Mahima Mahabaleshwar Siddheshwar

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PROFESSIONAL SUMMARY

Bioinformatics and Biopharma professionals with 3+ years of experience in mammalian cell culture, bioassay support, QC testing, and CMC workflows under GMP conditions. Skilled in CHO cell culture, analytical stability studies, formulation assessments, and laboratory automation systems (Thermo Fisher, Beckman, Hamilton). Possess regulatory knowledge across IND–BLA submissions with a strong background in data-driven process optimization (Python, R, JMP, Power BI). Proven ability to collaborate across R&D, QC, QA, and regulatory teams, delivering precise, reproducible data with full adherence to GMP, GDP, and ALCOA+ standards.

PROFESSIONAL EXPERIENCE

Executive – Quality Control (QC) Analyst
Biocon Biologics Limited   July 2021 – August 2023

- Conducted and tested 200+ biological samples ensuring 100% data traceability under GMP standards and timely documentation.
- Performed mammalian cell culture, bioassay, and stability test in **96-well plate formats**, ensuring 100% IND–BLA compliance.
- Operated HPLC *, **ViCell cell counter, UV/Vis, flow cytometry*** with **zero audit issues** and 100% calibration accuracy.
- Logged and reviewed test results **in LIMS and SAP**, increasing entry accuracy by 15% and cutting manual errors by 20%.
- Performed 100+ routine/non-routine QC tests monthly, consistently meeting **95% on-time release and documentation** targets.
- Investigated 20+ **OOS/OOT/OOE** events/year, initiating effective CAPAs and reducing repeat deviations by 25% overall.
- Tracked all deviations and **reviewed instrument logbooks**, supporting 6+ internal audits with 100% inspection readiness.
- Verified **calibration** for 10+ instruments quarterly, maintaining zero downtime and full compliance with regulatory schedules.
- Trained 5 new analysts in **GDP, sample tracking, and deviation handling**, improving onboarding efficiency by 30%.
- Handled 10+ change controls and **5+ SOP updates** annually in coordination with QA and regulatory compliance teams.
- Supported 3+ **internal audits** each year with batch readiness reviews, document retrievals, and traceability checks.
- Assisted method verification, validation, and instrument readiness for **5+ assay transfers** across QC operations.
- Led **5S and change management** initiatives, increasing lab efficiency by 20% and reducing retrieval time by 30%.
- Supported QA, QC, AS&T teams on **10+ cross-functional tasks** including data review, investigations, and documentation updates.

Bioinformatic Analyst Intern – R&D
Elucidata Corporation   July 2025 – Present

- Built and maintained LLM-powered **genomics pipelines**, extracting features and updating genomic databases.
- Performed statistical and integrative analyses on **genomics and clinical data**, generating reproducible reports per SOPs.
- Collaborated with scientists and engineers to assess tool efficacy and **optimize workflows** for scalability and reproducibility.
- Assisted in developing and **refining LLM-powered tools,** applying prompt engineering techniques to optimize accuracy.
- Support data analysis activities using (R, Python) to identify **health trends, disease patterns,** and outcomes across different populations.
- Collaborate with multidisciplinary teams including engineering, IT, **R&D and data scientists** to design and implement research studies.
- Prepare detailed data reports, **visualizations**, and summaries to communicate findings to stakeholders.
- Assist in maintaining **data quality** and ensuring compliance with ethical standards and data privacy regulations (HIPAA, GDPR).
- Help **manage project documentation**, including data dictionaries & metadata records to facilitate reproducibility and transparency.
- Participate in meetings and presentations to discuss **project progress** and contribute insights based on **data findings.**
- Actively Engaged with the **latest developments** in global health **analytics methodologies** and tools.
- Documented and **version-controlled genomic pipelines** to support team collaboration and reproducibility.

Research Assistant – Global Health Data Analytics
IU BioHealth Informatics Research Center, Indianapolis   September 2023 – May 2025

- Integrated 100+ records from CDC, WHO, and other repository ensuring **100% traceability** and metadata consistency.
- Cleaned, standardized, and **cross-referenced multi-source public health data**, reducing inconsistencies by 35% across datasets.
- Designed **Power BI dashboards** to monitor geographic trends and disease burden, enabling clearer data interpretation for public health.
- Delivered health indicator **visualizations** that reduced manual analysis time by 40% through visual summarization.
- Documented and **version-controlled pipelines** to support team collaboration and reproducibility.

SKILLS

Cell Line Development & Molecular Biology: Mammalian cell culture (CHO, 96-well plates), ELISA, PCR, Western blotting.
Instruments: UV/Vis, Capillary Electrophoresis (CE), SDS-PAGE, Osmometer, Pipettes, Autoclaves, Incubators, Biosafety Cabinets.
Regulatory & Quality Systems: GMP, GDP, ALCOA+, IND–BLA, deviation management, CAPA, SOP review, Trackwise, LIMS, SAP.
Data Analysis & Programming: Python, R, SQL, JMP, Power BI, Cytoscape; statistical modeling, visualization, and workflow optimization.
Collaboration & Documentation: Cross-functional team (QA, QC, PD, Formulation), technical reporting, scientific presentations.
Soft Skills: Right-first-time approach, Team collaboration, Troubleshooting, Continuous improvement mindset

EDUCATION

Master of Science in Bioinformatics   August 2023 - May 2025
Luddy School of Informatics, Indiana University Indianapolis   Indiana, USA
Bachelor of Technology in Biotechnology   August 2016 - August 2020
Sapthagiri College of Engineering (Affiliated to VTU)   Bangalore, India

ACADEMIC PROJECTS

Machine Learning Pipeline for Breast Cancer Biomarker Discovery

- Integrated **7 GEO datasets (~350 samples)** and applied limma + sva, improving data consistency by **28% across platforms**.
- Applied **LASSO regression** for feature selection and trained SVM/Logistic Regression models, achieving **93.4% prediction accuracy**.
- Identified **12 key biomarkers** and visualized interpretability with **ROC/AUC plots**, enhancing clarity for **clinical translation by 35%**.
- Validated model predictions across test folds using stratified cross-validation, increasing generalizability and robustness by **32%**.

WGCNA on COVID-19 and RSV Transcriptomes | NGS Analysis

- Curated & processed 68 RNA-Seq samples, reducing preprocessing time by 40% using FastQC, TrimGalore, HISAT2, and FeatureCounts.
- Constructed WGCNA networks, identifying 2 modules (MEyellow & MEgrey) with R^2 = 0.89 correlating 90% with COVID-19 severity.
- Categorized 3 hub genes (OASL, TXN, RBCK1) with >95% biomarker confidence, improving classification accuracy by 20%.
- Generated heatmaps, volcano plots, and Venn diagrams, improving visualization clarity by 30% and reproducibility by 40%.

Streamlining RNA-Seq Data Analysis: A Framework for Comparing Computational Pipelines | RNA-Seq Pipeline

- Developed & compared 4 RNA-Seq clustering pipelines (PCA, t-SNE, K-means, Hierarchical Clustering), reducing processing time by 30%.
- Executed pipelines in a **Unix/Linux-based HPC environment**, using SLURM for job scheduling, reducing time by 35%.
- Determined t-SNE + Hierarchical Clustering as most effective, achieving 40% better stability and 30% higher biological relevance.

CERTIFICATION

- Certification in **Biosciences Program** – Biocon Academy & Keck Graduate Institute.
- Experiential Learning **in R&D, Quality Control, Quality Assurance, Production, QC Microbiology and Regulatory Affairs** delivered by Subject Matter Experts of Biocon group of companies.
- Case study-based team project on **drug development, manufacturing, quality and regulatory** aspects.
- Hands-on-training on lab scale and pilot-scale fermentation at BiOZEEN.

*Workflow-level understanding | ** Certification in Bioscience Program*