Michelle L. Jump

MedSec, LLC | m: [redacted] | [redacted] | www.medsec.com

Summary of Qualifications

- Regulatory professional with extensive experience in medical device software, device security (cybersecurity), mobile apps, wireless technology, wireless coexistence, interoperability, MDDS, and emerging technology
- Served on standards and industry initiative organizations, co-authoring dozens of articles, standards, whitepapers, and technical reports on the topic of medical device technology
- Collaborative global expert in regulatory and compliance issues, working directly with global regulatory bodies on topics such as including cybersecurity, software, interoperability and wireless communication
- Certified RAC and M.S. in Regulatory Science from University of Southern California

Professional Experience

CEO

MedSec – Miami, FL November 2019-Present

- Developed and implemented overall strategic plan for company for financial and industry success
- Manage team of 18 compliance and technical staff
- Lead all new product development, marketing, and sales
- Provide regulatory and quality advisory services to medical device manufacturers
- Support companies in their development of product security programs
- Security and safety risk management support

Vice President of Cyber Program Initiatives

Nova Leah – Dundalk, Ireland June 2018-November 2019

- Thought leadership in the area of medical device cybersecurity regulation and compliance
- Business development and revenue generation
- Coaching, training and education

Director of Cybersecurity, Regulatory Affairs

CARESTREAM HEALTH – Rochester, NY - Feb 2018-June 2018

- Establish and lead corporate-wide product security program
- Represent Carestream Health in external activities to drive industry advancement in medical device cybersecurity
- Ensure regulatory compliance to global cybersecurity compliance expectations for all Carestream products

- Align all business units and corporate leaders around a common strategy for managing product security, in collaboration with corporate enterprise security
- Advise teams and internal stakeholders in the area of digital health and related regulatory issues

Principal Regulatory Affairs Specialist Sept. 2013-Feb 2018
Associate Regulatory Affairs Analyst, (May 2013-September 2013)
Sr Regulatory Affairs Representative (April 2010-May 2013)
STRYKER CORPORATION (Instruments) - Kalamazoo, MI, April 2010-Sept. 2013

- Develop regulatory strategy for small, technology group, focused on connected and interoperable software products and cybersecurity
- Lead the organization in establishing a corporate-wide product security program.
- Represent Stryker in all external product security, software, and wireless trade association and standards engagement, establishing the corporation as a solutions-driven industry leader
- Serving as Stryker's industry liaison with external stakeholders in the area of digital health, including cybersecurity, wireless, mobile apps, interoperability, software, and privacy issues
- Responsible for identifying and participating in relevant standards and trade organizations
- Project owner for corporate wide update to quality system, addressing cybersecurity risk management and security capabilities planning, including business impact assessments
- Provide formal comment, as necessary, for applicable standards, regulations, regulatory documents, or industry projects
- Conceptualized and developed a Regulatory/Quality Knowledge Center to serve as an internal Stryker resource for staff needing guidance on 18 topics in digital health, including cybersecurity, wireless, MDDS, 21 CFR Part 11, Software, Understanding IEC 80001, HIPAA, SaMD, Cloud Computing, Mobile Apps, and FDASIA. Each Knowledge Center contains a topics overview which provides a topic overview and lists relevant standards, directives, guidance documents, articles, and external activities in which Stryker is involved. Located on a secure internal server so the information can be accessed by global teams at their convenience.
- Help drive positive policy changes through various activities with FDA and remain dedicated to enhancing the productive relationship between regulatory agencies and industry
- Chair of Internal Working Groups:
  • Corporate Regulatory Working Group for Interoperability
  • Corporate Software Strategy Working Group

For a full list of standards organizational activities, publications, and presentations associated with this position, please see Addendum

Education

Certified HIPAA Administrator **April 2016**
Regulatory Affairs Certification (RAC) **Fall 2012**
M.S. Regulatory Science, University of Southern California **2008-2012**
M.S. Biotechnology, California State University, Channel Islands **2007- 2009**
B.S. Biology, University of California Santa Barbara **1994 - 1997**

*Addendum: Specific Standards Organizational Activities, Publications, and Presentations

- Participating author for the following standards and technical reports
    - International Medical Device Regulators Forum (IMDRF): *Software as a Medical Device (SaMD): Application of Quality Management Systems* (2015)
    - *IEEE Building Code for Medical Device Software Security* (2015)
    - AAMI TIR 57: *Principles for medical device information security risk management*
    - AAMI TIR 97: *Principles For Medical Device Security - Postmarket Risk Management For Device Manufacturers*
    - ANSI/AAMI SW96:2023 *Standard For Medical Device Security - Security Risk Management For Device Manufacturers*
    - AAMI TIR 69*: Risk Assessment of radio-frequency wireless coexistence for medical devices and systems* (pending)
    - AAMI White Paper: *Quality and Risk Considerations for Health Information Technology (HIT)*
    - AAMI/UL 2800 Joint Committee: *Safety and Security Requirements of Interoperable Medical Systems* (pending)
    - IEC 62304 *Medical Device Software - Software Lifecycle processes - Second Revision* (pending)
    - IEC 80001-1 *Application of Risk Management for IT Networks Incorporating Medical Devices - Second Revision* (pending)
- Leadership roles in various standards and trade organizations:
    - Convenor ISO TC 215 WG 4 Security, Safety, and Privacy
    - Member of Standards Board for the American Association of Medical Instrumentation (AAMI)
    - Co-chair AdvaMed Software Working Group
    - Co-chair AAMI SM-WG01 Software Committee
    - Co-chair AAMI SM-WG01-TG01 Health Software Quality Management TG
    - Project Lead and Initiator of AMI TIR 75: *Factors to Consider when Multi-Vendor Devices Interact via an Electronic Interface*
    - Project Co-Lead for New Work Item (ISO/TC 215 JWG7): *N2046 ISO 81001-1 Health software and health IT systems safety, effectiveness and security - Part 1: Foundational principles, concepts, and terms*
- Active voting and contributing member in numerous external working groups (both domestic and international), including:
    - ISO/TC 215 Joint Working Group 7
    - U.S. Primary Industry Representative of International Medical Device Regulators Forum "Software as a Medical Device" working group
    - AAMI/UL 2800 Joint Committee on Interoperability
    - AAM SM-WG01-TG02 Software Assurance Case TG
    - AAMI SM-WG03 Interoperability WG
    - AAMI SM-WG05 Device Security WG
    - AAMI SM-WG06 Wireless WG
    - AAMI ID/TG 01 Assurance Case Reports
    - AAMI Health IT Committee
    - AdvaMed Cybersecurity Working Group
    - AdvaMed Digital Health Working Group

    - Primary Company Voting Member for IEC TAG 62 - Electrical equipment in medical practice
- Active participant in meetings and activities to further solutions to challenges in emerging technology, serving as panel member, session leader, and presenter at a variety of events, including:
    - Presentations (2): *Emerging Standards and Technical Guidance for Medical Devices* and *Navigating Regulatory Issues for Medical Devices*, American Society for Quality (ASQ) Annual BOSCON conference, April 2016
    - Panel Member and Breakout Leader: *FDA Public Workshop – Moving Forward: Collaborative Approaches to Medical Device Cybersecurity*, Jan 20-21, 2016
    - Panel Leader: AdvaMed's *Cybersecurity in the Connected Health Care System Workshop*, Dec 1, 2015
    - Session Leader: *Regulatory Strategy for Medical Device Software*; RAPS Convergence Oct 2015
    - Discussion Group Leader: *IEEE Building Code for Medical Device Software Security* (led to publication of same name found at http://cybersecurity.ieee.org/) Nov 2014
    - Panel Member: FCC/FDA Joint Workshop on Wireless Test Beds: Industry Perspective *Overview of Current Public and Private Wireless Medical Device Test Bed Programs and Initiatives*, April 2015
    - Presentation and Panel Member: *Global Regulatory Considerations for Wireless Medical Devices*, BIOMEDevice Boston May 2015
    - Presentation: *The Connected Hospital and Health IT: An Industry Perspective*; Orthopedic Surgical Manufacturers Organization Annual Conference, Jan 2015
    - Presentation: *Bringing a Security Culture to the Large Corporation* (Cybersecurity) AAMI 2014 Conference and Expo (June 2014)
    - Presentation and Panel Member: *Assurance Case Theory and the Regulatory Submission* Q1 Productions Medical Device Regulatory Clearance and Approval Conference 2011

Additional background information and recommendations on my LinkedIn profile