SAINT-GOBAIN MEDICAL

Process Validation

Medical molded components

Saint-Gobain offers comprehensive process validation services that cover the complete lifecycle, starting with process design and risk assessment, progressing through Installation Qualification (IQ) to verify equipment setup and operational functionality, Operational Qualification (OQ) to validate performance for critical parameters, and culminating in Performance Qualification (PQ) to confirm consistent and reliable production under real-world conditions.

Preliminary Assessment

- **URS-Driven:** A consultative approach focused on understanding your User Requirements to align design and execution from the start.
- **DFM Excellence:** With over 40 years of experience, our DFM process integrates CAD analysis, simulations, and prototyping to streamline manufacturing and reduce costs.
- **In-House Tooling:** We manage the entire tool lifecycle – from design to maintenance – ensuring consistent product quality for the life of your product.
- **Proactive Risk Management:** We perform early-stage risk assessments (FMEA, Risk Matrix) to identify and mitigate potential issues, reducing delays, costs, and compliance risks.
- **Meticulous Evaluation:** Using SPC and Non-Destructive Testing (NDT), we ensure component integrity and process control delivering reliable, data-driven quality assurance.
- **Process Assessment:** Using Process Mapping, PFMEA, SPC, and Lean/5S, we streamline operations for consistent quality and efficiency.

CUSTOMIZABLE

Our experienced engineering and quality teams collaborate closely with you, tailoring our extensive validation protocols to your specific needs.

COMPLIANT

Manufactured at our ISO 13485 certified site, we ensure compliance with 21 CFR 820 requirements for finished medical devices produced under contract.

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Qualification process flow

Installation/Operational Qualification (IOQ)

- **Mold Shakedown:** Optimizes mold performance, reducing start-up delays.
- **Design of Experiments:** Optimizes key settings, minimizing variability and improving control.
- **High/Low Limit Testing:** Defines process parameters, ensuring consistent product quality.
- **Gage R&R & MSA:** Ensures measurement precision, validating system specificity.
- **First Article Inspection:** Verifies initial parts, confirming design compliance.
- **CpK Analysis:** Assesses process capability, ensuring adherence to specifications.
- **Statistical Sampling (QMS-Tailored):** Aligned with your QMS & regulatory requirements.

Process Qualification (PQ)

- **Nominal Process Run(s):** Multiple runs recreate production, demonstrating stable output.
- **Additional Capability Analysis:** Ppk review confirms capability, ensuring robust processes. Ppk measures both process variability and centering, providing a more accurate prediction of long-term conformance.
- **Detailed Final Report:** Documents validation results, providing comprehensive evidence.
- **Rigorous Sampling:** In-process & final sampling, monitors quality throughout.

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