ELIJAH WREH

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QUALIFICATIONS SUMMARY

Global Regulation & Compliance • Healthcare • Education • Leadership • Strategic Planning • Product Development

A board director, global regulation and compliance leader, accomplished published author and industry representative for the FDA Advisory Committee Neurological Devices Panel, recognized for subject matter expertise within the realm of medical device regulation. Embeds an in-depth knowledge of leadership in the healthcare sector, building high performing teams to drive the success of organizations. Initiates effective strategic planning to ensure the development of products across the international arena. Guides negotiations with global regulatory agencies to align audit results with operational transformation and implement compliance structures.

ROLES & NOTABLE CHRONOLOGY

Regulatory Affairs Manager • Zimmer Biomet **2021 – present**

- Assigns Regulatory Affairs (RA) professionals to serve on development project teams as core team members; communicates regulatory strategy for new products.
- Perform research, analysis, and communication of information pertaining to the appropriate regulatory pathway for new or modified products.
- Supports, supervises, and participates in the development of package inserts, evaluation of promotion and advertising material for compliance with applicable regulations.
- Establishes regulatory policies and procedures and ensures compliance. Directs and oversees the work of regulatory professionals, including training, mentoring and ensuring professional development.

Industry Representative • FDA Advisory Committee Neurological Devices Panel **2017 – Present**

- Provided recommendations to the FDA Advisory Committee panel in relation to clinical study data to support the safety and effectiveness of Class 3 medical devices and De Novo application.
- Delivered expert advice to the FDA on scientific, technical, and policy matters for Neurological and Circulatory Devices.

Regulatory Affairs Manager • Invacare Corporation **2015 – 2021**

- Advised on the annual operating plan for Invacare, making recommendations to establish the appropriate funding and resources to meet with business goals. Developed, and managed a top performing regulatory team of three (3) associates from 2015-2019.
- Transformed the approach to reduce cost and timeline to secure marketing clearance and product approval for Invacare. Authored eighteen (18) Premarket Notifications [510(k)] submissions and two (2) pre-submissions, seven (7) CE Technical Files, and seven (7) Health Canada license applications for new and existing products.
- Successfully negotiated resolution of several FDA 483 warning letters, import alerts and detention holds.
- Implemented FDA Unique Device Identifier (UDI) regulatory and compliance requirements.
- Successfully implemented ISO 13485:2016 and Medical Device Single Audit Program (MDSAP) certification at three manufacturing facilities.
- Successfully managed and closed several field actions such as recalls, product correction, removals, and withdrawals.

Senior Regulatory Affairs Specialist • Stryker Corporation **2013 – 2015**

- Authored ten 510(k) submissions and two Pre-Submissions for orthopedic medical devices.
- Managed and successfully implemented FDA Unique Device Identifier (UDI) regulatory and compliance requirements.
- Facilitated negotiation with Advanced Medical Technology Association (AdvaMed) for UDI labeling exemption for Orthopedic Kits with the FDA.

President • Wreh Regulatory Consulting **2012 – 2013**

- Guided the strategic development and analysis for clients in regulatory affairs issues through Wreh Regulatory Consulting.

Regulatory Specialist • Rochester Medical **2/2012 – 11/2012**

- Authored one 510(k) submission, and updated several CE Technical Files, and Design Dossiers.
- Managed regulatory submission, requirements and strategy for new product development.
- Managed CE Technical Files and Design Dossier for CE Marked products.
- Participated in FDA meetings, and Quality System Management (QMS) audits.

CDRH Medical Device Fellowship Program • Food and Drug Administration (FDA) **7/2011 – 9/2011**

- Facilitated the writing of the 2011 Draft Guidance Document on processing and reprocessing of medical devices in health care settings.
- Developed a technical report on guidelines and standards on how to reprocess reusable medical devices to staffs of the Center for Devices and Radiological Health (CDRH)

Research & Development Quality Control Chemist • Paddock Laboratories **2009 – 2010**

- Oversaw and managed assembly and publishing of all documents while maintaining adherence to FDA standards and internal requirements

Quality Control Chemist • Minntech Corporation **2003 – 2006**

- Analyzed raw materials and finished products for manufacturing using analytical chemistry techniques.

EDUCATION & PROFESSIONAL DEVELOPMENT

Master of Arts, Christian Ministry • Liberty University

U.S. Healthcare Compliance Certification Program • Seton Hall University School of Law

Executive Education Certificate, Risk Analysis Course • Harvard T.H. Chan School of Public Health

Master of Science, Regulatory Science • University of St. Thomas

Bachelor of Science, Human Biology • Minnesota State University, Mankato

BOOK PUBLICATION

Wreh, Elijah. *Medical Device Regulation: A Guidebook for Medical Device Manufacturers*. Singapore: Jenny Stanford Publishing, 2021.