ELIZABETH MALO

MS RA, Drugs, Biologics, and Devices

Principal Consultant, MedReg Consulting, LLC

Proven exceptional performance in medical product development and lifecycle management through provision of strategic and tactical regulatory guidance for product classification, development, and market approval by domestic and international regulatory authorities.

Key Skills & Experience:

- Regulatory affairs leadership for product pipeline and corporate strategic planning
- Quality and regulatory auditing services for due diligence and compliance assessments
- FDA submissions including: NDA/ANDA, PMA submissions/supplements, IDEs, EUAs and pre-submissions for medical devices, including traditional and alternative formats, numerous 510(k)s, CLIA Certification, waivers, and CLIA compliance and STED documentation for global submissions[i]
- Expert in product development process for *in vitro* diagnostic medical devices, companion diagnostics, electro-medical devices (surgical devices, patient monitoring technology), implanted devices (cardiology & neurology), laboratory developed tests, and streamlined QMS for combination products
  - Quality management system architecture and design control training and compliance for medical device manufacturers
  - IDE process and documentation for *in vitro* diagnostics and other medical devices
  - Training, preparation, and leadership for audits & inspections (BIMO, CLIA, FDA)
  - FDA appeals and subsequent product clearance
- Compliance and submission requirements for device constituents of combination products
- Highly team-oriented with recognized initiative, leadership, and communication strengths
- Well-developed listening, organizational, project, and resource management skills
- Excellent oral presentation skills and strong technical writing skills

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CAREER EXPERIENCE

MedReg Consulting, LLC
Boulder, CO **5/2017- Present**

Principal Regulatory Affairs Consultant

- Negotiate, direct, and perform regulatory consulting activities for a wide range of medical products with primary focus on medical devices; serve as client lead on RA consulting projects
- Frequent PMA and 510(k) submission work (original PMA drafts and supplements & various 510(k) submissions) as well as regulatory impact assessments for design changes through product lifecycle
- EU MDR remediation planning & implementation
- Manage client contracts and delivery of regulatory strategies and submissions for small and medium-sized enterprises as well as large, global medical products companies
- Due diligence assessments of regulatory compliance and remediation planning
- Coordinate and lead meetings with regulatory authorities

Dohmen Life Science Services
Denver, CO **9/2016- 6/2017**

Director, Regulatory Affairs Consulting

- Negotiated, directed, and performed regulatory consulting activities for a wide range of medical products with primary focus on medical devices
- Served as client lead on RA consulting projects; managed internal and outsourced team of associate and management level RA team members
- Served as US Agent for foreign medical device manufacturers
- Managed client contracts and delivery of regulatory strategies and submissions for small and medium-

sized enterprises as well as large, global medical products companies
- Coordinated and led meetings with regulatory authorities

INDEVR, INC. **6/2015- 8/2016**
Boulder, CO

Director, Regulatory and Clinical Affairs

- Developed and managed Regulatory Affairs and Clinical Affairs business strategy and execution; designed and implemented clinical study for class II IVD medical device
- Managed interactions with external resources including analytical and clinical test sites and technical contractors
- Provided regulatory strategy under BARDA development contract with planned CLIA waiver; regulatory strategy for product pipeline and product development activities
- Led design and implementation of verification and validation study plans and protocols; managed third-party review by government
- Coordinated and led face-to-face and teleconference meetings with FDA

BIODESIX, INC. **6/2014- 6/2015**
Boulder, CO

Director, Regulatory Affairs

- Developed and managed Regulatory Affairs and Quality Assurance departments and activities
- Managed interactions with US FDA and pharmaceutical partner in co-development of CDx, pharmacogenomics, correlative science, & laboratory developed test regulation
- Regulatory lead for product development activities of molecular *in vitro* diagnostic tests
- Primary liaison for interactions with all regulatory compliance and public health authorities; coordinated and led face-to-face and teleconference meetings with FDA

COVIDIEN, INC. *Acquired by Medtronic (2015)* **5/2011- 5/2014**
Boulder, CO

Regulatory Affairs Product Manager, Surgical Solutions

- Developed and implemented regulatory strategy for breakthrough energy- based surgical technologies and software devices; included electrosurgical cutting and coagulation devices and stand-alone software
- Provided regulatory leadership in entrepreneurial business unit designed to move nimbly under large corporate infrastructure
- Coordinated global registrations with ex-US Covidien RA team members

Senior Regulatory Affairs Specialist, Respiratory & Monitoring Solutions

- Supported product lifecycle and regulatory submission and registration activities for ventilator and oximetry devices; managed domestic and international regulatory submissions and interactions with health authorities
- Collaborated with and supported OEM regulatory partners in planning, integration, and registration of medical devices that incorporated Covidien OEM solutions; developed technical dossiers for OEM partners
- Coordinated and led face-to-face and teleconference meetings with FDA; proposed, authored, and submitted FDA appeal followed by SE decision
- Selected for participation in Covidien Sponsorship Program (2013); sponsored by executive leadership team member

VENTANA MEDICAL SYSTEMS, *a member of the ROCHE group* **8/03- 5/2011**
Tucson, AZ

Senior Regulatory Affairs Specialist

- Managed submission activities for *in vitro* diagnostic devices including CE mark, US pre-IDE, PMA and supplements, 510(k) premarket notifications, export certificates, and establishment registrations & listings
- Interfaced with domestic and international regulatory authorities
- Served in product development as Regulatory Affairs affiliate on numerous core teams; defined global regulatory pathways and design and development requirements
- Provided guidance and review on labeling design and design change activities
- Created and implemented departmental operating procedures

- Supported internal and external audits
- Regulatory Affairs department expert on Quality Assurance SOPs and software training

Project Management, Life Sciences Reagents, Molecular

- Managed product development planning, activities, and resources
- Responsible for preparation and review of product design deliverables
- Coordinated technical development staff and other functional areas to expedite projects
- Tracked project and departmental tasks and provided analyses to management
- Participated in selection, planning, and implementation of software solutions
- Managed corrective and preventative actions (CAPA) and labeling compliance
- Provided training on product development software and procedures
- Expert in Product Development Process Continuous Improvements Team

Product Documentation Specialist, Reagents, Molecular & Detection

- Coordinated publication of original PMA submission
- Coordinated large-scale revision of EU Regulatory submission documentation system.
- Reported to regulatory, product and marketing management team members regarding IVDD compliance
- Facilitated design change process
- Created and revised procedures to refine design control process and documentation

Project Assistant, Quality Assurance and Regulatory Compliance

- Produced EU technical documentation files, product inserts, labels, and design changes orders for IVDD CE Mark compliance project
- Established company Technical Documentation File program
- Conducted large-scale revision to device labeling for unified appearance & regulatory compliance
- Interfaced cross-functionally to ensure that RA & QA deadlines were met
- Coordinated with outside contractors to ensure compliance for labeling translations
- Researched and ordered periodicals and books to produce Document Services library

Early Professional Experience

Life Sciences Teacher, Cesar Chavez Middle School and Aztlán Academy (2001- 2003)

4-H Instructional Specialist, University of Arizona College of Agriculture (2000-2003)

Hiking Guide/Educator, Wilderness Outdoor Leadership Foundation & Canyon Ranch, Tucson, AZ (2001-2004)

Professional Pastry Chef: NY, NM, AZ (1994-2000)

Continued Education

M.S. in Regulatory Affairs for Drugs, Biologics, and Medical Devices Northeastern University, Boston, Massachusetts

B.S. in Business Management, Marketing University of Phoenix, Tucson, AZ

Zig Ziglar Presentation Training, Design Control and Risk Management for Medical Device Professionals, AAMI,

FMEA-Pro Software and process training, Dyadem; Project Management Professional **PMP Certification** (2008)

Expert in Microsoft Office Suite, Microsoft Office SharePoint Server, Enterprise Project Management, Oracle databases, and Agile software.

2009-2010- Ventana Chairperson for company *Mentoring-Networking Program*

2000-2003- Life Sciences Teacher at Cesar Chavez M.S. & Aztlan Academy

1993-2000- Professional Pastry Chef in NY, NM, & AZ

Fluent in Spanish

Volunteer member of Patient & Family Advisory Council at Boulder Community Health (2016-2020)

[i] Managed: P100027, INFORM HER2 Dual ISH DNA Probe Cocktail. Authored & submitted, then transferred: K101234, Ventana Anti-helicobacter Pylori (sp48) Primary Antibody; K110215, Confirm Anti-estrogen Receptor (sp1) Rabbit Monoclonal Antibody; K103818, Confirm Anti-Progesterone Receptor (1e2) Rabbit Monoclonal Antibody; Ventana HPV Probe, Modular PMA Submission.
Submitted and cleared: K121806, Bedside Respiratory Patient Monitoring System with Respiration Rate Software; K130320, Bedside Respiratory Patient Monitoring System with Respiration Rate Software (Submitted appeal to re-open K130320 after initial NSE determination with subsequent clearance); K163231 & K170635, Chameleon PTA Balloon Catheter.