James A. Barrow, BS Biology, J.D.

22 Governors Way
Madison, CT 06443
(203) 903-3400

Jamesbrrw@comcast.net

150 E. 44th St. apt. 29H
New York, N.Y. 10170
(203) 903-3400

COMPLIANCE IN FDA REGULATED INDUSTRIES AND LEGAL SERVICES

●CAPA ●SCAR ●Auditing ●Compliance ● Supplier Management ● Clinical Development ● Regulatory Affairs ● Labeling and Promotions ● Quality Assurance ● Manufacturing ●Law

I have a clear track record of success and innovation in FDA regulated industry including Pharmaceutical and Device Manufacturing (Aseptic Parenteral, Bulk Powder, Powder, Liquid, pre-filled syringes) and Packaging (unit-dose, multi-dose, form fill seal, card/blister/seal. I have considerable experience in Compliance Auditing, CAPA, Class II and III Medical Device QA/RA/Labeling/ Clinical Development, Blood Diagnostics QA/RA/Supplier Controls, Project Management, Product/Process Validation and Life Sciences (DNA Sequencing) Quality Assurance. Legal experience includes summer internship assisting in documentation harmonization, research for immigration case with oral argument before 2nd Circuit Court, and forensic discovery to defend patent interference case.

~~ *Selected Highlights* ~~

- Over twenty-five years' experience in all aspects of Quality Assurance in FDA regulated industries
- Have conducted hundreds of internal and supplier GMP and ISO Audits. Have developed programs and written SOPs for auditing at 5 companies. Have led teams of internal, external and global auditors.
- I have "owned" scores of CAPAs, written CAPA SOPs for three companies, and have successfully integrated a harmonized global CAPA system at Roche.
- I have expertise in all aspects of drug manufacturing including liquids, vials, powder fill anpules, pre-filled syringes and was promoted to Supervisor at Roche Nutley Headquarters
- Designed and implemented company wide document control system for U. S. Surgical (aka Tyco Healthcare/Covidien/Medtronic)
- Reengineered label review and labeling controls resulting in no further label related recalls during my tenure as Section Head at U.S. Surgical
- Supported Product and Process Validations for Class II and III medical devices.
- As Clinical lead for several successful class III devices, managed clinical studies, directed CROs, monitored, authored final clinical report, managed site supplies, initiated and trained sites, audited sites, hosted FDA pre-approval inspection, negotiated labeling with FDA.
- Participated in or was primary company spokesperson for more than 20 FDA or ISO inspections
- Trained hundreds of employees in GMP and ISO requirements, and for three consecutive years and I was invited to speak, and spoke as GMP expert at FDLI annual meeting.
- Built from ground up, supplier management and control systems at 3 companies. Was responsible for supplier auditing programs of suppliers.
- Recently graduated from law school with honors and was admitted to the CT Bar in 2013.
- Proficient in the development of department SOPs and use of all Microsoft applications
- Know basic operation of MRP and accounting software such as Misys and Sage 50 (Peachtree)
- Have led Design Control processes for software and hardware for CT Scanners
- Have managed Facilities including maintenance, security, fire protection, safety and pest control

PROFESSIONAL EXPERIENCE

CurveBeam LLC, 2015-2016

Manufacturer and Developer of CT Scanners

Consultant, Acting VP Operations

Performed as a Change Agent overseeing, drafting, and implementing systems at this company of approximately 30 people. Systems and responsibilities under my supervision included: GMP Compliance, FDA Liaison, R+D, Sustaining Engineering, Manufacturing, Quality Assurance, Clinical Development, Regulatory Affairs, Supplier Quality, Purchasing, Accounts Payable, Accounts Receivable, Radiation Safety, IT, Metrology, Facilities, Field Service, Complaints, Installations, Document Control and other duties such as the review of legal documents and most aspects of HR.

Accomplishments

- Reorganized my staff of 17 individuals into 4 cohesive groups
- Promoted 2 Senior Engineers to Managers to oversee groups
- Conducted cGMP, ISO 13485 compliance audits, preparing Company inspections
- Prepared 510k with for 3D CT Scanner for extremities
- Oversaw engineering activities including software, device and process Validations
- Initiated and closed CAPAs for Training, Metrology and CAPA
- Responsible for purchasing and expenses of 150,000 avg. per month
- Oversaw creation of Radiation Safety plan in response to state audit
- Managed all staff on site and actively intervened in resolution of personal conflicts
- Met with MD users in the field to gather customer feedback
- Drafted and/or approved all POs, invoices and payments
- Reviewed, negotiated, approved, multiple legally binding documents including leases, Sales Agreements, NDA agreements, Warranty agreements, Price lists etc.

Synergy Pharmaceutical, NY, NY 2014-2015

A Drug Development Company

Consultant, GMP Compliance

I was responsible for creating a sustainable, compliant, quality system for the manufacturing operation. Activities include SOP generation, training, establishment of CAPA, SCAR, and MRB systems, harmonization with Ht, process definition, and instituting supplier controls. Managed systems until they could be turned over to sustaining personnel.

Accomplishments:

- Established and implemented Quality System at CMC operations center
- Authored and implemented SOPs for document control, methods development, review of batch records, and release of product, process control, validation, and supplier control. (on-going)
- Successfully built communication bridge with HQ facility, while harmonizing quality systems

- Established CAPA system and assured open CAPAs were closed on time

454 Sequencing, a Roche Company, Branford CT 2012- 2014
DNA Sequencing/Life Sciences unit of Roche

Senior Quality Engineer, Compliance, Supplier Management, Auditing
Responsible for providing Quality Assurance services and solutions to Roche's 454 Sequencing operation.

Accomplishments:
- Managed internal auditing program, supplier auditing, and hosted third party audits including ISO, TUV, UL, Corporate, Divisional, and Customer, with one direct report and cross-functional teams.
- Re-engineered processes of supplier control and management to assure key suppliers received adequate monitoring and Supplier Corrective Action Requests were thoroughly satisfied
- Successfully closed all CAPAs on time which resulted from SCARS, Internal Audits, and Third Party audits. Acted as reviewer for other CAPAs which resulted from product defects
- Helped to address Validation issues present in design control processes.
- Assisted in-house patent agent in discovery activities which resulted in a favorable determination by the Patent Appeals Board, deciding ownership of emulsion PCR technology

Covidien/Medtronic, North Haven CT 2009 - 2011
Global Medical Device manufacturer with greater than 11 billion dollars in annual revenue

Manager Supplier Quality, Surgical Devices
Audit Team Leader
I led a department of up to six auditors. My responsibilities included development and execution of all compliance activities regarding suppliers including SOP writing, auditing, leading audits, monitoring, SCAR, supplier corrective action requests, and troubleshooting.

Accomplishments:
- Increased number of supplier audits from 20 to 70 in one year without the addition of resources
- Re-wrote SOPs and created intelligent checklists which scored suppliers objectively
- Assisted in investigation of device failures potentially related to supplier activities
- Hired and trained new auditors
- Was selected to spend 3 weeks in Manchester U.K. assisting facility in preparation for FDA audit, (needed to close 86 open CAPAs in a two week period).
- Created a Validation review program for suppliers in response to quality issues.

ITC Medical, Piscataway NJ 2007-2009
Manufacturer of Point of Care, blood coagulation instruments and reagents

Senior Manager, Quality Assurance
I drafted and established systems for internal auditing and supplier control. Participated in 2 month long FDA inspection and assisted in remediation of compliance issues.

Accomplishments:

- Created Supplier Management system from the ground up including SOPs for evaluation, qualification, selection, auditing, monitoring, managed the program.
- Participated in resolution of warning letter issues related to Product Validation and Supplier control and assisted in the hosting of two month long FDA inspection**.**
- Conducted all internal audits and acted as compliance resource for all department heads.

Diagnostica Stago, Parsippany NJ 2002 - 2006

Global manufacturer of large automated blood coagulation instruments and reagents

U.S. Director Quality Assurance and Regulatory Affairs
Responsible for Quality System and all FDA interactions

Accomplishments*:*

- Led all QA, RA, and Compliance efforts
- Hosted first company FDA inspection where no 483 was issued
- Reviewed and made all registrations and new product submissions to FDA
- Conducted internal and supplier audits

United States Surgical/tycoHealthcare, Norwalk CT 1992 – 2002

Surgical Instrument and Suture company which pioneered surgical stapling and Laparoscopic surgery.

Held roles of increasing responsibility including Section Head QA (4 reports), RA Labeling Manager (6 reports), Clinical Program Manager (3 direct reports, CRO oversight), RA Manager

Accomplishments*:*

- Led team of internal compliance auditors, assisted in hosting FDA inspections
- Helped achieve first time ISO certification, hosted ISO audits, acted as in-house advisor on FDA compliance issues
- Created corporate document control system for written procedures from ground up, influenced all departments to adopt new method
- Led RA Labeling review function with up to six direct reports. Revamped approval process assuring accountability
- As Clinical Lead for company, succeeded in revitalizing two troubled clinical trials by building strong relationships with sites and creatively solving issues.
- Led Clinical teams which were responsible for 2 class III device approvals, managed CROs, initiated sites, filed protocol amendments, authored final clinical reports, managed device supplies to sites, answered FDA questions, hosted pre-approval inspections, negotiated labeling with FDA
- Made several successful submissions to FDA and Canadian health authority for trial close outs, annual reports, and new product submissions (aneurism clip).
- Represented company when authoring responses to FDA request for public comment

Hoffmann-La Roche, Nutley NJ 1984-1992
Aseptic Parenteral Pharmaceutical Manufacturing

Pharmaceutical Production Supervisor (up to 4 direct reports, and 50 indirect reports)

Career at Roche began with work as a technician in cold kit production for the radio nucleotide Cinti-chem division. Was promoted to supervisor at Nutley Headquarters and was highest level person in Operations Department second shift. Was responsible for component preparation, automated and manual inspection, warehousing, DEA vault, product pasteurizations and packaging.
Was assigned to first shift operations where I was responsible for unit dose production. I supervised up to 5 lines each running ampules or vials at rates up to 288 per minute. Also responsible for powder fills and clinical manufacturing.

Accomplishments:

- While in charge of second shift operations managed up to 40 personnel
- Received awards for perfect attendance, PIP product improvement program, and was rated number 1 supervisor
- Successfully investigated product problems, equipment issues, and component failures
- Was credited with saving hundreds of thousands of dollars in re-inspection hours, after instituting a vision test for cracked vial necks at the pre-wash filling station
- Was personally responsible for salvaging 4000 liters of Agribon drinking water solution by writing an AANDA addendum which opened up the color specification

EDUCATION

State University of New York at Binghamton, BS Biology, 1983

Quinnipiac University School of Law, J.D. 2011

PROFESSIONAL AFFILIATIONS

American Bar Association
Connecticut Bar Association
Member of Connecticut Bar
Food and Drug Law Institute
American Society of Quality Control

PROFESSIONAL LICENSE AND CERTIFICATIONS

Law, State of Connecticut
Certification in Computer Programming, Airco Computer learning Center
Also: Certified NJ Substitute Teacher, PADA Advanced Scuba, CT Boating Certificate, NJ certified EMT