Regulatory Affairs Manager interview questions

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What to expect

Interviews for regulatory affairs manager roles usually blend technical regulatory knowledge with process and stakeholder questions. Employers want to see that you can interpret Australian requirements, manage a dossier from planning to approval, and keep internal teams and regulators informed without losing detail.

- **Technical and regulatory knowledge:** Questions about TGA and APVMA pathways, product classification, dossier requirements, eCTD format and post-market obligations.
- **Process and project management:** How you plan a submission, assign owners, track commitments and keep a review on schedule.
- **Behavioural and stakeholder:** Examples of working with regulators, scientists, quality teams and commercial managers, especially when time or information is tight.
- **Scenario and judgement:** Hypothetical changes to regulations, audit findings or gaps discovered after lodgement, testing how you prioritise and communicate.
- **Quality and safety:** GMP, ISO 13485, risk controls and recall or post-market responsibilities.

A first conversation with a recruiter or hiring manager, then a technical interview with regulatory or quality leads, sometimes a panel that includes commercial and scientific stakeholders. You may be asked to walk through a past submission, discuss a hypothetical regulatory change, or explain how you would handle a regulator question. Final stages often include a meeting with senior management and a chance to ask about the product portfolio and submission pipeline.

1. Walk me through how you would prepare and lodge a new prescription medicine dossier with the TGA.

Why they ask

This tests whether you understand the practical steps, the documentation standards and the TGA systems a regulatory affairs manager uses daily.

How to structure your answer

A step-by-step walk-through: confirm the pathway and classification, plan the modules and owners, check the format, lodge through the correct system, then track review milestones and post-approval duties.

Example answer

“I start by confirming the product classification and the correct TGA pathway, because a prescription medicine usually goes through the standard or priority review process. I map out the dossier modules, assign owners for quality, nonclinical and clinical sections, and set an internal timeline working back from the target lodgement date. I check the eCTD format and validate every file before it goes into TGA eBS. Once lodged, I track the review milestones and prepare the team for any questions the evaluator raises. After approval, I make sure the ARTG entry and post-market obligations are recorded and understood.”

2. Tell me about a time you had to respond to a regulator's question or audit finding under time pressure.

Why they ask

Regulatory reviews often turn on how quickly and accurately you can pull together a credible response without cutting corners.

How to structure your answer

STAR: situation, task, action, result. Focus on how you coordinated contributors, managed the deadline and documented the outcome.

Example answer

“At my previous company, the TGA asked for additional stability data late in a review. I gathered the available data, worked with the manufacturing team to confirm what could be provided within the deadline, and drafted a clear response with a summary of the evidence. I logged the request in Veeva Vault, set daily check-ins with the contributors, and submitted the response two days before the due date. The TGA accepted the response without extending the review, and I updated our internal tracking so similar requests could be anticipated earlier.”

3. A new regulation changes the labelling requirements for your existing device portfolio. How would you assess the impact and roll out changes?

Why they ask

This scenario checks whether you can translate a regulatory change into a practical plan across multiple products and teams.

How to structure your answer

Impact assessment, prioritisation, communication, implementation, monitoring. Show how you decide what comes first and how you keep everyone informed.

Example answer

“First I would confirm the exact scope of the change and which products are affected, because a labelling update may apply to some devices and not others. I would assess the risk and regulatory deadlines, then prioritise the products with the nearest submission or supply milestones. I would brief the commercial, quality and manufacturing teams on what needs to change, update the affected artwork and technical files, and lodge any required notifications or variations with the TGA. Throughout, I would keep a tracking log and report progress to management until every product is compliant.”

4. How do you keep across changes to therapeutic goods and chemical regulations across multiple markets?

Why they ask

Regulatory affairs managers need a reliable system for monitoring updates and deciding what actually matters to their products.

How to structure your answer

A process explanation: sources you use, how you triage changes, how you advise internal teams, and how you record actions.

Example answer

“I use a mix of official sources, industry alerts and regulator newsletters. I set a weekly review of TGA and APVMA updates, and I flag anything that could affect our current products or pipeline. For each change, I write a short impact note for the product and research teams, explaining what it means and what action is needed. I then add the item to our submission tracking system so it is not lost among other work. If a change is significant, I escalate it to the regulatory lead and commercial team early.”

5. Describe a situation where you had to advise a research or product team that their plan did not meet compliance requirements.

Why they ask

This behavioural question looks at how you handle pushback, explain regulatory obligations clearly and still keep the project moving.

How to structure your answer

STAR: situation, task, action, result. Emphasise the advice you gave, how you helped find a compliant path and what changed afterwards.

Example answer

“A research team once planned to run a study without the correct CTN approval. I reviewed their protocol and identified the gap before any participants were enrolled. I explained the requirement clearly, helped them prepare the CTN application, and set a realistic timeline for HREC and TGA review. We lodged the CTN, received approval, and the study started without further delay. I also ran a short briefing for the research group so future studies would factor regulatory approvals into their planning from the start.”

6. What would you do if you discovered a gap in a submission after it had been lodged?

Why they ask

This tests judgement under pressure, transparency with the regulator and your instinct for correcting the record rather than hoping the issue goes unnoticed.

How to structure your answer

Assess severity, notify internally, contact the regulator, correct the file, document and prevent recurrence.

Example answer

“I would first assess the severity of the gap and whether it affects product safety, efficacy or the validity of the submission. If it is material, I would notify my manager and the relevant quality lead immediately, then contact the TGA to discuss the best way to correct the record. I would prepare a correction or supplementary response, document the issue in our tracking system, and follow through until the regulator confirms the file is updated. Afterwards, I would review what caused the gap and add a check to the submission process so it does not happen again.”