**Summary:**

* Experienced in executing commissioning and qualification (C&Q) activities for automated systems including PLC-controlled equipment, BAS, BMS, and EMS across GMP manufacturing environments.
* Experienced in validating automation systems using Rockwell (Allen-Bradley) and Siemens PLC platforms, ensuring compliance with 21 CFR Part 11 and GAMP 5 guidelines.
* Experienced in developing and executing validation protocols (IQ, OQ, PQ) for critical equipment such as bioreactors, CIP skids, incubators, sterilizers, and process tanks integrated with automation controls.
* Experienced in conducting software validation for computerized systems, including PLCs, SCADA interfaces, and building management systems (BMS), ensuring adherence to FDA data integrity principles and ALCOA+ standards.
* Experienced in temperature mapping and environmental qualification using Kaye Validators, data loggers, and trending tools across cleanrooms, freezers, and controlled storage environments.
* Experienced in managing and executing automation validation deliverables including Factory Acceptance Testing (FAT), Site Acceptance Testing (SAT), Commissioning Test Plans (CTP), and Turnover Packages (TOP).
* Experienced in authoring validation documents such as Validation Master Plans (VMPs), risk assessments, requirement traceability matrices, and system design specifications (SDS) for automation projects.
* Experienced in collaborating with cross-functional teams to oversee Building Automation System (BAS) and Environmental Monitoring System (EMS) integration with utility systems (HVAC, cold rooms, clean steam, WFI).
* Experienced in the use and configuration of quality systems like TrackWise, LIMS, and electronic document management systems (EDMS) for controlled documentation and audit readiness.
* Experienced in supporting data integrity compliance through audit trail review, periodic system review, and validation of automated data capture systems in GMP-regulated environments.

**Experience:   
Amneal Pharmaceuticals, Bridgewater, NJ Mar 2023 – Feb 2025**

**Sr. Automation Engineer**

* Collaboratively conducted Risk Assessments, Impact Assessments, and established system boundaries for upstream and downstream equipment to identify potential risks and critical process parameters.
* Generated, reviewed, and edited Standard Operating Procedures (SOPs) and verified Engineering Test Procedures (ETPs) for process equipment such as 500L Bioreactors, Chromatography Skids, and Autoclaves.
* Experienced in authoring, executing, and finalizing IQ, OQ, and PQ protocols for automated systems controlled by Rockwell (Allen-Bradley) and Siemens PLCs, ensuring system functionality, alarm handling, and interlocks met design and regulatory expectations.
* Drafted and executed qualification protocols (IOQ, PQ) for cleaning validation of tanks, bioreactors, and isolators, including systems integrated with Building Automation Systems (BAS) and Environmental Monitoring Systems (EMS).
* Experienced in validation of facility and utility systems, including HVAC systems, Clean Steam Generators, and Water for Injection (WFI) loops, ensuring full BAS/EMS integration and compliance with GMP environmental controls.
* Generated and managed System Impact Assessments (SIA), User Requirement Specifications (URS), Risk Traceability Matrices (RTM), Design Qualifications (DQ), and FAT wrappers using KNEAT Gx for streamlined validation lifecycle documentation.
* Supported FAT/SAT execution for PLC-based systems, including Controlled Temperature Units and Sterilization Units, verifying system readiness and control functionality in alignment with URS and 21 CFR Part 11 requirements.
* Provided support for SCADA-controlled utilities and critical systems by reviewing automation logic, participating in IO testing, and supporting automated data capture validation to ensure data integrity (ALCOA+ compliance).
* Performed thermal mapping of autoclaves and cold storage chambers using Kaye Validators and temperature data loggers, validating critical temperature zones and system alarms.
* Collaborated with Engineering, QA, and Manufacturing teams to troubleshoot automation-related deviations, resolve alarms, and qualify systems with integrated BMS/BAS functions for cleanroom pressure, differential monitoring, and alarm control.

**M.C. Dean, Inc, Tysons, VA Nov 2021 – Mar 2023**

**Automation Engineer**

* Designed and executed IOQ test procedures for automated systems, including single-use bioreactors, mixers, and controlled environment modules, with control logic validation using Allen Bradley PLCs.
* Responsible for the development and execution of CQV documentation (URS, RA, FAT, SAT, IQ, OQ, PQ) across equipment, utilities, and facilities using Good Documentation Practices (GDPs) in accordance with 21 CFR Part 11 and GAMP 5.
* Coordinated mechanical and software changes on clean utility systems, including WFI, clean steam, reverse osmosis, and compressed air, integrated with Rockwell Automation and SCADA platforms for process control.
* Supported validation of facility monitoring systems such as BAS (Building Automation System) and EMS (Environmental Monitoring System), ensuring compliance with alarm logic, sensor accuracy, and audit trail capture.
* Developed and reviewed automation-focused validation documentation for systems including HVAC, spectrophotometers, autoclaves, and lyophilizers, ensuring consistent control system operation and data integrity.
* Executed qualification and validation protocols for equipment like freezers, fermenters, and roller mixers, ensuring compliance with FDA, cGMP, and Annex 11 guidelines for electronic records and signatures.
* Demonstrated experience in PLC, HMI, and SCADA programming, as well as testing of motion control and alarm response sequences across automated CIP/SIP skids, tanks, and environmental chambers.
* Performed risk-based qualification and troubleshooting for BMS-controlled HVAC units, addressing system interlocks, PID loops, and sensor alarms for temperature, pressure, and differential monitoring.
* Maintained validated state of automated systems by managing requalification schedules, calibration activities, and control logic updates; oversaw automation change control, including revalidation and documentation impact assessments.
* Developed SOPs, Data Integrity Assessments, Alarm Assessments, and ERES evaluations for automated systems, ensuring systems met integrity requirements aligned with ALCOA+ principles and audit readiness.
* Conducted WFI loop sanitization procedures and cleaning validation on shared equipment to prevent cross-contamination, supporting quality assurance in cleanroom classified areas.
* Authored and executed commissioning protocols and test scripts using a risk-based approach for utilities and automation infrastructure, including site prep for controlled environment zones and cleanroom support systems.
* Planned and tracked CQV timelines for internal and external teams, supporting cross-functional collaboration between Engineering, QA, Manufacturing, and Automation teams to meet project milestones.
* Executed FAT/SAT for PLC-driven utility systems (e.g., clean steam generator, WFI distribution skid) and ensured integration with centralized SCADA systems for remote monitoring and control.
* Supported deviation investigations and CAPA activities related to automated control system

failures, including communication loss between field I/O devices and central controllers (e.g., Siemens S7 series).

**Howse Corporation, North Reading, MA Jun 2019 – Nov 2021**

**Automation Engineer**

* Documented Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) protocols for automated systems and process equipment, collaborating with internal teams and third-party implementers to ensure regulatory compliance.
* Led automation validation efforts for cGMP manufacturing facilities, ensuring that control systems, including PLC, SCADA, and BMS, met qualification requirements for clean utilities, temperature-controlled chambers, and critical process equipment.
* Developed, executed, and maintained validation documentation for automated process equipment such as bioreactors, autoclaves, water for injection (WFI) systems, clean steam systems, HVAC, compressor systems, and laboratory equipment, ensuring full compliance with cGMP and FDA regulations.
* Managed Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT) for automation systems, including PLC-driven equipment and control system integration, verifying that equipment met performance and safety standards before installation.
* Developed User Requirement Specifications (URS), Risk Assessments (RA), and Functional Requirement Documents (FRD) for automation and control systems, following GAMP 5 guidelines for equipment and system qualification.
* Authored and executed Validation Master Plans (VMP) and validation protocols (IQ, OQ, PQ) for automated equipment and systems such as bioreactors, fermenters, freezers, incubators, CIP/SIP skids, and temperature-controlled chambers.
* Executed automated control system testing, including PLC programming validation (Allen Bradley, Siemens), SCADA integration, and BMS alarm management, ensuring all systems were compliant with operational and regulatory requirements.
* Performed risk assessments and developed Risk Traceability Matrices (RTM) for automated systems, including PLC/HMI integration, ensuring all critical process parameters were identified, monitored, and maintained.
* Coordinated cross-functional teams to write, review, and approve change control documents, including automated system updates and revisions, maintaining documentation integrity throughout the project lifecycle.
* Led training sessions and developed training documentation for SOPs related to automated systems and control processes, ensuring staff were trained on automation protocols and compliance requirements.
* Managed validation documentation for temperature-controlled systems, autoclaves, and lyophilizers, ensuring compliance with temperature mapping, cycle verification, and data integrity standards.
* Participated in the creation of SOPs for equipment commissioning, qualification, and automation validation, ensuring that all procedures were in line with 21 CFR Part 11, GxP, and ALCOA+ guidelines.
* Led the execution and documentation of IQ/OQ/PQ protocols for process systems, documenting results and ensuring compliance with cGMP and FDA regulations, while maintaining the validated state of automated systems.
* Supported change control activities, tracking and reviewing validation deliverables, ensuring compliance with regulatory requirements for automated manufacturing systems.
* Performed Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT) for automation systems such as water for injection systems, compressed air systems, and BMS/SCADA systems, verifying system performance before installation at the site.
* Collaborated with internal and external teams to ensure timely validation execution, focusing on maintaining high-quality and compliant automation systems to meet project timelines.

**Education:** Northeastern University – Boston, MA.