RITU MALI

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PROFESSIONAL SUMMARY

Research Associate in **Process Validation & MSAT** with nearly 4 years at Roche Diagnostics (GenMark) across validation, quality control and regulatory affairs, now also working a gig as an **Associate Product Manager** in Roche's Sequencing business. Experienced in executing validation projects driven by market demand and incorporating **Voice of Customer** input. **Hands-on NGS experience** spanning library preparation workflows and genomic data analysis. **Product lifecycle experience** across technical, CAPA-driven quality improvement, plus a regulatory background across FDA, CE and IVDR frameworks that support on-market product care. Partner across **R&D, Tech Transfer, Software, Finance and Manufacturing** to drive stakeholder alignment, including presenting to senior stakeholders.

PROFESSIONAL EXPERIENCE

Associate Product Manager, Sequencing Business Unit | Roche Diagnostics | Pleasanton / Carlsbad, CA

Aug 2026 – Present (Gig, ~15 hrs/week, alongside full-time role)

- Partner with an International Product Manager to co-create Target Product Profiles (TPPS) and prioritize core product requirements using Voice of Customer.
- Conducted competitive benchmarking of the sequencing sample prep portfolio against key competitors, identifying portfolio gaps and differentiation opportunities to strengthen product positioning.
- Developing a sales-enablement one-pager for commercial teams, drawing on the portfolio's website and flyer content.
- Drive portfolio-wide visibility across the sequencing sample prep portfolio for a business leader, synthesizing product content for the customer-facing website to guide customers from product browsing to the product site.

Research Associate, Process Validation & MSAT | Roche Diagnostics (GenMark) | Carlsbad, CA

Aug 2024 – Present

- Partnered in the launch of the cobas® ePlex Demo Consumable, translating IVD diagnostic functionality into a commercial-ready experience and ensuring product readiness across global operations.
- Partnered on the ePlex Tower Kit project, coordinating Operations, Commercial and Supply Chain teams to ensure a compliant market strategy.
- Authored and reviewed process FMEAs (PFMEAs) for IVD product processes, incorporating Voice of Customer considerations into risk assessment.
- Manage multiple concurrent validation projects independently, prioritizing by market demand and partnering with R&D, Tech Transfer, Software, Finance and Manufacturing to secure stakeholder alignment on deliverables.
- Supported product cost analysis and streamlined process flow to reduce product cost, aligning process improvements with manufacturing cost targets.
- Analyzed performance data across 100+ production batches using statistical process control (SPC), reducing waste by 12% and process variability by 10%, to support standard manufacturing cost (SMC) targets, inventory control, and demand forecasting models.
- Authored and executed IQ/OQ/PQ validation protocols for 2 new IVD product launches, maintaining full regulatory traceability per 21 CFR Part 820 and ISO 13485.

Quality Control Specialist | GenMark Diagnostics (Roche Group) | Carlsbad, CA

Jun 2023 – Aug 2024

- Led pilot testing and validation for two new diagnostic assays and instruments; translated molecular performance data into go/no-go recommendations for commercial leadership.
- Investigated 25+ non-conformance events across multiple departmental teams, coordinating root cause analysis and CAPA development and producing board-ready deviation reports.
- Designed and implemented 7 structured process improvements through root cause analysis and iterative testing, reducing product defect rates by 10%; partnered with QA Operations on FMEA risk assessments.

Regulatory Affairs Associate | GenMark Diagnostics (Roche Group) | Carlsbad, CA

Oct 2022 – May 2023

- Designed and built a centralized SQL-based regulatory compliance database spanning 61+ countries and 4 IVD products across EMEA and APAC, improving information retrieval efficiency by 25%.
- Maintained regulatory compliance and product registration documentation for IVD products across FDA, CE and IVDR frameworks in international markets.

NGS Library Preparation Intern | Volition America | Carlsbad, CA

May 2022 – Aug 2022

- Optimized 3 NGS sample workflows—including Oxford Nanopore library preparation—for downstream long- and short-read sequencing, applying statistical methods to large genomic datasets across two clinical trials.
- Analyzed data from clinical studies and designed follow-up experiments to inform next steps for product improvement.

Molecular Biologist | Lifenity Wellness International Ltd | Mumbai, India

Jul 2020 – Jan 2021

- Conducted RT-PCR analysis and root cause investigations for non-conformances across 100+ plasma samples in 2 clinical trials.
- Improved product testing processes based on analysis of product performance data.
- Partnered with Takeda on RT-PCR testing, increasing output by reducing product processing time.

LEADERSHIP

Site Lead – Roche Young Professionals | Roche | 5 U.S. Sites

Jan 2023 – Present

- Lead a team of 8 across 5 U.S. sites, prioritizing and executing 15+ initiatives and driving a 20% increase in inter-site engagement across the Roche ION network.

SKILLS

- **Product & Commercial:** Voice of Customer synthesis, product lifecycle (on-market product care), launch readiness, cross-functional coordination, milestone tracking, Competitive benchmarking, sales enablement, project prioritization.
- **NGS & Data:** NGS library prep (DNA-seq/RNA-seq), SQL, R (genomic data analysis), SPC, Google Data Analytics (certified)
- **Quality & Regulatory:** 21 CFR Part 820, ISO 13485, FDA/CE/IVDR, IQ/OQ/PQ validation, CAPA, root cause analysis, FMEA
- **Languages:** English (fluent), German (A1, actively developing)

EDUCATION

Master of Biotechnology | California State University San Marcos | May 2023

- Capstone: SQL-based regulatory compliance database spanning 61+ countries and 4 IVD products.
  Al Kern Award for Best Master's Thesis.

Bachelor of Engineering, Biotechnology | Shivaji University, India | May 2020

CERTIFICATIONS

- Google Data Analytics Professional Certificate – Google
- Genes and the Human Condition – University of Maryland, College Park