**Director Quality and Regulatory Compliance**

**AREAS OF EXPERTISE**

- **Quality Assurance**
- **ISO 13485**
- **GMP**
- **Cross-Functional Team Leadership**
- **21 CFR Part 11**
- **Design Control**
- **Medical Devices**
- **Quality Auditing**
- **V&V**
- **Six Sigma**
- **CAPA**
- **Validation**

## INTRODUCTION

Consultant is an industry professional with over 20 years of relevant experience. A proven leader with the ability to guide teams to success. Able to apply sound, systematic, problem-solving methodologies in identifying, prioritizing, communicating, and resolving quality issues. Successfully identifies and implements best practices to improve efficiency without risking compliance. A change and thought leader that champions quality management system and product quality improvement.

## WORK EXPERIENCE

**2017 – Present**
Industry Consultant

**2010 – 2017**
Philips Electronics NA, Bothell, WA
Director Quality and Regulatory Compliance
**Duties:**

- Ensure strategic alignment of quality activities between global business units to create a common quality management system direction for Philips.
- Provide leadership to all Philips business locations to ensure product quality and quality system compliance to ISO 13485 and FDA Quality System Regulation (21 CFR 820), Environmental compliance to ISO 14001, Canadian CMDCAS, Japan PAL regulation and all other worldwide medical device quality and environmental regulations.
- Provide quality leadership and oversight to ensure ongoing quality management system compliance, as measured by key performance indicators and audit (external and internal) results.
- Lead quality system improvement initiatives within business group including standardization of key processes.
- Provide operational support to business group supply chain, including support for manufacturing, supplier management, logistics and M&A integration.
- Interface with Q&R management to address product quality and regulatory compliance issues and requirements.
- Develop and implement a compliance strategy and Internal Audit program that ensures that Philips businesses are compliant to regulatory requirement.

- Conduct due diligence inspections for potential mergers and acquisitions to ensure Philips is fully aware of the regulatory compliance status of targeted company(s).
- Provide compliance expertise and guidance, including: information, opinion and interpretation to entire business.
- Create a quality community within the business groups.
- Analyze data for trends and recommend preventive actions as necessary.
- Lead quality system management reviews.

**2006 – 2010**
Boston Scientific Corporation, Natick, MA
Senior Quality Systems Manager (2008 – 2010)
**Duties:**
- Responsible for managing a team of eleven with four direct reports.
- Provide leadership in quality assurance and regulatory compliance on departmental or cross-functional initiatives.
- Provide direction, coaching, and mentoring on quality and regulatory compliance to departmental, functional, site and divisional personnel.
- Manage the implementation of process controls, and CAPA systems designed to meet or exceed internal and external requirements.
- Identify and manages the implementation of effective quality systems to support the development, qualification, and on-going manufacturing of products.

Global Regulatory Compliance Auditor (2006 – 2008)
**Duties:**
- Supported third-party audits, subject matter expert training and other initiatives which increased Boston Scientifics' corporate-wide FDA readiness.
- Performed as auditor and lead auditor for corporate audits of manufacturing sites and focused Quality System topic audits for medical devices and combination products.
- Identified best practices and highlighted in audit reports systemic areas for improvement within the organization.
- Communicated FDA responses and associated commitments throughout Boston Scientific.
- Facilitated FDA re-inspection readiness and general audit preparedness.
- Provided assistance to sites during regulatory inspections as Field Corporate Audit Support Representative.
- Developed audit document templates for agendas and report formats utilizing FDA QSIT technique, international standards (e.g. EN ISO 13485:2003) and other applicable regulations.

**2004 – 2006**
Abbott Laboratories, Abbott Park, IL
Corporate Inspection Administrator
**Duties:**
- Consulted and advised division on regulatory policies and quality related issues.
- Managed the inspection process, developed inspection strategy, delivered Audit Preparedness training.
- Conducted internal and supplier audits for the division.
- Served as point of contact during regulatory and non-regulatory inspections for the division.
- Creates and implements the inspection strategy for all regulatory and non-regulatory inspections.
- Facilitated and/or supported 40+ Regulatory and non-regulatory inspections on a yearly basis.
- Coordinated the organization response to all audit observations as well as facilitated the response process.

**1999 – 2004**
Aventis Behring L.L.C., Kankakee, IL
Quality Systems Engineer/Validation Specialist/Auditor
**Duties:**

- Responsible for reviewing change control documentation for compliance to cGMP regulations, federal guidelines and industry standards.
- Reviewed and executed validation protocols.
- Conducted internal and supplier audits.
- Supervised and trained all contractors associated with projects.

**1997 – 1999**
Novex Pharma, Richmond Hill, ON, Canada
Calibration Engineer
**Duties:**

- Supported the laboratory, R&D and production by ensuring instrumentation/equipment were calibrated and maintained per schedule.

## EDUCATION

**2010**
Babson College, F.W. Olin Graduate School of Business, Wellesley, MA
Master of Business Administration

**1996**
University of Western Ontario, London, Ontario Canada
Bachelor of Science: Chemistry