



William J. Regan

SUMMARY

Executive Regulatory Professional with 39 years Pharmaceutical and Medical Imaging (Squibb/BMS/BMS MI/Consulting Services) experience including the most recent 20 years with progressive appointments within Regulatory Affairs and establishing a regulatory consulting firm (Regan Advisory Services LLC). Interactions with FDA, EMEA and Health Authorities are characterized by a strategic, communicative, collaborative, and relationship building style. Demonstrated track record to deliver positive regulatory results within a continuously evolving environment. Results include developing and defining regulatory strategies, orchestrating interactions with U.S. FDA (CDER, CDRH, and Advisory Committees) and Global Health Authority Forums, executing submissions and negotiating requirements/approvals for Efficacy, Labeling, Device and Chemistry, NDA's, SNDA's, MAA's, PMA's, Variations, and country specific submissions, as well as, IND's, IDE's and CTA's.

PROFESSIONAL HIGHLIGHTS

- Submitted IND for novel Heart Failure Imaging agent, cardiac perfusion agent, and pharmacological stress agent.
- Negotiated and obtained first Written Request Letter (WRL) from FDA Medical Imaging Division. Successful completion of pre-clinical and clinical studies resulted in additional 6 months product exclusivity.
- Approval for centralized MAA procedure for echocardiography contrast agent.
- Lead efforts with CDRH to introduce a Class III Medical Device for the detection of vulnerable plaque.
- Multiple country specific approvals for echocardiography/abdominal contrast agent.
- Lead efforts to gain regulatory approval for Plant Cell Fermentation technology to produce paclitaxel. First novel chemistry process approved by FDA in previous 30 years.
- Canadian NDS for PET FDG utilizing existing and novel clinical data.
- 150 SNDA's, SNDS's, Variations, IND's, CTA's submitted/approved/cleared
- Developed and implemented global regulatory organization for the BMS Medical Imaging business.
- Established CDRH regulatory capability for in-licensed class III catheter product.
- Established global capability for CTD electronic publishing.
- Extensive change management experience including facility optimization, global change control, research process optimization, and due diligence activities.

PROFESSIONAL EXPERIENCE

PRESIDENT, REGAN ADVISORY SERVICES

- Provide a full range of consulting services to an array of pharmaceutical companies regarding FDA meetings (Type B/C) and Advisory Committee Meetings including development of related documentation, presentations, and rehearsals. Engage in similar activities with EMEA, Health Canada and other Health Authorities.
- Planning and development of IND and CTA submissions and ongoing management of subsequent regulatory development activities.
- Critical review of protocols, Investigator Brochures, Preclinical, Clinical, and CMC modules.



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- Develop essential elements of Annual Reports, SNDA's, and Variations.
- Develop and submit responses to Health Authority questions regarding development and marketed products.
- Develop and submit regulatory documentation packages for Investigators.
- Provide general regulatory direction, strategies, and intelligence gathering for pipeline and marketed product programs.

Bristol-Myers Squibb: 1991-2006

Head (VP) Global Regulatory Affairs BMS Medical Imaging: 2001-2006

- Responsible for all aspects of Regulatory Affairs related to Pipeline, Marketed Products and Life Cycle Management.
- Lead the Global Regulatory Organization in executing regulatory strategies.
- As an executive member, provide strategic input to the Research and Development Operating Committee and Brand Development Operating Committee for BMS MI products.
- Orchestrate meetings and interactions with Global Health Authorities aligned with corporate strategy.

Project Leader: 2000-2001

- Lead due diligence regulatory activities associated with acquisition of Dupont Pharma and Medical Imaging. Lead various aspects of the integration of Dupont Pharma and Medical Imaging into BMS.
- Provide organizational input to the re-engineering the R&D Pipeline process.

Director Regulatory Affairs and Global Change Control: 1995-2000

- Directed the submission of 150 SNDA's for chemistry, drug product and labeling changes and 2 NDA's/MAA's.
- Liaison to President Technical Operations on major operational initiatives requiring regulatory action.
- Led efforts to gain approval for major synthetic changes with significant cost saving.
- Chaired multifunctional task force to reconfigure North American manufacturing network.

Associate Director Regulatory Affairs: 1993-1995

- Responsible for regulatory activities related to 80 product NDA's.
- Developed CMC and LCM regulatory strategy for acquisition of Glucophage (metformin) from Lipha Pharmaceuticals.
- Consolidated Bristol Myers and Squibb marketed products CMC regulatory function and established group as primary contact for 6 North American manufacturing sites and 25+ global facilities.

Manager Regulatory Affairs: 1991-1993

- Facilitated the regulatory integration of the Bristol Myers and Squibb manufacturing facilities throughout Europe.



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Various Positions Prior to 1991

- Held various positions of increasing responsibility prior to 1991 in Manufacturing, Quality Assurance, and International Pharmaceutical Technology and Clinical Supplies.

EDUCATION

B.A., Rutgers University

Major: Chemistry

Resource Manager Certification Program

Tufts University Program for Pharmaceutical Development

HONORS, AWARDS, and GRANTS

BMS Medical Imaging Leadership Award 2002, 2005

Recipient of 14 BMS Innovation and President Awards

EXTERNAL ACTIVITIES & PROFESSIONAL ADVANCEMENT

MICAA Regulatory Co-Chair and Co-Chair for CORAR Clinical Practice and Reimbursement Committee. Key activities include interaction on Critical Path Initiative, reestablishing MIDAC, and interacting with CMS on reimbursement issues.

Board member of PharmaPros Corp, a Clinical Services Organization.

Medical Imaging regulatory representative to SNM Industry Coalition.

Regulatory representative to Global Vulnerable Plaque Meeting.

PhRMA/FDA task force to reduce regulatory burden for chemistry changes.

Center for Professional Advancement: Lecturer on regulatory implementation of chemistry changes and global change control.

Drug Information Association: DIA Critical Path Imaging Program Planning committee and Round Table participant.

Vulnerable Plaque Expert Meeting: Identify and recruitment of FDA and EMEA participants.

Society Nuclear Medicine.

Society Echocardiography.

Society Nuclear Cardiology.

Participant in Seminars and lectures related to diagnostic cardiology.