WEISS-AUG GROUP
MANUFACTURE SMARTER

https://weiss-aug.com/job/ppap-validation-engineer/

PPAP/Validation Engineer

Hiring organization
Weiss-Aug Group

Employment Type
Full-time

Job Location
6 Daniel Road East, 07004, Fairfield, NJ

Date posted
May 25, 2022

Responsibilities

- Represent the customer 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.

Education

Requires a 4-yr engineering degree or substitute experience; a graduate degree in engineering, technical, or management discipline is preferred.

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.
- 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.
- Knowledge of GMP/ISO/21 CFR 820 Quality Systems required.
- Knowledge of TQM, Six Sigma or Lean Manufacturing principles preferable.
- Knowledge of progressive metal stamping and/or insert molding processes desirable.
- Strong technical writing skills.
- Proficient in Microsoft Word, Excel, and PowerPoint.
- Knowledge or MRP or ERP software preferable.
- Exceptional analytical and computational skills. Knowledge of problem-solving tools and techniques preferable.
- Excellent verbal and written communication skills.
- Demonstrated high level of creativity and innovation.

- Demonstrated decision-making capability