

Robert Ellsworth Durgin

Dated: 5 February 2014

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Objective To provide Industry perspective and leadership to the FDA on significant regulatory questions requiring Panel consideration

Professional Experience

KaVo Kerr Group of Danaher Corp., Charlotte, North Carolina

Vice President, Regulatory Affairs & Quality Assurance, August 2012-present

- Provide strategic, platform-wide leadership for the KaVo Kerr Group's quality and regulatory functions
- Provide strategic vision and leadership for compliance with applicable U.S. and international regulatory requirements by the Group's multiple operating divisions and over 20 manufacturing facilities located in the United States, Germany, Finland, Switzerland, Italy, the Czech Republic and Brazil
- Plan, develop and execute the regulatory strategy to introduce new dental technologies in the United States including Pre-Submission meeting with FDA and the submission of 501(k)s
- Apply the Danaher Business system to implement process improvements in the Group's quality system and product registration processes

Biomet, Inc., Warsaw, Indiana

Senior Vice President, Quality/Regulatory/Clinical Affairs, January 2009-August 2012

- Provide strategic vision and enterprise-wide leadership for Biomet's quality, regulatory and clinical research including for compliance with applicable global regulatory requirements by 8 operating divisions and 15 manufacturing facilities
- Guide and counsel Biomet senior management by conducting Biomet, Inc.'s corporate management reviews and participating in subsidiary management reviews
- Manage enterprise-wide quality management system with corporate-wide quality metrics and corporate auditing/mock FDA inspection program and continuous improvement of the Corporate Quality Manual
- Lead global, corporate quality and regulatory support for the company's operational improvement and value creation programs, including the rationalization of Biomet's manufacturing facilities, as well as implementing Quality Management Systems at new Biomet facilities
- Chair Biomet's Clinical Research Review and International Clinical Research Review Committees and manage Biomet's global clinical research activities
- Contribute strategic input to the global reorganization of Biomet's orthopedics, sports medicine, trauma and biologics businesses
- Provided input to the FDA's and the Institute of Medicine's reviews of the medical device approval process at public hearings and in written comments

Biomet, Inc., Warsaw, Indiana

Corporate Vice President, Global Quality/Clinical/Regulatory Affairs, June 2007-January 2009

- Enhanced corporate oversight of divisional quality management systems by implementing corporate-wide quality metrics and an enterprise-wide Corporate Quality Manual and strengthening corporate auditing/mock FDA inspection program

- Restructured quality and regulatory functions to support post-acquisition managerial direction
- Initiated the implementation of a quality system software solution to enhance Biomet's quality system and overall regulatory compliance

Biomet, Inc., Warsaw, Indiana

Corporate Vice President, Global Regulatory Affairs, May 2006 – June 2007

- Implemented corporate-wide best-practices for regulatory submissions, regulatory compliance and quality assurance activities across Biomet's facilities world-wide
- Managed U.S. regulatory submissions (PMAs, IDEs, 510(k)s) and international registrations for Biomet's Warsaw, Indiana and Parsippany, New Jersey operations
- Globally managed Biomet's strategy for submitting design dossiers to comply with the EU's reclassification of total joint prostheses
- Developed organizational structure and corporate-wide processes for global coordination of clinical research activities for Biomet's reconstructive devices
- Provided regulatory and quality leadership and advice to Biomet's senior management and operating subsidiary management teams

Biomet, Inc., Warsaw, Indiana

Vice President, Regulatory Affairs and Quality Assurance, September 2003 – May 2006

- Represented Biomet within AdvaMed's T & R Regulatory Group and the AdvaMed-EucoMed Working Group on the Reclassification of Total Joint Prostheses
- Successfully managed Biomet's first PMA applications and approvals
- Directed the re-engineering of the Warsaw facility's design control procedures to obtain PMA-approval of Biomet's C2a-Taper ceramic-on-ceramic hip system
- Successfully managed corporate-wide transition to compliance with ISO 13485:2003, including management training, and the establishment of quality objectives and quality planning processes
- Managed the submission of approximately 30 successful 510(k)s clearances annually
- Enhanced Biomet's Corporate Regulatory Compliance audit program
- Developed and implemented effective Management Review, CAPA management and Risk Management processes, procedures and practices
- Upgraded Biomet's Complaint processing, Medical Device Reporting and Corrections, Removals and Recalls procedures and practices
- Developed the staff and effectively managed regulatory support for Biomet's combination product development efforts

Biomet, Inc., Warsaw, Indiana

Corporate Counsel/Associate General Counsel, June 1997 – September 2003

- Managed a significant majority of Biomet's domestic product liability, commercial and intellectual property litigation
- Provided advice and counsel to Biomet's senior management regarding litigation and other legal disputes
- Routinely advised the Vice President, Regulatory Affairs and Quality Assurance regarding product safety issues, including recalls
- Represented Biomet at trials, arbitrations, mediations and settlement conferences

Montgomery, Barnett, Brown, Read, Hammond & Mintz, L.L.P., New Orleans, LA

Associate/Partner, February 1988 – June 1997

- Civil litigator with a special emphasis on defending pharmaceutical and medical device manufacturers in product liability matters
- Represented Sterling Drug in litigation alleging a novel claim that aspirin caused Reyes' syndrome

- Represented Armour Pharmaceutical Company in complex federal and state litigation involving Factor VIII concentrates
- Admitted to practice before the United States Supreme Court, United States Court of Appeals for the Fifth Circuit, and all federal and state courts in Louisiana

Education Tulane University School of Law, New Orleans, Louisiana
Juris Doctorate (cum laude) 1984

University of Notre Dame, Notre Dame, Indiana
Bachelor of Arts (Government/Russian Language) 1981
Certificate of Soviet and Eastern European Studies

**Military
Experience**

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**Professional, Civic and
Personal Activities**

- *Orthopaedic and Rehabilitation Devices Panel of FDA's Medical Devices Advisory Committee, Industry Representative (2008-2012)*
- *Indiana Medical Device Manufacturers Council, Inc., Board Member (2004-2011); President, Board of Directors (2007-2009), Member, Advocacy Committee (2004-2012)*
- *Advanced Medical Technology Association (AdvaMed) Member of FDA Strategy Work Group; Danaher Representative to T & R Regulatory Group; Chair, Orthopedic Products Working Group (2007-2012)*
- *American Joint Replacement Registry (AJRR), a supporting organization of the American Academy of Orthopedic Surgeons, Board and Executive Committee member(2010-2012)*
- *Orthopaedic Surgical Manufacturers Association, Board Member (2008-2012)*
- *President, Board of Directors, Kosciusko Community YMCA (2005-2007)(Board member, 2002-2007)*

References: Upon request