COMPETENCY PROFILE:

# VALIDATION ENGINEER

## ROLE OVERVIEW

Validation engineers are qualified engineers who manage, inspect, calibrate, test, and modify the instrumentation, equipment, mechanics, and procedures used to manufacture many products. They test systems used to develop or manufacture products, including pharmaceuticals or automobiles. They also measure, analyze, and calibrate equipment and processes to ensure that production functions as efficiently as possible.

Validation engineers perform multiple tests, help establish validation standards, and develop testing protocols. They often coordinate with other personnel or departments on the testing impacts and adjust equipment or processes, as necessary.

## ALSO KNOWN AS:

- Commissioning, Qualification, and Validation (CQV) Engineer
- Quality Assurance Engineer

## NATIONAL OCCUPATIONAL CLASSIFICATION:

- 21321 – Industrial manufacturing engineer

## EDUCATION AND EXPERIENCE

- A bachelor's degree is essential in engineering or science-focused fields, such as mechanical, chemical, biomedical engineering, or applied sciences. These programs provide fundamental engineering and science principles, critical thinking, and problem-solving skills for validation work.
- Statistical software proficiency is highly valuable for validation engineers because it enables practical data analysis, trend identification, and assurance that processes and products comply with specifications. Statistical methods are crucial for experiment design, process capability analysis, and system performance validation.
- Depending on the sector, industry-specific knowledge is necessary to understand good manufacturing practices, regulatory standards, and quality assurance processes to ensure compliance with industry and regulatory norms.
- Practical experience is often required, including internships, co-op programs, or entry-level roles offering validation activity exposure, such as protocol drafting, test conducting, result documenting, and risk assessment. This experience is critical to grasping validation complexities and honing necessary skills.
- Certifications can enhance qualifications; for example, certifications in quality assurance, Six Sigma, or sector-specific regulatory compliance can be advantageous.
- Ongoing education and professional development are crucial for keeping up with industry trends, technological updates, and regulatory shifts.

## TECHNICAL

### Documentation

Contributes to, creates, and maintains extensive documentation of all system, action, or process performance evaluations to track and identify any new or existing shortcomings.

- Creates and maintains an evidence trail of the process throughout different actions, processes, or systems to ensure that there is documented scientific proof of consistent performance.
- Plans, organizes and tracks assigned tasks to ensure the schedule commitments are kept.
- Maintains a clean and orderly documentation trail to enable future analysis and decision-making.

### Data Management

Follows appropriate processes, as directed by organizational best practices, to ensure quality is maintained throughout data collection, analysis, and management.

- Analyzes operational data to evaluate environmental operations, processes, or products to ensure efficiency.
- Maintains historical information on operational environmental/contaminant data to reference and track overall trends.
- Applies appropriate processes to trace and record the data to understand its movements within the organization.
- Works with environmental/safety teams to ensure new chemicals and contaminants are logged, necessary data is attached, and proper labelling is affixed.

## Engineering Design

Coordinates engineering projects' technical planning and design aspects to ensure safe, efficient, and practical construction.

- Conducts site-specific risk assessment of the work area, identifying the hazards and implementing the control measures required to complete engineering work.
- Prepares complete technical drawings with sufficient details and specifications to ensure the effective and safe construction of products, structures, systems, or facilities.
- Considers information from multidisciplinary assessments to design effective engineering solutions for environmental problems.
- Proposes technical design or process changes to improve product, structure, and system efficiency, quality, or performance.

## Engineering Review and Analysis

Reviews and analyzes relevant technical design and complex system information to develop appropriate solutions.

- Evaluates technical data to assess performance and identify areas for improvement.
- Assesses the functionality, replicability, costs, and other factors to be considered to develop appropriate technical solutions to engineering-related problems.
- Evaluates the precision and accuracy of environmental equipment, facilities, structures, and systems to formulate a corrective action plan.
- Works with other technical staff to adjust designs of products, parts, or systems to ensure that they meet the industry standards and specifications for operations.

## Quality Assurance and Control

Follows appropriate processes directed by global engineering standards and industry best practices to ensure quality is maintained throughout operations.

- Directs testing activities for environmental components and equipment under designated conditions to ensure operational performance meets environmental standards with proven reliability.
- Consistently evaluates implemented solutions' effectiveness to guarantee sustained performance over time.
- Analyzes operational data to evaluate operations, processes, or products to ensure efficiency.
- Maintains historical information on operational data to reference and corresponding sources.
- Applies appropriate processes to trace and record the data to understand its movements within the organization.
- Creates and runs quality testing based on appropriate protocols to meet all quality standards.
- Identifies critical quality aspects of materials/products to determine crucial criteria for measuring the quality and fulfillment of function of said materials/products.
- Prepares and maintains testing equipment to continually get accurate quality testing results.

## Project Management

Works within a team of professionals to effectively and efficiently produce the required output to ensure project[s] are completed on time and within budget.

- Contributes to developing project plans and setting milestones to facilitate successful completion.
- Applies technical solutions and corrective measures to steer projects back on track, guaranteeing timely completion.
- Ensures that available resources are appropriately allocated to ensure optimal efficiency.
- Manages tasks according to the approved scope of work to deliver quality reports on schedule and within budget.
- Assesses and aligns immediate production support requirements with the department's long-term strategic goals regularly to develop a cohesive long-term strategy.

## Troubleshooting

Identifies operating problems and inefficiencies in current equipment, processes, or systems and reports issues to determine effective solutions.

- Addresses issues with new or existing products related to designs, materials, or processes to optimize manufacturing efficiency.
- Designs, installs, or troubleshoots manufacturing equipment for reliability and maintenance.
- Identifies and resolves issues in the manufacturing process, offering solutions to overcome challenges.
- Examines and understands problems in the manufacturing process, creating strategic solutions to reduce downtime and enhance efficiency.

# PERSONAL & PROFESSIONAL

## Attention to Detail

Review completed work by monitoring and checking information, organizing tasks and resources efficiently, and assessing all areas involved in achieving an objective.

- Identifies and rectifies errors or oversights where necessary to prevent future performance problems and ensure products, systems, or applications function as intended.
- Routinely verifies the accuracy of information and work outputs to ensure consistency and reliability.
- Establishes procedures or processes to validate information to minimize disruptions to ensure the project meets deliverables.
- Regularly communicates with team members to adjust to shifting priorities or expectations, aiming to enhance relationships and meet business goals.

## Communication

Positively directs outcomes by delivering communication that better understands goals and objectives, captures interest, and gains support for immediate action.

- Clearly communicates complex engineering concepts and related information to audiences, elucidating aspects of the design process and proposals.
- Actively listens to team members to address concerns and integrate ideas, values, and new information, where appropriate.
- Communicates manufacturing capabilities, product development schedules, or other information to facilitate production processes.
- Uses plain language for communication to aid team members in accomplishing their objectives more efficiently or effectively.

## Collaboration

Engages in professional collaborative efforts with other team members, including sharing information and expertise, utilizing input from others, and recognizing others' contributions to work towards a common goal.

- Collaborates effectively with team members, offering support and assistance to achieve shared goals.
- Identify and monitor quality and safety standards and create and maintain a climate of quality and safety within the team and other departments.
- Liaises with intra-departmental teams to establish priorities and provide general engineering support.
- Shares relevant and valuable knowledge, experience, or expertise to aid team members in accomplishing their objectives more efficiently or effectively.

## Problem-Solving

Identifies problems and uses logic, judgment, and evidence to evaluate alternative scenarios and recommend solutions to achieve a desired goal.

- Conducts root cause analyses to identify issues or failures to develop innovative solutions.
- Analyzes data to evaluate operational challenges to prevent recurrence.
- Evaluates multiple explanations or alternatives for a situation, anticipates potential challenges, and devises strategies to address them.
- Uses a mix of logic and creativity to devise innovative and thorough solutions to environmental issues, focusing on sustainability.

# LEGAL, POLICY, AND REGULATORY

## Regulatory Compliance

Adheres to specific regulations, codes, and legislation within a defined jurisdiction to ensure the health and safety of others.

- Consult with different government agencies to secure regulatory approvals and permits.
- Analyzes relevant regulations, legislation, and standards to ensure the project complies with them.
- Participates in developing internal policy and procedures to ensure assessments are conducted as per all legal requirements.
- Applies engineering codes and statutes of a defined jurisdiction in designing mechanical or software solutions to ensure the safety standards of designs are met.

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