Prioritize process validation to mitigate manufacturing risks

By Raghu Vadlamudi
Chief Research and Technology Director

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With patient lives, clinicians' trust and their own businesses on the line, prudent medical device manufacturers do everything in their power to make sure their Class I, Class II and Class III products will perform as designed and intended in the field. Part of those efforts should entail process validation best practices. Without them, manufacturers could face significant product quality risks leading to:

- Harm or even death to patients
- Delays, recalls, penalties and fines
- Damaged or, in especially adverse events, ruined industry reputation

This article outlines key considerations and components for process validation due diligence.

Understand what needs to be validated

The goal of process validation is to ultimately prove that, under normal manufacturing conditions, a product can be consistently, accurately and compliantly produced to meet exact specifications at desired volumes. For each medical device, it's essential to carefully define the requirements upfront in the device development life cycle, which usually comprises multiple manufacturing processes, such as injection molding, heat sealing, welding, sterilization, etc. All these processes need to be validated for the device and any of its components. The final assembly process also needs to be validated.

Anticipate that process validation can take several weeks and up to several months, or even years, depending on the complexity of the device. Creating the validation approach early in the development process and evolving it in parallel with design and development is ideal to avoid late-stage surprises that force your program into an "execute, fail" loop. This approach also helps speed time to market.

For reference, the Global Harmonization Task Force (GHTF) SG3/N99-10:2004 – Quality Management Systems – Process Validation Guidance provides the entire spectrum of processes requiring validation in medical device manufacturing.

Put together a validation team and plan

For any medical device program, planning is the most important aspect. A program's success hinges on good, thorough plans and executing them well. Process validation is one critical piece in the overall program plan – and putting together a thorough plan often involves more than executing it. To be sure all perspectives are covered, planning teams for any device should ideally have representatives from all accountable functional areas of the organization, e.g., operations, quality, production, maintenance, sales, etc. At a minimum, though, the team should include engineering, manufacturing, quality assurance and regulatory representatives.

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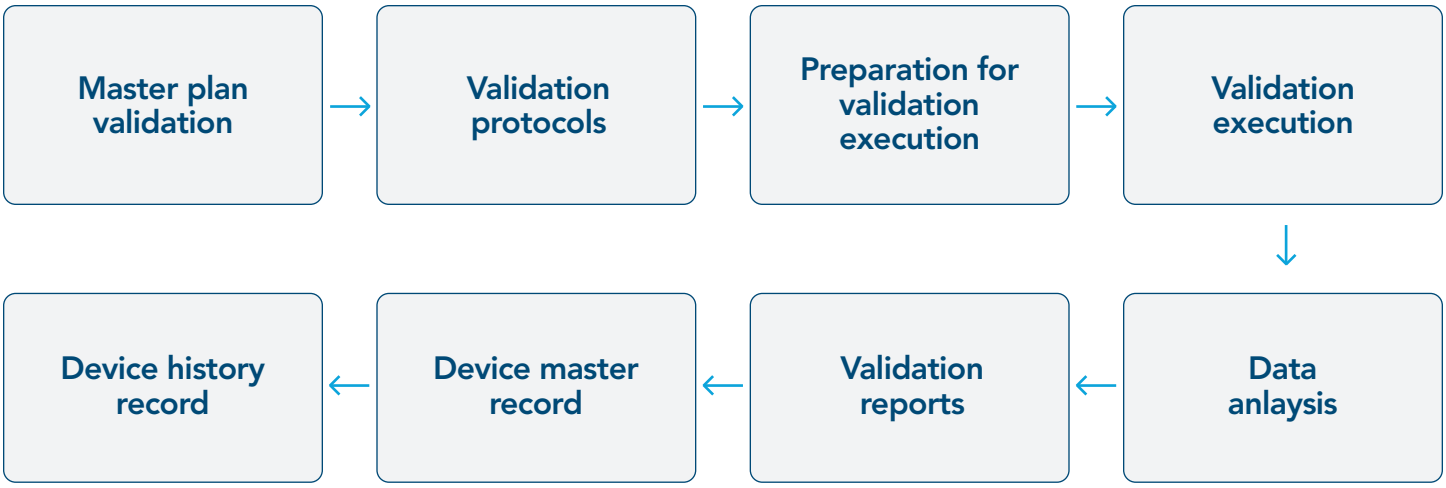
Together, this cross-functional team should develop a "master validation plan" to outline the validation strategy. Serving as a program roadmap for the validation team and reference document for management, such plans tend to include:

- Purpose and scope
- Responsibilities
- Reference documents
- Product and process specifications
- Process overview
- Validation approach
- Risk analysis
- Project timeline

Once the plan is developed, a typical flowchart looks like this:



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Factor in accountability

The medical device manufacturer is ultimately responsible for creating the process validation plan and managing each step from execution to document control.

If the medical device company plans to rely on a contract manufacturer for validation, the company should be sure the contract manufacturing team is adequately trained and has the appropriate resources to execute on the validation plan and produce accurate, repeatable products. A contract manufacturer should be able to show evidence of previously validated processes and knowledge-based methodologies. This evidence can be shown through many means, including through plant visits and its regulatory record history. For example, does the manufacture have any or many 483 notices from the FDA? If so, what has the contractor done to rectify the issues?.

Whether in-house or contracted, manufacturing team members should be thoroughly trained to understand engineering and manufacturing concepts, validation processes, standards and regulations, and have clear evidence they are competent in those activities. This can be achieved through a combination of specialized internal and external training to strengthen their knowledge and experience.

Beyond training personnel and having a plan in place, manufacturers should follow global standards and best practices for medical devices. This includes International Organization for Standardization (ISO) certification and FDA registration, both of which indicate the manufacturer meets and complies with industry regulations and quality standards.

Lastly, manufacturers should abide by and maintain Good Manufacturing Practices in creating Class I, II and III medical devices.

Stay committed

Knowing industry standards may evolve over time, it is important to stay abreast and ahead of any changes. The ISO standard 13485 offers guidance for process validation best practices. It is reviewed every five years. (Full details of ISO 13485 can be found in the ISO standards catalog.)

The FDA also offers guidance – Quality System Regulation (QSR) regulation 820.75 – which is very similar to ISO's standard, and in process of being harmonized to ISO's standard.

Process validation is a powerful tool to help attain highly effective processes. These processes help create high-quality devices that comply with standards, specifications and guidelines. When validation runs properly and input parameters are acceptable, the final product has the strongest chance of always being correct. Validation requirements must be understood and manufacturing processes for every aspect of the device should be selected that meet validation requirements, so the final specifications for each product are met.

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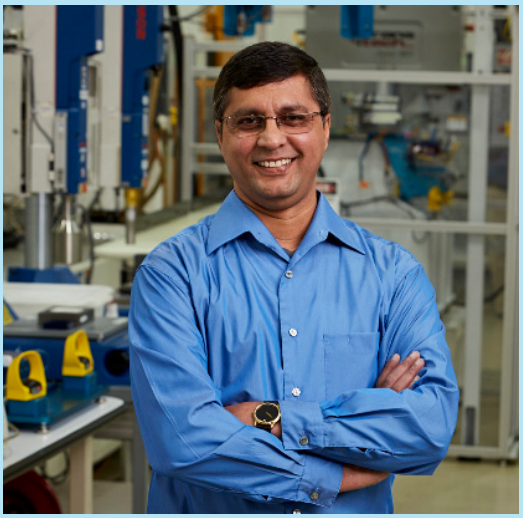

About the author

Raghu Vadlamudi is our Chief Research and Technology Director. He has more than 25 years of experience in the medical device manufacturing industry managing process development groups, directing and coordinating process validation activities utilizing knowledge-based manufacturing practices. Raghu is an ASQ certified Medical Device Auditor, Certified Metal Cutting Professional, Certified Medical Device Compliance Professional, and a Certified Process Validation Professional.

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