VETASSESS

Information sheet

Regulatory Affairs Manager

ANZSCO: 139917 | **Group B**

About this document

- The following Information Sheet is for your reference only and should be used as a guide to assist with your Skills Assessment application to VETASSESS. This information is subject to change.
- Please note that a Skills Assessment of the qualification involves assessment of both the qualification level and content. Qualifications are assessed according to the guidelines published by the Australian Government Department of Education.
- The employment assessment involves determining the skill level and relevance of the tasks undertaken.
- Integrity checks may be conducted to verify the qualification and employment claims made in an application.

Job description

Regulatory Affairs Managers plan, organise, direct, control, coordinate and promote adherence to regulatory frameworks and strategies within an organisation. They monitor regulatory environments and enable compliance.

Occupations considered suitable under this ANZSCO code:

- Regulatory Lead
- Regulatory Specialist
- Medical Affairs Advisor
- Regulatory Scientist
- Regulatory and Technical Affairs Associate

Occupations not considered under this ANZSCO code:

Quality Assurance Manager

These occupations are classified elsewhere in ANZSCO or are not at the required skill level.

Regulatory Affairs Manager is a VETASSESS Group B occupation

This occupation requires a qualification assessed as comparable to the educational level of an Australian Qualifications Framework (AQF) Bachelor degree or higher.

Applicants must have fulfilled at least one of the following four criteria (1–4):

GROUP B	Criteria for a positive Skills Assessment			
	Minimum comparable Bachelor or higher degree AQF level	With highly relevant major field of study	Additional highly relevant qualifications	Highly relevant employment duration
1	AQF +	+	N/A +	1 YEAR minimum
2	AQF +	No highly relevant major +	AQF Minimum AQF Diploma level with highly relevant major +	2 YEARS minimum
3	AQF +	No highly relevant major +	No additional highly relevant qualifications +	3 YEARS minimum
Pre-qualification methodology can apply to Group B occupations				
	Highly relevant employment duration	With or without highly relevant major field of study	Additional highly relevant qualifications	Comparable Bachelor degree AQF level
4	5 YEARS minimum + 1 YEAR minimum Within last 5 years	+ N/A +	N/A +	AQF

Description of Pathways

The information below describes the available pathways for a Skills Assessment under **Group B**. Please note that in order to achieve a successful Skills Assessment Outcome, a positive assessment for both qualifications and employment is required.

Pathway 1

This pathway requires a qualification assessed as comparable to the education level of an Australian Qualifications Framework (AQF) Bachelor degree or higher degree and in a field highly relevant to the nominated occupation.

Bachelor degree or higher degree includes AQF Master Degree or AQF Doctoral Degree.

In addition, it is essential for applicants to meet the following employment criteria:

- at least **one** year of post-qualification employment at an appropriate skill level, undertaken in the last five years,
- working 20 hours or more per week, and
- highly relevant to the nominated occupation.

Pathway 2

This pathway requires a qualification assessed as comparable to the education level of an Australian Qualifications Framework (AQF) Bachelor degree or higher degree and in a field not highly relevant to the nominated occupation.

Bachelor degree or higher degree includes AQF Master Degree or AQF Doctoral Degree.

An additional qualification in a highly relevant field of study at a minimum AQF Diploma level is required. Additional qualifications in a highly relevant field of study include those comparable to the AQF Diploma or AQF Advanced Diploma or AQF Associate Degree or AQF Graduate Diploma.

In addition, it is essential for applicants to meet the following employment criteria:

- at least **two** years of post-qualification employment at an appropriate skill level, undertaken in the last five years,
- working 20 hours or more per week, and
- highly relevant to the nominated occupation.

Pathway 3

This pathway requires a qualification assessed as comparable to the education level of an Australian Qualifications Framework (AQF) Bachelor degree or higher degree and in a field not highly relevant to the nominated occupation.

Bachelor degree or higher degree includes AQF Master Degree or AQF Doctoral Degree.

In addition, it is essential for applicants to meet the following employment criteria:

- at least **three** years of post-qualification employment at an appropriate skill level, undertaken in the last five years,
- working 20 hours or more per week, and
- highly relevant to the nominated occupation.

Pathway 4

This pathway requires a qualification assessed as comparable to the education level of an Australian Qualifications Framework (AQF) Bachelor degree or higher degree with or without a highly relevant major field of study to the nominated occupation.

Bachelor degree or higher degree includes AQF Master Degree or AQF Doctoral Degree.

In addition, it is essential for applicants to meet the following employment criteria:

- at least **six** years of employment at an appropriate skill level that includes at least **one** year of highly relevant employment within the last five years before applying,
- working 20 hours or more per week, and
- highly relevant to the nominated occupation.

Qualification

AQF Bachelor Degree or higher

This occupation requires a qualification in a field of high relevance to the occupational specialisation.
While there is no specific qualification in regulatory affairs, typical examples of highly relevant majors include (but are not limited to):

- Natural Science (Biotechnology, Biology, Chemistry, Molecular Biology, Biomedical Engineering, or a related field)
- Engineering
- Materials Science
- Agriculture
- Pharmaceutical Science
- Medical Science / Medicine
- Quality study/Quality management
- Health Science /Allied health
- Disciplines such as Business / Finance or others which are relevant to the employment context may be considered on a case-by-case basis (if employment is highly relevant)

Regulatory Affairs Managers may undertake professional development through industry-recognised courses or certifications offered by organizations such as ARCS Australia, TOPRA (The Organisation for Professionals in Regulatory Affairs), RAPS (Regulatory Affairs Professionals Society), and DIA (Drug Information Association). These credentials are highly regarded within the industry as evidence of expertise and commitment to the profession and may be considered as supporting evidence; they cannot, however, be assessed towards meeting the formal qualification requirements of this occupation as they are not generally comparable to the Australian Qualifications Framework.

Employment

Highly relevant tasks include:

- Developing and monitoring regulatory policies, procedures and strategies.
- Preparing, reviews and submitting regulatory documents and applications to regulatory agencies.
- Providing regulatory guidance and coordinating with other departments within an organisation to ensure that products and services are compliant with relevant regulations.
- Managing regulatory activities such as regulatory risks/audits, regulatory agency inspections or product recalls.
- Monitoring changes in the regulatory environment to determine potential impacts on organisational processes.

Other tasks include:

- Ensuring products meet local and international regulations before they reach the market, and for the duration of their lifecycle responsibility for the authoring and ownership of Standard Operating procedures (SOPs) and other guidance documents as required.
- Communicating with regulatory agencies/authorities e.g. Medsafe (New Zealand), TGA (Australia), FDA (U.S.A.), EMA (Europe), CDSCO (India,), DRAP (Pakistan), APRA/ASIC/ACCC (Australia).
- Advising on the best approaches to gain product approvals efficiently.
- Act as primary interface with local authorities and industry groups, and trade associations, representing the company's regulatory interests and fostering positive relationships.
- Compiling technical files, safety data, maintaining technical documentation e.g. For Pharma and MedTech, overseeing preparation, submission, lifecycle management of regulatory dossiers (e.g., new listings, variations, renewals) and other relevant regulatory documents).
- Keeping up with evolving laws and ensuring business compliance.

Educating staff about regulatory requirements and developing internal compliance guidelines.

Employment Information

Regulatory Affairs Managers oversee and manage regulatory processes to ensure the organisation's products comply with all relevant regulatory standards

Regulatory Affairs Managers can work in:

- Pharmaceutical & Biotechnology Companies (Regulatory submissions, drug approvals)
- Medical Device Manufacturers (Compliance with safety and efficacy regulations)
- Cosmetic & Chemical Industries (Safety and ingredient regulations)
- Food & Beverage Industry (Labelling, safety, and import/export regulations)
- Government & Regulatory Agencies (Developing and enforcing regulations)
- Consulting Firms (Providing compliance advice to companies)
- Banking, Insurance and Financial firms (Providing advice, insight and guidance on regulatory issues / Prudential standards and engagements)

As Regulatory Affairs Managers, they typically oversee a team of professionals, such as:

- Regulatory Affairs Associates/Senior Associates
- Compliance Officers
- Quality Assurance Specialists
- Pharmacovigilance Associates/specialists
- Technical Writers (for regulatory documents)

Note: It is noted that different organisations will have different career ladder levels associated with the 'Manager' position.

Supporting material for assessment

Applicants nominating this managerial occupation must submit an organisational chart. An organisational chart should include:

- The company letterhead,
- Your job position,
- The job position of your superiors and subordinates, as well as,
- All positions reporting to your immediate supervisor and to your direct subordinates.

If you are unable to obtain an organisational chart from your employer, please provide a statutory declaration outlining the required information and the reasons why this information cannot be provided.