

Curriculum Vitae



Stephen P. Rhodes
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Senior Consultant
Biologics Consulting Group, Inc.
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EXPERIENCE

Biologics Consulting Group, Inc., Senior Consultant
Chevy Chase, MD (March 2010 - present)

Food and Drug Administration, Office of Device Evaluation (1989 -2010)

Director, Investigational Device Exemption (IDE) and Humanitarian Device Exemption (HDE) Programs
(2007-2010)

- Responsible for developing and interpreting FDA policy and procedures on medical device clinical trials (IDEs) and orphan device approvals (HDEs).
- Responsible for the premarket Good Clinical Practice programs for devices
- Served as the CDRH representative on five working groups responsible for the Title VIII (ClinicalTrials.gov) provisions of FDAAA.
- Served as the CDRH Product Jurisdiction Officer, responsible for the CDRH recommendations on which FDA Center should take the lead on regulating combination products and improving the consistency in the review of these products.
- Served as the CDRH representative on the FDA Human Subject Protection Committee, Subcommittee on the Inclusion of Individuals with Impaired Decision-Making in Research, Emergency Research Consultative Board, Good Laboratory Practices Working Group, Tissue Reference Group.
- Led the Center for Devices and Radiological Health (CDRH) implementation of two titles of the Food and Drug Administration Amendments Act of 2007 (FDAAA): the Pediatric Medical Device Safety and Improvement Act of 2007 and the Clinical Trials Databases (ClinicalTrials.gov).

Acting Deputy Division Director, Division of General, Restorative and Neurological Devices (2005)

- Provided leadership on scientific, clinical and regulatory issues to the members of the

Orthopedic Devices Branch and the Restorative Devices Branch.

- Final signatory on IDE Supplements, 510(k) applications, and PMA Supplements.
- Prepared staff for public advisory panel meetings and provided guidance to 510(k), IDE and PMA review teams.

Acting Deputy Division Director, Division of General, Restorative and Neurological Devices (2002)

- Provided leadership for the Plastic and Reconstructive Surgery Devices Branch and the General Surgery Devices Branch.
- Represented the agency at public meetings and conferences and discussions with industry on specific device applications.

Acting Deputy Division Director, Division of Cardiovascular and Respiratory Devices (2001)

- Provided leadership to 25 staff members in the Pacing, Defibrillator and Leads Branch, the Cardiac Electrophysiology Monitoring Devices Branch, and the Anesthesiology and Respiratory Devices Branch.
- Final signatory on IDE Supplements, 510(k) applications, and PMA Supplements for cardiovascular devices.
- Provided guidance to 510(k), IDE and PMA review teams.

Branch Chief, Plastic and Reconstructive Surgery Devices Branch (1996 -2007)

- Managed the engineering, medical and clinical review of the data and subsequent approval of the following first-of-a-kind medical devices that have had a significant impact on public health:
 - the first approved saline-filled and silicone gel-filled breast implants
 - the first cyanoacrylate tissue adhesive
 - the first cyanoacrylate neuroembolization device
 - the first dural sealant
 - the first neurological stent for atherosclerosis
 - the first neurological stent for aneurysms
 - the first sealant for pulmonary surgery
 - the first sealant for cranial surgery
 - the first hyaluronic acid dermal filler
 - the first dermal filler for lipoatrophy in patients with HIV
 - the first non-viable human cellular product, for burn patients
 - the first viable human cellular product, for chronic ulcers
- Managed interdisciplinary staff consisting of 13 employees with diverse backgrounds, including chemistry, biology, veterinary medicine, cell biology, pathology, biomaterials, biomedical engineering, engineering mechanics, general surgery and occupational therapy
- Managed the regulation of a variety of important medical devices, including breast implants, liposuction devices, reconstructive implants, artificial skins, wound dressings, sutures, synthetic and tissue dura substitutes, neurological embolization devices, neurological stents, nerve repair devices, synthetic and tissue surgical meshes, lung sealants, stents and valves,



tracheal prostheses, abdominal adhesion barrier products, cyanoacrylate tissue adhesives, and synthetic and tissue hemostatic agents.

- Regulated a unique number of products that involve collaboration with the Center for Drugs and/or the Center for Biologics and raise important policy issues for the agency, such as human dura, xenograft products, human cellular skin substitutes, and devices with antibiotics.

Team Leader, Orthopedic Devices Branch (1995)

Supervised the review of data for new orthopedic devices.

Engineering Reviewer, Orthopedic Devices Branch (1989 – 1996)

- For five years reviewed most of the new artificial knee devices in the agency.
- Served as the agency's expert on artificial knee devices and arthroscopes. Developed the engineering testing necessary to evaluate the safety and effectiveness of new artificial knees.
- Sole author of the guidance documents for artificial knees and arthroscopes detailing the engineering and scientific information needed to evaluate the devices.
- Evaluated a variety of new orthopedic devices, including spinal implants, hip implants, shoulder implants, and ankle implants.
- Represented the agency in national and international organizations for the development of new test methods for orthopedic devices.
- Presented papers at scientific meetings on technical and regulatory issues to the orthopedic industry.

Non-FDA Experience

Reliability Engineer, Atlantic Research Corporation

Consultant on numerous NASA and DOD contracts (1987 – 1990)

EDUCATION

M.S. *Device Biomedical Science and Technology Management*, Georgetown University/Virginia Tech, Washington, D.C. (2008)

M.S. *Biomedical Engineering*, The Catholic University of America, Washington, D.C. (1989)

B.S. *Engineering Science and Mechanics*, Virginia Tech, Blacksburg, Virginia (1986)

SELECT AWARDS

PHS - Outstanding Unit Citation (2 times total)	2007
PHS - Unit Commendation (10 times total)	2006
PHS – Outstanding Service Medal	2002
PHS – Commendation Medal	2005
PHS – Achievement Medal (2 times total)	2005
FDA Group Recognition Award	2005
National Society of Professional Engineers, FDA Engineer of the Year	2006
FDA Outstanding Service Award (Group)	2006
CDRH Scientific Achievement Award - Outstanding Intercenter	

Scientific Collaboration	2005
PHS – Outstanding Service Medal	2002
CDRH Excellence in Review Science Group Award	1997
CDRH Group Productivity Incentive Award	1996
PHS – Engineering Literary Award – Regulatory Science	1995

FDA Related Publications

“Presubmission Meetings and Communication with FDA for 510(k)s, IDEs and PMAs” and “Best Practices and Useful Tips for 510(k)s, IDEs and PMAs”, Medical Device Submission & Compliance Strategies for the US Market, RAPS, Brussels Belgium, November 2009

“What is the Content and Format of Device Applications”, “How Can Sponsor’s Utilize Pre-Submission Consultation”, and “What Clinical Data from Outside the US Does FDA Accept?”, FDA’s Total Product Lifecycle – Regulatory Pathways to Medical Device Marketing in the United States, Tel Aviv, Israel, September 2009

“Adverse Event Reporting During Device Trials” and “Humanitarian Device Exemptions”, Association of Clinical Research Professionals (ACRP) Annual Conference, Denver, CO, April 2009

“The IDE Regulations”, IDE Submission Workshop, Medical Technology Learning Institute, Las Vegas, NV, February 2009

“Postapproval Studies and the Pediatric HDE Provisions of FDAAA”; “Panel Discussion: Current Initiatives with the FDA”; and “FDAs Investigational Device Exemption (IDE) Regulations – Balancing Science with the Needs of Patients”; 2008 Annual Public Responsibility In Medicine & Research (PRIM&R) Conference, Lake Buena Vista, FL, Nov 2008

“The Device Regulations and Good Clinical Practices (GCPs)”, Annual Human Subject Protections Conference, Covington, KY, Sept 2008

“Pre-IDE Process: Optimizing Your Results”, RAPS Annual Conference, Boston, MA, Sept 2008

“Combination Products Overview”, 2008 Parental Drug Association (PDA)/FDA Joint Regulatory Conference, Washington, DC, Sept 2008

“Humanitarian Device Exemptions for Pediatric Devices”, Pediatric Medical Devices Stakeholders Workshop, NIH, Bethesda, MD, July 2008

“Regulatory and Design Considerations for Clinical Research of Medical Devices”, Association of Clinical Research Professionals (ACRP) Global Conference on Human Subjects, Boston, MA, April 2008

“The Regulatory Aspects of Hyperthermia Studies”, ESHO Educational School on Clinical Hyperthermia, Munich, Germany, April 2008

“FDA Amendments Act of 2007: HDE Provisions of Title III – Pediatric Medical Device Safety and Improvement Act of 2007”, Pediatric Medical Device Innovation, Regulation and Legislation Seminar, Medical Technology Learning Institute, Falls Church, VA, April 2008

“The Legal Basis for an IDE Submission”, IDE Submission Workshop, Medical Technology Learning Institute, Las Vegas, NV, February 2008

“IDEs and HDEs for IRBs and Clinical Investigators”, IRB Educational Conference, University of Medicine and Dentistry of New Jersey, Cancer Institute of New Jersey, New Brunswick, NJ, January 2008

“The FDA’s Investigational New Drug and Investigation Device Exemption Regulations” and “Medical Device Postapproval Studies”, 2007 Annual Human Research Protection Program Conference, Boston, MA, December 2007

“CDRH Regulation of Tissue Engineered Medical Products,” 30th Annual Meeting of the Society of Biomaterials, Memphis, TN, April, 2005.

“CDRH Perspective on the Regulation of Cyanoacrylate Tissue Adhesives”, 30th Annual Meeting of the Society of Biomaterials, Memphis, TN, April, 2005.

“FDA Perspective on the Regulation of Medical Device Tissue Adhesives,” in: *Tissue Adhesives In Clinical Medicine*, BC Decker, Inc., 2005.

“Regulatory Issues for Medical Devices,” in: *Textbook of Cerebrovascular Intervention*, Saunders, 2005.

“CDRH Perspective on the Regulation of Biomaterials in Plastic and Reconstructive Surgery Devices,” 7th World Congress of Biomaterials, Sydney, Australia, May 2004.

“CDRH Perspective on the Regulation of Novel Wound Dressings,” DARPA Wound Healing Workshop, Baltimore, MD, September 2003.

“Clinical Studies and Least Burdensome Issues,” MASSMedic Annual Meeting, Boston, MA, March 2003.

“Regulation of Tissue-Engineered Products by FDA,” Georgia Institute of Technology Short Course on Tissue Engineering, April 1997.

"The Regulation of New Total Knee Prostheses," *Journal of Long-Term Effects of Medical Implants*, 4(1):1994.

Stephen P. Rhodes, M.S.



"The Evaluation of the Safety and Effectiveness of Total Knee Prostheses," Thirteenth Southern Biomedical Engineering Conference, April 1994.

"The Regulation of Revision Hip Prostheses," Orthopaedic Research Symposium on "Current Concepts in Total Hip Revision Surgery," November 1993.