MURALI JUJJAVARAPU

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SUMMARY

Analytical scientist with 13+ years in GMP analytical sciences and QC, including four years leading and building out a bioseparation/biophysical characterization group at a gene therapy CDMO. Developed, validated, or qualified 40+ analytical methods across HPLC/UPLC (RP, SEC, AEX/IEX), CE-SDS, DLS, ELISA, AUC, SoloVPE, and qPCR spanning method development, phase-appropriate qualification, validation, and technology transfer. Own the reference standard program and lead OOS/OOT/CAPA investigations end to end. Have contributed analytical sections to IND/BLA CMC packages and carry a clean track record across three FDA inspections (zero major observations). ASQ Certified Quality Auditor; Lean Six Sigma Green Belt.

TECHNICAL SKILLS

Biophysical / Separations: HPLC/UPLC (RP, SEC, AEX/IEX), CE-SDS, DLS (Malvern Zetasizer, Wyatt DynaPro), AUC, SoloVPE, osmometer/osmolality, electrophoresis

Bioassay & Molecular: ELISA, qPCR, plasmid DNA extraction and purification, reference standard characterization and lifecycle management

Additional Instrumentation: Malvern particle size, AAS, dissolution, Karl Fischer, UV-Vis, FTIR, coulometry, iBright gel imager, ID5 plate reader

Modalities: Plasmid DNA, AAV & LVV gene therapy vectors, small-molecule drug substance and drug product characterization

Method Lifecycle: Development, phase-appropriate qualification, validation, transfer, ICH stability (Q1A/Q5C), comparability, impurity/identity testing

Quality & Regulatory: GMP/GLP/GxP (FDA, ICH, USP/EP/JP), OOS/OOT/CAPA investigations, IND/BLA authoring, FDA inspection SME, Empower 3/LIMS data integrity, IQ/OQ/PQ

Leadership: Team hiring & mentoring, client/sponsor decision-making, Quality Agreement recommendations, CRO/CDMO program management, cross-functional liaison (CMC, Process Dev, QA), KPI trending, statistical analysis

PROFESSIONAL EXPERIENCE

Senior Scientist, Bioseparation Group Lead — *ProBio Inc., Pennington, NJ* Apr 2026 – Present

- Lead the Bioseparation group's day-to-day operations, growing the team to four people (three direct reports, up from two), supporting three modalities (plasmid DNA, AAV, LVV) plus raw material testing, and owning the full analytical test method lifecycle — development, transfer, and phase-appropriate qualification.
- Direct the group's LC method suite (SEC, AEX, RP) and biophysical techniques — AUC, SoloVPE, osmolality, DLS, CE-SDS — supporting product characterization and regulatory submissions.
- Hands-on with ELISA-based method qualification for AAV/LVV programs, working through robustness, linearity, and specificity to meet ICH and FDA phase-appropriate expectations.
- Own the reference standard program end to end: primary/working standard qualification, characterization, trending, and GMP documentation.
- Perform hands-on plasmid DNA extraction and purification, qPCR-based identity/titer testing, and osmometer-based osmolality testing directly supporting method development and release.
- Coordinate raw materials compendial testing (USP/EP) and instrument GMP compliance (IQ/OQ/PQ, Empower 3 data integrity) with QA, IT, and Automation.
- Partner across Analytical Development, Process Development, CMC, and Program Management to keep bioseparation strategy aligned with comparability and filing timelines.
- Act as a key decision-making partner for sponsor/client programs, advising Directors on timeline trade-offs and recommending changes to Quality Agreements to keep scope, roles, and deliverables aligned as programs evolve.

Scientist III, Analytical Development and QC — *ProBio Inc., Pennington, NJ* Jul 2023 – Mar 2026

- Owned the QC test method lifecycle across plasmid, AAV, and LVV platforms, from early-phase qualification through validation and IND/BLA submission authoring.
- Led OOS, OOT, and invalid-assay investigations from initial assessment through root cause, CAPA implementation, and regulatory-ready documentation, with statistical trending built into the review.
- Stood up and optimized core GMP analytical platforms — UPLC/HPLC, CE-SDS, DLS, SoloVPE, iBright gel imager, ID5 plate reader, qPCR — writing the SOPs and qualification protocols to keep them audit-ready.
- Managed external contract lab oversight, including GMP compliance monitoring and deviation management.

Laboratory Supervisor — *PLS Analytical, East Brunswick, NJ* Jan 2022 – Jun 2023

- Supervised a three-person team across HPLC, dissolution, UV-Vis, FTIR, Karl Fischer, coulometry, and compendial testing — workload planning, performance reviews, day-to-day GMP compliance.
- Authored OOS investigations, deviation reports, and CAPAs; partnered directly with CMO/CRO clients on method validation and verification design to meet FDA/ICH requirements.
- Led method transfer and troubleshooting efforts through a period of fast program growth.
- Served as analytical SME for one FDA inspection at this site, closing with zero major observations.

Senior Chemist II, Analytical Development — *Tulex Pharmaceuticals, Cranbury, NJ* Nov 2020 – Jan 2022

- Served as method validation SME for suspension formulations and impurity profiling; developed and validated UPLC/HPLC methods supporting 4+ ANDA submissions.
- Led impurity ID/quantification studies for complex small-molecule formulations, authoring ICH-compliant validation protocols and method transfer documentation.

Senior Analytical Chemist — *Apta Pharma Inc., Pennsauken, NJ* Nov 2018 – Nov 2020

- Managed the commercial finished-product stability program — real-time/accelerated testing, ICH-compliant data trending, OOT monitoring, and stability reporting for regulatory commitments.
- Handled method validation, verification, and transfer across a broad instrument base (Malvern particle size, AAS, dissolution, Karl Fischer, UV-Vis, FTIR); also covered commercial batch release testing.
- Served as analytical SME across two FDA inspections at this site, with zero observations issued, directly addressing investigator questions on data integrity.

EARLY CAREER

Analytical Chemist — *Apta Pharma Inc., Pennsauken, NJ* Mar 2017 – Nov 2018

- Performed HPLC method validation and verification supporting 4+ ANDA small-molecule submissions, with a focus on impurity profiling and method transfer.
- Prepared GMP documentation packages supporting regulatory filings, working closely with senior chemists on data review and report generation.

QC Chemist — *Quagen Pharma, West Caldwell, NJ* May 2016 – Feb 2017

- Executed validation protocols for small-molecule assays and impurity methods in a GMP environment.
- Contributed to analytical documentation and regulatory filing readiness, coordinating with QA on deviation and change-control paperwork.

QC Analyst — *Divis Laboratories Ltd., Visakhapatnam, India* Aug 2011 – Jun 2014

- Performed routine GMP quality control testing of raw materials and finished pharmaceutical products per USP procedures.
- Maintained lab safety, calibration, and documentation standards across day-to-day testing operations.

EDUCATION & CERTIFICATIONS

M.S., Chemistry — Eastern Michigan University, Ypsilanti, MI (2014 – 2016)

B.S., Pharmaceutical Sciences — Andhra University, Visakhapatnam, India (2007 – 2011)

Certifications: ASQ Certified Quality Auditor (CQA) • Six Sigma Green Belt • ORAQ Regulatory Affairs Training