ANISSIA VIXAMAR

PROFESSIONAL EXPERIENCE

TAKEDA PHARMACEUTICALS INTERNATIONAL CO. Cambridge, Massachusetts
Associate Director, R&D Ethics & Compliance Dec. 2019 – Present

- Partner with the R&D leadership to champion and shape the organizational mindset around the Patient-Trust-Reputation-Business model to embed ethical decision-making principles.
- Provide strategic advisory to R&D including but not limited to external partnership, engagement and clinical development activities.
- Identify and evaluate emerging industry trends and laws/regulations and communicate potential impact to R&D accordingly.
- Collaborate with R&D Ethics & Compliance Operations to develop and implement monitoring and risk assessment strategy.
- Provide assessment of and feedback for Global Ethics & Compliance Policies/SOPs, initiatives or programs as relevant.
- Interface with other Ethics and Compliance teams, as appropriate.

Senior Manager, Quality Compliance Mar. 2018 – Dec. 2019

- Directs continuous improvement to ensure programs remain compliant with FDA and other regulatory requirements.
- Develops and maintains a broad network of relationships within the local and global environment. Represents the company at corporate and regional meetings and, as necessary, with Regulatory Agencies, industry groups and business partners.
- Advises project teams on compliance strategies to ensure cGMP and company expectations are met. Ensures the establishment of remediation plans, if needed, to improve compliance standing.
- Leads due diligence activities to ensure risk based approaches are used and approves operations as part of self-assessment programs.
- Leads the Regional (cross-functional) Quality Council Program which assess compliance standing and risks associated to Quality Systems health to ensure any negative trends are properly communicated, discussed, addressed and effectiveness of actions taken monitored to assure good standing of our quality systems. Promote risk awareness and proactive remediation to drive compliance results.
- Manage staff responsible for Quality Compliance programs and compliance interactions with vendors, to assure timely and compliant operations. Makes recommendations regarding long-range resource planning, budgeting and restructuring to meet business needs.
- Escalate to Senior management as appropriate, compliance related situations that may arise as a result of self-assessments and that may represent significant risk to the organization.
- Represent the company at FDA or other regulatory inspections of TBOS, or contract manufacturing organizations and contract laboratories associated with the commercial product supply chain.

Manager, Quality Compliance Feb. 2017- Mar. 2018

- Lead and deliver Management Review to Oncology and Biologics (O&B) leadership team on a regular basis.
- Collect data and calculate metrics from Quality organization as well as coordinate compilation of Management Review metrics from GMP departments.
- Manage the O&B internal assessment program.
- Implement Inspection Readiness Program.

- Maintain current understanding of industry inspection trends. Lead projects to ensure compliance across regulatory expectations.
- Interpret and execute operating policies, procedures and directives for the department.
- Identify and plan projects/studies/reviews/investigations to address a specific issue. Act as an advisor to specialists executing projects.
- Lead or participate in supplier audits as needed in support of the Quality Systems department.

Senior QA Auditor Mar. 2014 – Feb. 2017

- Lead qualification audits of new and current third-party vendors/suppliers associated with Takeda's global supply chain.
- Develop quality metrics based on third-party vendors and Takeda's global audit division for dissemination to global senior leadership.
- Collaborate effectively with other Takeda regional groups to conduct audits according to the global audit schedule and support global initiatives as required.
- Manage the global audit plan by acting as primary contact for Regional Heads and GQA auditors.
- Serve as a liaison between Takeda and external parties to leverage services provided for execution of the audit plan and/or regulatory agency inspection support of local operating companies.
- Compile, trend and distribute quality-related actions/data and regulatory topics.

GENZYME Cambridge, Massachusetts

Program Manager Nov. 2013 – Mar. 2014

- Develop and implement Materials Management systems including Material Control, Supplier Qualification and Purchasing Controls.
- Collaborate with remediation teams to assist in executing detailed project plans defining Consent Decree activities, timelines and resource requirements.
- Build consensus across functional areas, obtain key stakeholder buy-in and implement changes in Materials Management systems.
- Monitor projects through major milestones and completion by ensuring assigned tasks are completed on scheduled by identifying resolutions for issues that may affect remediation timelines.
- Ensure programs are current with regards to compliance regulations, practices and costs.

Senior Quality Engineer Aug. 2012 – Nov. 2013

- Drove three numbered steps/departments to successful completion of the stringent Verification process.
- Contributed to the development of steps, work breakdown and milestones within the Consent Decree Work Plan relating to the relevant quality system requirements.
- Delivered against project plan deliverables and penalty-related milestones associated with the FDA Consent Decree Work Plan.
- Worked with the current business and system owners to ensure that the proposed remediation actions address the key points of compliance or standard.
- Provided ongoing monitoring of implemented actions to verify continued compliance in addition to identifying and proposing solutions for any issues preventing sustainability.
- Set clear objectives for team members and ensured they performed in an effective and efficient manner.

MILLENNIUM PHARMACEUTICALS, INC. Cambridge, Massachusetts
Manager Jun. 2012 – Aug. 2012
QA Specialist III Feb. 2010 - Jun. 2012

- Recipient of the 2011 Millennium Outstanding Team award which recognizes employees that participated in an event or project that contributed to the overall success of the company.
- Performed U.S./Ex-U.S. GMP vendor and supplier audits to ensure compliance with company policies, quality agreements and domestic/international regulatory regulations.
- Supervised and managed the internal audit program which ensures pro-active management of several Millennium departments and provides areas of improvement to the VP of Quality.
- Acted as recall coordinator for a voluntary product recall and primary triage coordinator for several third-party audits and regulatory agency inspections.
- Provided oversight and coordination for MHRA audits of GCP activities in Ex-U.S. locations.
- Business Administrator of an electronic audit management system (AMS) that allows oversight of Millennium's GMP, GCP and GLP suppliers, acts as a repository for pertinent documents and provides metric reporting to Quality and Senior Management.
- Managed the tasks and responsibilities of the department contractor for over four years.

QA Specialist II Feb. 2008 - Feb. 2010

- Recipient of the 2008 Millennium Outstanding Contributor award which recognizes individuals that embody Millennium's Core Values and have made a significant impact on their department's success.
- Served as the Business Administrator for AMS which requires collaboration and harmonization of processes across several business areas.
- Fostered positive relationships with external vendors to ensure Millennium's business needs were adequately met and appropriately incorporated into all project plans.
- Assisted with the creation and revision of quality/technical agreements by compiling Millennium's business requirements and negotiating contract terms with the other party.
- Drafted and revised SOPs pertinent to AMS and other Corporate Quality business functions.
- Oversaw project management aspects of department initiatives.

ABBOTT PERSONNEL CONSULTING Cambridge, Massachusetts
QA Supplemental Contractor at Millennium Pharmaceuticals, Inc. Jul. 2006 - Feb. 2008

- Participated as a triage team member and secondary triage coordinator for regulatory agency inspections (i.e. FDA & MHRA) and third-party audits.
- Recipient of the 2006 FlexStaff Reach Award which recognizes and rewards contractors for "above and beyond" contributions to the company.
- Implemented and maintained an electronic record of Millennium's Internal, third-party and supplier audit observations and CAPAs.
- Revised Millennium's service/quality agreements and updated an electronic document repository accordingly.
- Aided in the completion of regulatory inspection history for each supplier.
- Inventoried and tracked all distributed audit reports.

Strategic Sourcing Supplemental Contractor at MPI May 2005 - Jul. 2006

- Recipient of the 2005 FlexStaff Reach Award which recognizes and rewards employees for "above and beyond" contributions to the company.
- Offered constructive feedback to senior management on current database capabilities and implemented suggested solutions.

- Acted as support staff and a liaison between the Strategic Sourcing and Strategy Planning & Operations departments.
- Handled confidential contracts and agreements by entering information into company database.
- Revised computer software manual to provide more accurate information to current employees and future trainees.
- Trained new employees and users on company database software.

EDUCATION

M.S. Regulatory Affairs for Drugs, Biologics & Medical Devices
Northeastern University Boston, Massachusetts
Summa Cum Laude
Concentration: Biopharmaceutical Int'l & Domestic Regulatory Affairs

B.S. Communication Studies
Northeastern University Boston, Massachusetts

Study Abroad Semester at University of London – Goldsmith's College
London, England

Certification: International Register of Certified Auditors Sept. 2015
Boston University: Concepts of Project Management Nov. 2008

Professional Organization Memberships: Healthcare Businesswomen's Association (2009-Present)

Volunteer Experience: YBWS Volunteer Initiative (2009-Present), Millennium-Makes-A-Difference Volunteer (2008-Present), Mission Works Youth Tutor (2006), Northeastern University Legacy 2000 Mentor (2002-2005)