Ambareen Sheriff

Senior Regulatory Affairs Consultant

Core Competencies

- CMC Regulatory Strategy
- IND/BLA/NDA Authoring
- Labeling
- Formulation Background
- Orphan Designation
- Agency Type A & B Meetings
- Briefing Books
- Device/Drug Combo Products

Professional Summary

Ms. Sheriff has lead U.S. EMEA, HC and ROW regulatory and quality strategies supporting development and preparation of drug products, investigational studies, and marketing authorization. She has received FDA and EMEA approval for over 50 products for numerous INDs, ANDAs, NDAs, and Supplements, and has extensive working knowledge of 21 CFR, DDMAC, cGMPs, ISO, ICH, EMA and USP regulations.

With more than 32 years of experience, Ms. Sheriff is an expert in regulatory strategies for orphan drug designation, exclusivity, controlled correspondences, briefing books, etc. In addition to the different types of applications for the FDA, she has submitted drug applications to EMA, Health Canada and Scientific advice packages to MHRA, EMA and Brazil as part of global regulatory strategy. She has strong international experience of product registrations to regulatory authorities such as EMA, CE mark, TGA & TPD.

Education

B.S.	Chemistry	Northeastern Illinois University
B.S.	Pharmacy	University Of Karachi

Professional Experience

Design Space Iinpharmatics, LLC **2020 - Present**

Senior Regulatory Affairs Consultant

- 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 management of 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,
- Extensive compliance experience, warning letters, product recalls, facility inspections and 483 responses.

Celerity Pharmaceuticals **2013 - 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 departments 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 and compliance monitoring for all contract manufacturing organizations (CMO), contract research organizations (CRO),
- 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.

Marathon Pharmaceuticals **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 observations,
- 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.

Winston Laboratories **2008 - 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. **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,
- 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 resulting in the lifting of 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 **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) **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 **1988 – 1998**

Technical Management Chemist – Corporate RA & QA (1996)

- 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,

- 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 **1988-1996**

Quality/Sterility Assurance Chemist – Surgical Group (1993)

- 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.

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.