



# ROLE PROFILE

## General Information

**Job Title :** Process Validation Engineer

**Acronym** (filled in by HR) : AVAL

**Review :** 1

## Job Purpose

Coordinate the validation of the in charge manufacturing processes assuring that the Validation Team is involved and properly execute the validation activities according to the related internal procedures, protocols and, where applicable, international standards. Ensures that the monitoring activities are performed, and the changes are evaluated and, where needed, validated.

## Major Accountabilities

- Participate in the Validation Teams.
- Ensure the correct execution of the validation activities according to the related internal procedures, protocols and, where applicable, international standards.
- Ensure that the monitoring activities are performed.
- Ensure that the changes are evaluated and, where needed, validated.
- Formalize validation work instructions and protocols.
- Collect and keeps the validation records.
- Issue the final validation reports.
- Propose process/documents improvements.
- Manage the outsourcing of the tests to external laboratories, verifying the pertinent test reports.
- Support the Manager in preparing the function's budget.
- Participate in Product Development Project Teams.

## Background (State the required education, experience level, and competency profile)

**Education :** Technical Bachelor/Master Degree  
In alternative High school diploma in technical subjects (with appropriate experience).

**Experience :** In case of High school Diploma at least 3 years experience in manufacturing processes validation.

**Professional Requirement :** /

## Technical/Soft Skills

Description	Advanced	Intermediate	Basic
Knowledge of process validation guidelines	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Action oriented/self-starter	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Proactivity/Initiative	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Knowledge of engineering, manufacturing and product monitoring procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
English language (spoken and written form)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Knowledge of ISO 9001 (or equivalent)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>



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## Technical/Soft Skills

Description	Advanced	Intermediate	Basic
Proficiency in Office automation packages	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Mastery of calibration and maintenance operations for Laboratory equipment	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Teamwork	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Read and Approved

**Date:**

**Signature:**

**Area Vice President's Signature :** 29/10/2018

**Employee's Signature** (for acknowledgement) :