

Decus Biomedical, LLC

Grace T. Bartoo, Ph.D., RAC, CBA

Summary of Qualifications

- 25 years in biomedical industry, including research, clinical, regulatory, and management experience.
- Ability to lead a team to complete complex projects.
- Experienced in executive management for medical device companies.
- Experienced in design and management of multi-center clinical trials.
- Experienced in guiding and writing successful regulatory submissions (PMA, 510(k), CE mark, Canadian)
- Excellent communication skills; experienced speaker and writer.
- Strong research skills in image processing, image analysis and light microscopy.

Summary of Professional Experience

2004 – Present	CEO, Decus Biomedical, LLC, San Carlos, CA
2006 – 2008	Vice President, Clinical, Regulatory and Quality Affairs, iScience Interventional Inc., Menlo Park, CA
1998 – 2003	Vice President, Regulatory and Clinical Affairs, ISM, Inc., San Carlos, CA
1995 - 1996	Program Manager, Commercialization, NeoPath, Inc., Redmond, WA
1993 - 1998	Consultant, Bartoo Biomedical, Seattle, WA
1988 - 1992	Technical Founder and Director of Clinical Affairs, NeoPath, Inc., Redmond, WA
1982 - 1986	Research Engineer, MedaSonics, Inc., Milpitas, CA

- Decus Biomedical is a spin-off company from ISM, Inc., a medical device consulting firm. We provide services in the following areas:
 - Regulatory (strategy, submissions, compliance)
 - Clinical (design, execution and analysis of studies)
 - Quality (quality system establishment, audits and gap analysis)
 - Software development processes and validation
 - Technical services (basic research, verification, product documentation, risk management)
- iScience Interventional is a venture-backed start up company that develops microcatheter and imaging technologies for ophthalmology therapies. I helped to lead the transition of this company from an R&D focus through becoming an operating company with product launch and establishment of all commercial activities. Company grew from 30 to 55 people during my tenure. Responsible for setting strategic direction of the regulatory strategy of the company and overall regulatory compliance. Obtained US regulatory clearance for initial product line (4 devices), CE marking for all products, and Canadian license for 3 products. Completed successful transfer from design to manufacturing for all products, ISO 13485:2003 certification, successful FDA inspection, and improvement of manufacturing and customer support processes. Clinical activities include multiple concurrent clinical trials including surgical treatment study with approximately 300 subjects from over 14 sites from US and Germany.
- One of three senior partners of ISM, Inc., a medical device consulting firm. Provided technical, clinical, regulatory, and quality system services for clients. Also responsible for firm's finance management as CFO.
- First employee and one of the technical founders of NeoPath, Inc. (now known as Tripath), a class III computer aided detection device for cervical cytology. Managed clinical trials with 40,000 cases from 3 clinical sites. Managed commercialization programs of a medical device product into Australia and Europe. Experienced in presenting to investors, scientific leaders, FDA officers, and potential customers.
- At MedaSonics, I was project engineer for medical software product for blood flow measurements. I took the company's first software product from product concept through formal release, FDA audit, national sales staff training, and clinical testing.

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Summary of Services for Medical Device Companies (part of Decus or ISM)

- Acting VP of Regulatory and Clinical for three clients
- 510(k) applications
 - Imaging workstations
 - Lasers for dermatology
 - Ultrasound systems
 - Cranial electrotherapy stimulator.
 - RF controller
 - EEG
 - Endoilluminators
- PMA application
 - Medical Image Analyzer
 - FDA clinical inspection completed 6/2003, no 483's.
 - Approvable letter received 9/26/03
- Product documentation (design history file) for multiple medical device products
 - Multiple RF generators
 - Electroencephalogram (also product manager)
 - Mammography computer aided detections
 - Cranial Electrotherapy Stimulator (also product manager)
 - Ultrasound products
 - Ophthalmology products
 - Imaging products
- Set up and manage multi-site clinical studies for Class III device(s) and Class II devices
 - Medical Image Analyzer
 - Cranial Electrotherapy Stimulator
 - Catheter based surgical studies
 - Includes protocol and procedure writing, obtaining IRB approval, monitoring and data management.
- Provide data management operations (CRF design, database implementation, data entry operations, statistical analysis)
 - Medical imaging studies
 - Cranial electrotherapy studies
 - Catheter based surgical studies
 - ENT studies
 - Sleep Apnea studies
 - Wound healing studies
 - Cardiovascular studies
- Designed, analyzed or assessed numerous studies, both for bench studies and clinical trials.
 - Drug development studies (Mostly ANOVA analysis and factorial designs)
 - Sensitivity and specificity studies
 - Reader performance studies (ROC)
 - Comparison study for interventional device (Blackwelder null hypothesis approach)
 - Double blind placebo control, randomized clinical study designs
- Set up quality system processes and software development processes in start up companies
 - EEG device manufacturer
 - Image database/mining software development company
 - Computer aided detection companies
 - Ultrasound companies
 - Imaging companies
 - Ophthalmology catheter company
 - IVD company
- Establish and help with improvement of Quality Systems
 - Establish ISO 13485:2003, 21 CFR 820, and 21 CFR 11 compliant Quality Systems
 - Includes writing Quality Manuals, SOPs, Forms, Process Maps
 - Provide internal audits and gap assessments
 - Provide guidance for process improvement

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- Help prepare clients for FDA, CMDCAS and ISO inspections.
- Develop and execute verification and validation tests.
 - Product and process validation
 - Massager, Therapeutic, Electrical
 - Image processing software products
 - IVD products

Summary of Professional and Community Service

2003 – 2007	Industry Representative, General and Plastic Surgery Devices Panel, Food and Drug Administration
2003 –2005	Regulatory Columnist, IEEE Engineering in Medicine and Biology Magazine
2000 –2004	Region 6 Representative, IEEE Engineering in Medicine and Biology Society – Administrative Committee (AdCom) Voting Member
2003 – 2004	Medical Device Commercialization Theme Co-chair, IEEE Engineering in Medicine and Biology Conference, Cancun, Mexico (2003) and San Francisco (2004)
2000 – 2002	Chair, Professional Activities Committee, IEEE Engineering and Medicine and Biology Society Vice Chair, , IEEE Santa Clara Valley Engineering in Medicine and Biology Society
1999 - 2000	Chair, IEEE Santa Clara Valley Engineering in Medicine and Biology Society
1996 - 1998	Governor (School Board), Fishergate Primary School, York, England
1995 - 1996	Consultant, Alzheimer’s Disease Research Center, University of Washington, Seattle, Washington
1995	Referee, <i>IEEE Transactions in Biomedical Engineering</i> .
1991 - 1995	Image Analysis Consultant, UW Child Development Mental Retardation Center, Neuroscience Imaging Core.

Summary of Academic Experience

2005	Certified Quality Auditor – Biomedical (CQA-Biomedical), American Society of Quality
1999	Regulatory Affairs Certification (RAC) , Regulatory Affairs Professional Society
1991 - 1995	Ph.D., Bioengineering, University of Washington, Seattle, WA Dissertation: Quantitative Neuropathological Measures in Alzheimer's Disease.
1986 - 1989	M.S., Electrical Engineering, University of Washington, Seattle, WA Thesis: Automated Detection of Senile Plaques in Alzheimer's Disease Using Image Analysis.
1979 - 1983	B.S. with Honors, Bioengineering, University of California, Berkeley, CA

- Received three scholarship/fellowship awards during undergraduate and graduate school.
- Finalist in two international bioengineering graduate student paper competitions, IEEE and ITBM.
- Received two engineering awards during graduate school (SWE, IEEE).
- Participated in writing two NIH grants (both awarded).

Summary of Publication and Presentations

- Author of four peer reviewed journal publications.
- Author of 19 conference abstracts (15 as primary author).
- Invited lecturer for over 20 talks to academia, industry, and professional societies in areas of software development processes, software validation, 21 CFR Part 11 compliance, medical device industry, Alzheimer's disease, automated cytology, and image analysis.