



<https://weiss-aug.com/job/advanced-product-quality-engineer/>

Advanced Product Quality Engineer

Description

The Advanced Product Quality Engineer position is responsible for validation on new customer programs, as well as ensuring compliance is applicable regulatory bodies and standards (ISO13485, 21 CFR 820, GMP).

Responsibilities

- Represent the customer in order to ensure that the customer's quality expectations are clearly understood and being met.
- Support Program Management team on launch and management of medical device programs.
- Advanced Product Quality Planning (APQP) including completion of related documentation, including but not limited to: DOE's, FMEA's, Process Flowcharts, Control Plans, Capability Studies and Gage R&R's.
- Ability to participate in product design (R&D) meetings with Medical Customers in relationship with understanding key quality deliverables.
- Oversee the development and input of initial BOM and detailed Routing
- Oversee the initiation and/or coordination of the change control process (ECO) relating to Engineering documentation.
- Responsible for SOP and Technical Writing for New Programs
- Responsible for Master Validation Reports, including writing and execution of IQ, OQ, PQ Protocols
- Must have practical knowledge of GMP, ISO13485, and/or 21 CFR 820 Compliance
- Ability to Understand Statistics as related to SPC, GR&R, MSA Studies
- Participate in customer, internal and registrar quality system audits.

Qualifications

- Minimum of 5 yrs. experience in product quality position, with direct experience in quality system compliance. Experience in medical device/life science (GxP) industry required.
- Requires a 4-yr engineering degree or substitute experience; graduate degree in engineering, technical or management discipline is preferred.
- Ability to read blueprints and other technical documents. Understanding of ANSI/ISO drawing standards and GD&T dimensioning required.
- Ability to use SolidWorks for product/tooling design preferable.
- Ability to uses Minitab preferred.
- Knowledge of quality inspection tools and methods required. Familiarity with Statistical Process Control (SPC) tools and methods also preferable.

Hiring organization

Weiss-Aug Group

Employment Type

Full-time

Job Location

148 Prominence Dr, 15068, New Kensington , PA

Date posted

November 8, 2022