FATMA ZOHRA

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PROFESSIONAL PROFILE

In Vitro Diagnostic (IVD) Point of Care (POC) research and development (R&D) manager with track record of leading projects from concept to market. Go-to person for identifying problems and creating innovative solutions. Lead R&D teams to develop commercially successful test devices. Hands-on leadership style and a reputation for "making things happen," tackling tough challenges head-on, and driving teams to meet goals. Passionate about applying science to improve people's quality of life.

Core Competencies:

- Product planning and development
- Product lifecycle management
- Team building and leadership
- Verification and validation (V&V)
- Technology transfer
- Product scaling
- End-to-end product development
- Product launch
- Lead cross-functional teams
- Project management
- Risk assessment and mitigation
- Change management
- Stakeholder communications
- 510k and EUA FDA submissions
- Process improvement
- Resource allocation
- Design control

Software Skills: JMP, SPSS, JAMA

Technical Skills: LCMS, Proteomics, lateral flow immunoassays, latex-enhanced immunoassays, polypeptide-protein conjugation, enzymatic assays

WORK EXPERIENCE

InterVenn Bioscience, San Francisco, CA — January 2023- Current

Senior Manager – Tech Transfer

- Established a tech transfer team responsible for the transfer of technology from the translational sciences to CLIA lab defining major milestones including strategy lock, design and process lock, and confirmation runs within the defined timeline.
- Led phase gated internal tech transfer of the flagship product including Document Control, Feasibility and Validation runs, Hazard and Risk Analysis and Mitigation, and End to End product validation.
- Provide consult on Design Control, CLSI guideline-based study designs and Regulatory Affairs.
- Created framework for LCMS equipment pertaining to equipment qualification, maintenance, signal stability variance and instrument to instrument variance.
- Created framework for operations plan.
- Designed feasibility studies and post validation support studies for the successful transfer of the flagship product.
- Liaison between the development team and the CLIA lab including production activities.

SEKISUI DIAGNOSTICS, San Diego, CA — August 2020 – August 2022

Manager R&D – IVD Validation and Verification (March 2021 – August 2022)

Managed eight-person scientific team responsible for all technical and logistical activities involving new product development, including phase designing, study design, assay development, reports, FDA response, and technology transfer for lateral flow test devices used for qualitative and quantitative testing.

- Managed tech transfer including document control, feasibility and validation, scaling up, and process improvement.
- Optimized timeline and deliverables.
- Collaborated with cross-functional teams to meet deliverables.
- Presented R&D decisions and proposals to cross-functional teams.

- Designed studies for validation and verification of new lateral flow tests per CLSI guidelines, template for test developers, and used FMEA.

Scientist II – Research and Development (August 2020 – March 2021)

Responsible for assay development for lateral flow test strips (visual) and cassettes (Sekisui platform) – feasibility, stability, and flex studies.

- Designed and conducted feasibility studies per CLSI guidelines (EP25) for the development of new lateral flow assays.
- Executed technology transfer – feasibility studies, validation studies, documentation, and process validation.
- Served as in-house and outside consultant in area of technical expertise: process and product optimization and commercial readiness.
- Served as technical advisor for latex assay development to Sekisui global R&D teams.
- Authored protocols and compiled reports for submission per regulatory guidelines.

DIAZYME LABORATORIES, Division of General Atomics, San Diego, CA December 2010 – July 2020

Scientist II – Group Supervisor (July 2015 – July 2020)

Managed a team of 8-12 scientists responsible for developing cardiac and cancer biomarker immunoassays for use on fully automated chemistry analyzers. Led the manufacturing for each 510(k)-cleared analyte specific assay for a fully automated system (reagent, hardware, software).

- Performed complex analytical procedures and techniques for assay development and optimization.
- Led the launch of Kappa FLC and Lambda FLC Immunoassays involving feasibility, scale up process validation, kit design, and customer feedback.
- Led the operational activities of PLAC assay acquisition from Diadexus, which included intel and technology transfer, assay validation, and document change and control per Diazyme quality systems and training teams.

Scientist I Team Lead (Immunoturbidimetric Assays) (November 2012 – June 2015)

Responsible for leading a team of 3-10 scientists that designed experiments and conducted feasibility, optimization, and scale up experiments for enzymatic and latex-enhanced immunoassays.

- Managed the operational and technical aspect of multiple FDA 510(k) cleared product lines in an ISO/GMP environment based on project timelines and work plans.
- Created downstream process for latex immunoassays: SOP for manufacturing team, automated liquid fill, lyophilization, labeling, and kit packaging.
- Communicated with management, R&D, QA/QC, and manufacturing departments to identify and develop the best processes and set specifications.
- New product commercialization – authored, edited, and reviewed technical documents/SOPs and Bill of Material via document change orders, managed timelines and budget, and managed resource allocation and prioritization.
- Attended management review meetings to provide feedback on department goals, NCMR, deviation, and CAPA.
- Maintained communication with customers and vendors to establish effective working relationships.
- Visited domestic and international customer sites for troubleshooting and training of new and existing assays.

Biotechnician II/III (January 2010 – November 2012)

Delivered consistent productions of multiple FDA 510(k) cleared immunoassay reagents from small scale of 0.1L to production scales of 200L in an ISO/GMP environment. Activities involved purification and dialysis of antibodies as well as activation of polystyrene nanoparticles through Tangential Flow Filtration.

- Analyzed, summarized, and presented experimental data and recommended follow up actions.
- Collaborated with R&D department to commercialize and transfer new product lines to manufacturing.
- Project lead on enzymatic HbA1c POC and immunoassay hsCRP products including product development, 510(k) submission, commercialization, and scale up.

PRIMAPHARM INC., San Diego, CA August 2008 – September 2009

QC Analyst, Analytical Services

EDUCATION

Master of Science, Business Analytics, RADY SCHOOL OF MANAGEMENT, UCSD (On-Going)
Master of Advanced Studies (MAS), Leadership in Healthcare Organizations, UNIVERSITY OF CALIFORNIA, SAN DIEGO
Bachelor of Science, Biochemistry and Cell Biology, UNIVERSITY OF CALIFORNIA, SAN DIEGO

AWARD

Diazyme Excellent Performance of the Year
HbA1c POC and hsCRP immunoassay 510k completion, manufacturing, and delivering 2000 kits/month.