

Curriculum Vitae



Stuart Portnoy, M.D.
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Senior Consultant (with M.D.)
Biologics Consulting Group, Inc.
Arlington, VA

SUMMARY OF EXPERTISE

- Expert at gaining approval for new medical devices across a wide range of therapies.
- Five years consulting experience for start-ups and well-established companies.
- Eight years at FDA reviewing or supervising review of hundreds of cardiac device applications along multiple pathways - IDEs, PMAs, and 510(k)s.
- Extensive experience in developing successful regulatory strategies and negotiating regulatory, clinical, and technical issues with FDA.

EDUCATION

M.D. George Washington University School of Medicine (1991)

M.S. *Bioengineering*, University of Pennsylvania (1989)

B.S. *Chemical Engineering*, Tufts University, cum laude (1985)

EXPERIENCE

Biologics Consulting Group, Inc., *Senior Clinical Consultant*
Arlington, VA (Aug. 2007 - present)

PharmaNet, Inc., *Medical Device Consultant*
(Washington, DC) (2002 – July 2007)

- Advise medical device makers on regulatory strategy, clinical trial design, and technical issues to gain FDA market-approval for new products.

Food and Drug Administration, *Acting Deputy Director*, Division of Cardiovascular Devices,
Rockville, MD (2002)

- Assisted Director in managing 70-person cardiac device review division.
- Managed high-profile projects, clinical and scientific personnel, administrative staff, and made decisions for approval of cardiac devices.

Food and Drug Administration, *Branch Chief*, Interventional Cardiology Devices Branch, Rockville, MD (2001 – 2002)

- Managed a team of engineering and medical reviewers. Assigned manufacturers' submissions to team members. Reviewed, edited, and signed-off on team's work.
- Negotiated clinical trial design and FDA approval requirements with device manufacturers.
- Developed approach to regulating combination products, especially drug-eluting stents.

Food and Drug Administration, *Medical Officer*

Rockville, MD (1994 – 2000)

- Reviewed and approved or disapproved wide range of cardiac devices.
- Negotiated with medical device manufacturers on FDA requirements for clinical trial design, product labeling, post-approval studies, and device recalls.

George Washington University Hospital, *Internship in Internal Medicine* (1992)

BIOMEDICAL ENGINEERING RESEARCH EXPERIENCE

VA Medical Center, Washington, DC (1993-1994)

Weizmann Institute of Science, Rehovot, Israel (1985-1986)

MIT - Lab of Dr. Robert Langer, Cambridge, Massachusetts (1984-1985)

- Optimized a technique for growing human cells on industrial-grade synthetic fabrics.
- Harvested tissue plasminogen activator for use in treating heart attack patients.
- Researched underlying mechanisms of arrhythmias that result in sudden cardiac death and published research results in the Journal of the American College of Cardiology.
- Designed and performed experiments investigating techniques for controlled drug delivery.

PROFESSIONAL LICENSES & MEMBERSHIPS

- Licensed to Practice Medicine in Virginia (since 1992)
- Heart Rhythm Society (member)

PROFESSIONAL ACTIVITIES & PRESENTATIONS

- Stanford Biodesign Fellowship Program - Project Team Advisor, Stanford University Palo Alto, CA (2007)
- RAPS Annual Conference, Track Chair, Regulatory Affairs Professionals Society (2007)
- Health Care Compliance Certification Program, Advertising, Promotion & Labeling of Medical Devices, Seton Hall Law School, Newark, NJ (semi-annual)
- Chairman, Forging the Way for Combination Products for Drug, Devices, & Biologics, Center for Business Intelligence, Minneapolis, MN (2005)
- Horizons West Coast Conference, Conference Chair, Combination Products Track, Regulatory Affairs Professionals Society in Santa Clara, CA (2004)

Stuart Portnoy, M.D.



- Predicting FDA Approvals & Rejections of Cardiac Devices, Transcatheter Cardiovascular Therapeutics Lazard Healthcare Research , Washington, DC (2004)

PUBLICATIONS

- Advertising & Promotion of Medical Devices:" Stuart Portnoy. Journal of Health Law, Spring 2006.
- Combination Products -- Regulatory Strategy for Preclinical and Drug Testing": Stuart Portnoy and Steven Koepke. Medical Device & Diagnostic Industry (MD&DI) Magazine, May & June 2005.