Director, Regulatory Affairs & Compliance

AREAS OF EXPERTISE

- **Product Approval/Clearance Submissions (e.g., 510(k)s, PMAs)**
- **Common Technical Document for Pharmaceutical Products**
- **Quality System Manual and Quality System Procedure Origination**
- **FDA 483, Warning Letter and Notified Body Assessment Responses**
- **Quality System Training**
- **FDA QSR and ISO 13485 Audits**
- **Import/Export Issues (e.g., 801(e), Certificates of Exportability, etc.)**
- **Product Reports and Subchapter J – Radiological Health**
- **Combination Device/Drug Submissions**
- **Medical Device (IDE) Clinical Trial Protocol Design, Management, Analysis and Report Writing**
- **Design Control, CAPA, Complaint Handling, Process Control, and Records Development**
- **Technical Files and CE Marking**
- **Canadian Medical Device Licensing**
- **Auditing Medical Device and Pharmaceutical Clinical Trials**
- **Recalls, Safety Alerts, and Physician Advisories**

INTRODUCTION

Thirty years working in the Medical Industry in the areas of Regulatory Affairs, Quality Assurance, Clinical Studies, R&D, Test, Manufacturing and Technical Service. The last nineteen years have been spent serving numerous clients worldwide as a Regulatory Affairs Consultant, providing compliance, submissions and training services to the Medical Device, IVD, Pharmaceuticals and Biologics Industries. Expert knowledge of US FDA, Health Canada and the European Medical Devices Directive regulations.

WORK EXPERIENCE

10/1999 – Present
Industry Consultant
Example Engagements:

- Work with clients in the medical device and pharmaceutical industries to develop quality assurance, manufacturing, and regulatory strategies for compliance with the FDA and other worldwide regulatory bodies and gain product approval / clearance.
- Writing and submitting 510(k) Premarket Notifications, and Premarket Applications (PMA's), including for Combination (Device/Drug) Products.
- Creating Common Technical Documents.
- Designing and managing clinical studies on human subjects.
- Conducting assessments of client studies, procedures, and programs to determine compliance to cGMP's, GCP's and GLP's.
- Producing Quality Systems Manuals, Policies and Procedures to comply with worldwide regulations and standards.
- Developing and implementing corrective action plans to address deficiencies in companies' quality systems.

- Authoring responses to FDA-483's and Warning Letters and instituting strategies for bringing companies back into compliance.
- Compiling technical files to support the CE marking of products.
- Achieving ISO-13485 Registration and CE marking.
- Training company employees in all aspects of regulatory affairs and quality systems.

02/1998 – 10/1999
Fischer Imaging Corporation, Denver, CO
Director, Regulatory Affairs & Compliance
Duties:
- Managed corporate regulatory affairs and quality systems to comply with worldwide regulations and standards.
- Acted as Quality Management Representative at Executive level.
- Chaired Corrective Action Board.
- Managed Design Control and Technical File Teams.
- Handled clinical trials and product submissions for government approval/clearance.
- Managed FDA inspection and ISO-9001 assessments, along with the responses to deficiencies.
- Represented company for the National Electrical Manufacturers Association (NEMA).

08/1995 – 02/1998
GAMBRO Healthcare, Lakewood, CO
Senior Regulatory Affairs and Quality Systems Development Specialist
Duties:
- Prepared regulatory strategies, 510(k), IDE submissions and monitored clinical trials.
- Developed internal regulatory and quality procedures.
- Coordinated FDA inspections and ISO-9001 assessments.
- Managed FDA-483 and warning letter responses, along with all corrective actions leading to the clearing of warning letters.
- Coordinated recalls and other field actions.
- Managed quality systems audit program.
- Provided corporate quality systems training.
- Member of the Management Review Team and Technical Advisory Group.

1990 – 1995
Cochlear Corporation. Englewood, CO
Technical Manager
Duties:
- Managed Technical, Customer Service and Documentation departments.
- Handled PMA submissions and supplements.
- Coordinated FDA inspections and FDA-483 responses.
- Developed company quality system procedures.
- Assisted with the development of new products and accessories.

03/1988 – 12/1989
Bard Electro Medical Systems. Englewood, CO
Production Test Manager/Electrical Design Engineer
Duties:
- Managed Production Test department. Developed test procedures and fixtures.
- Designed new products and supported the design of current products.

EDUCATION

1996
Regis University, Denver, CO
Master of Business Administration: Operations Management

1988
Metropolitan State College, Denver, CO
Bachelor of Science: Electrical Engineering Technology

PROFESSIONAL AFFILIATIONS

- Regulatory Affairs Professionals Society (Certified).
- American Society for Quality – Biomedical Division.

AWARDS AND HONORS

- 1985 The National Dean's List.
- 1986 Tau Alpha Pi National Honor Society.
- 1986 Golden Key National Honor Society.
- 1987 National Collegiate Engineering Award.
- 1987 Academic All-American Collegiate Award.
- 1984, 85, 86, 88 Vice-President's Honor Roll.
- 1986, 87, 88 Colorado Scholar's Award.
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