Elijah N. Wreh

315 Garfield Drive • LaGrange, OH 44050 • (507) 254-3011 • elijahwreh@gmail.com

QUALIFICATIONS SUMMARY

Hands-on regulatory affairs leader with experience in multiple regulatory environments. Provide continuous monitoring and interpretation of regulatory requirements, identification of regulatory and compliance risks, and working with executive regulatory leadership to identify actions necessary to reduce or eliminate identified risks. Interprets guidance and laws in medical device evaluation and regulation.

PROFESSIONAL EXPERIENCE

Industry Representative, FDA Advisory Committee Neurological Devices Panel 2017 – present

- Provided recommendations to FDA Advisory Committee Panel regarding the evaluation of clinical study data to support the safety and effectiveness of the following Class 3 medical devices:
  - Endovascular Medical Devices Intended to Treat Intracranial Aneurysms
  - CORDIS INCRAFT® AAA STENT GRAFT SYSTEM
- Make referrals to the FDA to obtain independent expert advice on scientific, technical, and policy matters for Neurological and Circulatory Devices.

Invacare Corporation, Regulatory Affairs Manager (Pre-market) 2015 – present

Key Accomplishment:

- Successfully helped satisfy the FDA's requirements under the Consent Decree to manufacture and sell products without restriction. This includes managing FDA inspections and audits and remediation of Design History Files (DHF).
- Negotiated for resolution of several FDA 483 Warning Letters, Import Alerts and Detention Holds.
- Corporate Unique Device Identifier (UDI) Regulatory Affairs Lead.
- Successfully ensured all products meet the FDA UDI requirements and compliance dates.
- Authored several Premarket Notification [510(k)] submissions and pre-submissions, CE Technical Files and Health Canada License Applications for new and existing products. Plan, coordinate, and direct regulatory strategies for new products.
- Managed several FDA inspections/audits, Notified Bodies Surveillance audits, and Health Canada inspections.
- Successfully transferred several medical devices manufacturing facilities and Design History Files (DHF) from Canada to Mexico and from China to the United States.
- Developed several regulatory procedures for FDA, Health Canada and European Union.
- Reviewed product labeling (i.e., user manual, service manual, marketing literature and brochure).

Stryker Trauma & Extremities, Senior Regulatory Affairs Specialist 2013 – 2015

Key Accomplishment:

- Successfully implemented FDA UDI requirements for Trauma & Extremities products.
- Successfully authored ten Premarket Notification [510(k)] submissions and two [510(k)] Pre-Submissions for Trauma & Extremities Orthopedic devices.
- Represented Stryker Corporation at the AdvaMed UDI Orthopedic Kit Working Group meeting with the FDA at the Center for Devices and Radiological Health in Silver Spring, MD. The FDA provided exemption for Orthopedic Kits manufacturers after the face-to-face meeting.
- Introduced human cells, tissues and cellular and tissue-based products (HCT/Ps) in interstate commerce from Original Equipment Manufacturer (OEM).

Wreh Regulatory Consulting, President 2012 – 2013

Core Services and Areas of Expertise:

- Provide strategy development, analysis and recommendations to individuals and organizations in a wide variety of regulatory affairs issues**.**
- FDA regulated devices and combination products, including in-depth knowledge and understanding of FDA expectations, requirements and regulations for device submissions; preparation and/or review of device submissions including 510(k), and PMA; EU CE Mark Medical Device Directive (EU Technical File and Design Dossiers, and Change Notification) to EU Notified Body.

Rochester Medical, Regulatory Specialist 2/2012 – 12/2012

Key Accomplishment:

- Authored one Premarket Notification [510(k)] submission, updated several EU Technical Files, Design Dossiers, Annual Registration and Medical Device Listing.
- Represented Regulatory Affairs on several company projects.
- Communicate regulatory requirements and the impact of regulations to the Vice President of Regulatory Quality and Regulatory and the New Product Development Team.
- Participated in FDA Audit and Inspection, European Union Notified Bodies Surveillance Audit and Supplier Audit.

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

Key Accomplishments:

- Facilitated the writing of the 2011 Draft Guidance Document on processing and reprocessing of medical devices in health care settings.
- Developed and presented 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)
- Reviewed 510(k), Premarket Approval (PMA), Investigational Device Exemption (IDE) and Medical Device Reporting (MDR) submissions.
- Helped 510(k) reviewers at CDRH developed a checklist when reviewing for reusable medical devices.

Paddock Laboratories, Research & Development Quality Control Chemist 2009 – 2010

Key Accomplishments:

- Ensured team's compliance with FDA Standards, applicable laws, regulations and guidance documents reviewed regulatory documents and supervised regulatory files.
- Coordinated international regulatory standards and performed regulatory research.

Minntech Corporation, Quality Control Chemist 2003 – 2006

Key Accomplishments:

- Analyzed raw materials and finished products, using analytical chemistry techniques, ensured that clinical sites had needed tools and equipment for clinical trials and provided investigative support for successful product development.

MILITARY SERVICE

United States Army 2006 – 2012

- **Honorable Discharge**
  - Dedicated professional with six years of outstanding performance.

EDUCATION

- **Master of Science in Regulatory Science**, University of St. Thomas 2013
  - *Thesis*: Premarket Approval (PMA) Summary of Safety and Effectiveness Data (SSED) of a Tinnitus Therapy System™
- **Post-Baccalaureate Certificate in Medical Device Development,** University of St. Thomas 2012
- **Bachelor of Science in Human Biology**, Minnesota State University-Mankato 2009

CONTINUING EDUCATION

- **U.S. Healthcare Compliance Certification Program, Seton Hall Law School** 2017
- **Executive and Continuing Professional Education, Harvard T.H. Chan School of Public Health** 2016
  - Risk Analysis Course
- **Medical Education, Stryker Hand & Wrist Resident Dissection Course, Fort Lauderdale, FL** 2013
- **Trauma Research and Development Academy**, Solothurn, Switzerland 2013

ADJUNCT POSITIONS

- **Regulatory Basics and Strategy in Medical Device Design,** Cleveland State University 2015 – present
- **The 510(k) Submission: Requirements, Contents, and Options,** University of Akron 2015 – present
- **Premarket Notification [510(k)]**, Case Western Reserve University 2017 – present