

Quality Control Labs

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Process for an End-to-end Diagnostic of Quality Control Laboratory Performance

This page will describe a process for assessing the Impact of the quality control (QC) Lab on the Value Chain, in terms of:

- Lead Time
- Cost
- Quality

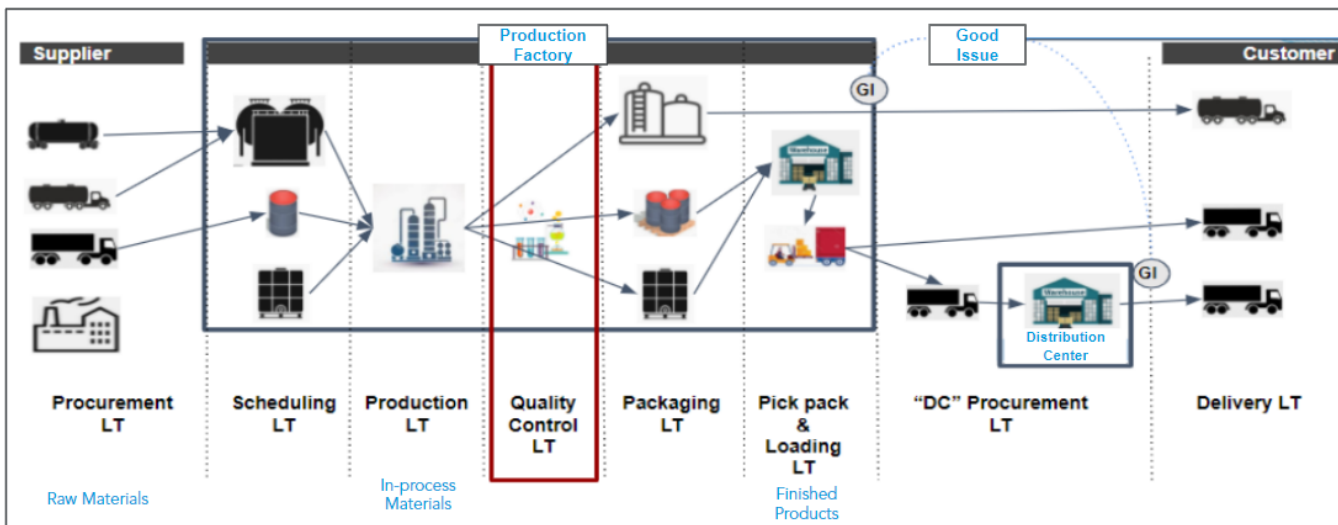
while also keeping safety as the first and foremost priority.

The mantra can be described as following: "put safety first, do the right things, do the things right, optimize costs and optimize lead times".

1. Principles, Definitions & Prerequisites

1.1. Principles

The QC Lab has a central position in Solvay's Operations and in the end-to-end Flow of Products. It is the last safeguard before a product is shipped to the customer. While safety is paramount, QC Lab test results impact important pass/fail decisions, therefore the results should be highly reliable, but with a keen view on costs and lead time.



Just like safety, quality must be everyone's responsibility, at all levels of operations.

The process described in this page, covers the End-to-end optimization of QC Labs Performance in terms of:

- Safety
- Quality of Data
- Lead Times
- Organization
- Equipment assessment & sustainability
- Costs

1.2. Definitions

- Quality Assurance (QA): The Quality Management System (QMS). Often linked to certification by external organizations like ISO, ASTM, etc...
- Quality of Operations: Standardized work increasing Right First Time (RFT) Operations
- Quality Control Laboratories (QC Lab): Any control / analytical test / mechanical test / application test made at line (*) or within the QC Lab in order to make a decision Pass or Fail (regarding Internal or Customer Specifications)

Other used acronyms:

- Ppk: Process performance. Essentially, it is a prediction of the ability of a process to meet a specification. See below actions related to different Ppk values:

| Indicator value | Interpretation | Action |
|-----------------|----------------|--------------------|
| < 0.67 | Not acceptable | 100% inspection |
| 0.67 - 1.00 | Not capable | Improve processes |
| 1.00 - 1.33 | Insufficient | More inspections |
| 1.33 - 1.67 | Acceptable | Maintain |
| > 1.67 | Too good | Reduce inspections |

- Gage R&R: Gage repeatability and reproducibility (GR&R) is defined as the process used to evaluate a gauging instrument's accuracy by ensuring its measurements are repeatable and reproducible.
- P/T: Performance / Tolerance:

P Performance 6 X Std Dev (from Gage R&R)

-- = ----- = -----

T Tolerance Tolerance Range

The outcomes are:

- P/T < 10% method OK, Improve Production
- 10% < P/T < 30%, test marginally acceptable
- P/T > 30%: Improve method's precision
- USL or upper specification limit and LSL or lower specification limit

1.3. Prerequisites

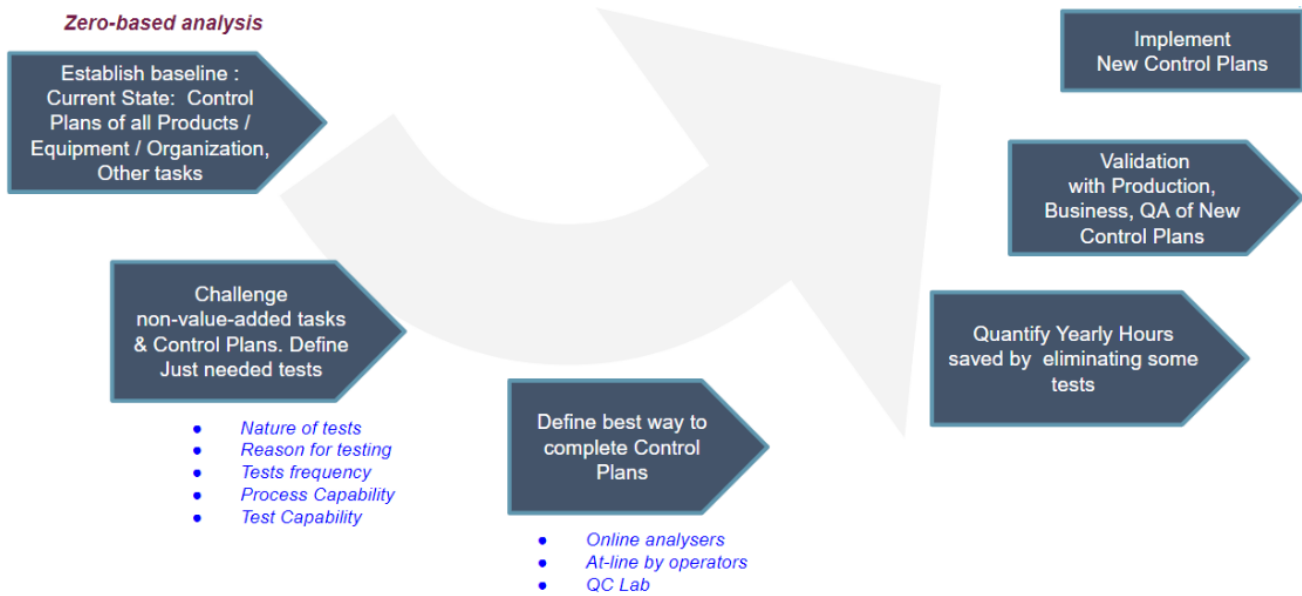
For a proper assessment of the QC Lab performance, the following documents must be prepared and collected:

1. List of all QC Lab tasks
2. Quality Team org chart
3. QC Lab equipment
4. Yearly QC Lab costs
5. List of Incoming Raw Materials tests
6. List of In-Process tests (Nature & Frequency)
7. Lists of tests made on Finished Products
8. List of environmental samples
9. Identification and challenge of Process Capability by sampling point (with focus when Ppk > 2 and when Ppk < 1) using a Pareto approach

2. How to set up the diagnostic

As quality is the responsibility of everyone in the organization, it is important that the GBU ME and site managers are aligned and define expectations for any diagnosis.

The overall process can be summarized in the following chart:



2.1. Challenge organization and non-value added tasks

A streamlined organization should be: 1 Manager and Lab Technicians. One should identify deviations from this: extra org layers, specialization vs. cross training, multiple locations, duplication of data entry, automatable manual work, subpar IT systems, etc. It should also be remembered to push for at-line analysis when possible, where Operators take responsibility for the test (faster turnaround and feedback loop).

To ensure you are doing the right thing, regular control plans of main Value Streams should be challenged on the following lines:

- Raw Materials analysis should be reduced when possible.
 - Instead, Supplier should be under control (QA task)
- In-Process analysis should be minimum
 - Instead, critical process parameters should be under SPC
- Lot Size of Finished products should be as large as possible
 - Review Ppk's. When Ppk are high, reduce tests frequencies

It is also important to assess the Quality Culture of the QC Lab team, but also of the site as a whole. This can be done through focus groups. Corporate resources and the QC Lab playbook can support to give typical questions for this goal to ask QC Labs manager, technicians but also Site Operators and Site Management.

2.2. Review Lab spend

A review of the QC Lab spend should be done with the Site Manager and the QC Lab Manager. The relevant KPIs to look at and benchmark are:

- % Tests carried out at-line (by Operators)
- % QC Lab Costs in Site Fixed Costs
- Average QC Costs / Site FTE

2.3. Identify the most resource-intensive tasks

Identifying the most resource intensive tasks in terms of staff, but also equipment (and eventually consumables or sample material used) are an important part of cost controls for the QC Lab. Identifying labor-intensive tasks will highlight the needs for automation, cross-training needs and process improvements. It can also show bottlenecks (in terms of staff and equipment) leading to improved lead times.

2.4. Map the competency matrices

In order to reduce costs in a QC lab but also to significantly boost the quality and reliability of QC Lab, it is recommended to have a transparent competency matrix that gives the lab the maximum flexibility.

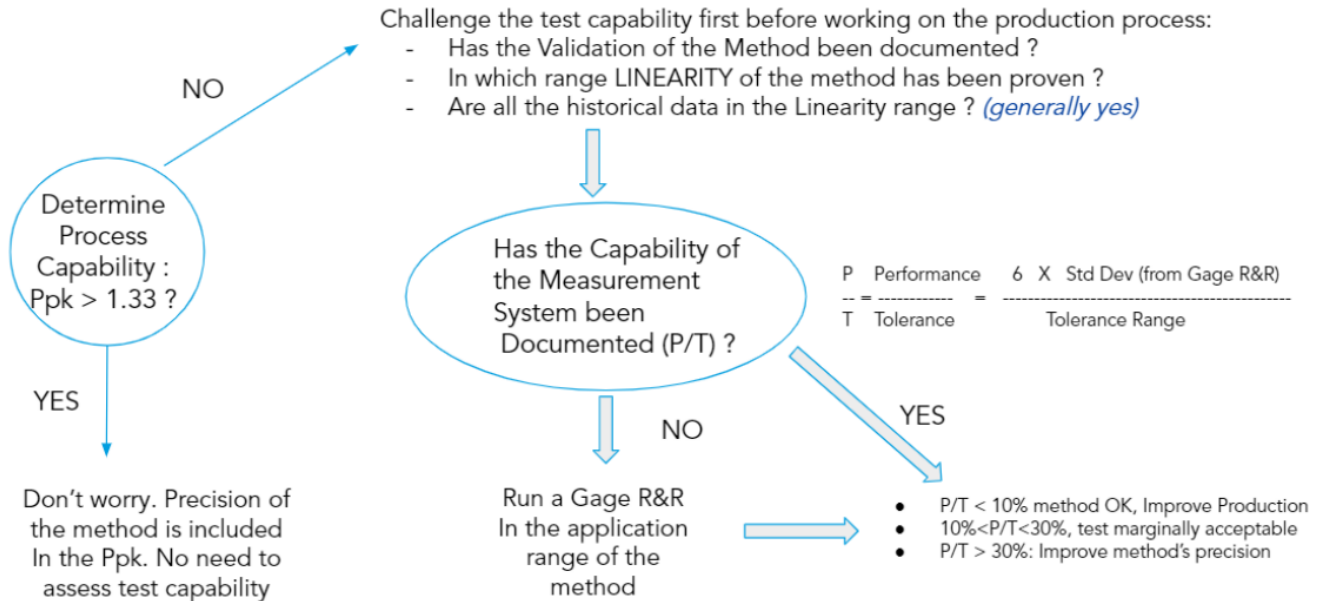
2.5. Assess the reliability and quality of data provided

Two aspects are important for the assessment of the reliability of the tests and data provided:

1. Identification of critical Product characteristics for which Process Capability as seen by Lab tests is low (Ppk lower than 1)
2. Identify QC Tests from which Imprecision can impact the perceived Capability of Production Processes

2.6. Assessing single test performance

The following flow chart shows the decision tree to evaluate the performance of a single test:



3. KPIs

The main KPIs for a QC Lab can be broken down into the three drivers of excellence:

1. Lead Time:
 - a. Average Lead Time on critical tests (time between sampling and communication of results)
 - b. Time in queue (average time spent for a sample waiting for a test to start)
2. Quality:
 - a. % Tests whose Capability to differentiate in-spec / off-spec has been proven (Measurement System Analysis (MSA) with Precision / Tolerance ratio < 30%)
3. Costs:
 - a. % Tests carried out at-line (by Operators)
 - b. % QC Lab Costs in Site Fixed Costs
 - c. Average QC Costs / QC FTE

Navigation tree

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