

1 Overview

As part of the Quality Assurance team, the Validation Chemist is responsible for processes & analytical method validations and equipment qualifications, to ensure compliance with cGMP requirements.

2 Qualifications

- Tertiary qualifications in chemistry
- TAFE qualifications

3 Salary Range

Permanent \$35,000 – \$65,000 pa

4 Previous Positions

- Method Development Chemist
- Validation Chemist
- QA Chemist
- QC/Analytical Chemist
- Stability Chemist

5 Industry Background

- Pharmaceutical
- Veterinary
- Consulting Laboratory
- cGMP compliant industries (personal care, cosmetics, h/hold products, food)
- Complementary Medicine

6 Career Progression

- Method Development
- Stability
- R&D Chemist
- Laboratory Manager
- Documentation Officer
- QA Systems
- Validation Chemist (non-lab based)

7 Typical Responsibilities

- Development of analytical methods for new/existing products that are suitable for use in development studies, stability studies and routine product analysis
- Documentation of all development and validation activities
- Validation of analytical methods including protocol and report preparation
- Validation, stability and investigational study documentation, including protocol development, reporting, specification development and test method write-ups
- Coordination of handover of new analytical methods once out of development phase
- Preparation of product development reports
- Standards certification for product development projects
- Stability sample analysis of products under development
- Calibration and maintenance of research instruments
- Review of analysis and other data generated by other analysts
- Perform Out of Specification investigations
- Prepare laboratory documentation to a high standard of cGLP compliance
- Support the various functions within Quality Assurance cGMP Compliance