JUDSON SMITH
An ATW Company

Buyer's Guide to Supplier Validation

What are the most important moves in ensuring that your supply chain is ready, willing, and able to help you with your validation package? Judson Smith's management team offers their guidance based on **over 50 years of medical device launches** to answer this question!

1 Common language

Strategies around IQ (Installation Qualification), OQ (Operational Qualification) and PQ (Performance Qualification) have evolved to meet the Code of Federal Regulations' requirements. While the CFR might be specific about what companies are expected to be able to provide around evidence of knowledge and control of a process, they are not as clear about how they want companies to go about doing it. That means that many companies might have different definitions and scope for their IQ/OQ/PQ strategies. Make sure you spend time with your supply base to understand what they mean about their validation lexicon. This should be clearly spelled out in their *Validation Master Plan*, or *Master Validation Plan* (see what we mean?), which you can find your initial quality audit.

Furthermore, there should be clear proposals from your suppliers about how they will fulfill your validation requirements. Take time to review these carefully, and iron out any differences in strategy early on.

2 Aligned measurement criteria and methods

What dimensions and characteristics are critical to quality (CTQ) or critical to function (CTF)? Often, initial drawings for devices or components are prepared by design engineers, not validation engineers, and have tolerances that are tagged as "critical" unnecessarily. Having too many CTQ's can slow your validation process down, adding months to your product launch. Take time with your engineering partners to understand the stack up of these characteristics, and validate the ones that truly matter.

Are you calling out the measurement method and criteria? Are you updating it during your capability studies as you go? Projects often slow down when gages are not aligned between supplier and buyer, or when methods differ even slightly. Worse, if your supplier's validation plans fail to call out these details, and your quality team misses it, product defects can arise after launch.

Make sure you are partnering with a team that has considerable experience in getting measurement method alignment early and often!

3 Clear approval pathways

Validation is a team effort. Determining the safest and most efficient way to ensure that product quality is built in, not designed in, takes expertise from both the buyer and the supplier. The buyer knows the product application and launch stack up, while the supplier knows his/her proprietary processes and how to control them. Finding a strategy that leverages both sets of knowledge is the key to a quick, successful validation.

One way to ensure the best practices are incorporated from both teams is to take time to spell out the protocol development and approval teams and their associated timelines. If all team members are clear who is writing the protocols, how comments can be incorporated quickly and efficiently, and when the product is due to launch, the team has a considerably better chance of hitting all goals for safety, cost, efficiency, and timing.

There is no "magic bullet" to creating a great validation team, but the process begins with an experienced team that is great at communicating. Ask your suppliers what their validation processes are, and make sure you're comfortable that validation is a core competency. If you have any questions,
please feel free to email us at **sales@judsonsmith.com**, and we'll get back to you.
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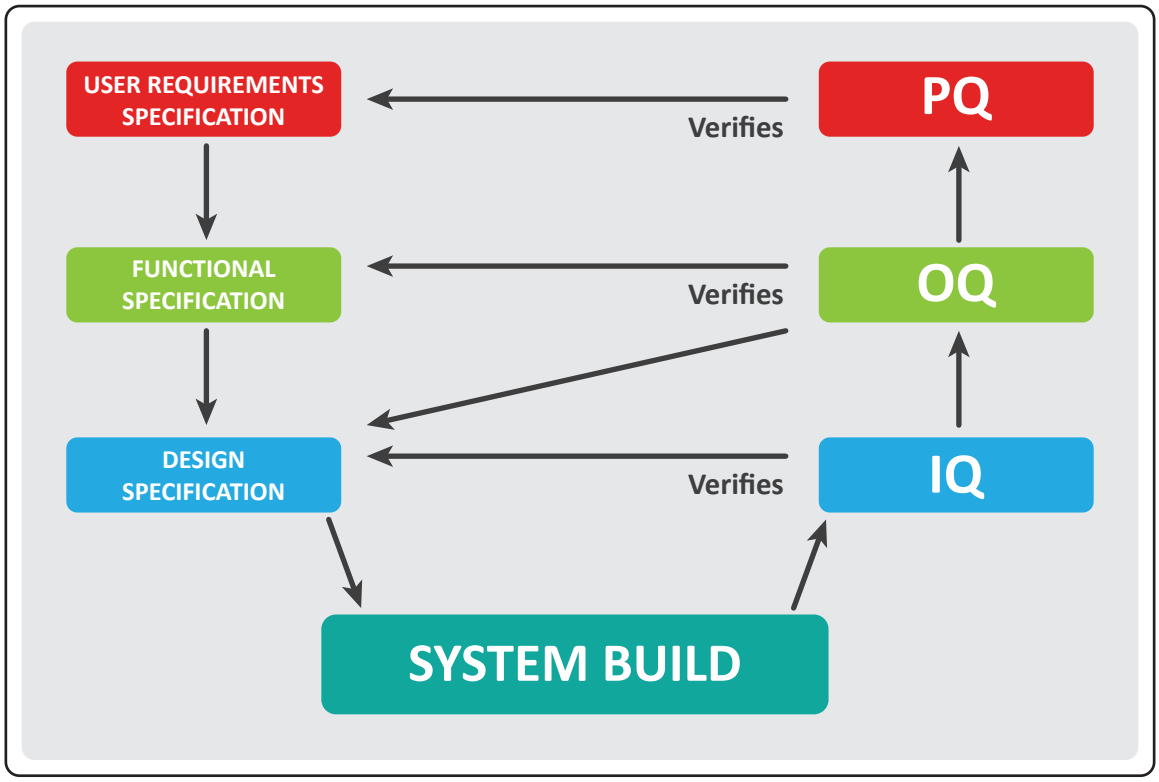

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