

Curriculum Vitae



Miriam C. Provost, Ph.D.
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Senior Consultant
Biologics Consulting Group, Inc.
Vienna, VA

EDUCATION

Ph.D. *Chemical Engineering*, University of Pennsylvania, Philadelphia, PA (1989)

M.S. *Chemical Engineering*, University of Pennsylvania, Philadelphia, PA (1986)

B.S. *Chemical Engineering*, University of Dayton, Dayton, OH (1983)

EXPERIENCE

Biologics Consulting Group, Inc., Senior Consultant (Medical Devices)
(Nov. 2008 - present)

M Squared Associates, Senior Project Manager
Alexandria, VA (2006 – Oct. 2008)

- Advised small and large medical device and combination product manufacturers on regulatory strategy, preclinical and clinical testing, FDA submission strategies and FDA communication issues.
- Prepared and served as point of contact for FDA submissions
- Provided “FDA review” of documents prior to submission
- Assisted medical device companies in preparation for advisory panel meetings

CDRH, FDA, Office of Device Evaluation (ODE), Deputy Director for Engineering and Science Review
(Jul. 2005- Sept. 2007)

- One of two deputy directors of ODE, comprised of approximately 350 scientists, engineers, medical officers and support staff responsible for premarket review and approval of all medical devices in the United States (with the exception of in vitro diagnostics)
- Signature authority for classification and Reclassification actions, 513(g) requests and Requests for Designation for combination products
- Responsible for the development of FDA Guidance documents and regulations
- Responsible for development of combination product policy for CDRH
- Assisted ODE director in the review and determination of appeals

CDRH, FDA, Division of General, Restorative and Neurological Devices (DGRND), ODE
Acting Director

(Mar. 2005- Jul. 2005)

- Led a group of approximately 74 scientists, engineers and medical offices responsible for the premarket review and approval of medical devices in the following areas: orthopedics, neurological devices, general and plastic surgery devices and restorative devices.
- Had final signatory authority for all premarket applications reviewed during this period, including PMAs, 510(k)s, IDEs, HDEs, 513(g)s, etc.
- Managed and participated in several Advisory Panel meetings as FDA representative.

CDRH, FDA, Division of General, Restorative and Neurological Devices (DGRND), ODE
Deputy Director

(Dec.2001-Mar. 2005)

- Had oversight (and sign-off authority) for two branches in DGRND (General Surgical Devices Branch and Plastic and Reconstructive Surgical Devices Branch). Provided leadership and technical and regulatory oversight regarding premarket review decisions for 510(k)s, IDEs, PMAs, PMA supplements, HDEs, 513(g)s.
- Led or served on several center-level and FDA level teams, including:
 - FDA Working group on innovative combination products
 - CDRH eRoom PMA review pilot team
 - Interagency working group on Image Guided Interventions

Division of Cardiovascular and Respiratory Devices, Cardiac Electrophysiology devices branch, Acting Branch Chief

(May 2000-Dec. 2001)

- Served as acting branch chief of the Cardiac Electrophysiology and Monitoring Devices Branch (CEMB) in the Division of Cardiovascular and Respiratory Devices.
- Responsible for assigning and managing the premarket review work (including 510(k)s, IDEs, IDE supplements, PMAs and PMA supplements) of subordinate staff and ensuring that documents were reviewed and processed in a timely manner, and that decisions were made that were consistent with regulations and reflective of ODE policy.
- For PMAs and other issues that were presented to the FDA advisory panel, worked with branch members to prepare panel presentations and panel briefing materials.

Division of Reproductive, Abdominal, and Radiological Devices, Gastroenterology and Renal Devices Branch, Chemical Engineer/Expert Scientific Reviewer

(Mar. 1994-May 2000)

- Responsible for the scientific and regulatory review of 510(k)s, IDEs, PMAs, HDEs and reclassification petitions. Ensured that all scientific and regulatory issues were properly addressed within the statutory timeframes.
- Participated as the primary author or a major contributor of five FDA guidance documents. These guidance documents summarized the technical and regulatory requirements for four different products in the branch.
- Lectured at numerous professional society meetings to publicize FDA regulatory efforts for devices.

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- Served as a liaison on the AAMI standards committee for hemodialysis devices.

FDA RELATED PUBLICATIONS

1. Interactive Review Process for 510(k)s and PMAs”, RAPS Webinar, October 2008.
2. Establishing Effective Communication with FDA”, RAPS Annual Meeting, September 2008.
3. “Biologics-Device Combination Products”, AdvaMed Conference on Combination Products, July 2008
4. “The Role of the FDA in Disseminating Novel Medical Device Technologies”, Conference on Improving the Evidence Base, April 2008
5. “US Regulatory Issues”, TMS Safety Conference, March 2008
6. CDRH in 2008:MDUFMA II and the Matrix”, Orthopedic Surgical Manufacturers Association (OSMA) meeting, January 2008
7. An Overview of Combination Product Review in CDRH”, Pipeline to Product, November 2007
8. “FDA’s Antimicrobial Guidance Document”, RAPS Webinar on Combination Products, November 2007
9. “510(k) Review Considerations” and “Points to Consider for a Successful PMA Submission”, MDMA Workshop, September 2007
10. “Medical Device Clinical Trials”, RAPS Annual Meeting, September 2007
11. “Timely and Efficient Premarket Review of a Combination Product: Device Perspective”, RAPS Annual Meeting, September 2007.
12. “How to Ensure a Timely and Effective Premarket Review: The CDRH Perspective”, PharmaMedDevice, April 2007.
13. “Developing Innovative Medical Devices: The FDA Perspective”, OCTANE Medical Device Forum, November 2006.
14. “Developing Innovative Devices to Meet Public Health Needs: The FDA Perspective” AIMS on BioDesign, Atlanta, GA, September 2006.
15. “Points to Consider for a Successful PMA submission”, AdvaMed workshop, March 2006 and MDMA workshop, September 2006.
16. “CDRH Perspective: Medical Device Regulations, Standards and Guidance”, American Society for Quality, Boston, MA, March 2006.
17. “Public Health Issues Related to Mutually Conforming Labeling: CDRH Perspective”, Drug Information Association and FDA joint workshop, May, 2005.
18. “Successful Pre-IDE Meetings”, Regulatory RAPS Annual meeting, Washington, D.C., October 2004.
19. “Regulatory Approaches for Biological/Device Combination Products – CDRH”, Drug Information Association National Meeting, San Antonio, TX, June 2003.

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20. "CDRH Perspective on Tissue Engineered Medical Products", Engineering Tissue Growth, Pittsburgh, PA, March 2003.
21. "FDA Role in Regulation of Medical Devices for ESRD", Health Care Financing Administration Annual ESRD Update, Chicago, IL, April 2002.
22. "Premarket Review Considerations for 510(k)s for Reprocessed SUDs", DSMA Device workshops, Phoenix and Orlando, 2001.
23. "The FDA Role in Dialyzer Reprocessing in the U.S.", International Symposium on the Challenge for ESRD Treatment in the Near Future, Perugia, Italy, 1999.
24. "Current FDA Initiatives for Tissue Engineered Products: Preclinical Safety Evaluations and Standards Development", Tissue Engineering Society Annual Meeting, Orlando, FL, 1998.
25. "FDA Issues on Hemodialyzer Reuse", AAMI National Meetings, 1996, 1997, 1998.
26. "FDA Regulation of Water Purification Systems for Hemodialysis", Water Quality Association Annual Meeting, Indianapolis, IN, 1996.

SELECTED HONORS AND AWARDS

- FDA Commissioner's Special Citation, 2005.
- FDA Engineer of the Year Award, 2005
- FDA Group Recognition Award, Combination Product Policy Development and Legal Services Group, 2005
- FDA Scientific Achievement Award for Outstanding Intercenter Collaboration (CDRH Finalist), Sculptra Review Team, 2005
- FDA Group Recognition Award for Embolization Devices Reclassification Team, 2004
- FDA Outstanding Service Award for Silicone Gel Filled Breast Implant PMA Review Team, 2004
- CDRH Special Recognition Award, PMA Review Teams Development Group, 2004
- FDA Group Recognition Award, DBS-ODE Partnership Improvement Group, 2003
- CDRH Special Recognition Award, for the Reuse Electrophysiology Group, 2003
- CDRH Staff College Certificate of Appreciation for outstanding contributions to training programs, 2000, 2002
- CDRH Special Recognition award for the Reuse of SUDs Risk Prioritization Scheme, 2001
- FDA Scientific Achievement Award for Excellence in Review Science for CDRH, 2000
- CDRH Special Recognition award for hemodialyzer reclassification team, 2000
- CDRH Special Recognition award for cellulose acetate hemodialyzer group, 1998
- FDA Group Recognition award for Hemodialyzer Reuse team, 1997
- CDRH Special Recognition award for Low Density Lipoprotein PMA review team, 1996