Validation Specialist

Reports to: Validation Supervisor or Manager

Pharmabio Développement
Comité sectoriel de main-d'œuvre des industries des produits pharmaceutiques et biotechnologiques

Main Duties

may vary from one company to another

- **Participates in prevalidation activities:** becomes familiarized with the project; participates in the determination of validation requisites and timetables; may draft and approve prevalidation documents; becomes involved in acceptance tests on the manufacturer's premises and installation testing; prepares the area for validation activities.
- **Designs validation protocols:** conducts a literature search; determines the scope and critical parameters to validate; drafts the validation protocol and other related documents; submits validation protocol for approval.
- **Performs validation activities:** coordinates protocol validation phases; performs and documents tests; ensures follow-up of laboratory tests, if applicable; analyzes test results against the protocol; writes up deviations, if applicable.
- **Finalizes validation protocols:** assembles documentation; drafts the closure report; submits final report for approval; advises concerned departments of validated parameters.
- **Acts as a reference person or advisor:** provides technical and professional support to other team members and concerned personnel; trains employees from other departments; helps draft and review validation support documents; helps assess and implement changes and corrective/preventive actions as part of the change management process; participates in the revalidation or requalification of systems, equipment, and procedures; takes part in audits.

Evolution of the Profession

- In 1996, Canada implemented new standards for validating procedures, methods, and equipment. Validation standards continue to evolve and are part of operational guidelines for companies.
- The scope of validation activities has expanded considerably with advances in the following domains:
  - automation;
  - software engineering;
  - continuous improvement processes;
  - risk management;
  - increasingly stringent standards.
- To justify their decisions, Validation Specialists must develop scientific rationale.

Best Practices

- Validation Specialists keep their knowledge up to date in various areas, including current standards, new technologies, and industry trends through:
  - monitoring technological advancements;
  - attending conferences and external training programs;
  - participating in in-house training sessions and meetings.

Main responsibilities[1]

Validation Testing

- Is involved in acceptance tests on the manufacturer's premises and installation testing.
- Properly performs operational tests on critical function as well as performance tests according to validation criteria.
- Schedules validation tests according to production schedule and equipment availability.
- Rigorously monitors test sequences.
- Meticulously collects samples and records measurements.
- Thoroughly records results and findings.
- Correctly labels samples and forwards them to the laboratory.
- Compares results with protocol acceptance criteria.
- Performs accurate statistical analysis and produces graphs.
- Clearly and accurately collects data.
- Properly analyzes the validity results.
- Assesses the impact of deviations on validation and product quality.
- Properly investigates problems.
- Is actively involved in the formulation of an action plan.
- Maintains diligent follow-up of corrective actions and repeats tests, if necessary.
- Draws conclusions about repeating tests with respect to acceptance criteria.

Draft Protocol and Validation Report

- Sets a search strategy according to validation requirements.
- Rigorously collects information from documents supporting the development of a protocol.
- Precisely determines the scope and critical parameters of the validation.
- Drafts a protocol reflecting the decisions made in the prevalidation stages and compliant with existing validation procedures.
- Reviews and approves all documents to ensure compliance.
- Generates a summary of the results, including a summary of deviations.
- Forwards the protocol to others for comment.
- Makes corrections, if applicable.
- Rigorously monitors the approval process.
- Forwards completed documents to the archives department.

Advisory Capacity for Stakeholders with Validation Requirements

- Is actively involved in investigations pertaining to validation, equipment configurations, and review of validation data.
- Properly trains personnel involved in validation studies.
- Adapts training to audience.
- Accurately interprets and integrates regulatory requirements.
- Assesses all risks and possibilities.
- Analyzes the impact of changes on validation status.
- Works in cooperation with department managers.
- Considers departmental objectives and operational constraints.
- Offers managers appropriate support when developing strategies to assess or implement control changes and corrective and/or preventive actions.

[1] As per the company's mode of operations.

Qualifications

Validation Specialists have:

- A bachelor of science (biochemistry, chemistry, etc.) or engineering (chemical, mechanical, computer, food industry, biotechnological, etc.) or
- A college degree in science
- In all cases, between one and five years of relevant experience in validation in the pharmaceutical industry or a related discipline.

Employers are seeking candidates who possess, among other skills, the following:

- Ability to work autonomously and a sense of responsibility.
- Ability to coordinate various projects.
- Ability to manage priorities, meet tight deadlines, and ensure follow-up.
- Ability to interact with users and meet their needs.
- Ability to work under pressure.
- Ability to communicate effectively and draft documents in French and English.
- Keen sense of judgment and critical-thinking skills.
- Negotiating skills and ability to influence decisions.
- Curiosity and scientific rigor.
- Analytical and synthesis competencies.
- Excellent relationship skills and ability to work effectively as part of a team.
- Flexibility and adaptability.
- Leadership skills.
- Meticulousness and attention to detail.
- Productivity- and quality-based focus.
- Planning skills and organized work habits.
- Listening skills.

Career-Path Options

Depending on experience and areas of interest, Validation Specialists can aspire to, among other positions, the following:

- Project Manager.
- Chief Validation Officer.
- Consultant.
- Manager.
- Trainer or Educator.
- Senior Specialist.
- Supervisor.

Some may decide to pursue their career in other pharmaceutical fields such as quality assurance, regulatory affairs, and production.

Competencies	Behavioral Indicators
Decision-Making Ability to make sound judgments to achieve product compliance.	• Evaluates facts and unforeseen situations in order to make the best decisions based on acceptable risk (production/quality/compliance). • Has a proactive attitude and is able to present one or more opponents with convincing arguments to influence and win them over. • Develops a scientific rationale to justify decisions. • Makes realistic and appropriate decisions within a regulatory context.
Communication and Interpersonal Skills Ability to build trust and demonstrate professional ethics.	• Shows diplomacy, calm, and patience. • Communicates clearly and effectively. • Establishes and maintains quality relationships. • Offers support to department employees involved in validation operations. • Ensures the confidentiality of all aspects of work.
Problem Solving Skills Ability to assess various situations and propose appropriate solutions.	• Obtains, selects, processes, and leverages information pertaining to validation operations. • Participates in solving deficiencies (mechanical, computer, etc.). • Manages risk situations; proposes and implements appropriate solutions. • Adopts a rigorous approach to problem solving.
Ensuring Compliance Ability to ensure the reliability and compliance of systems, equipment, and processes.	• Monitors and ensures compliance with instructions, validation criteria, and critical parameters for the manufacture and packaging of pharmaceutical products. • Drafts, revises, and approves validation documents and reports within prescribed time frames and in accordance with applicable good manufacturing practices and regulatory requirements. • Efficiently multitasks in order to manage multiple projects simultaneously.

Please refer to the *Validation Specialist's Analyse de profession** and *Profil de compétences** for all additional information.

The Competency Profile was made through funding by *the Commission des partenaires du marché du travail*.

* This document has not been translated yet.

Commission des partenaires du marché du travail
Québec