Shrikanth Yerragolla

Quality & Compliance | Deviation Investigation, CAPA, MSAT & Aseptic Manufacturing

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Available for Microsoft Teams calls | Relocating to Ireland
Requires employer-sponsored Irish employment permit | Open to nationwide relocation

Profile

Pharmaceutical quality and manufacturing specialist with 6+ years of combined industry, research and capstone experience across biologics drug substance, sterile drug product and QC operations. Led or closed 100+ major deviations, combining manufacturing insight with RCA, CAPA and inspection-ready technical writing. Results include over 35% deviation backlog reduction at Catalent, 25% improved on-time closure at Moderna and 28% fewer recurring process issues in Catalent MSAT. Brings hands-on experience in technology transfer, aseptic fill-finish, validation support and cross-functional problem-solving across clinical, PPQ and commercial operations. Authored deviation reports were never recalled or reopened for additional information. MS Chemical Engineering and MBA; targeting quality, compliance, MSAT and validation roles in Ireland.

Skills Profile

Quality systems: Deviation investigation | RCA (Fishbone, 6M, 5 Whys) | CAPA and effectiveness checks | OOS/OOT | Impact and risk assessment | Change control | Batch disposition support | Inspection readiness

Manufacturing: Aseptic fill-finish | Formulation | Upstream/downstream biologics | UF/DF and Protein A chromatography | Contamination control | Technology transfer | Process validation and CPV | IQ/OQ/PQ documentation | Lyophilisation

Regulatory knowledge: EU GMP Annexes 1 and 11 | FDA cGMP and 21 CFR 210/211, 600 series | ICH Q9/Q10 | PIC/S | ALCOA+ | Good Documentation Practice

Systems and analysis: Veeva Vault | TrackWise | ComplianceQuest | MES | LIMS | SharePoint EDMS | PowerApps | Python, pandas and matplotlib | Microsoft Office

Career History

Just-Evotec Biologics - Redmond, WA — Jan 2026 - Aug 2026

Manufacturing Compliance Specialist (contract assignment)

Biologics CDMO; J.POD monoclonal antibody drug substance manufacturing.

- Chaired cross-functional CAPA reviews with Manufacturing, Quality, MSAT and Engineering to resolve a high-volume deviation backlog, contributing to a 15% reduction.
- Investigated major and minor deviations across bioreactors, viral inactivation, UF/DF and Protein A chromatography, applying RCA and product impact assessment to support manufacturing continuity and batch disposition.
- Served as a manufacturing compliance SME, assessing product impact against safety, identity, strength, purity and quality; authored inspection-ready reports that were never recalled or reopened for additional information.

National Resilience, Inc. - West Chester, OH — Sep 2025 - Dec 2025

Lead Investigator (contract assignment)

Clinical and commercial biomanufacturing CDMO.

- Led non-critical and major investigations using Fishbone and 5 Whys, coordinating stakeholders to achieve 100% on-time closure of assigned investigations; delivered inspection-ready reports supporting batch release.
- Reviewed non-conformance, OOS and OOT trends with QA, Manufacturing and Technical Operations to focus investigation priorities, improve root cause assessments and implement CAPAs addressing recurrence.

Moderna, Inc. - Norwood, MA — Jul 2024 - Jun 2025

Deviation Investigator (contract assignment)

mRNA vaccines and therapeutics; clinical and commercial manufacturing.

- Streamlined RCA and CAPA implementation for major QC and laboratory deviations supporting downstream manufacturing, contributing to a 25% improvement in on-time closure and a sustained reduction in backlog.
- Led cross-functional resolution of manufacturing issues, coordinating change controls and technology transfer support to improve efficiency and Right First Time outcomes.
- Partnered with QA, Manufacturing and Supply Chain on new product introductions across clinical, PPQ and commercial stages, supporting operational readiness and regulatory inspections.
- Reviewed open deviations and prepared inspection defence narratives aligned with CAPA lifecycle status, giving audit teams clear summaries of investigation progress and corrective actions.

Catalent Pharma Solutions - Bloomington, IN **Apr 2023 - Jun 2024**
Senior Deviation Investigator (contract assignment)
Sterile biologics drug product and fill-finish CDMO.

- Led weekly cross-functional deviation and CAPA meetings to resolve outstanding investigations and effectiveness checks, reducing the deviation backlog by over 35%.
- Completed deviation investigations, product impact and risk assessments using Fishbone and 5 Whys, translating root cause findings into CAPAs addressing manufacturing quality events.
- Oversaw area-specific change controls and reviewed investigation evidence, then verified CAPA effectiveness against intended outcomes to support consistent quality decisions.
- Trended non-conformances and OOS/OOT failures to develop targeted investigation plans, helping manufacturing teams identify causes and reduce process deviations.

Pfizer, Inc. - Rocky Mount, NC **Jan 2023 - Mar 2023**
Aseptic Process Engineer (contract assignment)

- Trained filling-area personnel in aseptic technique and investigated events with Technical Sterility Services, producing formal reports and risk assessments to support appropriate CAPAs.
- Assisted in writing IQ/OQ/PQ documentation for aseptic process validation, supporting the preparation of qualification records.

Catalent Pharma Solutions - Bloomington, IN **Jun 2022 - Dec 2022**
Engineering Specialist, Manufacturing Sciences & Technology

- Monitored production-batch performance and presented quarterly technical reports to cross-functional stakeholders, informing continuous improvement plans that reduced recurring process issues by 28%.
- Supported client product transfer through facility walkthroughs and readiness checks; troubleshot floor issues across formulation, filling, packaging and inspection to support manufacturing execution.
- Trained operators and advised client technical representatives and Person in Plant observers on packaging and inspection, providing technical guidance for production activities.

Catalent Pharma Solutions - Bloomington, IN **Apr 2021 - Jun 2022**
Associate Manufacturing Technology Specialist

- Evaluated bench and pilot-scale data with Process Development and client teams, selecting equipment and single-use components and defining in-process testing strategies for large-scale manufacture.
- Authored or coordinated process flow diagrams, batch records, buffer/media records, sampling plans and bills of materials, translating process requirements into GMP manufacturing documentation.
- Analysed process trends, troubleshot technical issues and prepared campaign reports; guided validation teams on process validation and continued process verification to assess manufacturing performance.
- Assessed manufacturing technology with Process Development, Engineering and vendors; trained operators and mentored junior scientists and engineers to transfer process knowledge.

Selected achievement across Catalent MSAT roles | Apr 2021 - Dec 2022

- Drove a process improvement strategy during COVID-19 vaccine manufacturing that doubled yield.

Education & Qualifications

Master of Business Administration | Trine University, USA | Awarded May 2026 | GPA 3.56/4.0

MS Chemical Engineering | Purdue University, USA | 2020 | Pharmaceutical Engineering minor | GPA 3.74/4.0

BE Chemical Engineering | M. S. Ramaiah Institute of Technology, India | 2018 | GPA 3.4/4.0

Training: Six Sigma White Belt and Foundations; Minitab; MATLAB Applications in Chemical Engineering.
Available for interviews during Irish business hours. Start date subject to employment permit and entry clearance.