Shirlene Davis

Senior cGXP Biotechnology and Biopharmaceuticals Consultant

Professional Summary

Senior Consultant, Professionally skilled in the areas of Research and Development, Therapeutics, Oncology, Regulatory and Quality Operations regarding cGXP, (cGCP, cGLP, cGMP), cGDP, ICH regulatory standards, Biopharmaceuticals, Biotechnology Drug Development Process and Manufacturing, ISO 9001:2008 Guidelines and Regulations, Clinical Trial processes, (Phases I - IV), Clinical Research Organizations, (CROs), Contract Manufacturing Organizations, (CMOs); regarding Biologics, Solid Dose Capsules, Controlled Substance Drugs and API Manufacturing, Medical Device ; Combination Products, Quality Management Systems related to 21CFR Part 11, Investigating and Writing Deviations, CAPA Audit Reports and Manufacturing Technical Documentation Design.

In addition to my experience, I am FDA knowledgeable regarding Commercial facility FDA Actions; 483 Observations, Warning Letters, Consent Decree, Remediation's and Investigations regarding Operational and Process Improvements, Audits, FDA Readiness Inspections, (ADHOC) and Health Care Management Policy Process Improvements. I have the demonstrated ability to work both independently and within cross functional groups, interacting with business partners and investors at all levels of an organization which include working in a Matrix environment with relation to a strong skills and technology programs background , project management, problem-solving, negotiating, interpersonal and communication skills.

I have the proven ability to interpret US, EU, Canada, APAC, EMEA, World Health Organization, (WHO and ROW), Regulations and Compliance Guidelines.

Education

B.Sc., Organizational Communications, Northeastern University,
Boston, MA

Certifications

Surgical Technician - Certificate
Specialized Surgical Procedures and Techniques: Reconstructive, Cardiovascular, Ophthalmology, Orthopedics, Aseptic Technique, Equipment Sterilization Procedures and Medical Device Instrumentation.

Massachusetts Export Center,
Export School Fast - Track Program, Certificate
Global Export and Import Trades

Professional Affiliations

American Society for Quality (ASQ) Member – present

Harvard University - Biomedical Science Careers Program, (BSCP)
Alumni Member, 2004 - present

AmeriCorps, Massachusetts Service Alliance (MSA)
Volunteer Grant Reviewer, 2011- present

Systems / Equipment Expertise

Quality Management Systems related to 21CFR Part 11, Six Sigma / Knowledge, Track Wise, eDocs, SharePoint, FirstDocs, Pilgrim, Documentum, Electronic Common Technical Document (eCTD), Electronic Documentation Control System and Oracle OPM (ERP system), Laboratory Information Management Systems, (LIMS), Applied Systems SQL*LIMS, Clinical Trial Management, FACETS, Corrective and Preventative Action (CAPA) Systems, File Net, Clinical Electronic Data Capture (EDC), Electronic Case Report Forms (eCRFs) using Pharma Architect system, Crystal Reports, SAP, PRISM, PeopleSoft, Human Resource Information Systems (HRIS), Sales Logix, Plateau, Enterprise Learning Management System (ELMS), Open Text Live Link, Enterprise Quality Management Systems (EtQ), Microsoft Project, Microsoft Office, Java, Java Script, HTML, Pro/Engineer, Dream weaver, Flash and PageMaker, Visio, Adobe Acrobat, Illustrator and Writer.

Professional Experience

Senior Consultant Global Regulatory Affairs, CMC
September, 2016 – Present
Genzyme Sanofi, Allston, MA

Responsible for the direct interaction with regulatory authorities regarding global regulatory compliance of Commercial, Post-marketing submissions and Genzyme Sanofi products throughout the product life cycles. This includes providing SME guidance and management of the submissions regarding Annual and Yearly Biological Product Reports, collaborating with other developmental functional departments for the timely preparation, authoring and revising of regulatory submissions for IND's, CTA's, BLA's, NDAs and Amendments. In addition to managing the regional specific dossiers for the International Agencies regarding their compliance requirements for submissions.

Syrenity Design Consulting, MA
Principal Owner of Independent Regulatory and Quality Compliance Consulting Company
July, 2014 – Present

Remediation Projects; Consent Decree and Remediation's; Deviations and CAPA Investigations, Internal Audits, Quality Systems Management reviews, cGXP, Standard Operating Procedures, (SOPs).

Syrenity Design Consulting, MA
March 2013, - December, 2013

Types of services: 483 Observations, Warning Letters, Consent Decree Remediation's, Deviations and CAPA Investigations, Internal Audits, Quality Systems Management, Regulatory Technical Documents Design, Regulatory Technical Writer and cGXP, SOP revisions services for the Biopharmaceutical and Biotechnology Industry primarily focusing on Rare Cell and Gene - Disease Therapeutic Research.

Senior Regulatory Consultant, Regulatory Affairs and Compliance
January, 2014 - May, 2014
Shire Human Genetic Therapies, HGT, Biologics, Pharmaceuticals, Rare Cell and Gene - Disease Therapeutic Research Company, Lexington, MA

Reporting to the Head of Global Regulatory Affairs and Director of Regulatory Affairs, CMC, responsible for the global regulatory compliance of all Investigational/Commercial Shire HGT Biological products throughout the product life cycles. The key interface between CMC Regulatory, Quality Assurance, Quality Control, Manufacturing and International RA colleagues for all aspects of regulatory compliance.

Responsible for the management, evaluation and approval of the manufacturing change controls, ensuring the assessment of regulatory impact and supporting their implementation, the timely global regulatory assessments of change control proposals for both commercial and investigational products.

Primary liaison with QC/QA for management of material, stability and regulatory compliance interaction for all GMP documentation, managing timely regulatory approvals of new drugs and life cycle activities by ensuring the quality and appropriateness of submission documents and maintaining regulatory compliance for global submission plans for clinical trials and marketed products, the evaluation and management of regional specific dossiers for compliance requirements regarding Health Authority Agency Inspections and designed documents to support departmental metrics in regards to Regulatory Change Controls, CAPA's and Deviations.

Senior Regulatory Consultant for CMC, Regulatory Affairs, Compliance
August, 2012 - February, 2013
Shire Human Genetic Therapies, HGT, Biologics, Pharmaceuticals, Rare Cell and Gene - Disease Therapeutic Research Company, Lexington, MA

Reporting to the Director of Regulatory Affairs, CMC Compliance, responsible for the direct interaction with regulatory authorities regarding global regulatory compliance of all investigational /commercial Post-marketing submissions and Shire HGT products throughout the product life cycles. Managing the submissions of Annual and Yearly Biological Product Reports, collaborating with other developmental functional departments for the timely preparation, authoring and revising of regulatory submissions for IND's, CTA's, BLA's, NDAs and Amendments. In addition to managing the regional specific dossiers for the International Agencies regarding their compliance requirements for submissions. A senior member of the Change Control Review Board (CCRB) and a point of contact for the Regulatory Affairs evaluation of manufacturing change controls responsible for the review and Regulatory approval of US and International 60 Series, specifications for the packaging and labeling of drug products. The key interface between CMC Regulatory, Quality Assurance, Quality Control, Manufacturing and International Regulatory Affairs colleagues for all aspects of regulatory compliance, Regulatory Operational and Quality System Improvements and Point of contact for Regulatory Affairs regarding Agency Inspections, which include Health Canada, EMEA and APAC.

Senior Consultant for cGMP and cGLP, Quality Compliance Investigations, Commercial Finished Products
January, 2012 - July, 2012
Hospira, Contract Manufacturing Organization, (CMO) Rocky Mount, NC

Responsible for the investigation and auditing of the Contract Manufacturing Organization, (CMO), Packaging and Labeling of Controlled Substance, Fill Finish Goods pertaining to; Deviations, CAPAs, Production Line Document procedures regarding Finished Dosage Sterile Drug Manufacturing. Authored Investigator Deviation and CAPA Reports regarding the manufacturing of Biologic Controlled Substance Drugs. Collaborated with cross-functional teams to improve process and operational changes according to FDA guidelines relative to the investigation of cGMP Deviations, CAPAs and Audits and Performed Risk - Based Impact Assessments utilizing the either the following Risk Assessment tools and techniques: KAIZEN, FMEA, HAZOP/HACCP, Change Control Comparison Matrix and Risk Estimation Matrix Systems.

Senior Regulatory and Quality Assurance Consultant
June, 2011 - December, 2011
Seaside Therapeutics, Cambridge, MA

Reporting to the Sr. Vice President of Regulatory Affairs and the Director of Quality Operations, responsible for the monitoring and review of Seaside Therapeutics, Contract Manufacturing Organizations, (CMOs), Contract Research Organizations, (CROs), Laboratory Systems, Sponsors and cross - functional groups, i.e., Global Clinical Supply Chains, Research and Development, Safety and Risk Management groups in regards to the guidelines related to Clinical Trial Studies, (Phases I-IV) for

Regulatory Affairs. Monitored the development and implementation of a new Quality Document Management System to include all system maintenance processes, in addition to managing multiple cGXP projects, Authored and Revised New Submission and cGCP Annual Reports and provided support for Regulatory Inspections and cGMP audits.

Approved cGMPs, MPR's, BPR's regarding the Finished Goods Process, Specifications, Deviations, Regulatory Stability Study Protocols, CAPA's, Temperature Excursions, (OOS) related Batch Records from API, Drug Product and Drug Substance, Manufacturing, labeling and packaging process, Specifications, Deviations, Regulatory Stability Study Protocols, CAPA's and temperature excursions related to change controls; which may lead or support investigations and non-conformance reviews. Developed and maintained the metrics for vendor performance and compliance of suppliers of (raw materials) and contractors.

Approved the Clients process and procedures in regards to their Global Quality Manual, Quality Systems, i.e., External and Internal Audit Reporting regarding Materials and Management, Equipment and Facilities Systems and Vendor Validation Programs to include the Packaging and Labeling of the CMOs Finished Goods. Approved the Receipt of Documentation from vendors and contracted testing labs per Seaside Therapeutics Quality Compliance Guidelines and Authored and revised SOP's pertaining to cGXP regulations and guidelines.

Senior Consultant Regulatory Affairs and Compliance
January, 2009 - May, 2011
Genzyme Corporation, Biologics, Pharmaceuticals, Therapeutic Research Company,
Allston and Framingham, MA

A Senior Member of the Standards, Quality and Compliance Committee.
Provided SME guidance as a Reviewer and Investigator regarding Consent Decree & Warning Letter Remediation to identify and remediate departmental compliance issues regarding Deviations and CAPAs per FDA and International agency guidelines. Collaborated with cross-functional teams to improve process and operational changes according to FDA guidelines relative to the investigation of cGMP Deviations, Audits and CAPAs and collaborated on the design, implementation and validation of a new EDMS System, as a FirstDocs senior team member with the Quality Systems IT department. Reviewed and approved CSR reports for new regulatory submissions, Lead Regulatory Consultant responsible for the authoring and revisions of INDs, NDAs, Amendments, and Protocols and leading submission teams for NDA's. Approved Master Batch Records (MBR's), Deviations, CAPAs and Temperature Excursions related to Change Controls.

Consultant, Regulatory Affairs and Quality Assurance
Preclinical and Clinical Development Sciences (PCDS) Operations
March, 2008 - October, 2008
Biogen Idec, Inc., Biologics, Pharmaceuticals, Rare Cell and Gene - Disease Therapeutic Research Company, Cambridge, MA

Senior Project Manager for the planning, delivery and execution of the Good Laboratory Practice (cGLP) Quality Assurance Document Management Archive System regarding Rare Cell and Gene - Disease and Therapeutic Research. Designed, and implemented a new Archiving System according to the Compliance and Standards of the cGLP Guidelines and Standard Operating Procedures (SOP's) for the PCDS, Operations Department. Reviewed and Approved a new Electronic Scanning System Work Instruction (WI) Manual, provided SME guidance and review to the IT Department regarding the implementation and validation of the new Electronic Archive Scanning System, Audited the CAPA programs for cGLP compliance and effectiveness, Managed and conducted the internal and external vendor audits pertaining to laboratory documents and materials and Project Manager for the archiving process of backlogged CRO Laboratory archive materials per cGLP Guidelines pertaining to Protocols, Study Reports, Deviation Reports, Assays and Raw Data in a controlled environment.

Consultant, Quality Assurance, Compliance
Pharmaceuticals, Rare Cell and Gene - Disease Therapeutic Research Company
May, 2007 - September, 2007
Wyeth, Wilmington, MA

Project Manager responsible for providing Supply Partnership Site (SPS) Quality Assurance Compliance support to SPS Manufacturing and External Supply Testing Operations relative to the review and tracking of $2^{nd}/3^{rd}$ Party change controls, for Commercial Drug Substance/Drug Products. Responsible for activities all of which are related to setting and maintaining quality and regulatory compliance standards aligned with US FDA, cGMP and other applicable regulations and guidance, as well as Wyeth Standard Operating Procedures (SOPs), managed change control review program and (as needed) Chaired Change Control Review Board (CCRB) meetings to ensure that change control activities consistently meet the cGMP's, regulatory submission requirements and Wyeth Standard Operating Procedures.

Reviewed Deviations and CAPAs associated with $2^{nd}/3^{rd}$ Party Change controls, provided regulatory and quality compliance input for regulatory filings in regard to Change Controls, Regulatory Inspections and cGMP audits, Reviewed and Approved Batch Records from Drug Product Manufacturing regarding the Labeling and Packaging of Finished Goods and participated in internal and external compliance audit readiness activities.

Consultant, Regulatory Affairs, Biomedical Operations, Regulatory Affairs, Medical Affairs, Clinical and Compliance (BMRAC)
June, 2004 - July, 2006
Genzyme Corporation, Biologics, Pharmaceuticals, Rare Cell and Gene - Disease Therapeutic Research, Cambridge, MA

Project Manager for BMRAC / Regulatory Affairs, employee Student Development Plan and Resume Project regarding FDA Regulatory and Compliance Training Requirement updates.
Assisted with the Development of an Access Training Database workbook which included the use of how to access Queries, Forms, Reports and Macros that were essential for Implementation of a new Performance Management - Based Measuring System, regarding all training records and development plans for employees. Authored and revised SOP's, Work Instructions and Guides that pertain to Training, QSR and ISO requirements. Provided Live link training on document access and nomenclature for the BMRAC and General Division Quality Systems, Updated electronic Case Report Forms (eCRFs) using Pharma Architect system, assisted with implementation and testing of new employee portal system including, the training for the use of a new quality system module database, collaborated with management in BMRAC, Regulatory and Medical Affairs to assess the training needs and Development Plans of employees and provided technical assistance for employee password reset requests.

Provider Relations, New Business - Marketing Contract Specialist
July, 1998 - August, 2003
Private Healthcare Systems, Inc. / Global Managed Care Network, Waltham, MA

Demonstrated an understanding of managed care networks, general business principles, industry dynamics, marketing trends and specific operational details regarding payer contracts. Designed training material to educate clinical healthcare providers, medical device companies and vendors regarding provider /ancillary networks, risk management, regulatory mandates, State and Federal policy guidelines within their new business development contracts. Trained Physicians, Clinical Case Management Specialists and hospital billing groups utilizing spreadsheets and written materials developed specifically to explain the structure of the program and contract expectations. Collaborated with internal, external departments and medical device equipment vendors to ensure contract compliance and implementation of provider contracts, provided discounted pricing/reimbursement payment information to government agencies, Physician Health Organizations (PHO's), hospitals, pharmaceutical providers and health insurance carriers. Provided COE - (Centers of Excellence) hospital providers with verification of contract details, the percentage of payment on organ transplant procedures, Medicaid regulations, NCQA requirements and drug reimbursements.