

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			
Post-qualification Pathways					
	Minimum comparable Bachelor or higher degree AQF level*	With highly relevant major field of study	Additional highly relevant qualifications**	Highly relevant employment duration***	
1	 +	 +	N/A	+ 	
2	 +	No highly relevant major	+  Minimum AQF Diploma level with highly relevant major	+ 	
3	 +	No highly relevant major	+ No additional highly relevant qualifications	+ 	
Pre-qualification Pathway					
	Highly relevant employment duration***			Minimum comparable Bachelor or higher degree AQF level*	
4	 +  Within last 5 years	+ With or without highly relevant major field of study	+ 		

*Bachelor degree or higher degree includes:

- > AQF master's degree or
- > AQF Doctoral Degree

** Additional qualifications in a highly relevant field of study include those comparable to the following levels:

- > AQF Diploma
- > AQF Advanced Diploma
- > AQF Associate Degree or
- > AQF Graduate Diploma

*** Highly relevant paid employment duration (20 hours or more per week)

Pathways 1–3

Minimum years of post-qualification employment highly relevant to the nominated occupation, completed at an appropriate skill level in the five years before the date of application for a Skills Assessment.

Pathway 4

Minimum 6 years of relevant employment required – Five years of relevant employment (can be outside the last 5-year period) in addition to at least one year of highly relevant employment within the last five years before applying.

Qualification

AQF Bachelor Degree or higher

This occupation requires a qualification in a field of high relevance to the occupational specialisation.

Bachelor degree and higher in a scientific or technical field. While there are no specific qualification in regulatory affairs, typical examples of highly relevant majors include (but are not limited to):

- Science
- Engineering
- Materials Science
- Agriculture
- Pharmaceutical Science
- Medical Science

Other fields may include:

- Policy and planning
- Project management and organisation
- Quality study/management
- Strategic Leadership/Operations

Employment

Highly relevant tasks include:

- developing regulatory strategies and implementing plans for new products
- provide high level strategic and technical advice on regulatory requirements
- liaise between R&D
- marketing, and senior management
- manage regulatory risks and ensure timely responses to regulatory queries
- manage regulatory affairs team
- staying abreast of changes in regulatory guidelines

Employment Information

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

