Edward S. Chin, D.Ph., MBA

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REGULATORY AFFAIRS EXECUTIVE

Visionary global business leader with experience developing robust and scalable strategies to support solutions, regulatory documentation to obtain approvals. Internal business partner and consultant to key stakeholders in evaluating and assessing acquisition, distribution, and product collaboration opportunities. Recruit and engage high performing individuals and cross-functional teams to drive business objectives.

Key Areas of Expertise

Strategic Planning • FDA • New Product Development • Regulatory Requirements • Quality Management Systems • Advocacy Group Leadership • Compliance • SOP • Project Management • Metrics and Benchmarking • Budget Oversight

PROFESSIONAL EXPERIENCE

MEDTRONIC XOMED, Jacksonville, FL **2018 - Present**
Director, Regulatory Affairs & Office of Medical Affairs
Department head overseeing staff to develop and execute regulatory strategies, plans, activities to ensure global approval, registrations and compliance to country requirements. As a member of the business leadership staff, collaborate with cross functional teams to assure processes to develop innovative, iterative therapeutic solutions for Ear, Nose and Throat medical professionals and patients.

- Oversight includes recruiting, training, developing and retaining regulatory professionals.
- Member of the ENT leadership team to manage tactical and strategic opportunities for the ENT portfolio.
- Interface with internal and external stakeholders to assure alignment to strategic plans and regional portfolio strategies.
- Participate in the strategic planning process to ensure a timely market release of ENT devices.
- Execute regional regulatory strategic and tactical activities in accordance with development milestones.
- Ensure the timely submission and approval of regulatory deliverables to support the ENT portfolio globally.
- Collaborate on business development / acquisition due diligence and integration activities.

MEDTRONIC SPINE AND BIOLOGICS, Memphis, TN **1996 - 2018**
Senior Regulatory Affairs Program Director, Regulatory Affairs, 2014 – Present
Team Lead for numerous workstreams to assess, plan and implement programs for compliance to the European Union Medical Devices Regulation including Medtronic Spine Technical Documentation, Restorative Therapies Group EU MDR, Medtronic Corporate EU MDR Regulatory Affairs and Medtronic Corporate EU MDR Technical Documentation.

- Co-led the Orthopedic Surgical Manufacturers Association (OSMA) workstream to advocate European health authorities that spine devices maintain a class IIB designation in the EU MDR. In 2018, MedTech Europe had accepted an OSMA position document for spine devices to remain class IIB.
- Provided strategic support to Biologics and Core Spine Therapy Segment team during the expansion of spinal device indication(s) for worldwide licenses and approval, including the Globalization of biologics in Japan, Korea, China, and ASEAN.
- Interface with state and congressional representatives to advocate for Tennessee life science companies; pharmacy licensure for U.S. distribution of medical devices; advocacy of H.R.6, the 21st Century Cures Act and the companion U.S. Senate version.
- Contributed towards proposed position papers and advocated with EUCOMED (now MedTech Europe) to develop the text of the new European Medical Device Regulations.

Senior Director, Regulatory Affairs, 2010 – 2014
Consulted with FDA to develop panel meeting presentation for one of the remaining pre-amendments class III devices, pedicle screw spinal systems to either reconfirm to class III (subject to PMA), or reclassify to class I or class II (subject to 510(k)), as directed by section 515(i) of the FD&C Act".

- Participated in the September 2012 FDA Advisory Committee Hearing – "Classification of posterior cervical screws, including pedicle and lateral mass screws". This petition was submitted by the Orthopedic Surgical Manufacturers Association (OSMA) pedicle screw taskforce for unclassified cervical pedicle screws.

Medtronic Director, Regulatory Affairs, 2008 – 2009
Managed a team of Senior Managers, Managers, and Regulatory Affairs Specialists (30+) in International, Extradiscal Spine, and Rapid Development.

- Submitted and obtained FDA 510(k) approvals for core spine devices; worked with geography regulatory staff to obtain licenses from health ministries and regulatory bodies; approval of physician requested custom and special products.
- Collaborated with International Marketing for strategic product portfolios. Evaluated and revised the regulatory infrastructure to efficiently support international registration requests. Provided oversight and / or approval of FDA submissions, Letter to File, worldwide product Regulatory Strategy plans, design history files, and adverse event / vigilance reporting. Collaborated with Quality department on product hold orders, health hazard analyses, and quality issue reviews.

- Performed due diligence activities (regulatory and quality) for numerous acquisition candidates. Due diligence activities involved domestic and international acquisition targets.
- Led the regulatory integration activities following the acquisition of Kyphon Inc. This included alignment of regulatory / quality functions to the Medtronic Spinal and Biologics systems and management reporting of the Kyphon RA/QA team. Overall integration involved coordination of activities at Kyphon, Inc. locations in: Sunnyvale, California; Neuchatel, Switzerland; Brussels, Belgium; Tokyo, Japan with Medtronic locations in Memphis, Tennessee and Heerlen, Netherlands.
- Managed a budget that ranged from $10 Million to $25 Million.

Medtronic Director, Regulatory and Clinical Affairs, 2005 – 2008
Regulatory lead for the development, compilation, and submission of the INFUSE® Bone Graft Pre-market Application (PMA) (Approval for PMA #P050053) for certain oral maxillofacial and dental indications. Full approval was granted on March 9, 2007.

- Lead 'presenter' during the FDA Dental Branch Advisory Panel Hearing on November 9, 2006 which resulted in a unanimous 6-0 recommendation for approval. The project entailed project management and coordination with the original study sponsor (a Pharmaceutical Business Partner), a Contract Research Organization (CRO), internal marketing, product development staff, senior management, and surgeon consultants. Managed the CRO responsible for: clinical data retrieval and analyses; validating core labs data; monitoring clinical sites; and preparing sites for FDA bioresearch monitoring (BIMO) inspections.
- Managed the development of a pharmaceutical infrastructure to support Investigational New Drug applications (IND) and NDA. Guided the development of the MSB's first pharmaceutical pre-IND application and meeting, negotiated with FDA Center Drug Evaluation and Research for submission and approval of spine's first IND application.

SOFAMOR DANEK (acquired by Medtronic), Memphis, TN
Director, Clinical and Regulatory Affairs, 2000 - 2005
Director of Quality Systems and Clinical Affairs, 1999 - 2000
Group Director, Clinical and Regulatory Affairs, 1996 - 1999

ENCLARA PHARMACIA, Memphis, TN **2003 – Present**
Production Pharmacist, ExcelleRx, Inc. Hospice Pharmacy
Staff pharmacist in a high-volume hospice care pharmacy distribution center. Verify prescription accuracy, dosing regimen, drug interactions, and prescription dispensing.

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MILITARY EXPERIENCE

U.S. ARMY
Pharmacy Officer, Training Officer, Mobilization Officer, 330th General Hospital, Memphis, TN
Reserves; Honorable Discharge – rank of Major

U.S. Army Command and General Staff College Graduate, U.S Army Reserves, Memphis, TN

Pharmacy Officer, Martin Army Community Hospital, Fort Benning, GA
Active duty; Honorable Discharge – rank of Captain

EDUCATION

MEMPHIS STATE UNIVERSITY, Memphis, TN
Executive Master of Business Administration (MBA), Fogelman College of Business

UNIVERSITY OF TENNESSEE Center for Health Sciences, Memphis, TN
Bachelor of Science – Pharmacy, College of Pharmacy

UNIVERSITY OF TENNESSEE Martin, TN
Bachelor of Science

LICENSE

Tennessee Pharmacist License

PROFESSIONAL AFFILIATIONS

University of Tennessee Health Science Center College of Pharmacy Preceptor – Advanced Pharmacy Practice Experiences (APPEs) site for 4th year Doctor of Pharmacy Candidates

Life Science Tennessee Policy and Advocacy Committee

Medtronic Corporate Regulatory Council, Spinal Inclusion Council, and Employee Resource Groups

Orthopaedic Surgical Manufacturers Association (OSMA)
Treasurer and Board of Director

AdvaMed Workgroups: 510(k); State Associations; UDI, Cases, and Trays

Regulatory Affairs Professionals Society (RAPS)

American Pharmaceutical Association