

Assessment of Australia's regulatory science workforce needs

Final Report

July 2017



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Creating workforce solutions

Report preparation

This report was prepared by Human Capital Alliance (HCA) Principal, Lee Ridoutt, and Staff Consultants, Carla Cowles and Debbie Stanford, in July 2017 for the Environmental Health Standing Committee (enHealth), a standing committee of the Australian Health Protection Principal Committee (AHPPC).

Disclaimer

HCA prepares its reports with diligence and care and has made every effort to ensure that evidence on which this report has relied was obtained from proper sources and was accurately and faithfully assembled. It cannot, however, be held responsible for errors and omissions or for its inappropriate use.

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We acknowledge this country as belonging to the Aboriginal and Torres Strait Islander peoples of Australia. Australia is the only place in the world where Aboriginal and Torres Strait Islander Australians belong. There is no place in Australia where this is not true.

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- Ms Elizabeth Cheah – enHealth Secretariat.

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Acronyms & abbreviations

AHPPC	Australian Health Protection Principal Committee
APVMA	Australian Pesticides and Veterinary Medicines Authority
EHWWG	Environmental Health Workforce Working Group
enHealth	Environmental Health Standing Committee of enHealth
FDA	US Food and Drug Authority
FSANZ	Food Standards Australia New Zealand
FTE	Full-time equivalent
HCA	Human Capital Alliance
IOM	Institute of Medicine
PFAS	Per/Poly Fluoroalkyl substances
STEM	Science, Technology, Engineering and Mathematics
TGA	Therapeutic Goods Administration

Contents

Acronyms & abbreviations.....	3
1 Executive summary.....	6
1.1 Background	6
1.2 Method	7
1.3 Roles and responsibilities.....	7
1.4 Required skill sets	8
1.5 Emerging issues.....	8
Next steps	9
2 Background	10
2.1 Context of the project.....	10
2.2 What is the current project intended to achieve?.....	10
2.3 Study methodology.....	10
2.3.1 Research action 1: Literature and document review	11
2.3.2 Research action 2: Position description analysis.....	11
2.3.3 Research action 3: Critical incident interviews.....	13
3 What is already known?	15
3.1 Workforce boundaries	15
3.2 Roles and functions of the regulatory scientist	17
3.3 Competencies required to do regulatory science work.....	19
3.3.1 Communication and collaboration.....	20
3.3.2 Scientific knowledge base and other core knowledge	20
3.3.3 Understanding of the regulatory context	21
3.3.4 Risk assessment and management.....	22
4 Analysis of position descriptions	24
4.1 Competencies required for regulatory science work	24
4.2 Defining the regulatory scientist role by competencies required	26
4.3 Differentiation between position types.....	29
4.4 The sense of a career path?	32
5 Critical competencies required by a regulatory scientist	34
5.1 What does regulatory science work look like?	34
5.2 A collaborative workforce.....	34
5.3 Competencies and skills for effective regulatory science.....	35
5.3.1 Communication skills for relationship building	35
5.3.2 Judgement and anticipation	36
5.3.3 Specialist science knowledge	37
5.3.4 Understanding of government systems, processes, legislation and regulation	38

5.3.5	<i>Risk management</i>	38
6	Discussion of findings — Where to from here?	40
6.1	The start of the process	40
6.2	Roles and responsibilities.....	40
6.3	Required skill sets	41
6.4	Emerging issues.....	42
6.5	Next steps	43
6.5.1	<i>Step 1: Consolidate a list of competencies</i>	44
6.5.2	<i>Step 2: Define the parameters of demand for regulatory scientist competence</i>	44
6.5.3	<i>Step 3: Quantifying regulatory scientist competency requirements</i>	45
6.5.4	<i>Step 4: Validate the career path</i>	45
6.5.5	<i>Step 5: Undertake a stocktake of current supply</i>	46
6.5.6	<i>Step 6: Estimating adequacy of supply</i>	46
6.5.7	<i>Step 7: Developing appropriate workforce strategies</i>	47
6.6	Summary of next step	48
7	References	49
	Appendix A: Core Thematic Areas for Regulatory Scientist competence	51

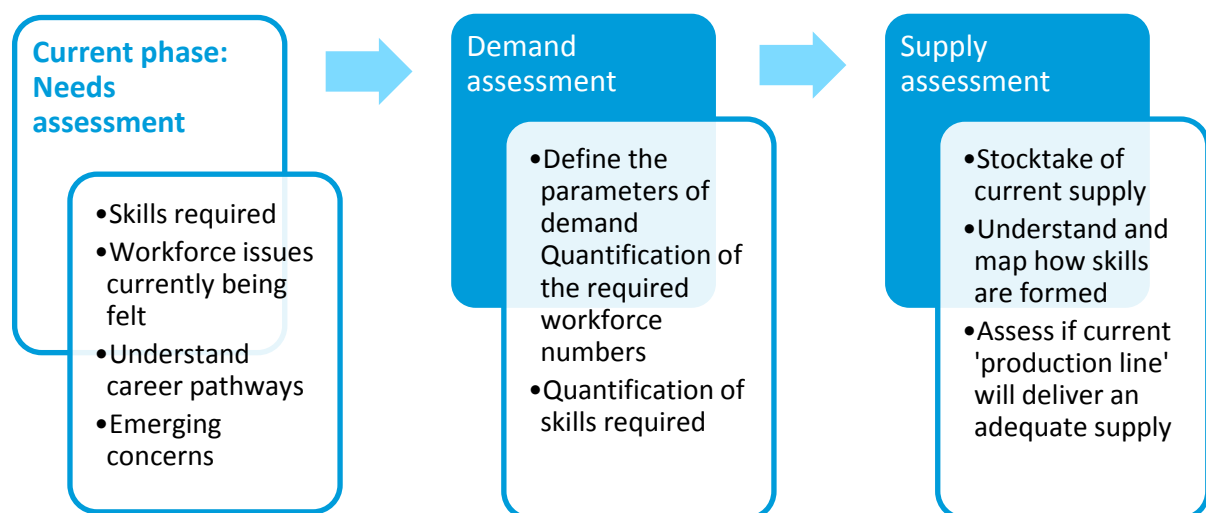
1 Executive summary

1.1 Background

The focus of regulatory science is to protect the health of the community through appropriate risk assessment and risk management of novel or emerging population health risks and administration of legislation and regulations set to protect human health and consumer safety. Skilled, competent regulatory scientists are required to effectively undertake this work, reiterated by recent incidents such as per – and poly fluoroalkyl substance (or PFAS) contamination at Department of Defence sites or other Australian locations and potential impacts on communities and agriculture.

There is a strong qualitative perception among managers in organisations where regulatory scientists work that in-house supply of specialist scientific knowledge has diminished in recent years, a direct result of the reduced number of specialist roles across all levels of government. Adding to a sense of general short supply (due to both trained specialists and available roles) identified by a number of participants, there is a more obvious limitation in some specific highly specialised area of science – in particular, toxicology. The literature is increasingly supporting claims of regulatory scientist shortages (e.g. Lease, 2017) and raising concerns that if a shortage exists, a ‘training’ solution to that problem could take many years to deliver a satisfactory result.

This study is the first of a series of proposed research actions (as shown in the Figure below) that will clarify areas of requirement for regulatory scientists, quantify the actual demand for regulatory scientist workforce within the Australian labour market, estimate current and future levels of supply, assess if supply is adequate both currently and in the projected future, and, if remedial action is required, determining the short, medium and longer term workforce strategies that would maintain a sustainable regulatory science workforce.



This first phase of effort (the ‘Needs Assessment’) had three specified outcomes:

- identify current regulatory science agency roles and responsibilities
- define the skill sets required to meet those responsibilities
- identify the current and emergent workforce issues confronting regulatory science agencies.

1.2 Method

The primary effort for this research project was to identify roles and responsibilities for regulatory scientists as well as the skills required to perform those roles and satisfy the responsibilities. Three separate research activities were undertaken almost simultaneously, viz.:

- *Literature and document review* – adopted a narrow scope and focus on literature identified in Lease (2017) and some supplemental literature search (including ‘grey’ literature provided through members of enHealth and AHPPC). These sources were re-analysed, primarily with the view of creating a list of roles and skills.
- *Position description analysis* - position descriptions for analysis were sought from a sample of regulatory agencies. The positions were either currently occupied or recently advertised. A total of 71 position descriptions, gathered directly from organisations or downloaded from recruitment websites, were able to be effectively analysed (that is, they were within scope and of sufficient detail to allow analysis). The text analysis of the position descriptions involved the categorisation of each position according to categories such as position type, level of the position and number of reports, and competencies / skills specified as required of the position.

Most of the employing organisations from which position descriptions were gathered were government departments or agencies (92%) but represented differing levels of government. These employers were located in nearly all Australian States and Territories

- *Critical incident interviews* - Critical incident interviews with 17 more senior regulatory scientists were undertaken. Each interview sought to obtain descriptions of at least four critical incident ‘stories’ but in most cases two to three incidents provided ample content for exploration.

Interviews with managers were originally planned to follow the completion of the above research actions in order to capture emerging workforce issues and concerns and to understand a possible pathway for regulatory scientist competence. However, since each of the critical incident interviews included regulatory scientists at senior and executive levels, these issues naturally emerged whilst the critical competencies and skills of regulatory science were explored.

1.3 Roles and responsibilities

Like many professions that have emerged in more recent times from the body of longer established occupations, the regulatory science profession has been required to slowly develop its unique set of roles, functions and practices, to gradually differentiate itself from where it has evolved, and to establish new workforce boundaries.

In terms of differentiation, the literature review and analysis of position descriptions identified four main areas of work that regulatory scientists currently perform or should perform:

- providing information & advice, to a range of audiences from regulatory colleagues to the general public, helping those audiences understand and access science concepts
- formulate, or contribute to the formulation of policy, regulations and guidelines through incorporation of evidence from scientific knowledge
- for effective collaborative relationships to both gather and disseminate information and help negotiate and promote legislative processes
- identify hazards and assess and manage risks.

The primary role of regulatory scientists has been described as navigating the interface between science and society. Regulatory scientists participate in communication that extends far beyond the audience range of normal scientists, since regulatory decisions do not influence just the scientific community but also the public at large. Regulatory scientists are distinguished as much for their capacity to communicate and forge relationships as they are for their technical scientific knowledge.

Depending on the specific role within the organisation and the level of seniority, regulatory scientists might also conduct regulatory affairs, manage and conduct research & other projects, manage work, and support business planning.

1.4 Required skill sets

Regulatory scientists *may* draw on a number of clusters of skills to perform their role effectively. In practice, though, three competency clusters in particular appear to underpin a common platform or skills set that is most characteristic of regulatory scientists and this comprises:

- provide information & advice
- formulate policy, regulations and guidelines (includes sound understanding of legislative processes)
- effective communication & relationships.

The data from the critical incident interviews, however, indicate that possession of this skills set alone, even though it might satisfy core competence requirements, is likely to be insufficient to produce superior work outcomes. In addition, the highly effective regulatory scientist needs:

- well-developed specialist science knowledge
- a capacity to manage risk.

Another critical competence highlighted by the critical incident interviews was good judgement and anticipation. This core competence is founded in knowing the science well and having a strong risk management framework, along with clear insight to legislative processes. *In addition*, it is linked to having confidence in your peers, having clear values about a specific issue or situation and being courageous enough to develop an informed view based on limited information and/or advocate for a particular position when professional judgement suggests that is required.

1.5 Emerging issues

In addition to broad concerns held about an existing or evolving shortage of regulatory scientists, a companion concern is that future supply of [capable and effective] regulatory scientists requires support for a minimum number of ‘feeder’ roles as well as a willingness to invest long term in those position occupants – and this may not be happening.

It is not only sustaining ‘feeder’ positions that is considered important - the way that the learning process that underpins progress from junior regulatory scientist to principal or executive levels is structured is also believed to be very important. Some respondents argue that structured experiential opportunities are a critical and central component of education and training in regulatory science. They note that the typical training period spans three years or more during which on-the-job or apprentice-like learning is complemented to a lesser extent by formal courses. More efficient training and development processes, underpinned by more effective learning strategies that are focused more directly on critical competencies, was thought to be optimal.

Next steps

A proposed series of seven steps to complete the exploration of the regulatory science workforce is provided in summary on the following page. Steps 1 to 7, as outlined in Figure A, and involving a combination of research, planning, validation and strategy development, should not require more than 12 months to achieve.

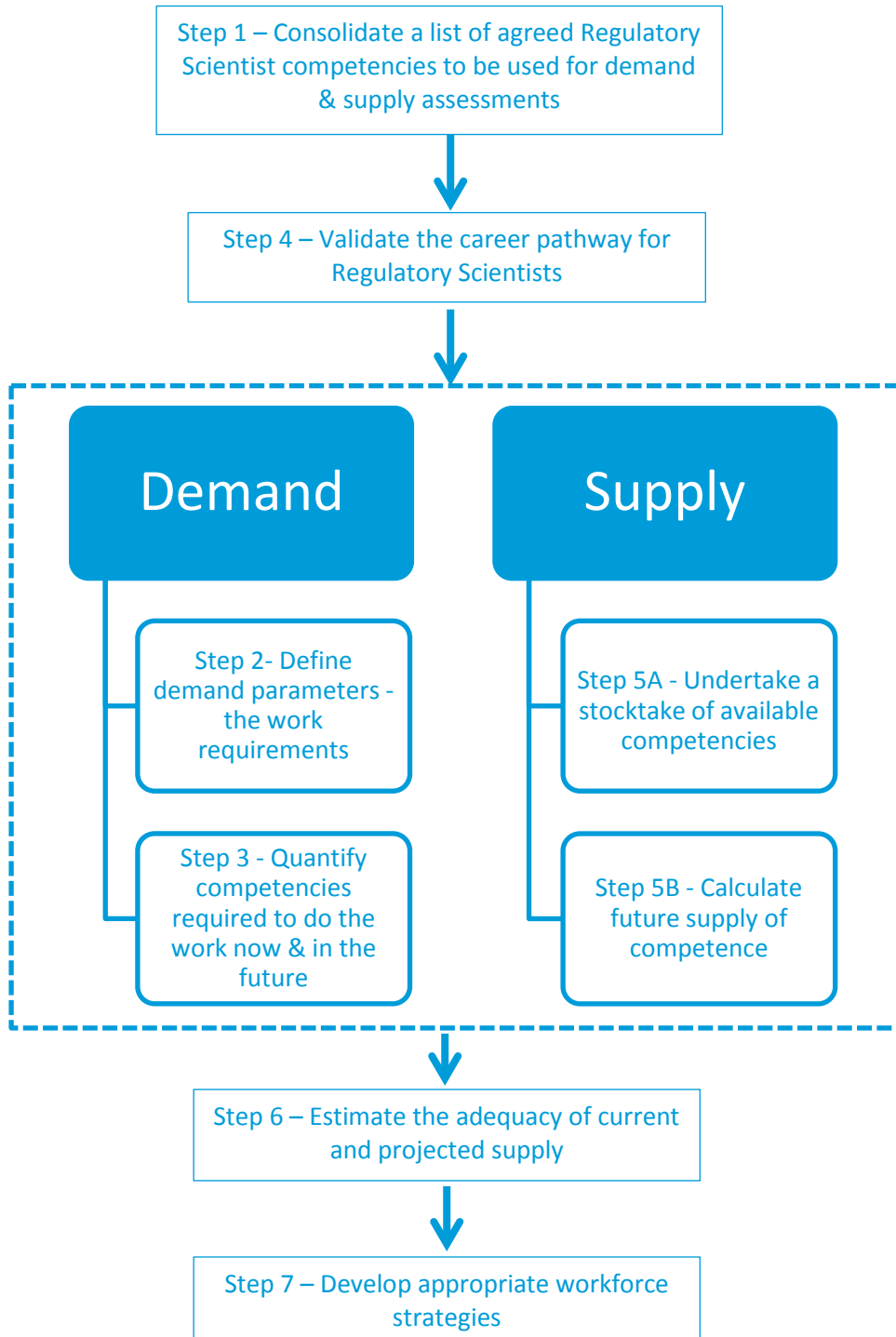


Figure A: Next steps for the exploration of the needs of the regulatory science workforce

2 Background

2.1 Context of the project

The focus of regulatory science is to protect the health of the community through appropriate risk assessment and management. To effectively undertake this work, skilled and competent regulatory scientists are required. This need has been reiterated by incidents such as the PFAS contamination at Department of Defence sites and its impact on communities and agriculture.

Such incidents emphasise the important role of regulatory scientists to effectively respond to major human health risks, as well as highlight the limited and decreasing pool of regulatory scientists available to lead this work, both in Australia and internationally (Lease, 2017). The time required to develop the skills, knowledge and competence of regulatory scientists has also come into focus, since this dictates a need for considerable forethought on the development of workforce supply and provision of on the job mentoring and learning.

Understanding the actual demand for, and supply of, the regulatory science workforce is therefore now imperative in order to support the preparation of an appropriate workforce development plan that recognises and addresses the education, training, experience, and government infrastructure and career paths relevant to this workforce. As a starting point, the workforce itself needs to be examined in terms of the work undertaken by regulatory scientists, the competencies and skills required, and the issues faced by the workforce.

This project is therefore part of a broader initiative, the objective of which is:

To undertake a series of workforce related actions to support the Australian Health Protection Principal Committee (AHPPC) better characterise the demand for regulatory scientists in Australian governments and identify the measures needed to ensure that demand is met into the future to ensure that the health of Australian’s is adequately protected.

The project has been coordinated and guided by the enHealth Environmental Health Workforce Working Group (EHWWG) on behalf of AHPPC. The enHealth EHWWG has a proven track record of engaging stakeholders, and developing and implementing workforce initiatives for the environmental health workforce across Australia.

2.2 What is the current project intended to achieve?

This study is intended to produce a report for stakeholders comprising information on the issues facing agencies in meeting their responsibilities, the regulatory science skills essential for them to effectively meet those responsibilities, and the current and emergent workforce issues confronting regulatory science agencies. In this way, the study is intended to progress the understanding of enHealth and the AHPPC and is the first step in a three-part process outlined in the ‘High Level Project Plan’ described by Lease (2017). That proposed process is illustrated in the figure below. The wording from the original Project Plan was modified (with the agreement of the enHealth EHWWG), especially in regard to the demand assessment in order to better reflect the concept of workforce demand.

2.3 Study methodology

The primary effort for this research project was to identify roles and responsibilities and the skills required to perform those roles and satisfy the responsibilities. Three separate research actions were undertaken almost contiguously, viz.:

- Research action 1: Literature and document review
- Research action 2: Position description analysis
- Research action 3: Critical incident interviews

Each research action is detailed below.

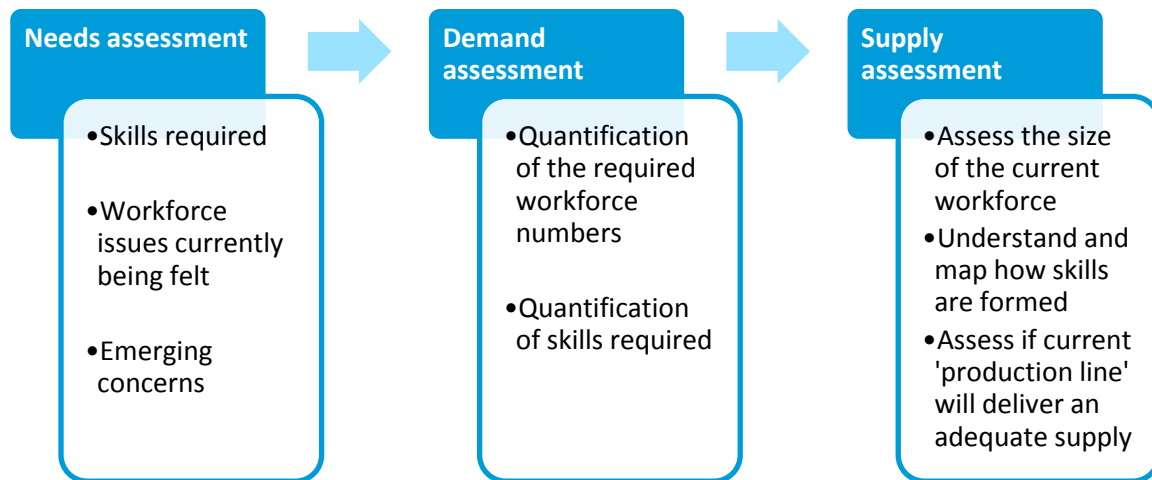


Figure 1: Process of needs assessment

2.3.1 Research action 1: Literature and document review

The literature and document review undertaken was not comprehensive, and applied only narrowly to focus on literature identified previously in Lease (2017), and some supplemental literature search (including 'grey' literature provided through members of enHealth and AHPPC). The review undertaken by Lease was considered to be sufficiently current and sufficiently broad in scope to not warrant an additional significant investment in reviewing the literature. Other electronic and printed literature was also sourced, including regulatory agency websites and information targeted at regulated populations and stakeholders.

Regulatory scientists apply professional expertise in a wide range of regulatory settings. However, for the purpose of the current project, the literature review focussed on publications that refer to regulatory roles with a linkage to human health. This also included the regulation of products and activities that can potentially affect the human food chain, the environments in which we live, and the safe use of consumer and therapeutic products.

2.3.2 Research action 2: Position description analysis

For this research action, position descriptions were sought for analysis from a sample of regulatory agencies (with the support of the enHealth EHWWG), including:

- Commonwealth, state and territory health authorities
- Australian Pesticides and Veterinary Medicines Authority (APVMA)
- Food Standards Australia New Zealand (FSANZ)
- Therapeutic Goods Administration (TGA).

The positions described were either currently occupied or recently advertised. Agencies providing positions for the analysis determined if the position related to a regulatory scientist role. The text analysis of the position descriptions firstly involved the categorisation of each position according to the following categories:

- position type
- specified position duties and functions

- level of the position and number of reports
- competencies / skills specified as required of the position.

A Microsoft Access database was created and data entered and analysed with fields created for the above categories. The final list of categories (and therefore fields in the database) for each component was derived from an analysis of the first 10 to 15 positions, which is normally enough to identify a comprehensive list of competencies¹. The varying quality of position descriptions was noted and, for the purposes of data analysis, an essential / minimum level of detail was identified. The database was then quantitatively analysed and frequency distributions of required competencies and types of function / duty were created. This approach has previously been utilised by HCA to identify both roles and skills of other workforces; for example, in order to identify specific competencies of public health physicians (Ridoutt et al., 2012).

A total of 71 position descriptions, which were either gathered directly from organisations or downloaded from recruitment websites, were able to be effectively analysed (that is, they were within scope and of sufficient detail to allow analysis). Position descriptions were collected from 14 employers, as follows:

- Agriculture & Water Resources, New South Wales (NSW)
- APVMA
- Brisbane City Council
- City of Newcastle
- Department of Health, Northern Territory
- Department of Health, Western Australia
- Department of Industry Skills and Regional Development, NSW
- Department of Environment and Energy, NSW
- Namoi Water
- NSW Health
- Queensland Health
- Sanitarium
- South Australia Health
- Victorian Department of Health & Human Services
- TGA
- FSANZ

Some employers were not identifiable in those instances where a recruitment service was withholding its client’s identity. Most of the employers from which position descriptions were gathered were, as one might expect, government department or agencies (94%) and differing levels of government were represented. The distribution between employer types is shown in Table 1.

¹ Of course provision remained to add competency fields to the database if new competencies emerged from review and data entry of subsequent position descriptions.

Table 1: Source of regulatory scientist position descriptions by type of employer (n=71)

Employer type	Frequency	Proportion of total position descriptions (%)
Government		
▪ Area/ region	3	4.9
▪ National	26	34.4
▪ State	37	52.5
Non-Government Organisation	1	1.6
Private company	4	6.6

The employers from which position descriptions were gathered were located in all Australian States and Territories and Tasmania (see Figure 2).

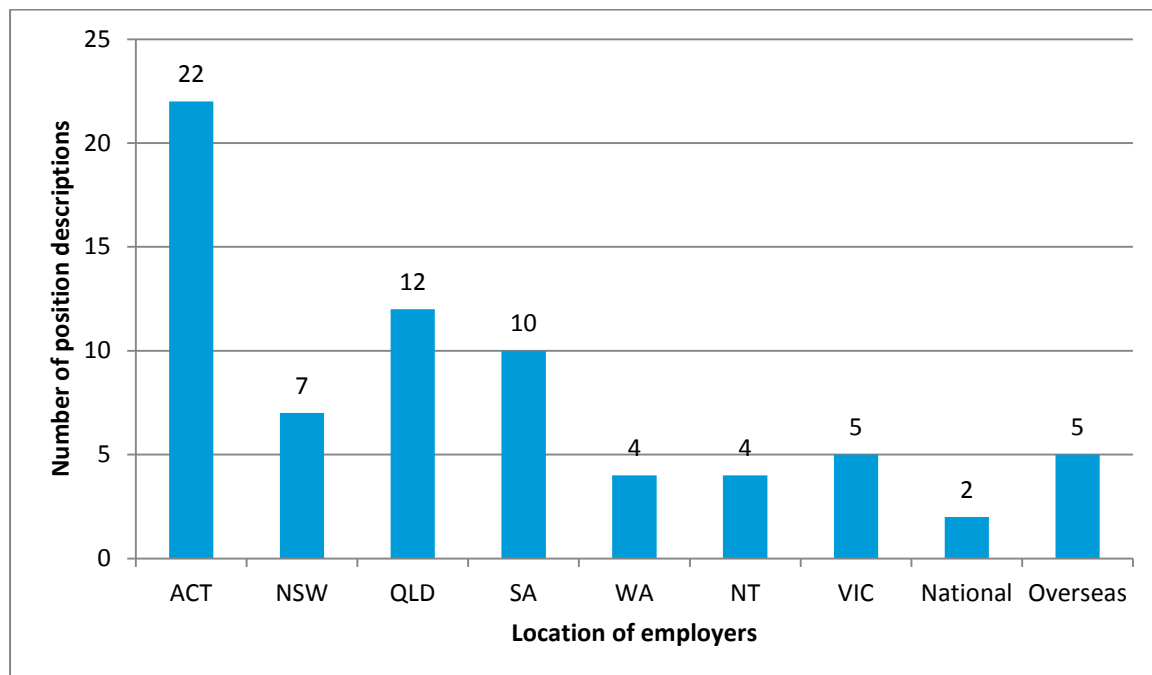


Figure 2: Source of regulatory scientist position descriptions by location of employer (n = 71)

2.3.3 Research action 3: Critical incident interviews

Critical incident interviews with regulatory scientists were undertaken and have provided an important source of information (that is, a “value add” to the existing knowledge base and information gained through position description analysis). A total of 10 interviews were conducted with 17 regulatory scientists (some in small groups), either by phone or face-to-face, sampled from the agencies from which position descriptions were accessed and/or sought. Each interview sought to obtain descriptions of at least four critical incident ‘stories’ but in most cases two to three incidents provided ample content for exploration. A critical incident for the purpose of this study is defined as:

“... any observable activity that is sufficiently complete in itself to permit inferences and predictions to be made about the person performing the act. To be critical, an incident must occur in a situation where the purpose of the act seems fairly clear to the observer and where its consequences are sufficiently definite to leave little doubt concerning its effects” (Flanagan, 1954).

Critical incidents therefore can make a significant contribution - either positively or negatively - to an activity or phenomenon. Critical incident stories were interrogated to investigate unique attributes of the incident (either in the delivery of the positive outcome or potentially to have rescued the negative outcome). In line with the desired effect of applying this methodology, strong themes and patterns have emerged in relation to the competencies required to obtain high quality regulatory science performance.

In summary, the three research actions have provided strong evidence of the roles and responsibilities of the regulatory scientist workforce and the skills set (including the more critical skills within that set) that regulatory scientists require in order to operate as required at the intersection of values, ethics, politics and scientific evidence (for example, assessing the weight and strength of scientific evidence, understanding population effects, and recognising community expectations, politics, ethics and societal values. The findings from these three arms of our research are analysed in more detail in later chapters of this report.

Interviews with managers were originally planned following the completion of research actions One to Three in order to capture emerging workforce issues and concerns and to understand a possible pathway for regulatory scientist competence. However, since each of the critical incident interviews included regulatory scientists at senior and executive levels, these issues naturally emerged while exploring the critical competencies and skills of regulatory science. Prior to progressing to a next stage of research, the findings of this study will need to be validated with a broad group of senior executives and regulatory scientists.

3 What is already known?

3.1 Workforce boundaries

For any workforce, a pre-requisite condition for being able to undertake workforce planning and development is to be able to place suitable boundaries around that selected workforce, thus defining what types of labour are to be included or not. This allows counting of the most basic and fundamental of workforce variables — the current size of the workforce. With regards to this project, it also allows consideration of the work, and what competencies are required to do that work. Setting workforce boundaries is not always easy when there is no single type of qualification required and where the workforce is dispersed across many sectoral and organisational settings. Ultimately, some ambiguity has to be accepted.

Setting the boundaries often starts with trying to define the workforce that is covered or definitely within scope. Two commonly cited definitions in the literature for regulatory scientists appear to be those defined by:

- a) the US Food and Drug Authority (FDA, 2011),

“... the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products”

- b) the European Medicines Agency (EMA, 2013)

“... a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. It encompasses basic and applied medicinal science and social sciences, and contributes to the development of regulatory standards and tools”.

Both these definitions relate to a pharmaceutical context, but can be extrapolated to other regulatory settings such as other health areas, the environment, water and soil, and agriculture. They both also highlight the unique place regulatory science holds as a linkage point between scientific endeavour and regulation designed to protect the community from harm; its definitional boundaries being somewhat different to other more traditionally defined fields of science.

In the Australian context, the regulatory science workforce has been described by Deloitte Access Economics (2014) in the following terms:

*“**Regulatory Scientists** cover a diverse cohort of different scientific, administrative and legislative skills and knowledge. Although many different definitions were discussed, it was largely agreed that a Regulatory Scientist is someone who (1) has some level of scientific knowledge, preferably across a range of fields and (2) understands and/or can apply the relevant regulatory framework and associated activities such as risk assessments. The overarching aim of many activities is to ensure that products going on to the market have been adequately assessed for their risk to both humans and the wider environment.*

Overlaying the existing workforce issues is the Australian regulatory system itself. In particular, the uniqueness of many of the Australian systems, requiring on-the-job knowledge, as well as the various State/Territory variations which need to be understood and accounted for. In addition, the regulatory environment, although consisting of three main regulatory frameworks, also covers more than 100 pieces of separate legislation. Moreover, it is continuously changing environment which requires all Regulatory Scientists to remain aware and up-to-date with these changes and developments” (p84).

In its draft regulatory science strategy, APVMA (2015) outlined the distinction between conventional science and regulatory science, and thus started to identify who was not within the regulatory science boundaries. The APVMA described **conventional science** (those who practice this are not within the regulatory science boundaries) as,

“... the application of the scientific method for the purpose of understanding some physical, chemical or biological phenomena. It tends to be curiosity-driven, forward looking and speculative. New results generate new ideas, with any uncertainty addressed through the conduct of additional research to the point where satisfaction is only attained when everything is understood”.

The draft strategy describes **regulatory science** (and those who practice this are within the regulatory science workforce boundaries) as,

“... a pragmatic application of the scientific method for the purpose of making a decision about whether to allow something (e.g. chemicals) to be used within the defined legislative framework and timeframes. What differentiates regulatory science from conventional science is that decisions are based on analysis and interpretation of existing scientific knowledge and, where necessary, assumptions to address data gaps or uncertainty. Regulatory scientists do not generate new lines of enquiry to answer questions, instead relying on available information (provided by applicants or in the literature) to make a decision one way or another”.

The APVMA draft strategy goes on to describe the boundary between the field of regulatory science and the closely related roles that are undertaken under the umbrella of **regulatory affairs** (‘the administrative aspects of regulation’) or **regulatory law** (‘the legal aspects of regulation’). While these are all distinct fields of endeavour, there is likely to be some overlap in functions as shown in Figure 3. A comprehensive regulatory affairs professional development framework published by the US Regulatory Affairs Professionals Society (RAPS, 2013), for example, provides an indication of the extent of actual and potential overlap of competencies that are likely to be found. Mostly overlap relates to the actual implementation of legislation, not its design and drafting.

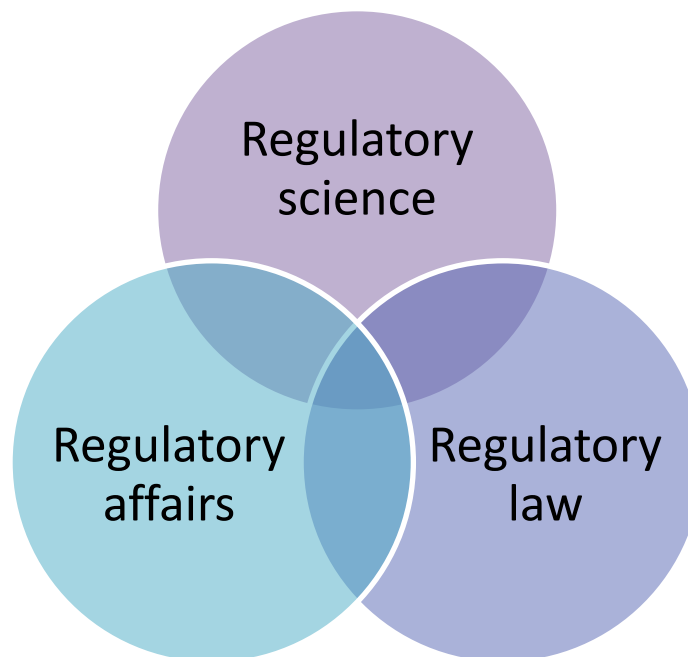


Figure 3: Overlap of the fields of regulatory science, regulatory affairs and regulatory law

The APVMA strategy also notes that, while regulatory science incorporates a variety of scientific disciplines, it is in itself a specialised field of science. In this regard, Adamo et al. (2015) point out that the fields of **regulatory science** and **translational science** “... have shared goals to ensure that the significant investments and advances in basic science research are transformed into products that improve public health.”

This view is borne out in numerous publications which deal with career and development issues for both of these fields of science in an aligned and/or coordinated approach, including the following:

- one of the key messages arising out of the 2011 Institute of Medicine (IOM) workshop discussions also proposed “*a strong relationship between regulatory science and translational science could provide a path to creating a well-rounded discipline.*”(IOM Workshop, 2012).
- Giacomini has suggested that the already-defined core competencies for translational medicine and therapeutic sciences can provide a framework in which would reside a subset of competencies needed for the regulatory sciences (Giacomini, K in IOM Workshop, 2012).
- Snyderman likened the development of a discipline of regulatory science to efforts to advance translational research and the conduct of clinical trials within academic medical centres. He stated that, “... *there is now a need to approach the regulatory sciences in a concerted, organized way, to define the discipline and competencies associated with its conduct, and to define it as an innovative science that is a valid career path for young scientists.*” (Snyderman, R in IOM Workshop, 2012).

Snyderman also made the following recommendations for the development and advancement of regulatory science to the same workshop, viz:

- recognise it as a discipline
- define the discipline
- define the qualifications
- define educational needs
- create academic homes and promotion/tenure tracks.

3.2 Roles and functions of the regulatory scientist

An understanding of the role and functions of any workforce – that is the work they perform – is foundational to an appropriate analysis of workforce demand (Ridoutt et al., 2002) and this equally applies to regulatory scientists. This is illustrated in Figure 4.

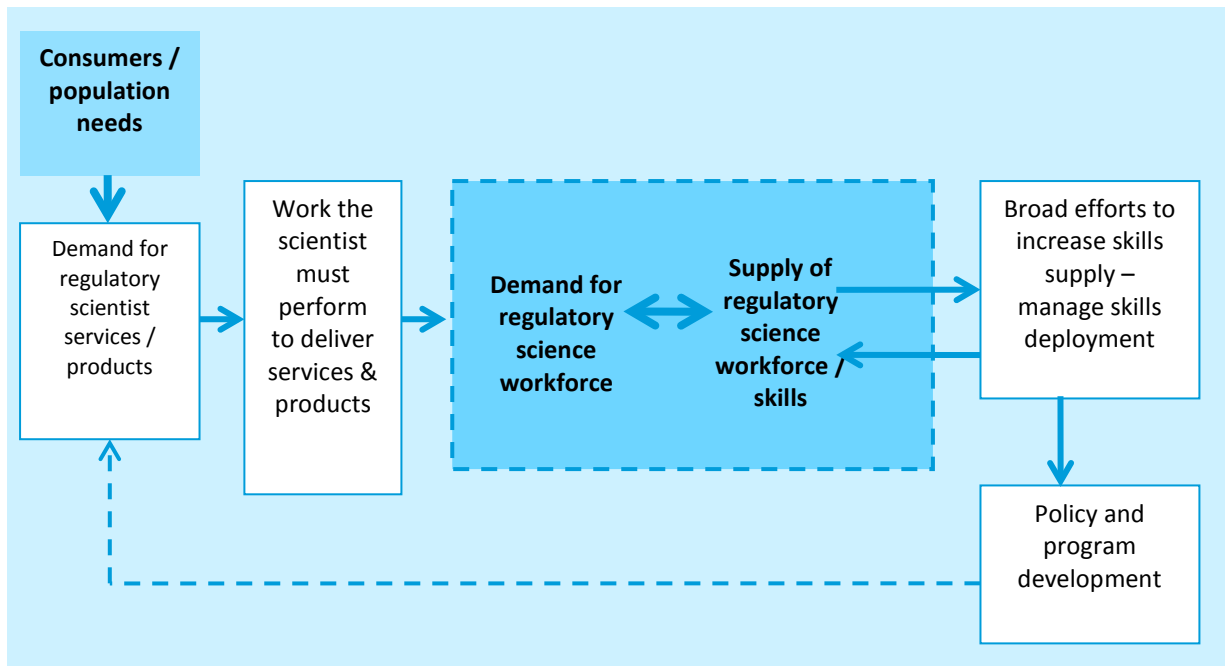


Figure 4: Overview of the approach to estimating workforce demand and workforce planning

The work of regulatory science is undertaken in a wide range of settings and by scientists who have undertaken formative training in a broad range of technical scientific disciplines. The duties of regulatory scientists can be summarised as “... the assessment of health risks and the provision of scientific advice so that regulatory decisions can be made, often when the scientific evidence on which to base these decisions is incomplete or disputed”, (Lease, 2017).

The APVMA (2015) describes regulatory science within its agency as:

“... a broad term relating to chemical, biological and other product regulations, regulatory standards, technical policies and procedures. It is a systemised body of knowledge compiled and utilised by regulatory agencies world-wide, with a focus on the protection of human health (public health and/or occupational health and safety) and the environment. Scientific methods employing empirical and causal evidence are utilised in the formulation of technical policies, risk assessment methodologies, and in evaluation and approval of the products an agency regulates. Regulatory science can encompass both pre-market and post-market activities.”

In the overview paper prepared to provide background information and strategic direction for the current project, Lease (2017) collated the following perspectives from the field:

- Regulatory science is more than just developing and applying methods for understanding and assessing risk, it also involves the consideration of cultural and societal issues relating to how individuals and society perceive and accept risk (IOM, 2016).
- An essential part of the role of a regulatory scientist is to consider the best available scientific advice and use this to explain the basis of any decisions made to the public (APVMA, 2015).
- The role of regulatory scientists has been described as, “*navigating the interface between science and society*”. Navigating this interface, coupled with the paradox of increasing responsibilities with reducing resources, has placed significant demands on regulatory scientists. They and their agency’s scientific credibility relies on their capability to be responsive, adaptable and - most importantly – right (IOM, 2016; FDA, 2015).

Philbert (IOM, 2016) points out that regulatory scientists participate in a social discourse that extends far outside of the laboratory and clinic, and correspondingly, regulatory decisions do not just influence the scientific community, but also the public at large. Weichold also highlights the importance for regulatory science of communicating priorities and dialogue with external stakeholders, such as policy makers, patient groups, and academia (IOM, 2016).

A key element of the practice of regulatory science is an understanding of societal and personal tolerance for risk and how society and individuals experience the benefits of new drugs and technologies (IOM, 2012). Participants called for a more developed approach to benefit-risk assessment that takes patient perspectives into account.

3.3 Competencies required to do regulatory science work

In 2013, the US Clinical and Translational Science (CTSA) Regulatory Science Working Group took the lead in developing a set of regulatory science competencies, using competencies identified for clinical and translational research as a starting point. Their current publication (CTSA, 2017) focusses on 11 core thematic areas. A list of associated competencies was developed as a result of discussion with academic, industry, and government partners at a 2014 workshop entitled: *Regulatory Science Core Competencies and Curricular Guidelines*. The identified core thematic areas are as follows:

1. Regulatory Science Research Questions and Priorities
2. Regulatory Policies and Process
3. Research Ethics
4. Drug Discovery and Development
5. Medical Device Innovation
6. Preclinical
7. Clinical Trials
8. Post-Marketing and Compliance
9. Analytical Approaches and Tools
10. Communication
11. Technology and Innovation.

The identified competencies associated with these thematic areas are further outlined in full at **Appendix A**. Although their practical focus is on the competencies of the regulatory scientist workforce of the FDA - one of the largest and most influential employers of regulatory scientists in the US (and probably the rest of the world), they are widely cited and considered to be broadly relevant in the field of regulatory science².

Other literature contains discussion of the competencies required by effective regulatory scientists according to a number of other specific themes. These include:

- communication and collaboration
- scientific knowledge base and other core knowledge
- understanding of the regulatory context
- risk assessment and management.

Each of these areas is discussed further below.

² This is particularly so when the work of the regulatory scientist is associated with the introduction of products like pharmaceuticals, agricultural chemicals and/or medical devices to the relevant regulated jurisdiction.

3.3.1 Communication and collaboration

In relation to the theme of communication, Fields (2013) writes that communication is a core part of the role of a regulatory scientist – “... making it clear to regulatory agencies what you are doing, and why, in what is essentially a massive peer review process.”

In the report of a 2016 workshop held by the US Institutes of Medicine to promote discussion on a US-based regulatory science workforce strategy (IOM, 2016), Honig distinguished “collective competency” from “collective experts.” He noted that the process of regulation relies on a wide collection of disciplinary expertise (collective experts), but “enlightened” regulatory science also relies on the integrated confluence of these disciplines (collective competency). The workshop report indicated his view that “... the most successful regulatory scientists at FDA are those who can leverage and integrate effectively the diverse expertise available at FDA to make informed, enlightened regulatory decisions”.

Dance (2013) provides insights from two senior regulatory scientists about the nature of the regulatory scientist’s role. Candice Jongsma (regulatory science fellow at the FDA Center for Tobacco Products in Rockville, Maryland) reported that, in some ways, working in regulation is like being a principal investigator in that she may not do the experiments herself, but she reviews data, asks questions and makes recommendations. Frances Richmond (Director of the International Center for Regulatory Science at the University of Southern California in Los Angeles) reported that regulatory science is “a field that you would enjoy if you don’t want to think one-dimensionally”. He works with experts in topics such as toxicology or law, and that communication skills and a team-oriented approach are essential.

3.3.2 Scientific knowledge base and other core knowledge

Regulatory science is applied in a wide range of scientific fields. Lease (2017) summarised the common disciplines relied upon by regulatory science in Australia as (Lease, 2017):

- Chemistry
- Toxicology
- Epidemiology
- Entomology
- Medicine
- Microbiology
- Modelling
- Engineering
- Risk assessment
- Nutrition
- Pharmacology
- Genetics
- Law
- Communication
- Environmental Science.

A similar but more extensive list of regulatory science fields was identified during the course of the 2011 IOM workshop (IOM, 2012) and is shown in Table 2.

Table 2: Disciplinary components of regulatory science for consumer or community health or safety

Disciplinary components of regulatory science		
Basic investigation	Drug disposition and metabolism	Pharmacology
Bioengineering	Economics	Pharmacy
Bioethics	Epidemiology	Protection of human subjects
Bioinformatics	Genetics	Public health
Biology	Government policy	Regulatory knowledge
Bio-nutrition	Information technology	Research pharmacy
Biostatistics	IRB experience	Risk assessment and

Disciplinary components of regulatory science		
		communication
Chemistry	Law	Surveying methods
Clinical investigation and clinical trial design	Medical informatics	Systems biology
Clinical pharmacology	Medicine	Technology transfer
Clinical research operations	Metrics	Toxicology
Communication	Microbiology	Veterinary
Decision theory	Monitoring and quality assurance	
Drug/device discovery and development	Nutrition	

A survey undertaken in relation to environmental toxicology for the National Public Health Partnership (2003) identified the following disciplines and skills required by that sub-set of the regulatory science workforce, with the most commonly mentioned skills / disciplines in the survey responses being reflected toward the centre of the circles.

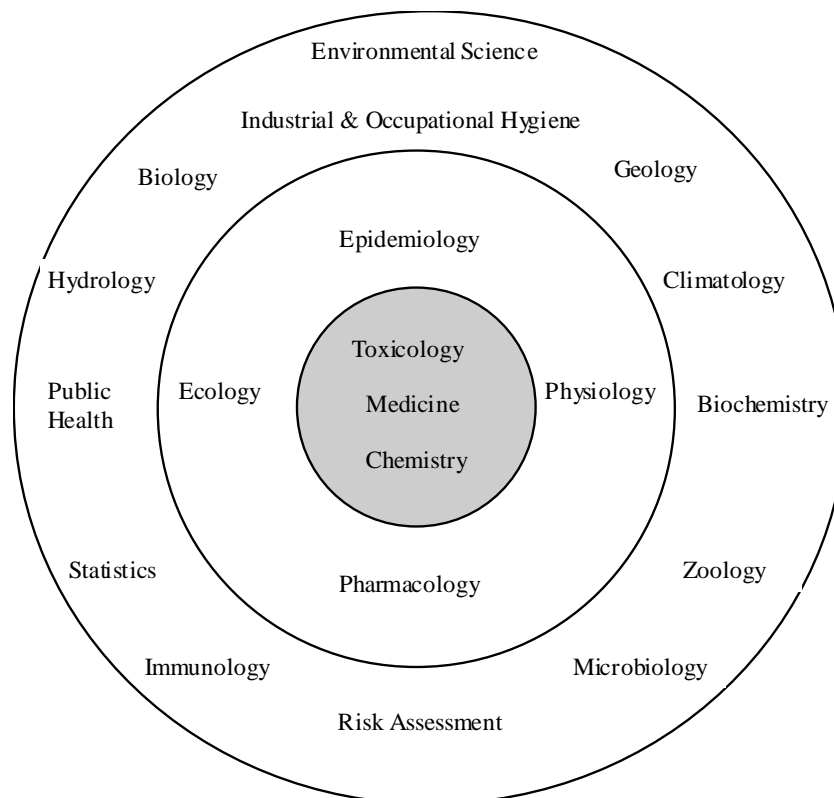


Figure 5: Disciplines identified as possibly required for environmental toxicology work

3.3.3 Understanding of the regulatory context

FitzGerald (IOM, 2012) noted that the environment in which regulatory science is situated is undergoing a multidimensional shift influenced by many outside factors, including technology, trade, politics, intellectual property, global influence, a desire for transparency, and patient empowerment.

He points out that those who engage in the discipline of regulatory science, whether in industry, government or academia, often contend with the traditional segregation of seemingly disparate but often intertwined disciplines. In his view, one of the major challenges for the conduct of regulatory science is integrating information and expertise across these sectors. This is because regulatory scientists use knowledge derived not only from their own background and expertise, but also from other disciplines that bear weight in the decision-making process, including statistics, informatics, or communication. FitzGerald and Honig (IOM, 2012) both emphasised in their contribution to the workshop proceedings that “... the true value of modern and future regulatory scientists will be in their ability to integrate knowledge across many different disciplines.”

As Lease (2017) points out, scientific advice has never been in greater demand nor has it been more contested. The authority and legitimacy of government agencies and their regulatory scientists is under increasing scrutiny, particularly in areas that spark intense debate. Any issue where science is an important factor but where values, ethics and politics are also in tension cannot be resolved by the simple statement of the scientific evidence. Evidence, values and political judgements combine to produce decisions and regulatory scientists are an essential part of this process (Wilsdon, 2014).

3.3.4 Risk assessment and management

The provision of advice to regulatory authorities on the identification and management of risk is widely discussed as a core role of regulatory scientists and thus forms a core component of the competencies required to undertake that role. The APVMA draft regulatory science strategy (APVMA, 2015) notes, for example, that:

“... regulatory scientists are trained in risk analysis - comprising risk assessment, risk management and risk communication - as well as being trained in public administration and regulatory decision making.”

The complexity and depth of this relationship with risk for regulatory science is also widely canvassed. In their analysis of the workforce and training needs for assessing environmental health risks, DeRoos et al. (1988) point out that effective regulatory science practice requires a well-developed understanding of the “Philosophy of Risk”. They note that:

“... people have always lived with risk, presently live with risk, and will continue to live with risk. Some degree of risk of adverse health effects from toxic substances is inevitable, as a consequence of exposure to both naturally occurring and man-made toxicants. The public should be made aware of the nature of risk. Public health risks that are not acceptable should be reduced or eliminated when feasible. Means to accomplish this goal should not pose additional significant risks. Risk is the possibility of an adverse health effect as a result of exposure to a hazardous substance. Risk assessment is the use of available information to evaluate and estimate exposure to a substance and its consequent adverse health effects.”

DeRoos et al., go on to describe risk assessment in the field of environmental health risk assessment as consisting of three elements:

- **hazard identification** is the qualitative evaluation of the adverse health effects of a substance in animals or humans
- **exposure assessment** is the evaluation of the types (routes and media), magnitudes, time, and duration of actual or anticipated exposures and doses, when these are known, and the number of persons who are likely to be exposed
- **dose-response assessment** is the process of estimating the probable incidence of an adverse health effect to humans under various conditions of exposure and describing the uncertainties involved.

The subsequent risk management process is then described by DeRoos et al. as,

“... the process of integrating risk-assessment results with engineering data and social, economic, and political concerns. Alternatives are weighed to select the most appropriate public health action that will lead to reduction or elimination of the identified risk. Appropriate actions may range from public education to interdiction.”

Figure 6 below, as published by Sexton and Perlin (1990), also provides an outline of the dynamic relationship between various data analysis activities and the types of risk that require attention in a regulatory scenario.

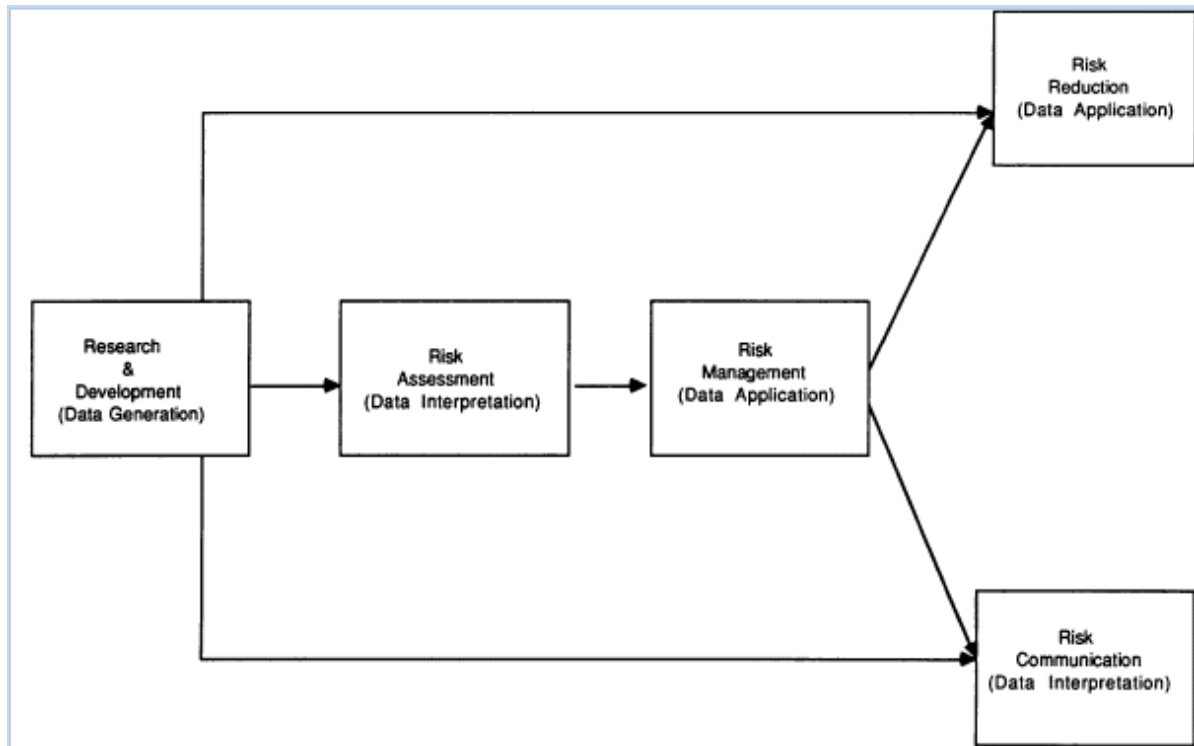


Figure 6: Relationships among Research and Development, Risk Assessment, Risk Management, Risk Communication and Risk Reduction (Source: Sexton and Perlin, 1990)

In focusing on the key role of regulatory scientists around identification and risk, DeRoos, et al. (1988) states that a successful risk assessment program at the state or local level includes interagency coordination and cooperation, well-established procedures, maintenance of a network of outside technical assistance, well-organized data management activities, and skilful handling of direct communications with the affected public.

4 Analysis of position descriptions

4.1 Competencies required for regulatory science work

An initial analysis of the first 10 collected position descriptions was undertaken, as well as reflection on the findings of the literature review, to identify all the possible competencies that could be included in relevant position descriptions as requirements to effectively perform a regulatory scientist job.

Before progressing, it is important to briefly discuss the concept of competence. Competency is generally defined as those qualities of individuals causally related to effective or superior performance in a job (Boyatzis, 1982). The concept of competence is understood and used in many different ways, and the perspective is influenced by whether it is considered as a personal attribute, an act, or an outcome of behaviour. Ridoutt, et al. (2008), however, argued that most competency perspectives can be simplified into two dominant and commonly used approaches — the **worker-oriented** approach and the **work-oriented** approach.

The *worker-oriented* approach focuses on the personal traits that an individual should possess to be effective on-the-job — traits such as initiative, interpersonal skills, technical understanding, analytical skills, flexibility, or innovativeness. The *work-oriented* (or behaviourist) approach requires competence needs to be described in ways where it can be objectively assessed; in other words, this approach identifies output—rather than focusing on input—and describes what would constitute competence within the context of a specific work role or task. For example, an ‘output’ competence might be ‘Establish and maintain health and safety induction and training programs.’

The list of competencies, obtained through the analysis described above and listed in Table 3 below, represents both definitional approaches but is more highly characterised by work-oriented competencies. In total, 45 competencies were identified initially. These competencies were able to be grouped into eight competency clusters.

Table 3: List of competencies from the position description analysis

Competencies from position description analysis
PROVIDE INFORMATION & ADVICE <ul style="list-style-type: none"> Provide expert advice Translate complex science concepts Provide information about regulations Facilitate community engagement in regulation application Represent organisation to key stakeholders Provide input and info into public health issues
FORMULATE POLICY, REGULATIONS, GUIDELINES <ul style="list-style-type: none"> Formulate policy Formulate guidelines, regulations Interpret & communicate current world best practice Apply knowledge of legislation Apply analytical skills
CONDUCT REGULATORY AFFAIRS <ul style="list-style-type: none"> Administer legislation Investigate possible regulatory breaches

Competencies from position description analysis
<ul style="list-style-type: none"> Investigate and report critical incidents Understand barriers to effective service delivery
<p>MANAGE AND CONDUCT RESEARCH & OTHER PROJECTS</p> <ul style="list-style-type: none"> Independently initiate research programs Manage projects Conduct & supervise research projects Apply advanced problem solving Apply population health research approach Knowledge of health system knowledge of environmental system
<p>MANAGE OWN WORK & WORK OF OTHERS</p> <ul style="list-style-type: none"> Provide leadership Demonstrate interpersonal skills Organisation / line management Develop staff and professional training Manage staff / a team Motivate staff
<p>EFFECTIVE COMMUNICATION & RELATIONSHIPS</p> <ul style="list-style-type: none"> Communicate to a range of audiences Conduct external liaison, negotiation, and / or collaboration with stakeholders Negotiate with stakeholders Develop collaborative relationships Develop and maintain internal relationships Work as part of a team Understanding cross cultural issues / diversity
<p>PLAN BUSINESS RESPONSE</p> <ul style="list-style-type: none"> Determine operational and strategic planning Build organisation capacity Maintain work systems Undertake business planning Work with executive team Undertake evaluation and implementation activities
<p>MANAGE RISKS</p> <ul style="list-style-type: none"> Understand emergency/ risk management principles Identify hazards Assess risk Manage risk

These eight competency clusters align reasonably well with the broad competency areas identified through the literature as being important, including effective communication, building relationships, strong collaboration skills, knowledge of legislation and the regulatory context, and being able to understand, assess and manage risk.

4.2 Defining the regulatory scientist role by competencies required

Each of the 71 position descriptions gathered was analysed to assess whether any of the 45 competencies in Table 3 were required to perform the position being described. Figure 7 provides a detailed overview of all 45 competencies and for each the number of position descriptions in which the competency was explicitly stated or strongly implied as a requirement. The top competencies by frequency of requirement (85% or more of the position descriptions) identified were:

- Apply analytical skills (70 - 99% of positions)
- Apply knowledge of legislation (68 - 96%)
- Provide information about regulations (68 - 96%)
- Demonstrate interpersonal skills (66 - 93%)
- Provide expert advice (66 - 93%)
- Apply advanced problem solving skills (65 - 92%)
- Conduct external liaison with stakeholders, negotiation, collaboration (65 - 92%)
- Develop & maintain internal relationships (61 - 86%)
- Translate complex science concepts (61 - 86%)
- Interpret & communicate current world best practice (60 - 85%)
- Develop collaborative relationships (60 - 85%).

Three areas or clusters of competencies are much more prominent than the others:

1. Provide information & advice (average requirement for six competencies of 76% of positions require the competence)
2. Formulate policy, regulations, guidelines (average requirement for five competencies of 88% of positions)
3. Effective communication & relationships (average requirement for seven competencies of 85% of positions)

The frequency of one competency in the last cluster - ‘Understanding cross cultural and diversity issues’ - was anomalous for its cluster in that it was required by very few positions (3 out of 71). It is possible that this competency actually is a requirement of many positions but this is not made explicit (or even implicit) in position descriptions because it is a part of broader organisational policy.

One interesting competency cluster to note is ‘Conduct regulatory affairs’, the four competencies of which are required on average in just over one-third of position descriptions (34%). As noted in an earlier chapter, functions associated with ensuring compliance to legislation (e.g. assessment of applications required by regulation, review of implemented actions in terms of compliance with regulations, actual assessment or breach of compliance with regulations) are not specifically a part of the regulatory scientist role — however, there is a degree of overlap in function. There would be other types of scientists (for example, the majority of environmental health officers working in food safety) whose only role would be regulatory affairs.

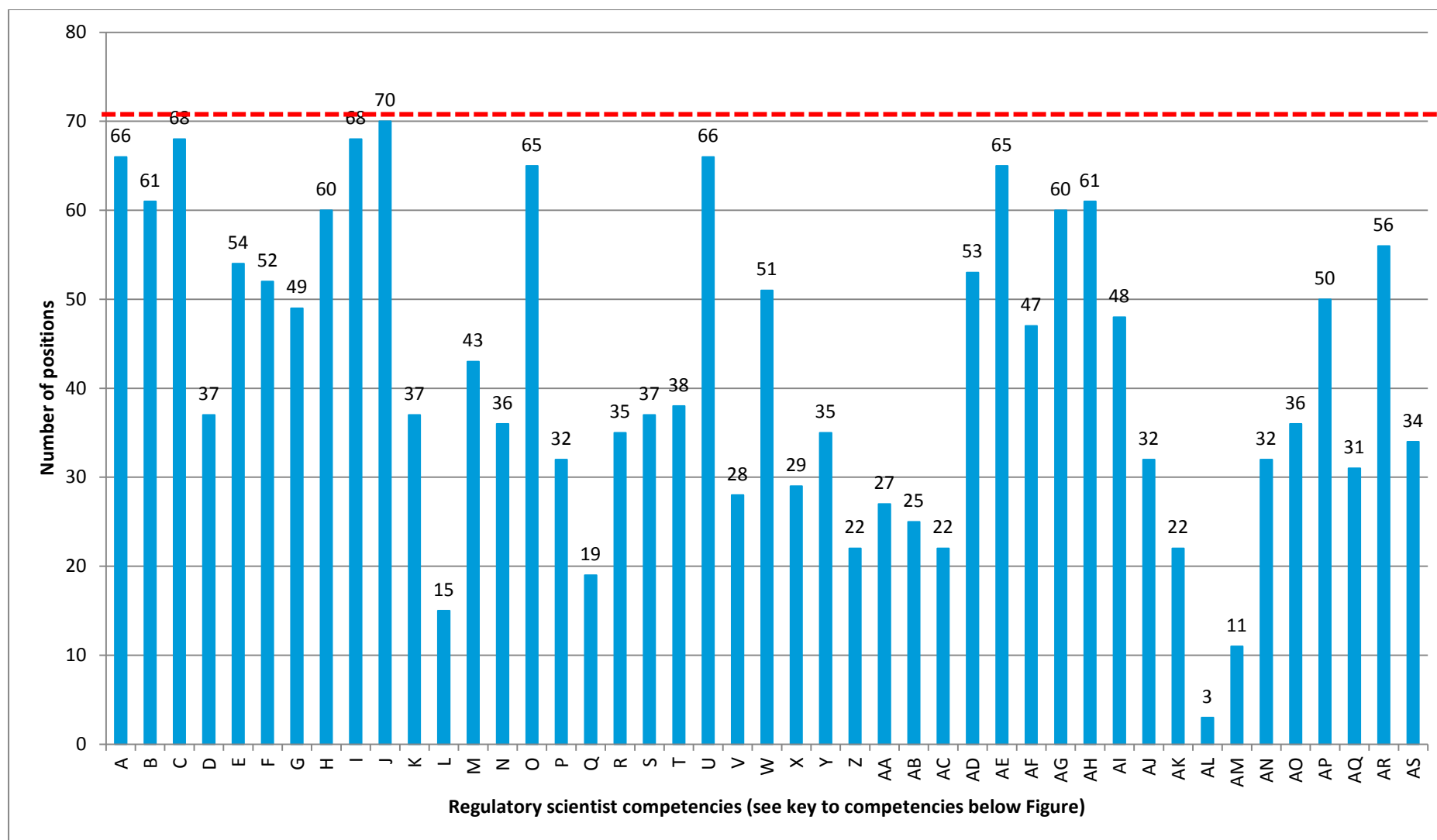


Figure 7: Frequency of competence requirement for job roles for all regulatory scientist positions captured in the database (n = 71)

Key to the list of competencies in Figure 8

A	Provide expert advice	W	Manage projects
B	Translate complex science concepts	X	Develop staff and prof training
C	Provide information about regulations	Y	Manage staff / a team
D	Facilitate community engagement in regulation application	Z	Motivate staff
E	Represent organisation to key stakeholders	AA	Determine operational & strategic planning
F	Formulate policy	AB	Build organisation capacity
G	Formulate guidelines, regulations	AC	Maintain work systems
H	Interpret & communicate current world best practice	AD	Communicate to a range of audiences
I	Apply knowledge of legislation	AE	Conduct external liaison with stakeholders, negotiation, collaboration
J	Apply analytical skills	AF	Negotiate with stakeholders
K	Administer legislation	AG	Develop collaborative relationships
L	Understand barriers to effective service delivery	AH	Develop & maintain internal relationships
M	Independently initiate research programs	AI	Work as part of a team
N	Conduct & supervise research projects	AJ	Provide input and info into public health issues
O	Apply advanced problem solving	AK	Investigate and report critical incidents
P	Apply population health research approach	AL	Understanding cross cultural issues / Diversity
Q	Investigate possible regulatory breaches	AM	Undertake business planning
R	Knowledge of health system	AN	Work with executive team
S	knowledge of environmental system	AO	Undertake evaluation, implementation
T	Provide leadership	AP	Understand emergency/ risk management principles
U	Demonstrate interpersonal skills	AQ	Identify hazards
V	Organisation / line management	AR	Assess risk
AS	Manage risk		

4.3 Differentiation between position types

A second analysis was undertaken of the 71 positions to determine if there was a difference in the pattern of competencies required at different levels of position seniority. The types of jobs gathered ranged from senior executive level to junior ‘starting’ level regulatory scientists. Four distinct broad categories of position type could be differentiated as shown in Figure 8.

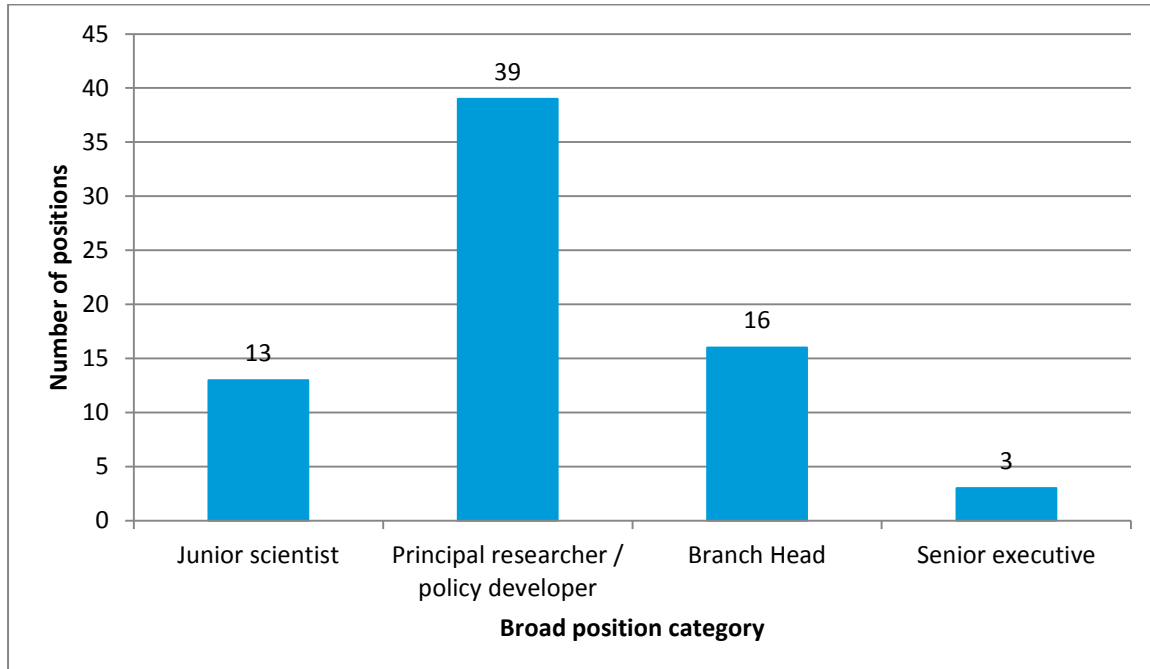


Figure 8: Categories of position types (n = 71)

As there were only three ‘Executive’ level positions so, for the purposes of analysis, these were combined with ‘Branch’ or ‘Section head’ positions to form three discrete position categories as follows:

- Junior scientist
- Principal researcher / policy developer
- Branch or Section Head / Executive.

The results of the analysis of all 45 competencies are shown in Figure 9. The figure shows the proportion (%) of positions in each of the three above classes of position that require each particular competence.

The top competencies (>80% of positions) required for each of the classes of position are shown in Table 4, along with the proportion of the total number of positions in each class requiring a particular competence (shown in brackets). Highlighted competencies are those which were only significant for a particular class of position.

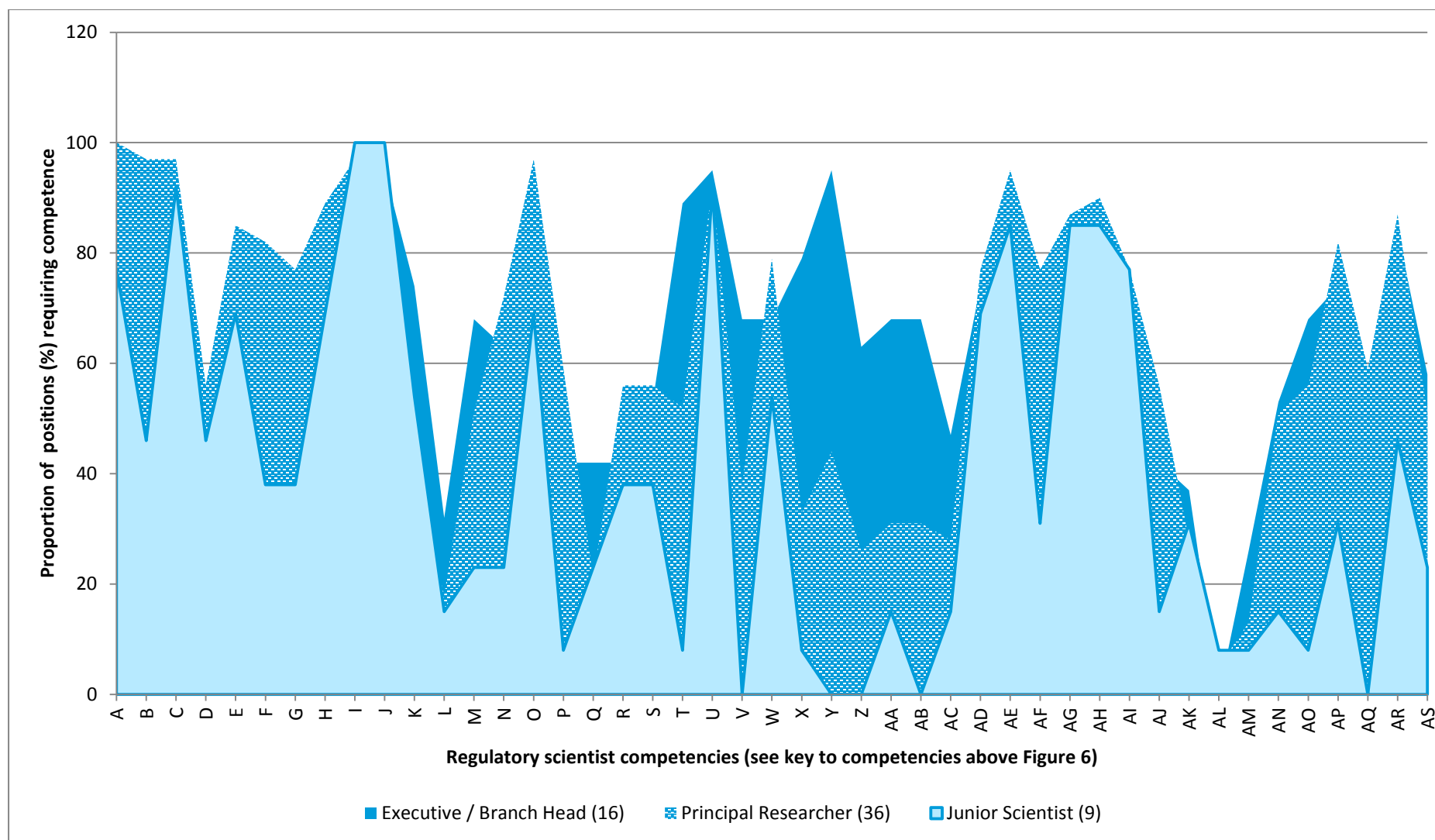


Figure 9: Frequency of competence requirement for job roles for regulatory scientist positions by level of position category

Table 4: Top competencies in terms of position requirement by level of position

Executive / Branch Head (n = 19)	Principal researcher (n = 39)	Junior scientist (n = 13)
Provide expert advice (89%)	Provide expert advice (100%)	
Translate complex science concepts (88%)	Translate complex science concepts (97%)	
Provide information about regulations (95%)	Provide information about regulations (97%)	Provide information about regulations (92%)
	Represent organisation to key stakeholders (85%)	
	Formulate policy (82%)	
Interpret & communicate current world best practice (84%)	Interpret & communicate current world best practice (89%)	
Apply knowledge of legislation (89%)	Apply knowledge of legislation (97%)	Apply knowledge of legislation (100%)
Apply analytical skills (95%)	Apply analytical skills (100%)	Apply analytical skills (100%)
Apply advanced problem solving skills (89%)	Apply advanced problem solving skills (97%)	
Provide leadership (89%)		
Demonstrate interpersonal skills (94%)	Demonstrate interpersonal skills (92%)	Demonstrate interpersonal skills (92%)
Manage staff / team (95%)		
Conduct external liaison with stakeholders, negotiation & collaboration (88%)	Conduct external liaison with stakeholders, negotiation & collaboration (95%)	Conduct external liaison with stakeholders, negotiation & collaboration (85%)
Develop staff and profession training (88%)		
Develop collaborative relationships (84%)	Develop collaborative relationships (87%)	Develop collaborative relationships (85%)
	Develop & maintain internal relationships (90%)	Develop & maintain internal relationships (85%)
Understand emergency and risk management procedures (88%)	Understand emergency and risk management procedures (83%)	
Assess risk (84%)	Assess risk (87%)	

Table 4 illustrates that, despite some differences in the ordering, there are significant correlations between levels of position in the requirements for competency. Executive / Branch Head-type positions typically require greater breadth of competence than the other levels, and most of these level positions require competence in areas such as ‘leadership’ and ‘staff management’ and personnel management more broadly that is not required at other levels.

This point is made clearer by Figure 10, which differentiates between the three levels of position at a competency cluster level. In the figure, the average proportion of positions within each position level (executive/branch head; principal researcher; junior scientist) requiring competencies from each cluster is shown. The general similarity between position levels in regard to requirements for formulating regulations/guidelines, communicating and creating relationships, and generally

providing advice is in contrast to the clusters for managing work and planning business where there are clear differences in keeping with the position level hierarchy. Possessing competence in initiating and conducting research and managing risk appear to be the requirement of more senior positions.

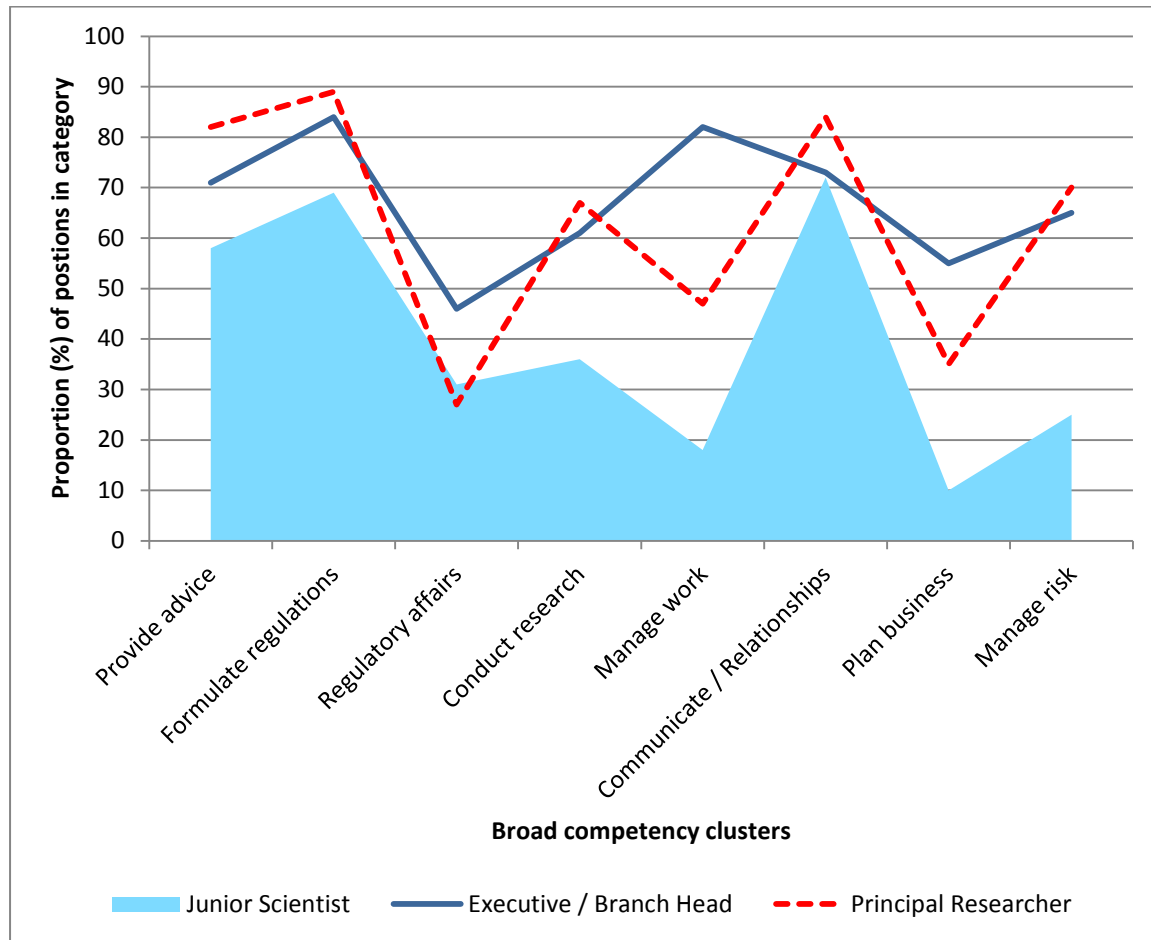


Figure 10: Proportional (%) requirement for competence by competency clusters and level of position

4.4 The sense of a career path?

From the above analysis, and from a deeper reading of the wording of position descriptions, a sense of a career path for regulatory scientists begins to emerge as shown in Figure 10. Like boundaries between workforces, as explored earlier, which can be fuzzy and slightly overlapping, boundaries within workforces between different levels of worker too can be ambiguous. However, Figure 11 indicates that, while there is much overlap of competencies required (and no doubt applied) for different levels of position along a career path, there is also some level of differentiation. This differentiation can occur in two forms:

1. **A different proficiency requirement in respect to the same competency cluster.** For instance, while all regulatory scientists require a capacity to provide information and advice, the levels of principal researcher and executive / branch head are expected to be able to translate and communicate complex science concepts more than junior scientists. Similarly, while all levels of regulatory scientist are expected to possess significant communication and relationship building competence, the higher order skill of negotiation is more expected of principal researcher and executive / branch head position levels.

2. **Additional competency requirements**, for instance in risk management, initiating, conducting and possibly managing research and other projects (that might help formulate legislative change) and managing work and workers, are all competencies that would be expected of higher level positions.

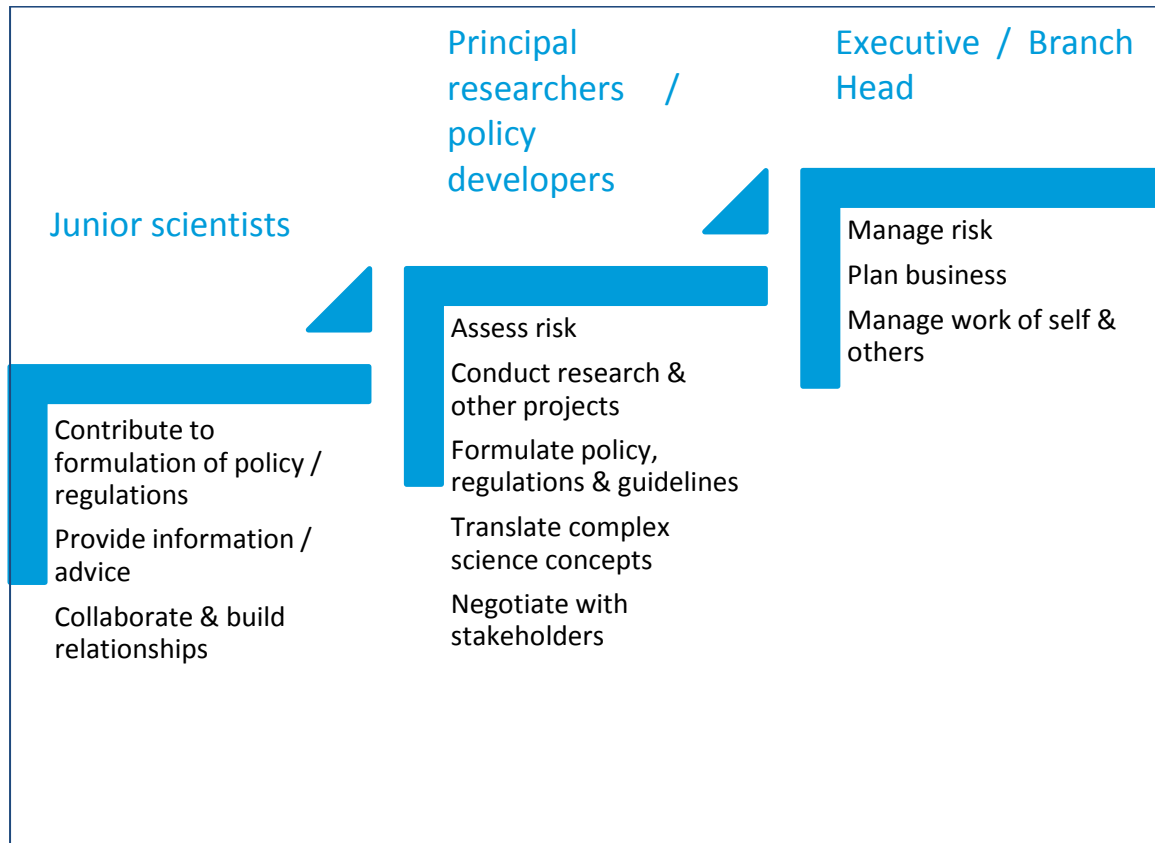


Figure 11: Overview conceptualisation of a regulatory scientist career path

5 Critical competencies required by a regulatory scientist

5.1 What does regulatory science work look like?

Across Australia regulatory science organisations (predominantly government) are involved in a wide variety of regulatory issues requiring a range of responses. Regulatory issues or critical incidents broadly fall in to two categories:

- those requiring a rapid response (either following a well-defined pathway or needing a response to be developed urgently, which is often more difficult)
- those that are anticipated and may require a more measured and planned policy response.

However, not all regulatory scientists are working as regulators. While some parts of the workforce work in enforcing and administering laws and regulations or investigating compliance, many regulatory scientists provide technical advice to policy areas and other regulatory agencies on a range of regulation-related issues (e.g. environmental or health policy development).

The broad scope of work of regulatory science not only requires a broad range of roles, it also requires a broad range of approaches and actions. While there were a number of approaches shared by interview participants, collaboration stood out as a defining feature and approach of regulatory science. Underpinning a collaborative approach are a range of critical and interrelated competencies and skills that are required for regulatory science. These collaboration-related competencies and skills, along with other critical competencies and skills, are explored further on.

The ways in which collaboration can successfully, or unsuccessfully, contribute to formulating and implementing a response to incidents is examined and described in the following section.

5.2 A collaborative workforce

Interview participants unanimously reported that a collaborative approach is a critical feature of the work of regulatory scientists. As they noted in their comments, collaboration is almost always required internally with colleagues and peers as well as externally with other agencies, research institutes, industry bodies and communities. More often than not, multidisciplinary teams and multi-agency teams are required to respond to critical incidents; it is clear that collaboration is central to a successful regulatory science response to such incidents.

Three core functions of collaboration were identified from the interviews. The first purpose of collaboration was the ability to draw upon and, if necessary, enlist specialist knowledge and expertise that may not be readily available within an agency. Many agencies only have a finite supply of in-house specialist knowledge and expertise. Therefore, depending on the requirements of a response, they may need to seek external specialists from other organisations or jurisdictions. Collaboration was thus critical to ensure specialist skills could be readily called upon, particularly when a rapid response may be required.

A second identified purpose of collaboration was the ability to discuss and examine a critical incident with a relevant network of peers. Depending on the complexity of an incident, it can be highly beneficial to have an opportunity to hypothesise, ‘brainstorm’ and formulate a response with a range of people who bring a range of knowledge, experience and even exposure to different situations. Whilst most interview participants noted that there was usually a network of people and organisations with which to collaborate, one interviewee (in reference to a specific critical incident) lamented that better developed networks and established committees in Australia could have resulted in a more rapid response.

The third important identified purpose of a collaborative approach is to promote and reinforce consistency. Collaboration facilitates a common understanding and enables information to be shared. This in turn can allow for consistent responses to be formulated, which is imperative for critical incidents that may involve a number of groups and that cross a number of jurisdictions. For high profile critical incidents that require intensive engagement and communication with a range of stakeholders, including with affected communities, regulatory scientists need to provide clear, accurate and relevant information. Thus, a collaborative approach between agencies, organisations, industries and with the general public can be an important strategy to reinforce a clear and consistent message to alleviate anxiety and concerns about a potential health risks.

Fostering a collaborative approach, however, requires a particular set of competencies, skills and personal attributes. As noted by a number of interview participants, such skills can be taught but at the moment are generally acquired through time and on-the-job experience. Collaboration was also seen as something that needs to be actively pursued, developed and nurtured to ensure networks and partnerships can be readily called upon to effectively respond to critical incidents.

5.3 Competencies and skills for effective regulatory science

To carry out the broad scope of work of regulatory science, a variety of roles and approaches are required. It follows then that a variety of competencies and skills are required to effectively undertake the work.

As defined by one interviewee, regulatory science means working in a ‘regulatory sense’. This means having the ability to communicate, to be confident but not dogmatic, to undertake risk assessments and to marry the cost and benefits, the legal issues and the political issues appropriately with the incident at hand. During the interviews, these characteristics of working in a ‘regulatory sense’ were echoed in the numerous critical incidents recounted by participants. In addition to the importance of an overarching collaborative framework as described above, an interrogation of the critical incidents in terms of successful and unsuccessful regulatory outcomes yielded the following five competencies and skills for effectively regulatory science:

1. interpersonal or communication skills
2. judgement and anticipation
3. specialist science knowledge
4. understanding of government systems, processes, legislation and regulation
5. risk management.

An exploration of each of these competencies and skills in the next section will illustrate their critical nature and also how they coexist with one another, rather than stand alone, to support effective regulatory science work. They are skills and competencies that could potentially be learned through formal training and education but by and large they are currently acquired and developed on-the-job and over time. And, as described by participants, there is a subset or package of skills that exists within each of these overarching competencies and skills and which are inherent or implied for all levels of regulatory science.

5.3.1 Communication skills for relationship building

The collaborative approach of regulatory science described above is highly dependent on effective interpersonal and communication skills which are, as noted by one interviewee, central to everything that is undertaken in regulatory science.

Interpersonal communication skill, or perhaps emotional intelligence as described by one participant, is about communicating in a subtle, nuanced and measured manner. They are skills that

are intrinsically linked with skills in judgement and anticipation (described below) and, as identified through the interviews, required across all areas of regulatory science.

Effective interpersonal and communication skills are relied upon strongly in order to relate to and work with peers and colleagues (internal and external) to communicate clear and concise information and to formulate effective strategies or responses. They are critical skills for effective collaboration and developing networks and partnerships. And they are imperative when dealing with a broader range of stakeholders, including affected communities and the general public. Within the regulatory science workplace, all respondents noted that high order mentoring skills are critical for workforce development and that these require a strong capacity for the provision of supportive and constructive feedback to those undergoing the long process of becoming an effective independent regulatory scientist. This is particularly so for those scientists who transition into the field from a research science career. This mid-career transition, if it is to be achieved, requires a great deal of humility on the part of the new entrant as they are likely to have achieved a high order of skill in their chosen scientific field. This dynamic makes it even more crucial that the more experienced regulatory scientists handle their communication role as mentors and guides with finesse.

Two participants described critical incidents where subtle and culturally sensitive communication was required with small and remote communities. The first step they described was to gain the trust of the community and the second step involved developing a working relationship with the community. Without effective interpersonal and communication skills, in a situation where at times close engagement was required (including the need to ask personal questions), the risks to health in those communities could not have been managed effectively.

In such situations, as described by one participant, interpersonal and communication skills require a:

“...need to understand how we talk to people and the kind of language used to convince people to support a strategy.”

Understanding how to talk to people and helping them to understanding the language of the response (including jargon) underpins the application of effective interpersonal and communication skills. A number of participants described the need for effective interpersonal and communication skills when providing advice or to attempting to advocate, negotiate and influence policy outcomes with senior levels of government. This was described as ‘communicating upwards’ by a number of participants.

The quality of interpersonal and communication skills can also determine the fate or the effectiveness of a response to a critical incident. If a collaborative approach is seen as a key feature of regulatory science, effective interpersonal and communication skills can also be seen as imperative to facilitate such an approach.

5.3.2 Judgement and anticipation

Alongside interpersonal and communication skills, is the need for skills in judgement and anticipation. It is also a skill or attribute that is inherently linked with competence in risk management (described below). In almost all cases, interview participants described the work of regulatory science as a juggling act balancing the needs and wants of a wide range of stakeholders within a regulatory, legal and political framework. Careful judgement and anticipation therefore emerged as a critical skill or personal attribute for regulatory science.

Effective judgement and anticipation were also reported as being embedded in the ability to have confidence in the science and/or your peers, being courageous to advocate for a particular position and in referencing clear values about a specific issue or situation. Without these attributes, it can be difficult for a regulatory scientist to make effective judgements or anticipate a situation or outcome. In the case of a food contamination incident described by one participant, a judgement was made by the agency to close down production despite opposition from the relevant industry body. The

regulatory scientist’s confidence in the robustness of the science and the information about similar past incidents, their courage to stand firm and their clear values about the broader implications of the incident allowed them to make a judgement to advocate for a particular response, influence the relevant government minister and effectively manage the incident.

While an example like this highlights the importance of effectively judging and anticipating when to act, effective judgement and anticipation is also required when deciding not to act or pursue a particular pathway. One participant described effective judgement and anticipation as knowing when to hold back, understanding uncertainty and understanding the limitations of science and regulations. In the face of conflicting and competing interests of stakeholders, effective judgement and anticipation are thus critical skills for working in the regulatory science space.

The personal attribute of courage was also mentioned as a critical ingredient required in forming hypotheses for understanding an emerging situation and the actual or potential risks based on incomplete and/or disparate data. In order to anticipate the best regulatory options in this uncertain scenario, there is a significant risk for regulatory scientists of “getting it wrong”, thus putting their reputation on the line, both within their agency and in the public domain. But respondents pointed out that an effective regulatory scientist understands that a too-cautious response can lead to greater harm to the community if they do not actively engage with the uncertainty using their best technical expertise and judgement.

5.3.3 Specialist science knowledge

Although it may be assumed as a core competence of regulatory science, specialist science skills and knowledge emerged as a critical competency from the critical incident interviews. Specialist science knowledge was cited as a critical competence, in some cases the lynchpin, for effectively and successfully managing critical incidents.

Specialist science knowledge and competence reported during the interviews included the disciplines of toxicology, microbiology, epidemiology, biology, entomology, immunology, public health, pharmacology and food science. Generalist scientists with a core body of scientific knowledge were also highly valued by participants in this respect.

A number of participants described incidents where specialist knowledge was sought either internally or externally to collect and critically analyse information for highly specific and unique incidents. This was particularly true for state and territory health authorities that may not ordinarily employ or have sufficient supply of specialist scientists such as microbiologists and toxicologists. As described by one participant, there is a trade-off with this approach as external specialist scientists may not necessarily work in the regulatory science sector. They may bring specialist knowledge but sometimes lack the ability to apply that knowledge to a regulatory framework or government context.

Where some knowledge of government processes and regulatory frameworks may be lacking, there is a set of implied technical skills that both specialist and generalist scientists bring to regulatory science. These skills include:

- understanding of scientific processes
- research and analytical skills
- data management
- scientific report writing skills – clear, structured and persuasive writing.

In instances where a rapid response is required, technical science skills are essential to develop effective strategies and responses.

Specialist science knowledge was also noted as including an understanding of relevant industry practice, such as in the fields of mining, construction and agriculture. Effective management of a disease outbreak, as described by one participant, was achieved through the input of a veterinary scientist who not only brought specialist science knowledge but also specialist knowledge of the agricultural industry. Knowledge of the structure and logistics of the industry including temperature controls, food packaging processes, system processes and farm practices enabled the agency to identify the source of the outbreak and then contain and manage the incident.

5.3.4 Understanding of government systems, processes, legislation and regulation

Understanding the context and environment of the work of regulatory science is critical for effective and successful outcomes. Across the interviews, an in-depth knowledge of government systems and processes as well as the associated legislation and regulation, was seen as a critical competence for an effective regulatory scientist. As described by one participant:

“Regulatory scientists work in a government world and so they need to be able to talk and describe the science using government language...”

After specialist science knowledge, this was seen as the most critical competence in order to effectively influence policies and departments. By using the government processes and placing an issue strategically within the relevant policy and legislative frameworks, regulatory scientists could be more effective in influencing and negotiating a particular position or response. Developing this knowledge, however, was not something that could currently be acquired through formal training or education but, rather, needs to be developed through quite extensive experience on-the-job. It was noted by a number of interview participants that, due to limited training opportunities for roles such as environmental health officers, knowledge about systems were generally took quite a long period of on-the-job development.

Underpinning (or coupled with) this systems-focussed area of regulatory science competence is the need for strategic thinking, diplomacy and skills in ‘politics’ or bureaucracy.

5.3.5 Risk management

Along with the areas of competence outlined above, interview respondents clearly indicated that that effective skills in risk identification and management are a defining feature of regulatory science.

In line with the information on risk management skills highlighted through the literature review, this skill base includes skills in assessing risk, identifying risk, managing risk and communicating about risk. And although risk management skills can be described as a set of important technical skills required for regulatory science, their effective application is strongly influenced and complemented by (and in fact, appear to require all of) the competencies and skills described in the previous sections of this chapter – interpersonal and communication skills, judgement and anticipation, specialist science knowledge (or a core body of scientific knowledge) and an understanding of government systems, processes, legislation and regulation.

Effective skills in risk management involve regulatory scientists finding a fine balance between being over cautious and over-zealous, as described by one participant:

“Officers who are too risk-averse can be a liability because they are unable or unwilling to recommend a level of risk containment that is defensible and commensurate with the key risks that truly require a regulatory response.”

An important example of a critical incident that drew upon all of the above-described critical competencies and skills is a chemical contamination that had emerged at a local, state and national level and required a complex and sensitive response. This incident was described in almost all interviews, not only because of the similarities of the incident but also because many agencies,

departments and governments were actively working together to manage the incident. This incident provided an important example in terms of the risk management required to not only rapidly respond to the immediate risks but to also anticipate the potential for the incident to expand and need to be dealt with in additional sites across Australia. Respondents reported that a collaborative approach was a critical feature of the initial and ongoing risk management plan, including:

- Specialist science knowledge was brought in to assess and identify the risks to human health.
- Judgement and anticipation was essential for timing the response.
- Knowledge of government systems, legislation and regulation was critical to formulate policies.
- Guidelines and strategies, and interpersonal and communication skills were imperative to sensitively and accurately communicate and liaise with communities and for collaboration between agencies, departments and governments.

6 Discussion of findings — Where to from here?

6.1 The start of the process

This research project, and accordingly this report, was always intended to be the beginning of a more comprehensive process to define the demand for and supply of regulatory scientists, now and into the future, and to ultimately ensure that this critical workforce is sustained into the future (see Figure 12).

This first phase of effort (the ‘Needs Assessment’) had three specified outcomes:

- identify current regulatory science agency roles and responsibilities
- define the skill sets required to meet those responsibilities
- identify the current and emergent workforce issues confronting regulatory science agencies.

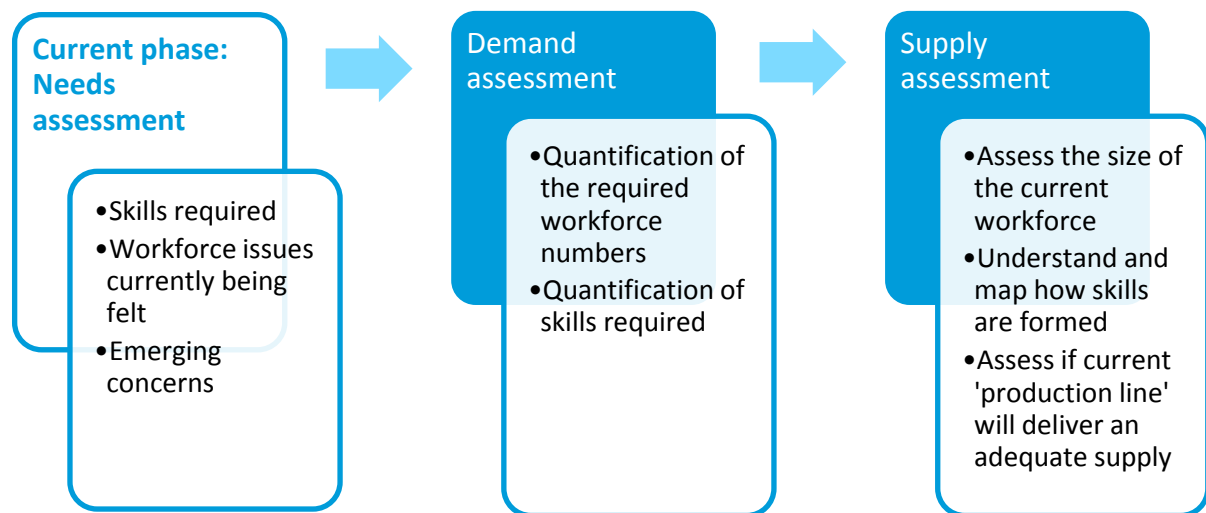


Figure 12: Overview of comprehensive regulatory scientist workforce analysis

In the following sections, the findings against each of the proposed outcomes are summarised.

6.2 Roles and responsibilities

Like many professions that have emerged in more recent times from the body of longer established occupations, the regulatory science profession has been required to slowly develop its unique set of roles, functions and practices, and to gradually differentiate itself from where it has evolved.

The literature largely suggests the key point of differentiation for regulatory science is in respect to (1) the use more of existing scientific knowledge rather than the generation of new knowledge³, and translating or pragmatically applying that current knowledge to define and support legislative decision-making, and (2) communicating the knowledge derived from science to a broader public – policy makers and legislators in the first instance but many other stakeholders and eventually the general public.

³ New knowledge can also come out of rapid risk assessment assumptions and health risk management decisions and/or through researching for policy development or at least inspire further exploration.

In regard to this last point, the primary role of regulatory scientists has been described as navigating the interface between science and society. Regulatory scientists participate in communication that extends far beyond the audience range of normal scientists, since regulatory decisions not influence not just the scientific community but also the public at large. Regulatory scientists are distinguished as much for their capacity to communicate and forge relationships as they are for their technical scientific knowledge.

Like any emerging profession (and perhaps like any profession), the boundaries of the workforce are ambiguous. Regulatory scientists inevitably overlap in role and function with other forms of regulatory occupations including regulatory law (framing of the legislation) and regulatory affairs (implementation and compliance with the legislation), but their specific focus is to inform and provide the evidence base for legislative framing and review over time. These scientists can be recognised not through an absence of any function in law and implementation but rather by a preponderance of effort in providing the supporting argument, advice and communication. Regulatory scientists also overlap in function (and of course competence) with other forms of science worker but again are differentiated by a preponderance of role effort in communication activity.

The literature review and analysis of position descriptions identified four main areas of work that regulatory scientists currently perform or should be able to perform:

- Provide information & advice, to a range of audiences from regulatory colleagues to the general public, helping those audiences understand and access science concepts
- Formulate, or contribute to the formulation of policy, regulations and guidelines through incorporation of evidence from scientific knowledge
- Conduct effective collaborative relationships to both gather and disseminate information and help negotiate and promote legislative processes
- Identify hazards, assess and manage risks.

In addition, depending on the specific role within the organisation and the level of seniority, regulatory scientists might also conduct regulatory affairs, manage and conduct research & other projects, manage people and workload, and support business planning.

6.3 Required skill sets

Through this study, a number of different perspectives have been obtained (via literature, analysis of position descriptions, and critical incident interviews) of the competencies required by regulatory scientists. At first, the different perspectives may appear to offer a confusing or even contradictory note, but together they actually provide a *comprehensive* picture of the totality of possible competence requirements. They also provide a *focus* on what competencies most help demarcate between regulatory scientists and other professions and then, within the regulatory science profession, they can distinguish between workers that perform at different levels of effectiveness.

At a comprehensive level, regulatory scientists may require the following clusters of skills to perform their role effectively:

- knowledge of a specialist area of science
- understand government systems, processes, legislation and regulation
- formulate policy, regulations and guidelines
- provide information & advice
- conduct regulatory affairs
- manage and conduct research & other projects

- manage own work & work of others
- effective communication & relationships (including collaboration)
- plan business response
- manage risks.

The actual competency clusters each regulatory scientist employs (or specific competencies within each cluster) will vary according to their precise role, which in turn will be most influenced by the work of the organisation in which they work, the specific functions of their branch, and their place in the career pathway (e.g. level of seniority, type of position).

What is clear, though, is that three competency clusters in particular provide a common platform or skills set that is most characteristic of regulatory scientists, and this comprises:

- provide information & advice
- formulate policy, regulations and guidelines (includes sound understanding of legislative processes)
- effective communication & relationships.

However, the data from the critical incident interviews indicates that possession of this skills set alone, although it might satisfy core competence requirements, is likely to be insufficient to produce superior work outcomes. The interviews indicated that, in addition, the regulatory scientist needs:

- well-developed specialist science knowledge
- a capacity to manage risk.

As indicated in the data described above, generally speaking neither of these competencies are emphasised currently in position descriptions except for in comparatively senior roles. It is possible the importance of these competencies is being underestimated and, as a consequence, insufficient signals are being sent to those developing training and learning resources for regulatory scientists.

Another critical competence highlighted by the critical incident interviews was judgement and anticipation. Interview subjects hypothesised that good judgement emanated from knowing the science well and having a strong risk management framework, along with clear insight to legislative processes, but that having confidence in peers, having courage to advocate for a particular position and having clear values about a specific issue or situation are additional competencies. Only a few position descriptions specified the need for courage as a personal attribute.

6.4 Emerging issues

During the critical incident interviews several broader issues were canvassed beyond immediate competency requirements.

There was a strong perception from most participants that in-house supply of specialist scientific knowledge has diminished in recent years - a direct result of the reduced number of specialist roles across all levels of government. Adding to a sense of general short supply identified by a number of participants (in terms of both trained specialists and available roles), a limitation was noted in some specific highly specialised areas of science – in particular, toxicology. Some agencies reported only having one toxicologist on staff, resulting in a perceived high degree of risk in terms of capacity to respond if multiple incidents need to be addressed.

The perceptions of interview subjects as to an emerging shortage of workers cannot be verified in the absence of an objective workforce planning approach (something argued for by Lease, 2017, and to which an approach is outlined later in this chapter). Claims of ‘shortfall’ only make sense when supply is compared to a well-articulated estimate of demand.

However, it is possible that, under increasing government budget constraints, establishment regulatory science positions are being lost, and typically these would be at the lower level of the career pathway or through early retirement if redundancy packages are offered as part of organisational downsizing. Given that these positions are likely to be both critical ‘feeder’ positions for future supply and the senior positions providing mentoring to more junior staff, there might therefore be cause for concern.

In this light, an Australian Chief Scientist commissioned report in 2014 which surveyed employers in relation to the Australian Science, Technology, Engineering and Mathematics (STEM) workforce (Deloitte, 2014) and used the field of regulatory science as its key case study found that:

“Anecdotal evidence ... suggests that large investments are being made to build the capabilities of new employees in the workplace. This is a result of a significant gap between the qualifications that students are obtaining and the minimum level of knowledge required to be effective in the workplace.”

The APVMA draft regulatory scientist strategy similarly highlighted that most regulatory scientists trained and worked in conventional scientific research, but then transitioned into regulatory science through a long process of on-the-job training, mentoring and ongoing peer support (APVMA, 2015). Thus, future supply of [capable and effective] regulatory scientists requires support for a minimum number of ‘feeder’ roles, and a willingness to invest long term in the position occupants.

The way the next generation of regulatory scientists is developed was clearly an emerging issue for persons interviewed for this study. An exploratory career pathway based on evolving competence mastery was developed in an earlier chapter, consisting of at least three but possibly four levels or career progress points. This possible career pathway needs to be investigated further.

Not only is the sustaining of ‘feeder’ positions considered important, but also the structure of the learning process to progress from junior regulatory scientist to principal or executive levels. IOM (2012) argue that structured experiential opportunities are a critical and central component of education and training in regulatory science. They note that the typical training period spans three years or more where the on-the-job or apprentice-like learning is complemented by formal courses. From a training content perspective IOM (2012) identified a series of key messages in relation to regulatory scientist workforce development that included:

- collaboration among federal agencies
- more than just developing new methods for understanding and assessing risk; it also includes consideration of cultural and societal issues relating to how individual patients and society view the trade-off between reward and risk
- making promising scientists aware of regulatory science as an attractive, respected career option
- having willing capacity in the workplace of the regulatory scientist to train, mentor, develop, upskill.

6.5 Next steps

As noted on a number of occasions already in this report, the commissioned study was always intended to be the start of a research process, not the finish. On the basis of this study’s findings, it would be achievable to sharpen the process of recruiting regulatory scientists, to get greater focus into training and development planning, design and processes, and to think more objectively about appropriate career pathways as well as career development and progression strategies.

It would not be possible, though, to make any definitive statements about whether there is a regulatory science workforce shortage or not, and therefore whether more or less people need to be

recruited and trained (and with what competencies) to satisfy future demand for the work performed by regulatory scientists until the next steps are done.

To progress to this level of insight and understanding, the following research steps are recommended. Ideally these steps would be undertaken contiguously since this would provide the most effective use of research resources and the most efficient form of data collection.

6.5.1 Step 1: Consolidate a list of competencies

A common unit of analysis is necessary to compare demand with supply. In most workforce studies this is a full-time equivalent (FTE) unit of relevantly qualified labour. ‘Relevantly qualified labour’ in this case can be widely interpreted according to different science backgrounds or different levels of workers.

A more appropriate and objective unit of analysis to employ is competence (or specifically units of competence, which are impartial in relation to individual worker background and qualification). On the demand side, this is expressed as competence **required** (to perform the work effectively), and on the supply side, is expressed as competence **possessed** to satisfy requirements.

A comprehensive list of 45 competencies needed to effectively undertake regulatory scientist work was collated through this study from an analysis of position descriptions and a review of the literature. This list needs to be further tested and validated by regulatory scientists. It is likely that the list will be validated with little change, but findings from the critical incident interviews and considerations of scientists (on reflection on the current list) may add further competencies.

6.5.2 Step 2: Define the parameters of demand for regulatory scientist competence

The way work (demand for competence) is generated is best understood and assessed at an organisational level. To simplify the next research phases, it is recommended to narrow the study inclusion to only those organisations who were significantly involved in this first study. This includes:

- Departments of Health across all states and territories and Commonwealth agencies
- APVMA
- FSANZ
- TGA

Narrowing of the study may be challenging in terms of obtaining a broad estimate of demand and supply for the total regulatory science workforce, however, the study may prove more manageable and more accurate for those organisations in scope. It could be argued that the chosen organisations employ a significant proportion of the workforce, and therefore if an estimate of the total workforce can be obtained (for instance through an analysis of Australian Bureau of Statistics (ABS) Population Census data or a limited survey of all employing bodies) the findings from the selected organisations can be meaningfully extrapolated to the broader workforce population.

Each of the chosen organisations would then need to be helped to define the work they currently perform by agency branches or sections (e.g. Food Information, Science and Technology Branch), legislative programs (e.g. Scientific Assessment and Chemical Review Program) or projects (e.g. special investigation of PFAS contamination).

Consideration may also need to be allocated to work that might need to be performed into the future, such as new types of challenges are foreseen or as changes might be envisaged with a new strategic direction or a planned organisation restructure.

6.5.3 Step 3: Quantifying regulatory scientist competency requirements

Working within parameters defined by each organisation, organisations will need to be assisted to translate the assessment of work into an assessment of competence requirements (in terms of hours, days or months of worker time required per year). This method of estimating demand has been used with segments of the public health workforce (Gadiel, et al. 2011), and more recently, with a single population health organisation (Cowles, et al., 2016). A simple example of what the tool for data collection at the organisational level might look like is shown below.

COMPETENCIES FOR REGULATORY SCIENCE	AREAS OF WORK REQUIREMENTS (FTE)		
	Communicate implications of new legislation to stakeholders through a variety of means	Assess the environmental safety aspects of application of legislation	XX
Provide expert advice	0.2	0.2	<div>Estimate of FTE of this competency required to complete environmental safety assessments</div>
Translate complex science concepts	0.3	0.0	
Assess risk	0.5	0.5	
XX	Xx	Xx	Xx

The sum of all the FTE competency requirements provides an estimate of total demand for each organisation. This method has previously has been used to highlight competencies that are most in demand (which tend to also be the most in supply) but also those that are deployed sparingly but have critical consequences if not available. Specialist knowledge and experience in toxicology, as identified through the critical incident interviews, is an example of a competency that is often in short supply and sparingly deployed yet can result in critical consequences if it is not available.

6.5.4 Step 4: Validate the career path

A potential career path has been outlined but not yet sufficiently delineated nor validated. Further research is indicated by:

1. Canvassing the hypothesised career path through a workshop process with senior managers from across the identified organisations. The discussions would clarify and further distil the types of positions along the career pathway, perhaps identify intermediary steps, agree on a starting point for the career (that might for instance commence with regulatory affairs type positions that feed into junior regulatory scientist roles) and crystallise an endpoint to the career. The workshop will provide senior managers with an opportunity to consider and agree upon training and development requirements for workers progressing from one career path step to the next.
2. Improving on the database of position descriptions created for this study by selectively gathering and adding more junior and very senior positions to the database. Information from one hundred or more positions will provide sufficient data to undertake a cluster analysis, possibly directed by key variables such as salary bands and number of direct reports. The clusters derived will allow an objective comparison with the results of the workshop deliberations noted above.

A clear career path, with a detailed description of the expected competencies at each career step level, will facilitate appropriate training and recruitment processes once the demand and supply balance situation has been established (see below).

6.5.5 Step 5: Undertake a stocktake of current supply

Each organisation included in the study will be assisted to undertake a stocktake of the competencies currently possessed by each of their workers designated as a regulatory scientist. Some judgement may be required initially to ascertain whether a worker is part of the regulatory science career path (and at what identified level), not part of the workforce, or perhaps only a part of their time is performing regulatory science work.

Competence will be deemed to exist only if the worker has complete mastery. For example, if a worker understands the tenets of risk management but cannot undertake a risk assessment independently, they would not be deemed ‘competent’. The ‘amount’ of each competence they possess would equate to their FTE employment status (full time employed = 1 FTE).

A simple example of the tool to collect competence supply data at the organisational level is provided below.

COMPETENCIES FOR REGULATORY SCIENCE	INDIVIDUAL REGULATORY SCIENCE WORKERS (FTE)		
	Worker A (1FTE)	Worker B (0.5FTE)	Worker X
Provide expert advice	1.0	0.5	Xx
Translate complex science concepts	1.0	0.0	Xx
Assess risk	0.5	0.5	Xx
XX	Xx	Xx	Xx

The total supply of all competencies at the organisation level and across the entire workforce (at least that part included in the study) can then be estimated.

6.5.6 Step 6: Estimating adequacy of supply

Estimates for supply of competence and the requirements (Step 3) will be interrelated through mathematical modelling, first, at an organisational level (since the capacity for workers to supply their labour outside of their organisation in the first instance is limited), and then at a broader workforce level. Critical competencies, those where the ratio of available supply to the required demands are small, will be allocated first in the modelling.

If overall supply is found to be adequate (in terms of total FTE and specific areas of competence) a surplus supply will be evident at the conclusion of the modelling. If supply is found to be inadequate, then a number of scenarios will be presented for each area of competency requirement where supply is limited.

The analysis is likely to indicate, even in a potentially over-supplied workforce scenario, areas of competence that are in critical shortage or areas of competence that are scarce and difficult to acquire without causing service disruption.

6.5.7 Step 7: Developing appropriate workforce strategies

The analysis from Step 6 will provide the basis for interpretation of future workforce strategies. Typical strategies include, but are not limited to:

- **Training** – either training more people, training them in a different way (e.g. a stronger emphasis on critical competencies), or training them more efficiently (that is,, reducing the lead time for developing sufficient competence to progress between career stages from, for example, 5 years to 2-3 years). Adoption of this strategy, in any or even all of the above forms, would require an audit of current training arrangements and would likely lead to changes in both external and on-the-job training and development arrangements.
- **Recruitment** – increasing the number of workers in the regulatory science workforce, through judicious selection based on required competencies, with at least partial competency sets⁴. For instance, scientists with critically demanded science skills (e.g. toxicology) might be recruited to support teams of regulatory scientists that had sufficient other competencies but lacked the specialist science skills. As another example, a scientist with strong communication skills might be recruited to support a less complex information program, freeing up a senior regulatory scientist to deploy more critically demanded risk management competencies.
- **Management of resources** – using available competence resources, particularly those defined as critical, in a more flexible way could obviate the need for extensive development of new resources, at least in the short term. For instance, as alluded to earlier, scarce specialist scientific skills within an organisation might be freed from the boundaries of section or branch control, and be made more easily available to work demands in other parts of the organisation. The same principle could be applied across organisations, where more structured collaborative arrangements could make scarce competencies more available on a ‘just in time’ basis.
- **Demand management** – this is a long term strategy and follows changes in strategic business direction. For example, a new direction might be taken where standard information functions are undertaken by regulatory affairs scientists and others, and the competencies of specialised regulatory scientists are deployed more narrowly to risk management work. This would have the net effect of reducing demand for regulatory scientists (but at the same time making that demand more technical).

⁴ It is assumed that the fall-back option of recruiting from overseas might not be appropriate, since a key regulatory scientist competence is an understanding of the specific legislation. However, recruitment from some other countries may be appropriate (e.g. FDA in the USA), and require only limited re-training to the Australian context.

6.6 Summary of next step

On the following page the proposed series of next steps to complete the exploration of the regulatory science workforce is provided diagrammatically. In all, the steps 1 to 7 outlined, a combination of research, planning, validation and strategy development, should not require more than 12 months to achieve.

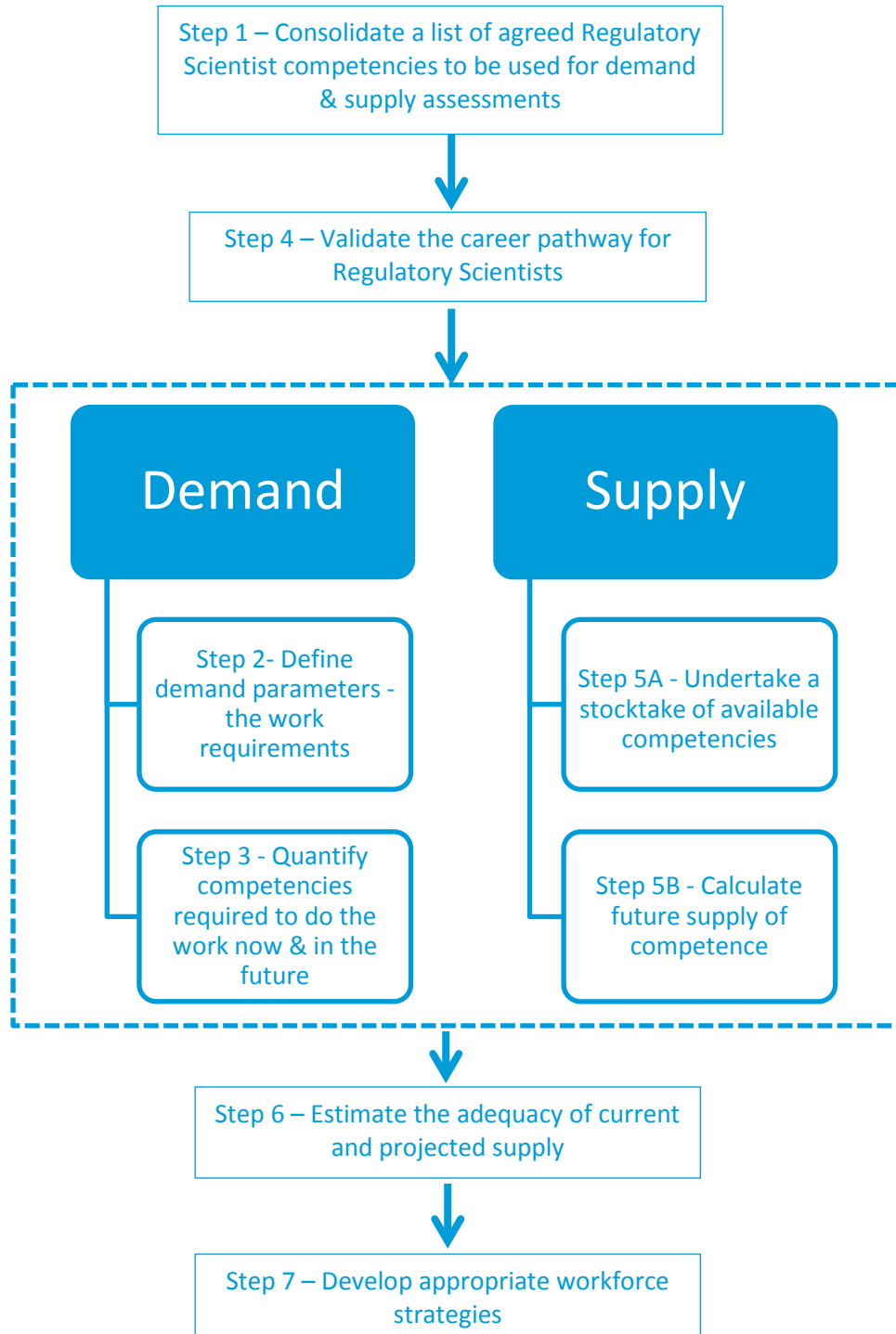


Figure 13: Next steps for the exploration of the needs of the regulatory science workforce

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Appendix A: Core Thematic Areas for Regulatory Scientist competence

1. Regulatory Science Research Questions and Priorities

- i. Summarize current and emerging Regulatory Science priorities, including FDA Priority Areas and others
- ii. Identify additional Regulatory Science questions via gap analysis of translational research pathway, considering current evaluation and approval process of medical
- iii. products
- iv. Critique Regulatory Science research questions and priorities
- v. Identify approaches and techniques to address areas of Regulatory Science; outline a vision for a research program
- vi. Describe principles of decision science and evidence based decision making, considering the role of patients, patient advocates, clinicians, payors, and regulators
- vii. Describe principles of Team Science, including the specific roles within a multidisciplinary network of individuals in and across organizations.

2. Regulatory Policies and Process

- i. Understand current regulatory system and structure appropriate to the relevant field of study
- ii. Evaluate and analyze laws, regulations, and guidance documents relevant to the field of study
- iii. Apply proposed regulatory strategies for the design and development of a medical product from bench to bedside, analyzing opportunities and challenges within
- iv. current regulatory framework.

3. Research Ethics

- i. Explain the ethical principles and requirements related to the development of new regulations and guidance documents
- ii. Identify current and emerging research ethics issues in Regulatory Science, including clinical trials
- iii. Discuss issues of risk-benefit disclosure during the process of consent
- iv. Define COI and discuss financial and non-financial examples of conflict with nascent approaches including mediating and monitoring techniques
- v. Develop an understanding of current risk-benefit assessment initiatives and requirements; while identifying opportunities and challenges of implementing new
- vi. approaches to risk-benefit assessment, including for emerging innovative technologies
- vii. Define, identify and apply ethical issues and implications for dual-use research.

4. Drug Discovery and Development

- i. Describe the traditional process of drug discovery and development, including target identification, validation, lead molecule identification and optimization
- ii. Discuss incorporation of new technology to further target identification (High-Throughput Screening, in vitro models, lead optimization and qualification, systems
- iii. biology, network analysis, human organs on chips)
- iv. Describe importance of correlating in vitro models for applicability to toxicology, target mechanism, metabolism
- v. Identify and understand the relative the utility of biomarkers and surrogate endpoints for addressing questions of efficacy and toxicity

- vi. Outline parameters for clinical proof of mechanism and proof of concept.

5. Medical Device Innovation

- i. Outline the process to translate a preclinical or clinical observation into a clear statement of Regulatory Science need
- ii. Discuss how to filter and prioritize needs based on safety, quality and regulatory impact and other considerations
- iii. Identify needs in applying quality systems regulations to product development
- iv. Describe preclinical and clinical tests necessary to show effectiveness
- v. Understand how to apply Regulatory Science approaches to respond to necessary post market changes.

6. Preclinical

- i. Evaluate the stages of preclinical testing in the context of drug and device development
- ii. Describe how to define preclinical testing requirements and design appropriate pre-clinical study
- iii. Describe the basic principles for GLP research and when such methods are needed
- iv. Explain how the preclinical results fit with formulation and clinical aspects of drug development
- v. Describe selection, qualification and innovation of animal models and animal model alternatives to promote novel clinical trial design
- vi. Explain the need to develop better preclinical models of human adverse response (e.g. cell/tissue based assays) that more accurately represent human susceptibility to adverse reactions
- vii. Explain the need to evaluate data at multiple levels (e.g., genes, proteins, pathways, cell/organ function) to better understand toxicity mechanisms
- viii. Describe the need for identification and evaluation of biomarkers and how related endpoints can be used in pre-clinical evaluations.

7. Clinical Trials

- i. Describe the stages of individual clinical trials
- ii. Outline the design/elements of an appropriate clinical trial for a medical product
- iii. Understand options for alternative/novel clinical trial designs (including adaptive trial design) that may be more informative, impactful and/or efficient for special needs (e.g., small trials for orphan indications, designs and endpoints for pediatric and neonatal trials)
- iv. Describe adverse event management strategies within individual trials and development programs, both pre and post-marketing
- v. Outline potential for pharmacogenomic approaches to refine target populations and opportunities for parallel co-development of drugs and diagnostics
- vi. Describe the role for pharmacometrics in clinical studies and the drug approval process
- vii. Discuss parameters for testing in specialized populations (e.g., pediatrics, geriatrics, altered organ function, cardiac toxicity)
- viii. Understand how outcomes of trials might vary if the study population differs significantly from the targeted population for use.
- ix. Explain the need to identify improved clinical endpoints and related biomarkers
- x. Describe the use of modeling and simulation to enhance clinical trial design and effectiveness.

8. Post-Marketing and Compliance

- i. Outline the role of the FDA in post-marketing processes
- ii. Describe the range of enforcement options available to the FDA when dealing with compliance issues

- iii. Understand the role of new technology as it applies to sampling and product testing for contaminated or counterfeit product.

9. Analytical Approaches and Tools

- i. Explain potential applications of computational methods and in silico modelling to predict human efficacy, toxicity and risk-benefit and to inform regulatory decisions
- ii. Evaluate applications of statistical approaches, biomedical informatics and models (e.g., missing data, multiple endpoints, patient enrichment, adaptive designs) to promote novel clinical trial design
- iii. Describe basic statistical concepts (e.g., identify a research question, conceptualize hypotheses, identify sources of data, utilize appropriate study designs, determine appropriate analytical methods, draw valid and meaningful conclusions)
- iv. Describe the process to identify, evaluate, and synthesize information from RCTs, observational studies, and other study designs
- v. Identify appropriate applications for various scientific methods to gather and validate information (e.g., systematic reviews, meta-analysis, etc.)
- vi. Describe principles and applications of various analytic tools and techniques (e.g., bioinformatics, patient-reported outcomes, clinical effectiveness research, translational research, etc.)
- vii. Discuss results from data mining techniques to explore existing clinical trial data (e.g., analysis of electronic health records from accessible large healthcare databases to identify sources of variation among studies, differentiate subsets of diseases, improve understanding of relationships between clinical parameters and outcomes, evaluate clinical utility of potential biomarkers and evaluate post-marketing data)
- viii. Describe use of informatics to inform both clinical trials and pharmacometrics
- ix. Outline current legal and policy requirements related to data storage, maintenance, access, privacy and security
- x. Discuss approaches to address data storage, access, sharing, privacy and confidentiality (including patient, industry, government and other data sources)
- xi. Describe requirements and permissions associated with biobanking tissue and others collections
- xii. Describe use of novel strategies and existing data sets for repurposing.

10. Communication

- i. Compare and contrast communication, evidence-based communication, and risk communication
- ii. Explain approaches to risk communication and the underlying social and behavior sciences that inform these approaches
- iii. Describe various research approaches that inform regulatory decisions (e.g., focus groups, surveys, experiments, etc.)
- iv. Discuss results-oriented approaches, and corresponding evaluation criteria, to achieve short- and long-term goals of communication strategies
- v. Effectively communicate the value of Regulatory Science, including priorities and gaps to stakeholders, including colleagues, policy-makers, the media, and the public
- vi. Discuss the need to provide guidance to sponsors and manufacturers about how to effectively and transparently communicate the risks, benefits and uncertainties of regulated products to the public
- vii. Recognize international and cultural aspects in developing communication plans, including the roles for international organizations.

11. Technology and Innovation

- i. Describe emerging key technology areas and how they may impact Regulatory Science processes and policies (e.g., manufacturing, toxicology, etc.)
- ii. Explain the global nature of medical product innovation and technology development
- iii. Outline aspects impacting economic viability of novel medical products, including the role for payors in coverage and reimbursement decisions.

Human Capital Alliance

HCA is a management and research consultancy firm specialising in helping clients align their human and capital resources to their (organisational, occupational, industry, national) objectives. As part of this broad expertise, HCA has developed highly valued evaluation and review expertise employing strategic and analytical approaches.

HCA was established in 1989 and has consulted to public, not-for-profit and private sector organisations employing well-researched, innovative and effective methodologies. Two important themes that run through all of HCA’s work has been a commitment to:

- understanding and acting upon client needs through a strategic rather than operational research approach; and
- employing the best possible (within budget constraints) research methodology to find answers that meet unique client needs.

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