- The goal of any business is to deliver what a customer wants at an affordable cost.
- Ensuring that a process or service is delivered in specification requires robust process validation.

BACKGOUND

Process validation confirms whether the process effectively controls the quality of a final product. Misunderstanding between the product development team, quality, and operations can be disastrous when products are released to the commercial phase, causing substantial economic losses.

THE SITUATION

Flower Tea Co* is a tea co-packer company that serves the major branded coffee shops chains. Production and Quality Assurance were frustrated with the new processes because they did not adhere to the established standards at launch.
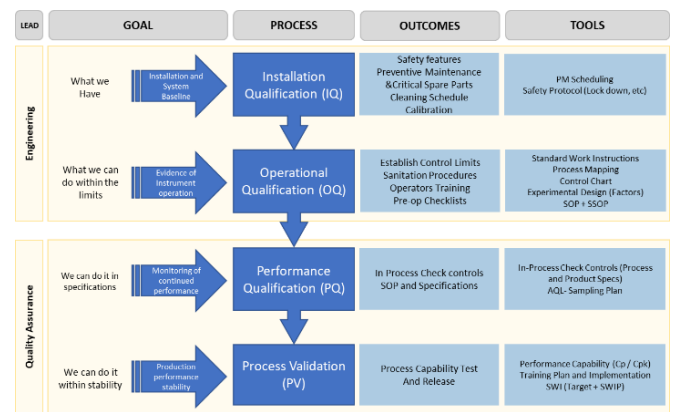

Tea packaging in constant struggle to perform.

THE SOLUTION

The Team proposed a Qualification and Validation Framework based on the pharmaceutical GMP system. The framework consisted of qualifying the equipment to fulfill the "Voice of the Customer" (VOC). Subsequently, a protocol was developed to include the standard operating procedures, work instructions and pre-operational checklists for equipment qualification.

Based on quality risk assessment and the process map, the critical process parameters (CPP) were identified to satisfy the Critical to Quality (CTQ) requirements.

This is what we were looking for to test the process performance with the product parameters. An assessment of the Process Validation protocol included a Process Capability test, as well as a product sampling plan to assess critical product characteristics. The In-Process Controls were the result of this application.

The Process Validation Framework.

We developed customized training for the stakeholders to align knowledge base and improve communication. We created protocols, process mapping directives, risk assessment frameworks, and process capability analysis templates to help the user with the tasks.

THE SUCCESS

During the following months, the out of specification product was reduced by 80%.

Time to deliver process / product to commercial scale was reduced from 16 weeks to 10 weeks with almost perfect process design.

* The company's identity has been disguised for the sake of privacy; however, the case study is genuine.