



Curriculum Vitae of

CHARMAINE SUTTON

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The Tamarack Group - Minneapolis, LLC

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EDUCATION & CERTIFICATIONS

- B.S. in Applied Physics University of California, Davis CA
- AAS in Laser Technology North Central Technical College, Wausau WI
- Regulatory Affairs Certified (RAC) Regulatory Affairs Professional Society
- Blackbelt Quality Engineering Statistics Certificate American Society for Quality
- Technical Project Management Certificate College of St. Thomas, St. Paul MN
- Industrial Safety Certificate Lawrence Livermore National Laboratories, Livermore CA

EXPERIENCE

1991 Present The Tamarack Group ♦ Consultant, President

- Consulting services focus on medical devices, diagnostics, and combination products
- Advises medium, small, and start-up medical product developers and manufacturers on a broad range of US Food and Drug Administration (FDA) regulations and EU medical product directives
- Helps US and European companies develop regulatory strategies for product approvals and manufacturing facility compliance
- Helps prepare regulatory submissions (RFDs, IDEs, 510(k)s, PMAs), and leads companies through early collaboration meetings with the FDA
- Designs and analyzes quality systems for FDA/QSR and ISO compliance, assists with post-market compliance matters (inspections, warning letters, removals / recalls, MDR / vigilance reporting)
- Helps develop quality and regulatory management staff

1998 2000 Vascular Solutions, Inc., Minneapolis, MN ♦ VP Regulatory, Quality, and Clinical

- Directed all regulatory strategies for Class III combination device from conception through commercial distribution, including pre-clinical testing, clinical investigations, PMA approval, and post-market surveillance.
- Established ISO 9001/13485 and FDA/GMP/QSR-compliant Quality Systems for start-up companies.

1990 1991 AngeLase, Inc., Plymouth, MN ♦ Manager of Quality Assurance, Clinical & Regulatory

1989 1990 Medilase, Inc., Plymouth, MN ♦ Optical Systems Engineer

- Developed clinical investigation and product approval strategies for catheter-based laser treatment of cardiac arrhythmias and coronary artery disease.
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1987 1989 Lawrence Livermore National Laboratory, Livermore, CA ♦ Physicist
1986 1987 ThermaWave, Inc., Fremont, CA ♦ Engineer
1981 1984 LLNL, Livermore, CA ♦ Laser/Electro-Optical Technologist
1980 1981 Bendix Field Engineering Corporation, Livermore, CA ♦ Laser System Technician

- Developed new laser technologies for defense and energy applications.
 - Developed semiconductor configuration monitoring system.
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PROFESSIONAL SOCIETIES

- Regulatory Affairs Professional Society (RAPS)
- American Society for Quality (ASQ)

PATENTS

Vercimak, C., Savage, S.D. and Brucker, G.G. "Multi-fiber Linear Array Laser Catheter Connector" Patent Number 5,290,277, March 1, 1994.

PUBLICATIONS

Books

DeSain, C.V. and Sutton, C.V. (2000) Risk Management Basics, Advanstar Communications, Cleveland, OH.

DeSain, C.V. and Sutton, C.V. (1998) Validation for Device and Diagnostic Manufacturers, second edition Interpharm Press, Buffalo Grove, IL.

Sutton, C.V. and DeSain, C.V. (1996) Meeting GMP and ISO 9001 Expectations for Product Development, Parexel International Corporation, Waltham, MA.

DeSain, C.V. and Sutton, C.V. (1996) Documentation Practices: A Complete Guide to Document Development and Management for GMP and ISO 9000 Compliant Industries, Advanstar Communications, Cleveland, OH.

DeSain, C.V. and Sutton, C.V. (1994) Validation for Device and Diagnostic Manufacturers, first edition Interpharm Press, Buffalo Grove, IL.

DeSain, C.V. and Vercimak, C.L. (1994) Implementing International GMPs: A Guide to Drug, Device and Diagnostic Manufacturers, Interpharm Press, Inc., Buffalo Grove, IL.

Industry Journal Publications

DeSain, C.V. and Sutton, C.V. (2000) "Process Hazard Analysis and Critical Control Point Identification", BioPharm, October, pp. 36-40.

DeSain, C.V. and Sutton, C.V. (2000) "Canary in the Coal Mine: A New Model for Effective Risk Management", Pharmaceutical Executive, November, pp. 60-67.

DeSain, C.V. and Sutton, C.V. (1998) "Facility Qualification Studies", BioPharm, January, pp. 38-41.

DeSain, C.V. and Sutton, C.V. (1997) "Test Method Development and Validation", BioPharm, April, pp. 60-63.

DeSain, C.V. and Sutton, C.V. (1996) "SOPs: Content, Format and Management", Pharmaceutical Technology, October, pp. 110-116.

DeSain, C.V. and Sutton, C.V. (1996) "SOPs: Process Development", Pharmaceutical Technology, September, pp. 96-108.

DeSain, C.V. and Sutton, C.V. (1996) "Document Processing and Control in FDA-Regulated Industries", Pharmaceutical Technology, June, pp. 76-82.

DeSain, C.V. and Sutton, C.V. (1996) "The Data Collection Process: Defining Raw Data", Pharmaceutical Technology, April, pp. 98-106.

DeSain, C.V. and Sutton, C.V. (1995) "Process Development that Supports Process Validation", Pharmaceutical Technology, October, pp. 130-135.

DeSain, C.V. and Sutton, C.V. "**Validation for Device and Diagnostic Manufacturers:**

- Part 1: Basic Principles, BioPharm Vol. 7, No. 8, October, 1994, pp. 46-50.
- Part 2: Working with Vendors and Contractors, BioPharm Vol.8, No.2, March,1995, pp. 40-46.
- Part 3: Detecting Change in Validated Systems and Processes, BioPharm Vol. 8, No. 4, May, 1995, pp. 42-43.
- Part 4: Decision Making, BioPharm Vol. 8, No. 5, June, 1995, pp. 73-74.

DeSain, C.V. and Vercimak, C.L. "Implementing a Quality System, Part II", Medical Device Technology, Vol. 5, No. 2, March, 1994, pp. 32-36.

DeSain, C.V. and Vercimak, C.L. "Implementing a Quality System, Part I", Medical Device Technology, Vol. 5, No. 1, January/ February, 1994, pp. 28-30.

Documentation Basics that Support Good Clinical Practices,

by Carol DeSain and Charmaine Vercimak

- The Master Plan: BioPharm, Vol.6, No.5, June, 1993, pp. 27-30 and Applied Clinical Trials, Vol.2, No.8, June, 1993, pp. 48-52
- Documentation: BioPharm, Vol.6, No.5, July-August, 1993, pp. 20-25 and Applied Clinical Trials, Vol.2, No.7, July, 1993, pp. 51-53
- Clinical Standard Operating Procedures and Clinical Study Protocols: BioPharm, Vol.6, No.6, September, 1993, pp. 32-37 and Applied Clinical Trials, Vol.2, No.8, Sept., 1993, pp. 60-64
- Data Collection Documents: BioPharm, Vol.6, No.8, October, 1993, pp. 26-31 and Applied Clinical Trials, Vol.2, No.10, Oct., 1993, pp. 56-59
- Systems of Accountability and Traceability: BioPharm, Vol.6, No.9, Nov-Dec, 1993. pp. 28-33 and Applied Clinical Trials, Vol.2, No.11, Nov-Dec, 1993