PRASANTHA PUJARI, M.S., CSSGB

Senior Validation Engineer & Pharmaceutical Systems Researcher

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PROFESSIONAL PROFILE & FELLOWSHIP QUALIFICATIONS

Certified Six Sigma Green Belt (CSSGB) and Industrial Engineering professional with extensive expertise in pharmaceutical equipment, utility, and Computerized System Validation (CSV) within cGMP-regulated environments. Recognized subject-matter expert in thermodynamic mapping, risk-based qualification frameworks, and regulatory inspection readiness. Demonstrates sustained technical leadership through leading cross-functional audit teams (FDA, ANVISA), engineering process innovations, and peer-reviewed scientific publications advancing modern Quality Management Systems (QMS) and sterilization assurance in the biopharmaceutical industry.

SCHOLARLY BOOKS & PEER-REVIEWED PUBLICATIONS

Demonstrating independent contributions to high-quality engineering research, corrective action frameworks, and sterilization cycle design:

- *Pujari, P. (2026). Engineering Framework for Risk-Based Autoclave Steam Sterilization Cycle Design: A GMP Validation Methodology for Complex Mixed Loads in ADC Biopharmaceutical Manufacturing. Comprehensive Engineering Monograph*. URL: https://a.co/d/09J4va6V

  Impact: Authored a specialized engineering reference establishing an industry-standard methodology for risk-based steam sterilization validation and thermodynamic mapping for complex Antibody-Drug Conjugate (ADC) biopharmaceutical manufacturing loads.

- *Pujari, P. (2026). Modern Strategies for Managing Deviations and Corrective and Preventive Actions in the Pharmaceutical Quality System*. Universal Library of Engineering and Technology (ULETE), Vol. 03, Issue 01, pp. 1–10. DOI: 10.70315/uloap.ulete.2026.0301014.

  Impact: Established advanced methodologies for managing CAPAs and deviation handling within cGMP quality systems.

- *Pujari, P. (2026). Risk-Based Autoclave Steam Sterilization Cycle Design and Validation for Mixed Biopharmaceutical Loads: Thermodynamic Mapping Integrated with FMEA*. International Journal of Advanced Engineering, Management and Science (IJAEMS), Vol. 12, Issue 2 (Mar-Apr 2026). DOI: 10.22161/ijaems.122.11.

Impact: Integrated thermodynamic mapping with Failure Mode and Effects Analysis (FMEA) to optimize steam sterilization cycles for complex biopharmaceutical loads.

CORE AREAS OF EXPERTISE & TECHNICAL INNOVATION

- Engineering & Equipment Qualification: Risk-Based Autoclaves, CTUs (Incubators, Freezers/Refrigerators, Depyrogenation Ovens), and manufacturing equipment lifecycle validation (IQ, OQ, PQ).
- Utility Systems & Aseptic Processes: Water for Injection (WFI), Clean Steam, Nitrogen, Oxygen, CO2, Compressed Gases, steam quality testing, cleanroom smoke studies, and aseptic sampling.
- Computerized System Validation (CSV) & Data Integrity: 21 CFR Part 11 compliance, GAMP 5 principles, HPLC Empower Waters systems, ALM QC test script management, and analytical lab instrumentation.
- Quality Management & Regulatory Defense: FDA and ANVISA audit management, Pre-Approval Inspection (PAI) leadership, CAPA resolution, Root Cause Analysis, and Lean Facility Design.

PROFESSIONAL EXPERIENCE & TECHNICAL LEADERSHIP

PFIZER INC., Validation Engineer II

(May 2023 – Present / Dec 2024 – Present)

— Regulatory Leadership & Audit Defense: Served as Validation Request Manager supporting critical U.S. FDA and ANVISA regulatory audits, ensuring inspection readiness and rapid compliance resolutions.

— Innovation in Facility Design: Developed dual-use equipment protocols to support lean facility design and optimized manufacturing operations.

— Critical Utilities & Thermal Validation: Led validation activities for WFI, Clean Steam, Nitrogen, Oxygen, and CO2 systems, alongside executing steam quality testing and cleanroom smoke studies. Created and executed risk-based IOPQ protocols for Incubators, Freezers/Refrigerators, and Drying Ovens using Kaye Validator thermal mapping systems.

— Computerized Systems & Documentation: Managed Empower test scripts and CSV protocols within ALM QC. Developed end-to-end validation packages including Validation Plans, GMP/Risk Assessments, Requirements/Design/Functional Specifications, Traceability Matrices, and SOPs in compliance with Good Documentation Practices (GDP).

SEAGEN, Validation Engineer II / Validation Lead

(Feb 2022 – May 2023 / Dec 2024)

— PAI Leadership: Led the REF Pre-Approval Inspection (PAI) Support Team, providing strategic alignment across Validation, Quality Assurance (QA), Manufacturing, and Regulatory groups to drive inspection readiness.

— Risk-Based Qualification: Directed risk-based IQ/OQ/PQ validation for GMP equipment (Refrigerators, Incubators, Freezers). Oversaw temperature mapping studies utilizing Vaisala thermistors and Ellab data loggers, producing audit-ready qualification reports.

— Cross-Functional Collaboration: Served as primary validation representative in site-wide forums with QC, QA, Materials Management, and Supply Chain. Facilitated critical smoke study qualifications for the Cell Culture Manufacturing Area (CCMA).

— Quality Governance: Authored, executed, and approved change controls, CAPAs, gap analyses, validation protocols, and exception reports, aiding in the closure of notified body inspection commitments.

PASSAGE BIO, Validation Engineer II

(Oct 2021 – Jan 2022)

— CSV & Data Integrity Leadership: Spearheaded the Computer System Validation (CSV) Risk Assessment for the implementation of the HPLC Empower Waters system, guaranteeing adherence to 21 CFR Part 11 electronic record regulations across GxP operations.

— Laboratory Systems Integration: Authored and executed IQ/OQ/PQ protocols for diverse analytical instruments including Capillary Electrophoresis, CADs, HPLCs, Liquid/Airborne Particle Counters, and Microplate Readers.

— Traceability & Governance: Conducted GxP/21 CFR Part 11 risk analyses and maintained full Requirements Traceability Matrices (RTM) from URS to final reporting.

TAKEDA PHARMACEUTICALS, Validation Engineer

(Jun 2021 – Oct 2021)

— Sterilization & Thermal Cycle Development: Led the qualification of Controlled Temperature Units (CTUs) and autoclaves. Developed innovative sterilization cycles for new load patterns and executed OQ/PQ protocols for Autoclaves and Depyrogenation Ovens.

— Utility Qualification: Generated and executed IQ/OQ/PQ protocols and final reports for WFI, Clean Steam, and Compressed Gas systems. Performed aseptic water sampling and clean steam/gas sampling utilizing specialized qualification equipment.

— Requirements Engineering: Collaborated across QA, Engineering, and IT to author User/Functional Requirement Specifications (URS/FRS) and Validation Master Plans (VMP).

EDUCATION & PROFESSIONAL CREDENTIALS

- ***Master of Science (M.S.) in Industrial Engineering***, Wichita State University,
- ***Bachelor of Engineering (B.E. / B.S.) in Mechanical Engineering***, University of Mumbai, India
- ***Six Sigma Green Belt*** (CSSGB) | Professional Certification in Foundation of Six Sigma & Quality Improvement
- Professional Memberships: American Society for Quality (ASQ)