Michael Zagorski

Strategic Consultant
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Michael Zagorski is a Strategic Consultant with EBG Advisors, Inc. Michael has extensive experience and expertise in all aspects and phases of a product development lifecycle - from feasibility and research, through post-production - and brings a practical, pragmatic and flexible approach helping medical and heath technology companies meet global regulatory requirements.

Michael brings fresh insight into managing quality system and expertise in domestic and international regulations for medical devices and healthcare technology. He has worked with many small and large organizations in the medical device and engineering industries, including leading companies such as Philips, Lockheed Martin, and General Electric. He also provides guidance and support to medical device start-ups with all aspects of Design Quality and Risk Management, Quality Systems, and Regulatory Affairs.

Representative Experience

Michael's experience includes all aspects of Quality & Regulatory Affairs for a medical device software start-up that measures, documents and tracks a patients/athletes objectively measured outcome. As Director of Q&R, he managed the full implementation of a quality system compliant to FDA QSR and ISO 13485. He directed regulatory affairs, including international strategy, submission preparation, labeling/claims review, regulatory intelligence, product portfolio analysis, and due diligence. Michael oversaw quality systems and quality assurance programs, including management review, audit management, CAPA/Investigations, product development, design changes, risk management, and usability and clinical performance validation studies, among other areas.

Michael also previously served in various positions at Philips Healthcare, a world wide leader in professional healthcare products and solutions. As a Regulatory Engineer he prepared and submitted 510(k)’s, IDE’s, and other product submissions according to FDA guidelines. He defined regulatory strategies and provides regulatory advice, support and expertise to assigned product development projects from technical approach to post marketing phase. He was responsible for analyzing and creating internal regulatory assessments for new product releases, product modifications and service notifications. As a Design Quality Engineer, Michael was responsible for ensuring compliance to company quality procedures and forms as well as external standards (ISO13485, ISO14971) and all regulatory requirements (FDA QSR, MDD, CMCDAS) for new and sustaining product development efforts and supported product commercialization by serving as QA department's representative on organizational development teams.

Michael has also made his mark in academia, serving as an adjunct instructor and researcher at Drexel University.

Education

- Drexel University (M.S.)
  - Engineering Management
- Drexel University (M.S.)
  - Biomedical Engineering
- Drexel University (B.S.)
  - Electrical Engineering