Dr. Trymore Magomana, MBA, DrPH

Executive Regulatory Affairs Leader | Global Medical Devices | Market Access & Governance
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Executive Profile

Enterprise regulatory affairs leader with 15+ years of experience directing global regulatory, clinical, and vigilance functions for Class I–III medical devices. Trusted advisor to executive leadership on market access strategy, regulatory risk, portfolio governance, and lifecycle execution across FDA, EU MDR, Health Canada, and international markets. Proven ability to build scalable regulatory organizations, lead authority engagements, and align compliance strategy with commercial and patient-safety objectives.

Core Leadership Capabilities

- Enterprise regulatory strategy and governance
- Global market access and portfolio prioritization
- Executive and board advisory on regulatory risk
- Health authority and Notified Body engagement
- Post-market surveillance, vigilance, and inspections
- Organizational capability building and talent development

Professional Experience

Ambu A/S – Noblesville, Indiana
Manager, Global Regulatory & Clinical Affairs and Vigilance | 2024–Present
Direct global regulatory, clinical, and vigilance strategy across the U.S., Canada, EU, UK, LATAM, and APAC. Advise senior leadership on regulatory risk, market access sequencing, and lifecycle governance. Lead FDA, Notified Body, and global authority interactions; oversee submissions, post-market surveillance, vigilance, UDI governance, and clinical evidence strategy.

Cook Medical – Bloomington, Indiana
Regulatory Affairs Specialist II | 2023–2024
Led EU MDR transition activities for multi-product portfolios, supporting new product approvals, lifecycle changes, and labeling governance. Partnered cross-functionally to deliver compliant, inspection-ready technical documentation.

CVRx – St. Paul, Minnesota
Manager, Regulatory Affairs | 2022
Provided regulatory leadership for PMA-class devices and clinical programs. Acted as primary interface with FDA and Notified Bodies; advised leadership on regulatory strategy, risk acceptance, and submission planning.

Abbott Laboratories – St. Paul, Minnesota
Senior Regulatory Affairs Specialist | 2021–2022
Supported global regulatory strategy across U.S. and international markets. Led submissions, EU MDR remediation, and regulatory assessments for manufacturing and product changes.

Baxter Healthcare – Chicago, Illinois
Regulatory Affairs Project Manager (Contract) | *2020–2021*
Served as regulatory lead for global lifecycle projects, QMS activities, labeling governance, UDI strategy, and post-market surveillance initiatives.

Wipro Technologies – Global Life Sciences Consulting
Senior Management Consultant | *2016–2020*
Advised multinational life sciences organizations on regulatory strategy, market entry, and post-market governance. Led global submissions and regulatory intelligence initiatives.

Education

Doctor of Public Health (DrPH), Global Health Systems – Indiana University
Master of Business Administration (MBA), International Business & Strategy – University of Illinois Urbana-Champaign
Master of Regulatory Affairs (MRA) – University of Pennsylvania
Master of Arts, Bioethics & Health Policy – Loyola University Chicago
Bachelor of Arts, Biology – Grinnell College

Certification

Regulatory Affairs Certification (RAC)