Compliance Director

AREAS OF EXPERTISE

- **Conduct FDA/International Agency Inspections**
- **Domestic and International contractor GMP Inspections**
- **Pharmaceutical QA Leadership in both Manufacturing and R&D**
- **Multi-faceted experience (QA, QC, Tech Support, Regulatory Affairs)**
- **Quality Systems & Continuous Improvement**
- **FDA GMP Regulations/ ICH Guidelines**
- **Departmental Management**
- **New Facility Design and Qualification**
- **Global Networking**
- **Branded and Generic Pharmaceutical experience**
- **Advanced degrees (MS Chemistry and MBA)**
- **ASQ Quality Auditor (Certified)/ RAPS Regulatory Affairs Certification (RAC)**
- **Regulatory submissions and promotional materials**

INTRODUCTION

Consultant is a GMP Quality Assurance and Regulatory Affairs leader with extensive experience in regulatory inspections, global cross-functional collaboration, and quality systems creation in large and small international pharmaceutical companies. Expertise spans both development and post market approval, in API and finished drug product. As a member of global organizations, well versed in the development of matrix management techniques and accomplishing standardization across the business.

WORK EXPERIENCE

2016 – Present
Industry Consultant
- Regulatory Project Manager for a multinational global biopharmaceutical company.
- Conduct domestic and international GMP Audits for a biopharmaceutical company.

2014 – 2016
Siegfried-USA, Pennsville, NJ
Compliance Director
Duties:
- Lead continuous improvement project with annual savings of over one million dollars through more efficient cleaning, vendor certification and more focused sampling.
- Instituted continuous process verification for Siegfried's products using risk assessment techniques.
- Lead a department of 35 professionals including QC laboratories, QA Managers, Quality Systems personnel and Regulatory Affairs.
- With over 20 customer audits in 2015, kept our compliance record of no critical observations intact.
- Hosted FDA GMP inspection with no 483 issued.

2003 – 2014

AstraZeneca Pharmaceuticals, Wilmington, DE

Associate Director and Group Manager Regulatory Affairs, (2010 – 2014)

Duties:

- Key member of the Regulatory Project Manager management team, responsible for developing 13 direct reports, resourcing drug projects, and implementing continuous improvement projects globally to drive efficiency and effectiveness.
- Developed professional capabilities for the Regulatory Project Managers by leading global meetings designed to define areas of expertise and improvement, by compiling information from various regulatory areas, and utilizing other AstraZeneca function's established capabilities.
- Effectively integrated US regulatory strategies for Prilosec Rx and OTC across several global product teams. Led communication of risk identification and mitigation measures to ensure successful Health Authority interactions.
- RAPS (Regulatory Affairs Professional Society) Chair representing AstraZeneca for Philadelphia Section. Responsible for planning events and strategically delivering networking opportunities for the company and RAPS members.

Site Head, R&D GMP QA, (2003 – 2010)

Duties:

- Created and implemented a successful Quality Improvement plan with a critical labeling supplier to raise their acceptability for continued partnership.
- Implemented a new risk based quality system for Phase I clinical development and manufacturing to reduce the time to First Time in Man.
- Established a GMP Discussion group between development quality assurance personnel from a dozen large pharmaceutical companies to facilitate benchmarking.
- Utilized my knowledge of EU GMP regulations to lead the inspection activities of the Swedish MPA, in order to obtain certification to supply clinical trials in Europe.
- Conducted numerous due diligence audits for in-licensed products integral to the success of the company.

1986 – 2002

The DuPont Pharmaceutical Company/Bristol-Myers Squibb

Associate Director R&D QA – Chem Process, Deepwater, NJ, (1996 – 2002)

Duties:

- Responsible for all Quality Assurance activities and personnel for the Chem Process Pilot Plant where API (Active Pharmaceutical Ingredient) for clinical supplies was manufactured and then transferred to a contract manufacturer.

Head Multisource R&D Quality Assurance, Wilmington, DE, (1995 – 1996)

Duties:

- Responsible for all Quality Assurance activities for the Generic Division R&D group where finished dosage forms were developed and filed.

Site Head Quality Assurance/Quality Control, Garden City, NY, (1986 – 1994)

Duties:

- Responsible for Quality Assurance and the Quality Control laboratories at the finished dosage form/API facility. Lead a team of fifty plus professionals.

Previous roles included: Head of Purchasing, QA Contract Manufacturing Specialist, and QC Chemist.

EDUCATION

Adelphi University
Master of Business Administration (MBA)

St. John's University
Master of Science: Chemistry

St. John's University
Bachelor of Science: Chemistry

CERTIFICATONS

- Certified Quality Auditor (CQA)
- Regulatory Affairs Certification (RAC)