Manish Baviskar

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PROFESSIONAL SUMMARY

Experienced Pharmaceutical Validation Engineer with a strong background in FDA-regulated pharmaceutical manufacturing, computerized system validation, and capital project execution. Proven expertise in equipment, utility, process, and software validation (IQ/OQ/PQ/PPQ), regulatory compliance, and risk-based validation programs aligned with FDA, ISO, cGMP, GAMP 5, and ALCOA++ standards. Demonstrated leadership in qualifying multiple manufacturing lines, leading cross-functional technical teams, and representing validation functions during regulatory inspections and audits. Strong record of supporting sterile and non-sterile operations, automated and AI-enabled systems, and end-to-end validation lifecycles across product development and commercial manufacturing environments.

PROFESSIONAL EXPERIENCE

Hubot CDMO/Tri-Pac, Inc – South Bend, IN

Validation Engineer | **February 26, 2024 – Present** | Supervisor: Nirali Patel

- lead end-to-end capital projects, ensuring on-time delivery, cost efficiency, and compliance with GMP, OSHA, ISO 13485, and ISO 9001 standards.
- Quantified and validated 9 manufacturing lines for aerosol, liquid, and powder filling operations in alignment with cGMP and ALCOA++ principles.
- Process, Equipment, utility, process, Software and computerized system validation (IQ/OQ/PQ/PPQ) in FDA-regulated pharmaceutical environments, Develop and execute IQ, OQ, PQ protocols; generate validation summary reports.
- Developed and implemented a risk-based Validation Program integrated with FMEA, improving equipment reliability and reducing downtime (e.g. AI-enabled automated systems, computer system and software's.)
- Represented the validation department during FDA, ISO, and client audits; conducted gap analyses and updated SOPs, protocols, and FMEAs to meet current regulatory expectations.
- Conduct biweekly technical team meetings to monitor project updates and execution Provide status updates, perform gap analysis, FMEA, and ensure validation is ALCOA++ and cGMP compliant.
- Represent the Validation Department during regulatory inspections and audits (FDA, ISO, and customer), and serve as the primary Hubot CDMO point of contact with the U.S. Environmental Protection Agency (EPA) and the City of South Bend for pharmaceutical wastewater and environmental compliance management.

Gill's Process Control, Inc – Rocky Mount, NC

Validation Specialist | **July 26, 2022 – December 29, 2023**, | Supervisor: Joey Parris

- Led validation and commissioning of pharmaceutical and utility modification projects in compliance with FDA regulations, 21 CFR Part 11, and ISPE GAMP 5 guidelines.
- Developed complete validation lifecycle documentation including URS, FRS, DDS, SDS, and IQ/OQ/PQ protocols for GxP-compliant automated and manual systems.
- Performed Factory and Site Acceptance Testing (FAT/SAT), managed protocol execution, test scripting, data collection, and summary report generation for critical GMP systems.
- Collaborated with clients to lead validation assessments for proposed changes, performed risk-based evaluations, and ensured alignment with Good Automated Manufacturing Practice (GAMP).

- Supported installation and qualification of pharmaceutical manufacturing systems such as sterilizers, isolators, HVAC systems, fillers, utility systems, and associated HMI interfaces.
- Delivered technical writing and document control support, ensuring accuracy and compliance of validation documents in alignment with SOPs and regulatory standards.
- Acted as Subject Matter Expert (SME) for C&Q and CSV documentation hierarchy, offering guidance across validation planning and change control processes.

E-CQR, Inc – Austin, TX

Validation Engineer | **April 11, 2022 – July 15, 2022,** | Supervisor: Ravi Kumar

- Provided validation engineering supporting both onsite and remotely—for pharmaceutical manufacturing systems, ensuring timely execution and documentation of validation activities in compliance with cGMP, FDA 21 CFR Part 11, and ICH Q7/Q8 requirements.
- Assisted in the development, execution, and review of validation protocols (IQ/OQ/PQ) and final reports for critical GMP equipment, lab instruments, and computerized systems, maintaining traceability throughout the validation lifecycle.
- Reviewed and edited technical documentation, including validation Protocol, FAT/SAT summary reports, SOPs, and change controls, ensuring alignment with internal quality standards and client regulatory expectations.

Carnegie Pharmaceuticals, LLC – Delran, NJ

Quality Control Analyst (Analytical Chemist) | **March 3, 2021 – April 8, 2022,** | Supervisor: Keval K Prasad

- Performed routine and non-routine analytical testing on raw materials, in-process samples, and finished products using HPLC, GC, FTIR, UV-Vis, and wet chemistry techniques to ensure compliance with internal specifications and regulatory standards.
- Supported the execution of stability studies and method validation/verification for three generic drug products during development and scale-up. Prepared validation protocols and summarized data to support method lifecycle documentation.
- Supported new product development (NPD) and manufacturing operations by drafting, reviewing, and maintaining technical documentation including Product Evaluation Reports (PERs), Evaluation Batch Reports, Validation Protocols, and Preventive Maintenance (PM) documentation.
- Acted as a liaison between Quality Assurance, R&D, and Production departments to ensure accurate and timely communication of product performance and compliance metrics.

Quality CDMO – Fort Worth, TX

QA/QC Associate | **January 4, 2021 – February 28, 2021** | Supervisor: Poonam Jasani & Mayuriben Patel

- Supported the initial establishment and operational startup of the Quality Control and Production departments in a newly launched CDMO facility, ensuring systems and processes aligned with FDA and ISO regulatory standards.
- Played a key role in equipment onboarding, installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) of critical laboratory and manufacturing equipment, including HPLC, GC, purified water systems, and production utilities.

AmSpec, LLC – Pasadena, TX

Lab Technician | **May 20, 2019 – December 30, 2020** | Supervisor: Brett Downs

- Conducted testing of petroleum products, petrochemicals, and refinery intermediates in accordance with ASTM, UOP, and EPA standardized methods, including flash point, viscosity, density, distillation, sulfur content, RVP, and water content.

- Performed daily sample preparation activities, including homogenization, dilution, and filtration for both bulk and trace component analysis.
- Operated, calibrated, and maintained analytical instruments including Gas Chromatography (GC), Density Meter, Flash Point Tester (Pensky-Martens & Abel), Viscosity Baths, Auto-Titrators, and Distillation Units.
- Reviewed and cross-checked test data for accuracy and integrity prior to final reporting; flagged discrepancies and initiated corrective actions when necessary.
- Actively contributed to continuous improvement efforts by identifying inefficiencies in workflow and suggesting enhancements to streamline sample throughput and reporting timelines.

AmerisourceBergen – Sugar Land, TX

Quality Control Investigator | **April 22, 2019 – May 19, 2019** | Supervisor: Kelvin Kulesza

- Investigated product quality complaints, manufacturing deviations, and laboratory discrepancies in compliance with cGMP and FDA regulations.
- Executed root cause analyses using tools such as 5 Whys, Fishbone Diagrams, and Ishikawa methods to identify sources of process failures or non-conformities.
- Supported data review for batch release by evaluating batch records, test reports, and equipment logs.

A & B Environmental Services, Inc – Houston, TX

Analytical Chemist | **March 18, 2019 – May 14, 2019** | Supervisor: Janardhan Dongre

- Maintained strict adherence to EPA Method guidelines (e.g., EPA 6010, 6020, 8260, 8270) for sample collection, preparation, and testing.
- Operated and calibrated analytical instrumentation performed preventative maintenance, and documented performance checks to ensure data reliability and accuracy.
- Interpreted chromatograms and spectral data, ensuring compliance with project-specific reporting limits and regulatory criteria.

Woodfield Pharmaceutical, LLC – Houston, TX

Quality Control Analytical Chemist | **October 1, 2018 – February 13, 2019** | Supervisor: Orlando Arroyo

- Managed Notice of Events (NOEs) and initiated quality investigations for laboratory deviations, equipment malfunctions, and procedural non-compliance in alignment with cGMP and internal SOPs.
- Authored and implemented Corrective and Preventive Actions (CAPAs) to address recurring issues, improve laboratory practices, and enhance product quality assurance processes.
- Coordinated Customer Complaint Investigations, including batch history review, retention sample analysis, and trend evaluation to determine complaint validity and root cause.
- Collaborated with Quality Assurance, Production, and Regulatory teams to ensure timely closure of complaints and deviations while maintaining regulatory compliance with FDA and ICH Q10 expectations.
- Participated in internal audits and supported regulatory inspections by providing investigation histories, complaint logs, and associated documentation.

EDUCATION

Master of Science (M.S.) – Chemistry, Lamar University, Beaumont, TX (2015 – 2018)

Master of Science (M.S.) – Microbiology, North Maharashtra University, India (2007 – 2009)

Bachelor of Science (B.Sc.) – Microbiology, North Maharashtra University, India (2004 – 2007)

Diploma in Business Management, North Maharashtra University, India (2009)

Diploma in Bioinformatics, North Maharashtra University, India (2008)

TRAINING & CERTIFICATIONS

- **Machine Learning: Modern Computer Vision & Generative AI,** Udemy | Issued Jan 2025
- **Generative AI Overview for Project Managers,** Project Management Institute | Issued Oct 2024
- **Good Documentation Practice and Data Integrity-ALCOA,** Velocity 360 Training | Issued Jun 2024, Credential ID: 104152794
- **Pharmaceutical - CGMP and ISO 13485 Lead Auditor,** Velocity 360 Training | Issued Jun 2024, Credential ID: 106717860

RESEARCH EXPERIENCE

Graduate Research Assistant | Lamar University – Beaumont-Port Arthur Area | Part-time, **January 2016 – May 2018** | Supervisor: Nguyen, T.T.M

- **May 2018 – Master's Thesis, Lamar University**, completed his M.S. thesis titled *"Microbial Analysis and Isolation of Iron-Reducing Bacteria from the Marquez Impact Crater, Texas, USA,"* forming the basis for subsequent peer-reviewed research.
- **June 2017 – Invited Participant, NASA Proposal Writing Retreat**, selected for the NASA-supported Proposal Writing Retreat (June 2–5, 2017), reflecting competitive selection and advanced research standing in federal grant development.
- **October 2017 – Peer-Reviewed Conference Publication (TMS 2017,** co-authored *"Potential of Magnetotactic Bacteria for the Fabrication of Iron Nanoparticles"* (TMS 2017 – 146th Annual Meeting & Exhibition Supplemental Proceedings). The publication has received citations, demonstrating scholarly impact.

PUBLICATION AND RESEARCH

- **2025 – Peer-Reviewed Journal Publication,** *"Risk-Based Validation of Software, Automation and Artificial Intelligence in Pharmaceuticals,"* published in **Biosciences Biotechnology Research Asia**, Vol. 22(4), contributing to GxP-compliant AI validation frameworks.
- **2017 – Peer-Reviewed Conference Publication (TMS 2017),** *"Potential of Magnetotactic Bacteria for the Fabrication of Iron Nanoparticles"* (TMS 2017 – 146th Annual Meeting & Exhibition Supplemental Proceedings). The publication has received citations, demonstrating scholarly impact.
- Polyherbal Loaded Nano Emulsion Gel Intended for Topical Route: Design, Development, and Evaluation for Psoriasis Treatment, Co-author. Submitted to *Scientific Reports* (Springer Nature), December 2025. Submission ID: c70057ee-9b4d-4b79-82f6-46b32e26023b Under Review / Submitted
- Development and Optimization of Polyglutamic Acid Enriched Lip Balm Using Experimental Design Approach Co-author. Submitted to *Asian Journal of Pharmaceutics*, December 2025. Under Review / Submitted

PATENTS & INTELLECTUAL PROPERTY

- **AI-Powered Microbial Sampling and Profiling Device** | Indian Patent No. 211,722 |2025
- **Livestock Stress Monitoring Device with Relief System**| Indian Patent No. 217,488 | Granted (2025)
- **AI-Based Dermatoscope** | Design No. 471890-001 | | Granted (2025)
- **Bio-Fingerprinting and Auto-Formulation Device (BioFormID™)|** Application No. 482881-001|In process
- **Multi-Parameter Analytical Scanner (QualiScan™)|** Application No. 482882-001 |In process
- **Real-Time Medicine Verification Tool**| Design No. 470813-001 |In process
- **AI-Controlled Intravenous Fluid Infusion Device**| Design No. 470816-001 |In process

HONORS & AWARDS

- **September 2025 – Invited Guest Speaker, MET Institute of Pharmacy, Nashik,** delivered an invited lecture on *"Integration of AI in Pharmaceuticals,"* reflecting international academic recognition.
- **November 2025 – Editorial Manager & Peer Reviewer, Journal of Strategy & Innovation** (ISSN: 3050-7901) Ongoing editorial and manuscript evaluation responsibilities.
- **September 2025 – Peer Reviewer, Pharmacotherapy (ISSN: 1875-9114)**, Formal editorial service contributing to scholarly quality control in pharmaceutical sciences.
- **June 2018 – NASA Astrobiology Graduate Conference (AbGradCon) Presentation**, presented *"Geochemical and Geophysical Gradients from a Meteoroid Impact Result in a Unique Pattern of Microbial Distribution"* at AbGradCon, Georgia Institute of Technology, aligning with NASA astrobiology priorities.
- **June 2017 – Invited Participant, NASA Proposal Writing Retreat**, selected for the NASA-supported Proposal Writing Retreat (June 2–5, 2017), reflecting competitive selection and advanced research standing in federal grant development.
- **October 2017 – Third Place, Graduate Division, Research Poster Competition**, received **3rd Place** at the 7th Annual Departmental Student Research Poster Competition, Lamar University, demonstrating sustained research productivity.
- **September 2016 – First Place, Graduate Division, Research Poster Competition**, received **1st Place** at the 6th Annual Departmental Student Research Poster Competition, Lamar University, Beaumont, Texas, USA, recognizing excellence in graduate-level research and scientific communication.
- **January 2015 – Invited Lecture, Indo-Europe Educational Program – International Conference on Biodiversity,** delivered an invited lecture on *"Eutrophication and Environmental Impact"* at the Indo-Europe Educational Program, chaired by international academic experts, reflecting recognition of his subject-matter expertise in environmental microbiology.
- **December 2014 – Oral Presentation, 7th International Congress of Environmental Research (ICER-14)**, delivered an oral research presentation at ICER-14, held in Bangalore, Karnataka, India, addressing environmental research themes linked to public health, sustainability, and applied microbiology.
- **December 2014 – Attendee, Third Global Sustainable Biotech Congress 2014**, attended the Third Global Sustainable Biotech Congress 2014, organized by North Maharashtra University (NMU), Jalgaon, in collaboration with Global Biotech Forum, Nagpur, and CETYS University, Mexico. The congress was held at R.C. Patel Arts, Science & Commerce College, Shirpur, Maharashtra, India, on 15 December 2014 and focused on sustainable biotechnology and global scientific collaboration.
- **October 2006 – Technical Paper Presentation at "Convergence '06"**, presented a technical paper titled *"Genetic Engineering Applications of the Plasmid Vector pBR322"* at "Convergence '06," a technical paper presentation competition organized by R.C. Patel Institute of Technology, Shirpur, Maharashtra, India. This work demonstrated early exposure to recombinant DNA technology, molecular biology, and applied biotechnology.
- **December 2006 – University-Level Research Presentation at AVISHKAR-2006**, presented *"Combination Antibiotic Therapy Against Resistant Microorganisms: Sulbactam and Cefotaxime"* at AVISHKAR-2006, the University-Level Research Festival organized by North Maharashtra University, Jalgaon, Maharashtra, India. Participation in this competitive, peer-reviewed forum reflects early research aptitude, analytical thinking, and scholarly engagement.

PROFESSIONAL MEMBERSHIP

- **December 2025 – Professional Membership, American Association of Pharmaceutical Scientists (AAPS)** Affiliation with a leading U.S. pharmaceutical science society. **AAPS Member ID:** 309355
- **April 2023 – Professional Membership, Project Management Institute (PMI)** Affiliation with the world's leading professional association for project, program, and portfolio management. **PMI Member ID:** 8863576