Director, Regulatory Affairs & Quality Assurance

AREAS OF EXPERTISE

- **Over 25 years' experience in medical device industry**
- **IVD 510(k) submissions, *de novo* applications, and clinical studies**
- **Regulatory affairs and quality systems for start-ups**
- **Standalone software 510(k)s and PMA**
- ***de novo* application, neurology**
- **Pre-submissions (Pre-IDEs) for multiple device types**
- **ROW product registrations (EU, Asia-Pacific, Australia/New Zealand, Central/South America, Africa, Eastern Europe/Russia)**
- **CLIA'88 requirements for IVD manufacturers**
- **Point of care testing devices**
- **Breath analyzers**
- **Regulatory strategy**
- **Software-controlled devices**
- **Physical therapy and orthopedic devices**
- **Neurological devices**
- **Ophthalmic devices**
- **Aesthetic devices**
- **CE marking (MDD, IVDD) & Technical Files**
- **Canadian Medical Device License submissions**

INTRODUCTION

Consultant has over 25 years' progressive experience in product development, regulatory submissions, regulatory compliance, clinical studies, and quality assurance in the medical industry, with particular expertise in developing and implementing regulatory, quality, and clinical functions in start-up and small company environments. Consultant has extensive experience with point of care testing devices, *in vitro* diagnostic devices, electro-mechanical and software-controlled devices. Consultant brings a pragmatic, practical approach to regulatory, quality, and clinical functions to assist medical device companies in achieving their business goals. Consultant's track record of successful submissions ensures that commercialization schedules are met with a minimum of questions from FDA and with desired claims intact. Consultant's work with internationally distributed medical devices has given her a global perspective on product registrations and compliance. Consultant has been Regulatory Affairs Certified (RAC) since 1998.

PROFESSIONAL EXPERIENCE

Regulatory Affairs

- Primary contact for major regulatory agencies: CA State, US FDA, Canada, EU Notified Bodies
- Developed regulatory strategies for FDA Class I, II, and III devices; EU/MDD Class I, IIa and IIb devices; Canadian Class I, II, III devices.
- Prepared, submitted, negotiated regulatory applications, including FDA pre-IDEs, Traditional 510(k)s, Special 510(k)s, *de novo* petitions, and PMA submissions; international product registrations (worldwide)

- Established and maintained Technical Files, Design History Files, global product dossiers
- Analyzed new or revised regulatory requirements for impact on development, operations, sales/marketing
- Labeling and advertising review and approval

Quality Systems
- Management Representative to senior management, as required by FDA QSR, ISO 9001, and ISO 13485
- Experienced with FDA Quality System Regulations, ISO 9001/ISO13485 standards, EU/Medical Device Directive (MDD) and In Vitro Diagnostic Devices Directive (IVDD), Canada's Medical Device Regulations, Japan's PAL, Australia's Therapeutic Goods' Regulations
- Developed and implemented initial Quality System framework for start-up clients
- Managed compliance audits and inspections; performed internal audits
- Managed and documented product field actions: recalls, market withdrawals, field corrections
- Investigated and reported adverse device events (FDA MDR, EU EVS, Canada, AUS)
- Developed and implemented employee training for regulatory compliance (FDA and ISO Quality Systems topics), advertising/promotional activities, laboratory safety practices (including biohazard training)

Clinical Affairs
- Established clinical studies function in start-up phase companies, including study design, protocol development, site selection, IRB submissions, study personnel training, site monitoring
- Designed and managed clinical studies for Class II *in vitro* diagnostic devices (both in manufacturer's laboratories and at external sites of use). Analyzed and summarized results for regulatory submissions.
- Directed animal and human studies for Class II minimally invasive surgical devices

Management/Corporate
- Supported four employers through venture capital funding and/or Initial Public Offering activities
- Established regulatory and quality systems framework for start-up phase companies

Technical
- Responsible for initial assay development activities for serum T4 assay for POC application
- Over 14 years' experience in all disciplines of clinical laboratory science (chemistry, hematology, coagulation, serology, immunohematology, microbiology), including daily interaction with physicians and other healthcare practitioners
- Skilled phlebotomist

WORK EXPERIENCE

2003 – Present
Industry Consultant

2016 – Present
Dexcom, Inc., San Diego, CA
Sr. Director, Regulatory Affairs, Software Center of Excellence – Portland, OR (1/2 time)

2004 – 2005
Apieron Biosystems, Menlo Park, CA
Director, Regulatory Affairs & Quality Assurance

2000-2002
Natus Medical, Inc., San Carlos, CA
Director, Regulatory Affairs & Quality Assurance (2002)
Director, Regulatory Affairs (2001-2002)
Manager, Regulatory Affairs (2000-2001

1998-2000
ORATEC Interventions, Menlo Park, CA (acquired by Smith&Nephew)
Director, Regulatory & Clinical Affairs

1989-1998
Biocircuits Corporation, Sunnyvale, CA
Director, RA/QA/CA (1998)
Manager, Regulatory and Clinical Affairs (1995-1998)
Manager, Technical Service (1997-1998)
Regulatory Affairs Specialist (1993-1995)
Assay Development Scientist (1991-1993)
Research Technician (1989-1991)

1977-1989
Kennewick General Hospital, Kennewick, WA
Clinical Laboratory Technologist

1975-1977
Kadlec Medical Center, Richland, WA
Clinical Laboratory Technician

EDUCATION

Saint Mary's College, Moraga, CA
BA, Health Services Administration

Shoreline Community College, Seattle, WA
Associate of Applied Arts and Sciences, Clinical Laboratory Technology

Continuing Education courses to maintain RAC and CLS certifications (ongoing)

PROFESSIONAL AFFILIATIONS

Certifications
Regulatory Affairs Certified (RAC), Regulatory Affairs Professional Society
Clinical Laboratory Scientist (CLS), National Certification Agency for Medical Laboratory Personnel
Medical Laboratory Technician (MLT), American Society for Clinical Pathology

Memberships
Regulatory Affairs Professional Society (RAPS)
American Association for Clinical Chemistry (AACC)
American Society for Clinical Laboratory Science (ASCLS)

Professional Activities
Instructor, medical device webinar series, BioPractice, 2012-present
Instructor, Oregon Bioscience Association (OBA) BioPro Workplace Training, 2007-2014
Guest Lecturer, UC-Santa Cruz Extension Certificate Program in Regulatory Affairs, 2006-2010
Speaker, RAPS Medical Device Overview Webcast, June 2006
Speaker/Moderator, RAPS 510(k) Webcast series and Workshops, 2002 - 2003
Program Committee Member, RAPS Medical Device Seminar, San Francisco, CA March 2003
Guest Lecturer, Biomaterials Engineering course, San Jose State University, 1999 - 2001

Publications
Expedited Medical Device Submissions in the US: Special 510(k), Abbreviated 510(k), HDE, Regulatory Affairs Focus, March 2015
Design Controls Overview: The CMC Section for Devices, Regulatory Affairs Focus, June 2005