**Terence Musoni**

**International Regulatory Affairs & Emerging Policy Leader**  
(214) 309-8175 | [Tmusoni81@gmail.com](mailto:Tmusoni81@gmail.com)

**Summary**

Accomplished regulatory affairs and policy professional with 17+ years of experience translating complex technical requirements into actionable policy frameworks across global markets. Proven expertise in navigating international regulatory landscapes, building stakeholder relationships with government authorities, and leading cross-functional teams to achieve compliance objectives. Distinguished track record in managing regulatory transitions (EU MDR, UKCA), developing comprehensive surveillance systems, and engaging with competent authorities across multiple jurisdictions. Currently expanding expertise into AI/ML regulatory frameworks with applicable knowledge of EU AI Act and emerging U.S. AI policies. Exceptional ability to distill complex technical information into accessible policy recommendations for diverse stakeholder audiences.

**Key Qualifications**

* **Bachelor's Degree** in Evolution, Ecology & Organism Biology from The Ohio State University
* **15+ years of international regulatory experience** across medical devices, combination products, and emerging technologies
* **Proven stakeholder engagement** with regulatory authorities including FDA, Health Canada, BSI, DEKRA, LNE, TGA, MHRA, and SWISSMEDIC
* **Global policy implementation expertise** spanning EU, EMEA, LACAN, and Asia-Pacific regions
* **Emerging technology regulatory specialist** with deep knowledge of EU AI Act and U.S. AI frameworks
* **Cross-functional team leadership** managing international compliance initiatives and regulatory transitions
* **Strategic policy development** with demonstrated success in translating technical requirements into operational frameworks

**Professional Experience**

**CooperSurgical | Post-Market Surveillance Manager & Technical Writer | January 2022 - Present**

**International Regulatory Leadership:**

* **Manage team of 5 Post-Market Surveillance Technical Writers** ensuring compliance across international markets
* **Lead EU MDR implementation** across entire product portfolio, coordinating with notified bodies (BSI, DEKRA) and competent authorities
* **Spearhead UKCA regulatory transition** post-Brexit, establishing new compliance frameworks for UK market access
* **Coordinate international regulatory submissions** and maintain relationships with global regulatory authorities
* **Develop comprehensive surveillance methodologies** incorporating multi-jurisdictional requirements

**Policy Development & Stakeholder Engagement:**

* **Successfully navigated complex regulatory transitions** affecting global market access and product compliance
* **Established standardized international surveillance frameworks** improving regulatory efficiency across regions
* **Led cross-functional teams** in developing policy responses to emerging regulatory requirements
* **Built strategic relationships** with international regulatory bodies to ensure proactive compliance positioning

**Stryker Corporation | Post-Market Surveillance Consultant | January 2021 – December 2022**

**International Regulatory Compliance:**

* **Updated PMS procedures** to align with EU MDR requirements across global markets
* **Coordinated with clinical affairs teams** to ensure international regulatory data requirements were met
* **Served as primary liaison** with competent authorities and notified bodies for surveillance data requests
* **Developed compliance timelines** incorporating multi-jurisdictional submission requirements

**Alexion/AstraZeneca | Post-Market Surveillance Consultant | September 2020 – December 2021**

**Combination Product Policy Development:**

* **Created comprehensive post-market surveillance framework** for combination devices prior to commercialization
* **Developed PMCF plans** under EU MDR requirements with international applicability
* **Established data relationships** between global stakeholders and surveillance systems
* **Created regulatory reporting decision trees** outlining jurisdiction-specific requirements across global markets

**Beckman-Coulter | Post Market Surveillance EU MDR Consultant/Lead (Contract) | September 2020 – May 2021**

**Technical Documentation & Policy Implementation:**

* **Led EU IVDR transition** across multiple business units ensuring regulatory compliance
* **Coordinated with notified body (BSI)** for technical documentation reviews and feedback implementation
* **Established standardized PMS governance** across international business units
* **Conducted scientific literature reviews** for global safety and performance evaluation

**Terumo BCT Corporation | Post Market Surveillance EU MDR Consultant (Contract) | October 2019 – September 2020**

**International Technical Documentation:**

* **Reviewed Clinical Evaluation Reports** for EU MDR alignment across device classifications
* **Created comprehensive tracking matrix** for international technical documentation maintenance
* **Developed design dossiers** meeting conformity assessment requirements for multiple jurisdictions
* **Analyzed global CAPA and complaint data** to inform international risk-benefit analyses

**Stryker Corporation | Supplier Auditor (Contract) | April 2019 – October 2019**

**Global Supply Chain Compliance:**

* **Led risk-based international supplier audits** ensuring global regulatory conformance
* **Guided suppliers through applicable regulatory landscapes** across multiple jurisdictions
* **Developed supplier agreements** establishing sustainable international compliance frameworks

**Philips Corporation | Post-Market Surveillance (Complaint Specialist) (Contract) | May 2018 – April 2019**

**International Surveillance & Reporting:**

* **Coordinated with Adverse Event teams** for multi-jurisdictional regulatory reporting
* **Collaborated with Product Safety Committees** on international correction and removal processes
* **Provided surveillance data** for global periodic reports and management reviews

**Oxford Global Inc | Quality Systems Consultant (Contract) | January 2018 – May 2018**

**International Standards Implementation:**

* **Conducted compliance audits** for ISO 13485:2016 and MDSAP across multiple markets
* **Reviewed technical documents** for EU MDR alignment and international applicability
* **Performed gap assessments** against international regulatory standards

**Allergan Inc | Senior Quality Engineer (Projects) | April 2016 – January 2018**

**Global Regulatory Program Management:**

* **Managed international audit program** hosting notified bodies (DEKRA, BSI, LNE) and regulators (FDA, Health Canada)
* **Responded to international competent authority requests** for clarification and product information
* **Trained multi-site personnel** in MDSAP requirements across global operations
* **Served as liaison** between company and international regulatory authorities

**Previous International Experience (2007-2016)**

**Alcon/Novartis | Country Organization RAQA Representative (2013-2015)**

* **Managed quality and regulatory compliance** for 21 countries across LACAN, EMEA, and Asia regions
* **Provided regulatory intelligence** for EMEA business development activities
* **Developed audit responses** to global competent authority inspections (FDA, TGA, MHRA, SWISSMEDIC)
* **Hosted international audits** (TUV, BSI) across global affiliate sites

**Additional Global Experience:**

* **Hospira** (2013): International compliance consulting with expertise in 13485 and 21 CFR Part 820
* **Grifols-Talecris** (2008-2013): Regional quality management across multiple international facilities
* **Talecris Plasma Resources** (2007-2008): International quality assurance program management

**Education and Certifications**

**Education**

* **Bachelor of Arts, Evolution, Ecology & Organism Biology** | The Ohio State University, Columbus, OH

**Current Certifications**

* **Certified EU MDR 2017/745 Auditor** | Oriel Stat-a-Matrix
* **American Society of Quality (ASQ) Member**

**Specialized Training Completed**

* **EU MDR Implementation of Surveillance Requirements**
* **UKCA Implementation of Surveillance Requirements**
* **ISO 13485 Quality Management Systems**
* **ISO 14971 Risk Management**

**Professional Development in Progress**

* **ISO/IEC 42001 AIMS Standard Certification** (pursuing)
* **EU AI Act regulatory framework development**

**International Audit & Engagement Experience**

**Completed International Contract Audits**

* **Showa Denko Materials** (2021, Yokohama, Japan) – For-Cause Audit of Origen Bio (Supplier)
* **Alkermes** (2018) – MDSAP Audit of Kason Corp (supplier)
* **West Pharmaceutical** (2018) – ISO 13485:2016 Audit (compliance)
* **Terumo BCT** (2019) – Internal Audit of PMS System for EU MDR alignment
* **Innovative Product Brands** (2021) – ISO 13485:2016 (Implementation and compliance

**Core Competencies**

**International Policy & Regulatory Affairs**

* **Global regulatory landscape navigation** across medical device and emerging technology sectors
* **International standards implementation** (ISO 13485, EU MDR/IVDR, MDSAP, FDA QSR)
* **Cross-border compliance strategy** development and execution
* **Emerging technology regulation** including EU AI Act and U.S. AI frameworks

**Stakeholder Engagement & Relationship Building**

* **Competent authority engagement** with proven track record across FDA, Health Canada, BSI, DEKRA, TGA, MHRA, SWISSMEDIC
* **International team leadership** managing cross-functional global initiatives
* **Strategic partnership development** with regulatory bodies and industry stakeholders
* **Complex technical communication** to diverse international audiences

**Strategic Program Management**

* **International regulatory transition management** (EU MDR, UKCA implementation)
* **Global surveillance system development** and optimization
* **Cross-functional project coordination** across international markets
* **Risk assessment and mitigation** for global compliance initiatives

**Technical Expertise**

**Regulatory Frameworks**

* EU MDR 2017/745 & EU IVDR 2017/746
* ISO 13485 (Quality Management Systems)
* ISO 14971 (Risk Management for Medical Devices)
* FDA QSR & 21 CFR Part 820
* UKCA Requirements
* MDSAP (Medical Device Single Audit Program)
* EU AI Act & U.S. AI Frameworks
* ISO/IEC 42001 AIMS Standard

**International Markets Experience**

* **European Union** (27 member states)
* **United Kingdom** (post-Brexit UKCA)
* **North America** (USA, Canada)
* **Asia-Pacific** (Japan, Australia)
* **Latin America** (Mexico, Brazil)
* **EMEA Region** (19 EU countries + additional markets)

**Specialized Skills**

* International post-market surveillance program development
* Global risk assessment and management methodologies
* Multi-jurisdictional regulatory submission coordination
* International audit management and regulatory inspection preparation
* Cross-cultural team leadership and stakeholder engagement
* Emerging technology regulatory framework development