**Validation Engineer**

**Summary**

* Senior Validation Engineer with 7 years of experience in the medical device industry.
* Expert in developing validation plans, protocols, and reports for complex assembly and packaging processes.
* Extensive knowledge of GMP, ISO, and QSR regulations.
* Skilled in statistical data analysis, quality engineering support, and continuous improvement initiatives.

**Technical Skills:**

* Validation Protocol and Report Development
* GMP, ISO, QSR Compliance
* Statistical Analysis (Minitab)
* Test Method Validation (TMV)
* Equipment URS, FAT/SAT Review
* CAPA/NCR/SCAR Management
* Continuous Improvement
* Design for Six Sigma
* Quality Engineering
* ASQ Certification (preferred)
* Lead Auditor Certification (preferred)

**Experience:**

**Senior Validation Engineer  
DEF Medical Systems, Minnetonka, MN  
June 2022 – Present**

* Developed comprehensive validation plans, protocols, and reports for assembly and packaging processes.
* Established and managed validation standard operating procedures to meet regulatory requirements.
* Created and maintained validation protocol and report templates.
* Developed and executed test method validation (TMV) protocols for inspection methods.
* Provided quality engineering support for semi-manual and automated equipment.
* Reviewed equipment URS, FAT/SAT to ensure compliance with quality requirements.
* Supported the design transfer of manufacturing processes.
* Performed advanced statistical analysis of validation and production data.
* Led CAPA/NCR/SCAR investigations, documenting and resolving issues.

**Validation Engineer  
GHI Pharmaceuticals, St. Paul, MN  
June 2019 – May 2022**

* Managed validation activities for new and existing equipment.
* Conducted statistical analysis to support validation efforts.
* Developed and maintained validation documentation in compliance with GMP and ISO standards.
* Supported manufacturing process development and qualification.
* Led root cause analysis and implemented corrective actions for quality issues.
* Participated in internal and external audits.

**Validation Technician  
MedDevice Solutions, Minneapolis, MN  
June 2017 – May 2019**

* Assisted in the development and execution of validation protocols.
* Conducted validation activities and documented results.
* Supported quality assurance teams during audits and regulatory inspections.
* Prepared validation reports and summaries for management review.
* Collaborated with cross-functional teams to ensure compliance with regulatory standards.

**Education:**

* Bachelor of Science in Biomedical Engineering  
  University of Minnesota, Minneapolis, MN, 2017