PEAQ Solutions Ltd
Reach new heights

Validation IQ, OQ, and PQ what are they, and Why Are They Required?

Validation processes there are a number of steps with an alphabet soup of acronyms identify common terms that you'll see in many guidance documents, and typically refer to equipment**. IQ stands for Installation Qualification. OQ is Operational Qualification and PQ is Performance Qualification**.

Before you even get to IQ, OQ, PQ, if you're acquiring a new piece of equipment, you'll need design specifications that define exactly what's in that piece of equipment. Everything from the type of power source it will utilize to the exact materials used in its construction.

Once you have your final/approved design specs, you order the equipment, it comes in and now you're developing your IQ and OQ. Quite often, the basis for the IQ and OQ will be the equipment manual itself. To save time and, prior to delivery, we'll ask the equipment manufacturer for the manual and we'll use the manual as the basis of our protocols.

Installation Qualification (IQ) evaluates means of accommodating new equipment and testing it meets requirements

For installation qualification, we'll first look at the equipment material. For example, if we specified 316 stainless, is it in fact 316 stainless steel. Sometimes finishes on welds and seals in stainless steel pipework and tanks can be substandard with residues from installation not correctly removed.

Check critical parameters to ensure it's adequate for installation you might have specified a 12Kw power motor in your equipment, for example which is critical to process. Confirm that the installation meets requirements in your specifications. The room that the equipment is installed in can accommodate the processes related to mixing and making product including temperature, ventilation and services. Review installation is adequate for cleaning, segregation, and handling requirements. PEAQ will ensure commissioning has been completed to requirements. Once completed review of the installation and everything is in order, you can trust that the equipment is going to operate the way in which it was designed.

Operational Qualification (OQ) is essential in challenging your equipment parameters

The next phase is OQ, operational qualification. At this stage, if you've specified that your equipment is going to run in a range of 50-150 RPM, physically verify that the equipment is achieving those operational requirements, and pumps will deliver the flow required to make process efficient. Review parameters and challenge them. Again, make sure your equipment actually runs the way it's supposed to run. We take a modular approach working through process from water to raw materials, mixing, filling bottles all the way to

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putting bottles in cases and palletising. This can all take place under tight control trials to identify any issues and before a product is put through the process and any risk of it going out to a consumer.

Performance Qualification (PQ) puts your equipment to the final test

In the PQ - performance qualification – phase, we like to challenge the equipment, much like in the OQ phase, but now under load making trial product at production scale and speeds. While it's great that it runs at 50 RPM or 150 RPM when it's empty, what happens when there's 300 kilos of material in it? Or if a line speed is set at 200 bpm what can be achieved with product? Can it achieve intended product parameters mix and efficiency to design or expectation? SOP's and Specs optimised and expectations fully explored and met. That's the essence and focus of the PQ phase. Once you've completed these three phases, the equipment is available for use in whatever process you intended for it.

What are benefits of Validation process

The IQ, OQ, PQ process is very important It will validate plant or process execution and establish its operating parameters and capability:

- It is a method of establishing documented evidence that shows that we have a high degree of assurance that our manufacturing process will consistently yield a product of predetermined quality.
- If a manufacturer fails to demonstrate capability, the results can be disastrous. It can cost hundreds of thousands of Pounds in out of spec products down time and lost production.
- Potential increase the risk of product recall and potentially contribute to a loss of market share.
- Demonstrate plant Capability to potential customers or for potential NPD.
- Controlling operation parameters and consequences for product ensuring that it account for change in our day to day operations.
- Many quality systems now require some evidence proof of performance and risk to product and compliance to standards.

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- Optimising Efficiency is key parts of validation and this will help optimise cost of goods and minimise waste.
- Validation process helps to reassure a customer that the change or new process will quickly and smoothly enable a new product or change to be integrated successfully. Quick to market process helps clients realise NPD process and set specs and establish what equipment they need and quickly and efficiently identify the process equipment requirements, install it, set it up, and get it ready to go.
- Allow for rapid integration into other systems and factory processes with detailed mapping of process to aid change management.
- Standard operating procedures SOP's and specifications are assessed as part of the PQ work and validated this will aid training and firm operation as intended.

The way PEAQ Solutions run the IQ, OQ, PQ process really facilities a manufacturer to adopt a new process or make a transition efficiently with minimum risks. We will as part of the process ensure best practices are followed and any limitation or risks flagged appropriately. The output will aid integration and efficiency in manufacturing.

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