures associated with zones where contaminants in the air are highly controlled	
6. Regulatory affairs	Regulatory affairs professionals ensure regulatory compliance and prepare submissions to regulatory authorities for new medicines and for any change to a marketed medicine.	
7. Government Affairs	Engagement with government departments and personnel	
8. None of the above	[EXCLUSIVE GO TO Int3]	
9. Data management	Broadly this involves the development, execution and supervision of plans, policies, programmes and practices that control, protect, deliver and enhance the value of data and information assets.	
10. Data science	The process of analysing data to find correlations or patterns in large sets of data, possibly from multiple sources.	
11. Epidemiology and pharmacoepidemiology	Epidemiology is the study of health and disease conditions in a defined population to identify patterns. Pharmacoepidemiology uses these techniques to study the uses and effects of medicines in large, well defined, populations.	
12. Engineering	Utilising scientific understanding to invent, design, or build, or solve problems,. Wide applicability	

Impressions of Workforce Skills in Question Loop

*(IF G1=1-6 - LOOP for G1_1 through G1_6)

G1a: Thinking about {INSERT G1 area}, is there a problem with the number of candidates in this area?

1. Yes

2. No

*(IF G1a=1 - MULTIPLE RESPONSE)

G1b: At which levels is there a problem with the number of candidates? Tick all that apply

- 1. Entry level / junior
- 2. Mid-level
- 3. Senior level

*(ALL)

G1c: Is there a problem with the quality of candidates in this area?

- 1. Yes
- 2. No

*(IF G1c=1 - MULTIPLE RESPONSE)

G1d: At which levels is there a problem with the quality of candidates? Tick all that apply

- 1. Entry level / junior
- 2. Mid-level
- 3. Senior level

*(ALL)

G1e: Is recruitment for this area expected to become more difficult in future?

- 1. Yes
- 2. No

*(ALL)

G1f: How much of a priority is recruitment in this area?

- 1. Low priority an area to watch
- 2. Medium priority requires action
- 3. High priority requires immediate action

Section H: Impressions of Business Skills and Commercialisation Expertise Across the Sector

Int3. This section is designed to capture your overall impressions across all of the specialties and areas that you are familiar with in your work. It asks your opinion of skills and commercialisation expertise and concludes with some more general questions.

NOTE: We recognise that due to the COVID-19 crisis, your organisation is unlikely to be operating in the usual manner at this time. Please answer the questions assuming 'business as usual' – that is, based on your experiences before any changes to your role as a result of the COVID-19 crisis.

*(ALL)

H1: Across all of the sectors and areas that you are familiar with in your work, please rate your overall impression of the following business skills:

Statements

Business Skills

- 1. Clarity of vision for the business
- 2. Project planning and management
- 3. Budget development and financial analysis
- 4. Corporate governance understanding
- 5. Fund raising capability
- 6. Communication and presentation (of both science and business) to key stakeholders oral and written
- 7. Negotiation and persuasion ability
- 8. Marketing
- 9. Leadership and decision making
- 10. Risk assessment & mitigation
- 11. Global experience

Response Options

- 1. The overall level of this skill is a major concern
- 2. The overall level of this skill is a concern
- 3. The overall level of this skill is a not a problem
- 4. Not applicable I can't comment on this skill from my experience

*(IF ANY H1=1 or 2 - MULTIPLE RESPONSE)

H1a: Thinking about those skills you rated as 'a concern' or 'a major concern', please indicate at what levels [tick all that apply for each skill]

Statements [Carry Forward If C1=1 Or 2]

- 1. Clarity of vision for the business
- 2. Project planning and management
- 3. Budget development and financial analysis
- 4. Corporate governance understanding
- 5. Fund raising capability
- 6. Communication and presentation (of both science and business) to key stakeholders oral and written
- 7. Negotiation and persuasion ability
- 8. Marketing
- 9. Leadership and decision making
- 10. Risk assessment & mitigation
- 11. Global experience

Response Options

- 1. Concern or major concern at Entry level / junior
- 2. Concern or major concern at mid-level
- 3. Concern or major concern at senior level
- 4. Not applicable can't comment or not a concern

*(ALL)

H2: Across all of the sectors and areas that you are familiar with in your work, please rate your overall impression of the following areas of commercialisation expertise:

Commercialisation

- 1. Investor communication
- 2. Commercial judgment
- 3. Opportunity/Unmet need identification
- 4. Intellectual property strategy and management
- 5. Business development plan
- 6. Stakeholder management
- 7. Project planning and management
- 8. Budget development and management
- 9. Market analysis local and global
- 10. Regulatory requirements local and global
- 11. Funding track record local and international
- 12. Sales
- 13. Strategic partnerships and networking
- 14. Translational understanding
- 15. Training (individuals and groups)

Response Options

- 1. The overall level of this skill is a major concern
- 2. The overall level of this skill is a concern
- 3. The overall level of this skill is a not a problem
- 4. Not applicable I can't comment on this skill from my experience

*(IF ANY H2=1 or 2 - MULTIPLE RESPONSE)

H2a: If you rated any areas as 'a concern' or 'a major concern', please indicate at what levels.

Statements

- 1. Investor communication
- 2. Commercial judgment
- 3. Opportunity/Unmet need identification
- 4. Intellectual property strategy and management
- 5. Business development plan
- 6. Stakeholder management
- 7. Project planning and management
- 8. Budget development and management
- 9. Market analysis local and global
- 10. Regulatory requirements local and global
- 11. Funding track record local and international
- 12. Sales
- 13. Strategic partnerships and networking
- 14. Translational understanding
- 15. Training (individuals and groups)

Response Options

- 1. Concern or major concern at Entry level / junior
- 2. Concern or major concern at mid-level
- 3. Concern or major concern at senior level
- 4. Not applicable can't comment or not a concern

*(ALL)

H3: Across all of the sectors and areas that you are familiar with in your work, are there any other skills or areas of commercial expertise that are of concern to you?

1. _____ [open text, consider word limit]

*(ALL)

H4: Based on your experience in this sector, what are the top three areas in which skills will be needed in 2030?

1. _____ [open text]

- H6. Is it company policy that candidates have a degree, or are experience and transferrable skills taken into account ?
- 1. Candidates must have a degree
- 2. Experience and transferrable skills are taken into account
- 3. Something else (please explain) _____

*(ALL - NON-MANDATORY)

H5: Please provide any additional comments if you wish regarding any aspect of this survey:

1. _____ [open text - consider word limit]

That's the end of the survey questions. When you click the 'next' button your answers will be submitted.

Appendix B Other Areas of Concern: Verbatim Responses

Appendix B: Other Areas Of Concern: Verbatim Responses

- 1. Access to strong reg advisors.
- 2. Accountability for budgets. Understanding Return on Investment and justification of business case needs. Identifying and measuring meaningful metrics for business decision making. Leadership developing self and others.
- 3. All areas regarding commercial expertise are a concern.
- 4. All preclinical development stages and non-clinical pharmacology/toxicology.
- 5. Assessment of scientific merit. Some terrible technologies are picked up and soak up dollars and time because we lack people trained to detect puffery, fraud and over-selling in primary research. (At least outside the pharmaceutical space). There's no appropriate qualification we can look at and think somebody has the appropriate critical eye, or that we can send people to train.
- 6. Broader appreciation of cross-functional aspects pertinent to successful drug discovery and development.
- 7. Clinical Research.
- 8. Clinical Research Associate skillset monitoring.
- 9. Clinical trials site staff are all incredibly vulnerable and on year-to-year contracts. They are neglected and undervalued.
- 10. Commercial/Client acumen, digital competency, working in a team.
- 11. Competitor analysis.
- 12. Digital.
- 13. Digital marketing and Digital capability across all roles.
- 14. Drug development, drug pharmacology, toxicology for drug development (PK, PD, pharmacometrics). Without an industry to provide jobs and experience for ongoing competence, then it's not possible to sustain these skills. Which comes first? Chicken or egg? Have to have the industry to provide a home for these skills. Otherwise, we'll continue to train "cannon fodder", like the 100s of pharmacology/pharmaceutical science graduates our Universities train each year, who have no workplace to go to.
- 15. Electronic engineering at a deep level.
- 16. Engineers to service equipment.
- 17. Ethics and the application of relevant ethical frameworks and thinking in product development, particularly in health informatics and digital health technologies. Very few in the digital health sector have any type of ethics training and even fewer see the importance of ethics in technology development.
- 18. Experienced CRAs.
- 19. Fundamental understanding of seamless interoperability across national/regional eHealth ecosystems in terms of the end-to-end patient journey cycle including all stakeholders (providers, patients, carers, communities, employers, funders, regulators, peak bodies, vendors, etc.)
- 20. General lack of computational mathematical and statistical skills knowledge and awareness
- 21. Global regulatory affairs understanding of FDA and EMA requirements. HTA evidence needs. Accessible market usually overstated.
- 22. Health economics and financial modelling.
- 23. HEGA, Regulatory, Digital Marketing, Capital Equipment.
- 24. High end international healthcare grade manufacturing. Global sales.

- 25. I am in early stage research translation. It is very difficult to do in Australia because of: 1. Entrepreneurial capability and culture, both in researchers and TTO's e.g. 80% US researchers see industry important to careers vs 36% in Aus (UniSA 2015 report on end user engagement). 57% of researchers network is supportive of industry engagement (UniSA report 2015 as above). Upto 2.1x fewer inventions disclosed by Australian researchers vs US or EU (NSRC 2016, KETECH UK report 2015) 2. Willingness to take risks. 3. Openess of Research institutes and universities to trust/ empower researchers with early translational activities e.g. industry engagements, early de-risking of ventures. Lack of this severely hinders the agility of an institution, and ability to build a bigger and higher quality pipeline of potential ventures e.g. best ranked Aus university for industry co-authored papers =264th (CWTN Leiden 2019 report). 4. Fast de-risking of early stage research translation.
- 26. I wish that there was more understanding of QMS from all of the PhD programs in biomedical areas. There are a lot of PhDs being pumped out and if they had some more working knowledge of QMS then it would be much quicker for them to move into industry positions.
- 27. Identification of translational health research/technology opportunities, particularly in the engineering space. Translational and multidisciplinary communication and collaboration. Raising funding for small business start-ups within the commercial and university sector.
- 28. Intellectual property valuation, particularly at early stages post discovery.
- 29. IP translation to secure patent and commercialisation.
- 30. Irrespective of the specific technical skills listed in this survey, generally there is a significant lack of analytical, critical thinking skill at several levels. With all due to respect to many people, their behaviours are far too often 'robotic', following a 'recipe'.
- 31. It is often less about the skill set itself and more about the lack of experience in the industry and where/how the role fits into the bigger picture. Without this broader context, things are often over- or under-engineered, rather than fit for purpose.
- 32. Lack of ability to see the 'big picture'.
- 33. lack of commercial 'real world' experience of graduates.
- 34. Major concern about lack of international experience within industry.
- 35. Matching ideas to clinical needs and identifying clinical partnerships required to test ideas at the earliest stages to ensure commercial viability and technology needed.
- 36. Our challenge is primarily finding the sort of people who can fit into our biotech environment, with sufficient experience, flexibility in approach and being able to tolerate being more of a generalist than the large pharmas require.
- 37. Practical, hands on training in emerging manufacturing sectors; Cell Therapy, Viral Vector, mAb, cell based flu vax and other biologics. Local Manufacturing capacity in this space is a major concern.
- 38. Pressure to really accelerate adoption of digital which is impacting a number of roles in the organisation, innovation skills new business opportunities, and data/analytics.
- 39. PV, RA, MA.
- 40. Risk management. Government affairs.
- 41. Soft skills!!! Teamwork. Collaboration and problem solving.
- 42. Software development under IEC 62304 for medical device software is a significant gap in Australia, both interns of recruiting individuals to work in house -likely impossible and outsourcing to contractors. Reimbursement strategy for the MedTech space is another big gap. Manufacturing capability under IS013485. There aren't enough good reg affairs consultants to go around.

- 43. Strategic account management, strategic management.
- 44. Technical expertise in Electrophysiology procedures.
- 45. The basic scientific skills are lacking too much emphasis on what results a machine can spit out, rather than an ability to interpret the results and recognise if they are wrong. Need more of a combination of scientific and business and financial skills.
- 46. There is a big disconnect between the academic environment and the commercial environment in terms of commercial expertise, speed, business acumen and IP management and strategy.
- 47. Under-appreciation of the need to understanding the various differences between the state and private jurisdictions in regulatory component of clinical trials.
- 48. Understanding in biomanufacturing, bioprocess, product development (how to bring proof-of-concept into product)
- 49. Understanding the manufacturing and translation process.
- 50. Very junior an inexperienced manager within Federal and State government offices
- 51. We have a chronic lack of internationally and industry experienced drug development professionals who have taken products from discovery to clinical



Appendix C Top 3 Skill Areas for 2030: Verbatim Responses

APPENDIX C: TOP 3 SKILL AREAS FOR 2030: VERBATIM RESPONSES

Area #1	Area #2	Area #3
Ability to convert ideas into commercial programs - need more people with development skills (research is strong - but not development) need more of the D in R & D		
Ability to think globally (global + local)	Storytelling to inspire	Agility to work in remote teams anywhere in the world
Adaptability	Digitalisation	Communications
AI	Bioinformatics	
AI	IT and Biomaterials interfaces	Rapid prototyping & personalised manufacture
All preclinical development stages and non-clinical pharmacology/toxicology	Access to international fund-raising	
Analytical, critical thinking skills.	Ability and competence to communicate or translate mathematical, scientific and statistical information clearly.	Professional engagement with and encouragement of non-professional personnel employed in the biotech- clinical-medical & nano sectors.
Animal Technology	Machine Learning	Commercialisation of medical research
Any "-Omics" related skills.	Communication - the ability to clearly listen, analysis and share	Collaboration - the ability to network, be flexibility, engage with multiple stakeholders to establish a common purpose
Artificial Intelligence and Machine Learning	Quantum Computing	Open Source eHealth Interoperability Standards
Automation	Digital	Project management
Background in Medical science and technology		
Big data analytics	Non-interventional human study design (especially with AI and with large data sets)	Regulatory affairs in SAMD, especially with extended regulatory capture
Bioinformatics	Research translation	Health economics
Bioinformatics	Biochemistry	Chemical biology
Bioinformatics - particularly in clinical trial design and execution	Understanding of drug development pathway from lab through preclinical development	IP understanding to academic researchers
Biomanufacturing	Product development	Regulatory
Business Development	Clinical trials and integration of disparate technologies to solve problems	
Clinical Research Associates	Clinical Project Managers	

Area #1	Area #2	Area #3
Clinical trial investigators	Clinical trial coordinators	Project management
Clinical trial management	Transaction skills	Manufacturing capabilities
Clinical trials support staff	Bioinformatics and biostatistics	
Commercial Strategy	Negotiation	Project Planning & Execution
Commercialisation	Investor management	Clinical development planning
Commercialisation	Strategic partnering with businesses & R&D	Capital raising
Communication	Negotiation	Capital Markets engagement
Consumer relating	Commercial acumen	Managing for future not just for now
Core science skills	Related skill sets such as marketing	Sales
Data	Digital	Customer experience
Data analytics	Problem solving	Rapid prototyping
Data analytics	Communication	Problem solving
Data/analytics/business insights	Innovation skills	Leadership/change management
Developing experience holistically across all technical	Commercial	Leadership elements to meet the mid- level and senior level maturity and depth of experience required for the future.
Digital	Project Management	
Digital marketing and sales	Regulatory	Data analytics and translation
Digital platform integration	Advanced manufacturing capacities	Commercial investors
Drug development	Application of big data, in silico modelling and artificial intelligence	International regulatory expertise
Electronics	Physiology	Systems
Electrophysiology technical skills		
Engineering	Product development	Regulatory
Engineering graduates targeting meddev do not understand basic product realisation/design controls	No education in protocol to report writing, sample size justifications, requirements management, etc, the bread and butter of product development.	
Enterprise skill	Negotiation	Business development

Area #1	Area #2	Area #3
Entrepreneurship	Networks and negotiation	Technical manufacturing skills
Formulation and analytical scientists	Medical device engineers	Project managers
Funding	Funding	More funding
Global experience	Investors	Developing a budget
Global perspective	Cybersecurity awareness	Strategic networking
Global Quality regulations	Funding strategies	Senior biologic experience
Global reg	Global risk and governance	Global commercial and marketing
Global sales	Advanced manufacturing	Applied and commercially viable technology development
Good science!!!		
Government Access	RA / PV / MA	
Hands-on International industry experience	International understanding of patents (IP)	Understanding of international competitive environment
HEMA	Regulatory	Digital Marketing
High throughput manufacturing	Engineering	Increased use of AI
IEC 62394 compliant software development.	Reimbursement strategy as opposed to reg affairs for Med Tech.	ISO 13485. Compliant manufacturing.
Leadership	Negotiation	Communication
Localised, and therefore dispersed, small scale manufacture of a variety of therapeutics, e.g. going from large scale small molecule to localised manufacture of CAR-Ts. Large scale joint manufacture to localised tailoring of personalised joints.	Integration of technologies, i.e. will need people who can understand and translate between technologies. Not just a molecule or a device, but a drug, interacting with a device, with a data interaction as well.	If we are to commercialise within Australia, then we need to have the expertise to manufacture.
Machine learning	E-health	Dealing with people
Manufacturability	Clinical needs assessment	Product development planning/costs
Manufacturing	Reg	
Manufacturing	Scientific consulting and testing	Regulatory
Manufacturing (CMC) to GMP, global and commercial scale	Regulatory to global needs	Non-clinical or pharmacology skill that has understanding of their part in complete product development

Area #1	Area #2	Area #3
More agile and entrepreneurial researchers and research institutions. This means that hierarchy re research commercialisation within institutions are replaced with small, agile, interdisciplinary (business x science) and outcome focussed teams.	Focus on institutions/researchers with a convergence science mentality E.g. software x biology, engineering x biology. This will open up new industry even outside of health e.g. synthetic biology/BIO with California as an example. There is too much focus on building capability and infrastructure on small molecule drug development that is clearly a past focus of industry e.g. most of top 10 drugs a biologics, not small molecules!	The future is clearly cell therapies, personalised med e.g. Crispr, and health empowerment of individuals as commonly known (and lesser known in the case of BIO/synthetic biology).
Practical experience working within a QMS	Practical experience working within a QMS	Practical experience working within a QMS
Problem solving	Teamwork	Communication
Problem/solution identification	Translational multidisciplinary communication	Fundamental engineering/technical skill
Project and Quality Management	Regulatory knowledge and skills	Biomanufacturing
Project Management and Communication	Financial understanding of clinical trial budgets	Communication and business opportunities to get work placed
Quality Assurance	Regulatory Compliance	Training
Quality management system management	Regulatory knowledge	
Regulatory	Manufacturing processes	Commercialisation processes
Regulatory	Project management	E-health
Regulatory Affairs	Health Economics	Clinical Research
Regulatory Affairs	Market access	Clinical trials
Regulatory Affairs	Clinical trial operations	
Regulatory Affairs	CMC	Preclinical development
Remote Monitoring	Project Management	Risk Analysis / Problem Solving
Reputation management	Issues management	Strategic stakeholder engagement
Resilience	Adaptability	Innovation
Risk-based assessment of research quality	Digital health	Innovation
Science	Maths	Engineering
Senior Fermentation Scientists	Downstream Scientists	

Area #1	Area #2	Area #3
Soft skills - people management		
software development	Biomedical engineering	Regulatory & clinical trials management
Stakeholder Management	Commercial Understanding	Risk Management
Stakeholder management	Project management	Understanding business needs
Stats	HEOR	Pharmacology
Strategic management	External networking / collaboration / incubator companies	Empathy / people skills
Systems approaches	Synthetic biology	Data integration
Technology integration	Health cybersecurity	Creative thinking
This is impossible to say given what we are experiencing at the moment.	We have an aging workforce, many of our senior researchers will need to retire (across a variety of specialisations) but we don't currently have succession plans in place for people to move up	
Training	Training	Training





CONTACT US FOR FURTHER

Phone +61 3 7019 0917

Email info@mtpconnect.org.au

MTPConnect Level 20 / 15 William Street Melbourne VIC 3000 Australia

VIC Melbourne Hub New Horizons Building Monash University 20 Research Way Clayton VIC 3168

Australia

NSW Sydney Hub

Level 5 J12 School of IT University of Sydney 1 Cleveland Street Darlington NSW 2006 Australia

QLD Brisbane Hub

Translational Research Institute Level 7, 37 Kent Street Woolloongabba QLD 4102 Australia

WA Perth Hub

The University of Western Australia Harry Perkins Institute of Medical Research Building QEII Medical Centre 6 Verdun Street Nedlands WA 6009 Australia

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