Ambareen Sheriff

QUALIFICATION SUMMARY

Highly skilled, goal-oriented regulatory executive with a proven record of excellence in Regulatory Affairs, Quality Operations, Manufacturing and Product Development for pharmaceutical drugs, medical devices, combination products and biological products. A full cycle regulatory professional providing strategic and regulatory leadership to global project teams in all areas of drug development and lifecycle management. Expert in strategic planning, management, and execution of the review and evaluation of technical and scientific data into documents for submission to the FDA (CDER, DDMAC, CBER, CDRH), and European Regulatory Agencies. A team player working effectively with senior executive management, research, clinical, marketing and manufacturing to accomplish company's goals and objectives.

REGULATORY & TECHNICAL EXPERTISE

Regulatory & Quality executive with strong industry experience in the pharmaceutical, biopharma and biologics field as related to product development, CMC lead, cGMP and GCP/GLP compliance. Proven skills in Regulatory/ Quality/Manufacturing include:

- Ability to lead global regulatory projects in both a matrix and direct report environment, directly interacting with FDA, and global health authorities and leading face to face FDA and global health authorities' meetings
- Expertise in understanding the market, analyzing regulatory requirements, and planning strategies to achieve results in areas of product development, product launch and life cycle management
- Successful track record of managing and preparing regulatory submissions to US and EU authorities and obtaining approvals - NDA, ANDA, IND, PMA, 510K, MAA, NDS, CTD, CE Mark Drug/Device Dossier including Orphan Drug Designation (NME) and Color Additive petition
- Support BD in new product acquisitions and provide material for assessment of new product opportunities
- Successful management of corporate Regulatory and Labeling group to ensure consistency and compliance of CMC and labeling across product lines and with applicable regulations for both new and marketed products
- Strong international experience of product registrations to regulatory authorities such as EMA, CE mark, TGA, TPD
- Extensive compliance experience, Warning Letters, product recalls, facility inspections and 483 responses
- Working knowledge of 21 CFR, DDMAC, cGMPs, ISO, ICH, EMA and USP Regulations
- Expertise in Managing Internal GMP Compliance Audits and External FDA/TUV Facility Inspections
- Led Quality Audit of Contract Manufacturing Facility, API Manufacturer, CRO and PV service provider
- Created and Maintained Quality System Standards, SOPs, Guidelines and Policies to meet regulatory expectations
- Managed Quality System Processes such as Change Control, Deviation Reports, Management Review, Trending, Batch Reviews and Regulatory Review/Approval of Marketing Advertising & Promotional Materials and Product Label
- Defined Budgets and Capital needs for Regulatory Affairs, Quality and Labeling groups
- Started the career in medical devices, then transitioned to Drug-Device and finally to Drug experiences

PROFESSIONAL EXPERIENCE

AMS REGQUAL CONSULTANTS, LLC, Long Grove, IL **Feb 2020 – Present**

Principal SME –Regulatory Affairs & Quality Assurance

- Provide technical guidance on regulatory requirements to clients R&D product development and project teams
- Successful track record of managing and preparing regulatory submissions to US and EU health authorities
- Experience with CMC regulations for drug and biologics products and small molecules in US and EU
- Exposure to document management systems, artwork management systems and regulatory information management sys
- Expert in global CMC strategies (US, EU and Growth & Emerging Markets) and its implementation
- Leadership skills - leading a workstream/aspect of a project in a matrix environment (vendors, contractors, company employees), ability to come up to speed relatively quickly
- Strong communication skills (written and verbal) in directly interacting with FDA, and global health authorities and leading face to face FDA and Scientific Advice meetings
- Expertise in global regulatory strategies providing regulatory guidance throughout the product development process and directing the non-clinical, clinical and CMC regulatory activities such as meeting with FDA for orphan drug designation, exclusivity, controlled correspondences, EOP meetings, briefing books, CMC and clinical issues for investigational products and post approval changes of marketed products

CELERITY PHARMACEUTICALS, LLC, Rosemont, IL **Nov 2013 – July 2020**

Vice President –Regulatory Affairs & Quality Assurance

- Provide strategic input and technical guidance on regulatory requirements to R&D product development and project teams
- Successful track record of managing and preparing regulatory submissions to US and EU health authorities; obtaining 10 approvals in 6 years – NDA(4), ANDA(5), MAA(1), PAS, IND, Bio-IND. Additional MAA(2) and ANDA(1) in review
- Anticipate regulatory obstacles and emerging issues throughout the pharmaceutical product development lifecycle and develop solutions with other members of regulatory and related teams
- Set-up the RA/QA depts to ensures compliance to cGMP's, regulatory agency requirements and company initiatives
- Designated regulatory responsible head and lead communicator with all regulatory agencies
- Manages preapproval compliance activities and formulates company procedures to respond to regulatory authority queries
- Responsible for qualification activities for all contract manufacturing organizations (CMO), contract research organizations (CRO), and vendors/suppliers and monitor ongoing CMO, CRO and vendor/supplier compliance
- Manage the audit program for internal and external (vendor) systems, process, to support cGMP compliance, GCP oversight, company policy, and industry best practice. Follow-up with CRO/CMO to address audit findings
- Oversee the development and/or revision of SOPs as relate to cGMP, GCP quality and regulatory compliance.
- Contributes to project teams providing regulatory expertise and guidance on regulatory and quality matters
- Recruit, develop, and mentor personnel in Regulatory Affairs and Quality Assurance (GMP and GCP)

MARATHON PHARMACEUTICALS, LLC, Deerfield, IL **March 2010 – 2013**

Director –Regulatory Affairs & Quality Assurance

- Regulatory Lead for interfacing with FDA on issues arising out of the development, commercialization and manufacturing of company products. Developed regulatory strategies to ensure regulatory compliant submissions
- Coordinated and conducted face to face meeting and T-Con with FDA to discuss orphan drug designation, CMC and clinical issues for investigational products and post approval changes of marketed products including labeling
- Responsible for development and execution of regulatory and labeling strategy, across all phases of product commercialization - negotiated with FDA and revised NDA product labeling
- Managed & Executed current products submissions such as, IND, SNDA, Orphan Drug Designation, DDMAC, Briefing Package for FDA meeting, AR, PADER, received Orphan Drug Designation (NME) for chronic diarrhea
- Primary company liaison with government agencies, CROs and vendors, providing regulatory & quality expertise in the areas of, promotion and advertising materials, labeling, licensing, document control, compliance and vendor audits
- Formalized the Quality oversight and introduced QMS thus ensuring a successful FDA inspection with no observation
- Work across functional groups such as marketing, business development, manufacturing and CMO to approve all manufacturing changes, product release and new product due diligence
- Responsible for pharmacovigilance of marketed products to ensure all AEs are reported in a timely manner
- Provide companywide training on policies and procedures, FDA regulations, and guidance on existing and emerging issues impacting the company's existing product line and future product acquisitions

WINSTON LABORATORIES, INC., Vernon Hills, IL **May 2008 – Feb 2010**

Director – Operations & Regulatory Affairs

- Regulatory lead contributing to the approval of prescription drug in Canada/ utilizing regulatory and quality expertise in development and implementation of Drug Development Program for product registration in Europe, Canada & US
- Contributed in the development of regulatory strategies for interfacing with MPRH, MPA TPD & FDA and prepared/submitted oral & written communication to support the new drug applications for NME
- Interpreted and defined regulatory requirements to address key regulatory, CMC, promotional, labeling, and compliance aspects associated with development, commercialization and manufacturing
- Managed and executed timely submission of drug application for Europe & Canada ensuring compliant and persuasive documents - NDS Approved in 7/2010 with no CMC or Labeling issues and NDA submitted, MAA under review
- Interfaced with contract manufacturers for the manufacturing of novel drug substances, validation batch and clinical drug supplies in different strengths & drug application forms – obtained IND approvals for patch, nasal, & oral soft gel
- Created Clinical labeling for INDs and new product labeling for submission in NDS & NDA
- Tracked evolving regulatory developments that impact the business and applications and implemented changes as needed
- Managed and executed the review and approval of pre-approval materials for pain management investigational compound. Regulatory lead at NDS label negotiations meeting with Health Canada and pre-MRPH & MPA meetings

AKORN INC., Buffalo Grove, IL **2002 – 2008**
Manager – Regulatory Affairs

- Managed the Regulatory Department and reported to the president for 2 years in the absence of VP of QA/RA. Worked diligently with R&D, QA/QC, and manufacturing facilities for management and compliance of current products
- Responsible for regulatory strategy and submissions of new drug application and NDA supplement to FDA
- Served as lead contact with the FDA and submitted NDA's, ANDA's, supplement, and amendment for injectable & ophthalmic products. Received Approval of 2 NDA and 14 ANDAs and numerous SNDAs and SANDAs
- Created, established and managed the labeling group and trained associate to design artwork in-house ensuring consistency and compliance of labeling across product lines and with current regulations for new and marketed product
- Led the relocation of regulatory department to corporate and strategically managed the move of all product related regulatory documents, ensuring all future regulatory submission were conducted in a compliant and timely manner
- Effectively motivated, mentored and developed professionally six direct reports in the submission and labeling groups
- Led the labeling group for a successful transfer of 53 products labeling to a new vendor within a year– thus saving $1M in redesigning costs. Updated all product labeling to comply with FDA regulations (RSS Barcode)
- Approved final printed labeling, advertising and promotional material for submission to DDMAC to ensure compliance
- Interacted with FDA to successfully lift the Warning Letter for Product labeling within a month
- Worked closely with multi-functional team to design Product Catalog and implement Product Website
- Participated in the facilities compliance programs, GMP/QSIT Audits, Gap Analysis and approved all change control
- Successfully addressed numerous FDA inspection observations and thus to the lifting the warning letter
- Implemented process improvements to submission & labeling process; created content policies and generated SOP's
- Proven Experience in Developing Package Insert, Patient Package Insert, Medication Guide and Brief Summary

BAXTER HEALTHCARE CORPORATION, Round Lake, IL **2001 – 2002**
Manager, Regulatory Affairs – Fenwal Division

- Regulatory Lead for Pathogen Inactivation of Platelets to obtain European product registrations - Approved in Q2, 2002
- Managed and Prepared Submissions for Modular PMA, 510k, CE Mark Dossier/Technical File Updates, and sNDA
- Developed regulatory strategies, managed preparation and submitted regulatory package to TUV (Drug/Device dossier supplement, Change Notifications) for pathogen inactivation programs
- Reviewed and approved scientific and technical documents intended for regulatory submission to meet both domestic and international requirements for the drug/device combination product
- Managed all regulatory strategies and supported in development for Modular Pre-Market Approval (PMA) application, of Drug/Device combination to the FDA (CBER)
- Interacted with the clinical group to review, provide feedback and submit clinical reports to evaluate therapeutic efficacy and safety of the drug/device combination in Phase 3 Clinical Trials
- Ensured that products met regulatory requirements through development, market approval, and post marketing phases. Made recommendations on Drug-Device combination product to senior management as needed

CIBA VISION (formerly Wesley Jessen Corporation), Des Plaines, IL **1998 – 2000**
Senior Regulatory Affairs Specialist

- Responsible for effectively managing all new & existing contact lenses (Class II & III) products; assessed regulatory impacts of product changes, draft strategies, established timeline, and determined appropriate pre-clinical testing
- Managed, prepared and submitted regulatory submissions (PMA, 510k, CAP, IDE and IRB) for federal agencies; received approvals within six months for regular PMAs and within a month for Real Time PMA reviews
- Interacted with regulatory agencies concerning regulatory submission, pre-approval inspections and/or labeling to expedite product approval; defined Japanese regulatory requirements for contact lenses
- Successfully submitted the Color Additive Petition to include 'Mica' as an ingredient for contact lenses, thus creating the Radiance Brand
- Facilitated Design Control process and participated in extensive FDA inspections, KEMA -CE Mark audits

ALLEGIANCE HEALTHCARE CORPORATION, McGaw Park, IL (Baxter Spin-off) **1988 – 1998**
Technical Management Chemist – Corporate RA & QA 1996 – 1998

- Designed R&D studies to evaluate and approve new materials for EO processing. Conducted studies to collect data and evaluate the effect of materials, sterilization cycles, temperature, and packaging on EO residual
- Interpreted data and defined acceptance parameters to support all plants in resolving aeration issues
- Designed, managed and conducted pharmaceutical stability projects, developed method for the determination of Drug Shelf-Life and Expiration Date, led the project to evaluate drug stability following EO sterilization
- Participated extensively in FDA inspections and yearly corporate audits
- Incorporated the ISO Standards in company corporate policy and specification

BAXTER HEALTHCARE CORPORATION McGaw Park, IL **1988-1996**
Quality/Sterility Assurance Chemist – Surgical Group 1993-1996

- Led project to evaluate the effect of time and temperature on the Ethylene Oxide residual in materials and medical devices after sterilization; accomplished faster release of product, from 10 to 5 days
- Investigated different factors to decrease aeration time for compliance of EO residual in products
- Successfully implemented the environmental program in the facility and introduced the Assay Technology
- Designed and developed a Process Challenge Pack for process validation and created database for future studies

BAXTER HEALTHCARE CORPORATION, Round Lake/McGaw Park, IL **1988 – 1993**
Senior Technician / Solutions & Containers Group – Renal Division

- Worked on the development of the new (non PVC) dialysis container for Europe
- Successfully coordinated production of new nutritional solution at global manufacturing plants within 6 months
- Designed and conducted Stability, Preclinical, End-user, and Test Market trial protocols in Europe & U.S.

EDUCATION

Northeastern Illinois University | Chicago, IL ***Bachelor of Science in Chemistry***

University of Karachi | Karachi, Pakistan ***Bachelor of Science in Pharmacy***

AWARDS

- Baxter Renal Technical Achievement Award for "Technical Innovation- New Nutritional Solution"
- CIBA Vision (Wesley Jessen) "Enterprise Award" for the introduction of ColorBlends to market