

Cory J. Smith

Professional Strengths

Extensive experience in quality, production of medical devices, and management

- Facilities design, start-up and qualification
- Process and facilities validation
- Product development and transfer
- Reagent process scale-up
- Quality assurance: preproduction, medical device, and pharma
- Manufacture of high quality, Quality Systems Regulations (QSR and ISO)-compliant products

Excellent managerial, organizational, motivational and interpersonal skills

Experience

2003 to Present

Independent consultant helping medical device and biotherapeutic companies achieve their outsourcing, production and compliance goals.

- Perform grant writing and assist in business development activities
- Technical writing to support Master Validation planning and facilities validation for biotherapeutic products
- Outsource manufacturing and conduct compliance and capability audits
- Project manager for regulatory and clinical affairs for a medical device clinical trial
- Provided technical instructions for a medical device for physician and distributor training programs

1992 to 2002

Ostex International, Inc.: Ostex made diagnostic tests using either serum or urine to detect the levels of type I collagen. Ostex was acquired by Inverness in 2003. The tests are used to monitor response to osteoporosis therapy.

Positions held: Manufacturing Engineer, Manufacturing Manager, Director of Manufacturing and Vice President of Manufacturing

- Responsible for construction of 2 manufacturing plants (a 7,000 sq. ft. microtiter plate product plant and a 14,500 sq. ft. point-of-care device manufacturing plant)
- Specified and validated all major manufacturing equipment
- Created and managed the manufacturing documentation system
- Recruited and trained manufacturing staff
- Served on management committee to optimize our corporate business strategy

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Experience, continued

1984 to 1992

Genetic Systems: Genetic Systems makes many different clinical diagnostic tests and supports those tests with custom software.

Positions held: Development Biologist, Senior Technician, Project Coordinator, and Quality Assurance Manager

- Participated in the development of two enzyme immunoassays
- Coordinated the generation of information required for product and establishment license approvals for process modifications to an FDA approved product.
- Participated in the design and facilities validation of a BL-3 containment laboratory.
- Transferred medical device software, an enzyme immunoassay, and a rapid synthetic peptide-based immunoassay from Research and Development to Manufacturing
- Directed the Quality Assurance department (reagent and software QA) to achieve corporate goals and satisfy regulatory requirements

1981- 1984

Research Technologist
Department of Oncology
University of Washington

- Conducted experiments, monitored animals, and reported the results of *in vivo* and *in vitro* adoptive chemoimmunotherapy experiments
- Developed T- lymphocyte-depleted mouse colony
- Participated in the investigation of the *in vivo* role of Interleukin-2

Education

Bachelor of Science in Fisheries
University of Washington

Additional Training

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| Project Management | (American Management Association) |
| Basic Management | (Battelle) |
| Process Filtration | (Society of Manufacturing Engineers) |
| Biohazards in the Laboratory | (Johns Hopkins) |
| Fermentation Microbiology | (American Type Culture Collection) |
| Lateral Flow Immunodiagnostic Devices | (Millipore) |
| Certification in Materials Requirements Planning | (American Production and Inventory Control Society) |

Advisory Board Experience

Seattle Community College Biotechnology Program Advisory Board (15 years)
International Society of Pharmaceutical Engineers Medical Device Advisory Committee (3 years)

Courses Taught

Manufacturing Project Management (Institute of Validation Technology, 2006)
The Fine Art of Project Management: Keep Your Writing Projects on Track
(Northwest Chapter of the American Medical Writers Association [AMWA-NW], 2009)

Professional Affiliations

Organization of Clinical and Regulatory Associates (ORCA)
American Medical Writers Association (AMWA)