

Decus Biomedical, LLC

Marc L. Bartoo, Ph.D., R.A.C.

Education and Certifications

- 2005 **Regulatory Affairs Certificate (RAC)**, Regulatory Affairs Professional Society
1995 **Ph.D., Bioengineering**, University of Washington, Seattle, WA
1983 **B.S., Chemistry**, University of California, Berkeley, CA

Professional Experience

2003 - present **Technical Services Manager**
Decus Biomedical, LLC, San Carlos, CA

Relevant Client Responsibilities:

Allergy Therapy Device Client

- Wrote and established Document Control system, initial Design Control, and Risk Management Plan and procedures. Assisted in moving toward a more complete Quality System in support of planned Clinical Device Trials.

Nystagmograph Client

- Guided client on regulatory strategy and content of 510(k); revised large sections of client 510(k). FDA granted 510(k) approval in October of 2004.

Electronic Stimulator Client

- Onsite engineering troubleshooting in Russia, specified hardware and software changes to fix stalled clinical trial.
- Ongoing visits to clinical sites to monitor device reliability and safety.
- Wrote clinical protocol and created case report forms for additional study designed to test for a different intended use.

1999 - 2003

Senior Scientist
Instrumentation for Science and Medicine, San Carlos, CA

Relevant Client Responsibilities:

Electronic Stimulator Client

- Wrote clinical protocols, SOPs, 510k and other regulatory or quality documents in support of device development and clinical trial.
- Trained physicians/nurses/staff members in protocols and SOPs. Performed monitoring visits of clinical site.
- Wrote specifications, verification procedures, tested and verified hardware and software components of device.
- Performed project management duties in the development of clients' device.

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Drug Delivery Client

- Hired as outside consultant to help the product team review and verify all product data. Performed analysis and wrote research reports in support of NDA filing with the FDA.
- Project manager of team to define and measure product air pressure tolerances, reducing manufacturing test time 10-fold from 2.5 minutes to 15 seconds.
- Project manager for development of microprocessor controlled, data logging heat sealer device.
- Designed and built test instrumentation, designed and performed experiments to address shipping characteristics of the drug blister package.
- Performed data analysis on shipping study findings, wrote reports recommending future actions, and made presentations to senior executives.

Blood Test Client

- In conjunction with client engineers, developed prototype microprocessor controlled, magnetically driven, blood testing needle.
- Performed experiments with prototype device utilizing high-speed camera to analyze interaction of needle with finger tissue.

Radio Frequency Device Client

- Updated requirements, assembly, test and verification documents for device.
- Performed verification and validation testing on devices for human clinical trial.

1996 - 1999

Senior Research Fellow University of York, York, England

Built dual-mode laser tweezers apparatus to make sensitive measurements of the displacement, stiffness and forces generated by the interaction of *individual* muscle protein molecules. Technique uses optics, high intensity lasers, electro-acoustic beam steering, epi-fluorescent and bright field microscopy, computerized data acquisition and electronics control. Biological specimen preparation required animal handling techniques, the growth, purification and biochemical characterization of bacterially expressed protein fragments, or of genetically engineered proteins from *drosophila melanogaster*. Purified, functional proteins were fluorescently labeled, then introduced into the apparatus to make measurements of nanometer displacement and picoNewton forces.

1995 - 1996

Postdoctoral Fellow University of Washington, Seattle, WA

Using the apparatus built for my doctoral thesis, I performed experiments on isolated myofibrils in order to determine the transient behavior of relaxed and activated single, isolated muscle myofibrils. I have collaborated with laboratories in Oxford and Heidelberg to help them duplicate and improve on this apparatus. Served as a lecturer in biomechanics and instrumentation courses for graduate and undergraduate students.

1986 - 1995

Research Assistant University of Washington, Seattle, WA

Worked with engineers and machinists to develop a novel specimen chamber, micro-imaging system and force transducer to perform experiments on isolated myofibrils. Wrote software to control electronics and collect data via computer. The host computer controlled a photodiode array, temperature regulator, specimen motor drive, and a fiber-optic force transducer. The combination of hardware and software allowed millisecond resolution of

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sarcomere-length changes of a few nanometers and changes in tension of less than one microgram.

1983 - 1986

Research Chemist

ALZA Corporation, Mountain View, CA

Research and development chemist on controlled release, oral dosage forms of pharmaceuticals. The initial project led to a patented dosage form for acid sensitive agents. Later projects included dosage forms for ruminants (push-melt technology), and design of a pulsed delivery dosage form for non-steady state release. Development of these technologies was based on broad familiarity with FDA approved substances, their chemical and physical properties, and creativity to employ them in novel ways. Supervision of technicians and interaction with a range of engineers, biologists and regulatory professionals was required. Several commercial products based on technology I invented or developed are currently being sold.

Publications and Presentations

Seven published articles in peer-reviewed journals, many scientific abstract and poster presentations. Copies of articles or abstracts are available upon request.

Patent

Bartoo, M.L., Wong, P.S.L., Theeuwes, F., and Barclay, B.: Dosage Form for Delivering Acid Sensitive Beneficial Agent. Assignee: ALZA Corporation. U.S. Patent Number: 4,743,248, Issued 5/10/88. European Patent Number: 87306451.3, Issued 8/24/87.