

CAROL DESAIN

The Tamarack Group - North Shore, LLC
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CONSULTING EXPERIENCE SUMMARY

Carol DeSain has been an independent consultant with The Tamarack Group-North Shore, LLC www.thetamarackgroup.net for 25 years - working with start-up companies, global corporations, contract manufacturers, and suppliers to the regulated industries in the US, Europe, and Japan. Carol's practice focuses on the development and commercial production of drug substances, pharmaceuticals, bio-pharmaceuticals, devices, diagnostics, and combination products. For example:

- Author and reviewer of drug substance, pharmaceutical, biologic, device, and combination product CMC market applications, comparability protocols, and dossiers (NDA, BLA, PMA, DMF, QOS and Module 3 of CTD formats)
- CMC product development leadership role for establishing product requirements (e.g., target product profiles or design input), establishing product manufacturing control strategies, and meeting market authorization requirements with a risk-based approach to compliance with ISO 13485, 21 CFR 820.30 or Quality-by-Design expectations.
- New facility start-up leadership role in establishing facility requirements, evaluating effectiveness of installations, and implementing supporting quality systems for routine operations.
- Master batch records creation and implementation.
- Documentation system design and implementation.
- Analysis of manufacturing facility operations and current staff for adequacy of staffing levels and effective organizational design.
- GMP, Quality System, and Risk Management training for management and staff.

Carol is known for her broad knowledge of the industry, a practical hands-on approach to compliance, interactive and informative training sessions, numerous articles, and for the ten books she has written on documentation, risk management, validation and product development. Books include www.thetamarackgroup.net/books *Risk Management Basics*, *Documentation Basics*, and *Documentation Practices*.

RECENT CONSULTING PROJECTS

- Agent for DMF from foreign company
- Detailed review of Module 3 and author of Quality Overall Summary for three different drug-lead combination products – for US, EU and Japan
- Detailed review of PMA CMC sections for device-lead combination product; authored a CTD Module 3 attachment to PMA.
- Authored master batch records for biopharmaceutical operations.
- Led troubleshooting investigation team for moisture uptake issue in drug product.
- Reviewed and re-designed stability study program for compliance with ICH.
- Reviewed environmental monitoring program for completeness, effectiveness, compliance.
- Audits of outside testing laboratories for clinical studies.
- Audits of contract manufacturers to select one for commercial manufacturing operations and authored Quality Agreement.
- Training of product development staff in risk-based product development.

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EXPERIENCE

1986 - now The Tamarack Group-North Shore, LLC - President and Independent Consultant

1980 - 1986 Smith Laboratories, Inc., Chicago - Director of QC for a parenteral drug manufacturer

- development and production of protein API product for human, parenteral use
- managed API product development, QC, QA operations for commercial production
- provided technical support to international markets for product registration
- directed contract manufacturing services for aseptically filled drugs and biologics

1978 - 1980 Envirodyne Engineers, Chicago - Laboratory Supervisor for EPA project

- wrote Environmental Impact Statements
- supervised Microbiology laboratory

1971 - 1978 University of Minnesota, University of Illinois and Loyola University
- Laboratory technician and supervisor in Medical/Dental/Graduate Schools

- isolation, purification and characterization of sugars, carbohydrates, enzymes and nucleic acids from plant, viral, bacterial and animal cell culture

EDUCATION

- Lawrence University; Appleton, Wisconsin; B.A. Biology, 1971.
- Northeastern University; Boston, Massachusetts; Electron Microscopy, 1971.
- University of Minnesota; Minneapolis, Minnesota; Graduate Studies in Genetics and Biochemistry, 1973-76.
- Kepner-Tregoe, Inc.; Princeton, NJ; Analytical Troubleshooting Instructor Certification, 1987.

Publications of Carol DeSain

BOOKS

DeSain, C. V. (2001) Documentation Basics that Support Good Manufacturing Practices and Quality System Regulations, second edition, Advanstar Communications, Cleveland, OH.

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.

DeSain, C. V. (1993) Documentation Basics that Support Good Manufacturing Practices, first edition, Advanstar Communications, Cleveland, OH.

DeSain, C.V. (1993) Drug, Device and Diagnostic Manufacturing: The Ultimate Resource Handbook, second edition, Interpharm Press, Inc., Buffalo Grove, IL.

DeSain, C.V. (1990) Drug, Device and Diagnostic Manufacturing: The Ultimate Resource Handbook, first edition, Interpharm Press, Inc., Buffalo Grove, IL.

INDUSTRY JOURNAL PUBLICATIONS:

DeSain, C.V. (2010) "Design Specifications: Pharma's Missing Link to Knowledge Management". PDA Letter (accepted for publication)

DeSain, C.V (2007) "Risk-based Quality Systems - What are we waiting for?", BioProcess International, March, pp. 12-18.

DeSain, C.V (2007) "Product Requirement Documents - Establishing Consensus about Product Design", BioProcess International, February, pp. 22-31.

DeSain, C.V (2007) "Process Risk Profile Documents - Effective Communication between Product Development and Operations", BioProcess International, January, pp. 18-26.

DeSain, C.V (2006) "Product Risk Profile Documents - Effective Communication between Product Development and Operations", BioProcess International, December, pp. 18-26.

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, pp.

"Documentation Basics that Support Good Manufacturing Practices", by Carol DeSain, appeared in *BioPharm Magazine*:

- Part Numbers, *BioPharm*, June 1991.
- Part Number Specifications, *BioPharm*, August 1991.
- Lot Numbers, *BioPharm*, September 1991.
- Standard Operating Procedures, *BioPharm*, October 1991.
- Master Production Batch Records, *BioPharm*, Nov.-Dec. 1991.
- Equipment Installation and Identification Documentation, *BioPharm*, January-February 1992.
- Equipment Monitoring, Repair and Preventive Maintenance Programs, *BioPharm*, March, 1992.
- GMP Protocols and Facility Qualification Master Protocol Design, *BioPharm*,

- April, 1992.
- Master Validation and Equipment Validation Protocols, BioPharm, May 1992.
- Master Method Validation Protocols, BioPharm, June 1992.
- Process Validation Protocols, BioPharm, July-August 1992.

TECHNICAL PUBLICATIONS:

Schachtele, C.F., C.V. DeSain, L.A. Hawley, and D.L. Anderson. 1972. "Transcription During the Development of the Bacteriophage ϕ 29-specific Ribonucleic Acid." *Journal of Virology* 10: 1170-1178.

Schachtele, C.F., B.E. Reilly, C.V. DeSain and D.L. Anderson 1973. "Selective Replication of Bacteriophage ϕ 29 Deoxyribonucleic Acid in 6-(p-hydroxy-phenylazo) Uracil-treated *Bacillus subtilis*." *Journal of Virology* 11: 153-155.

Schachtele, C.F., C.V. DeSain and D.L. Anderson. 1973. "Transcription During the Development of Bacteriophage ϕ 29: Definition of "Early" and "Late" ϕ 29 Ribonucleic Acid." *Journal of Virology* 11: 9-16.

Banks, R.S., C.V. DeSain and T.N Duening. 1988. "Tumor Promotion, ODC Induction and 60 Hz Electric and Magnetic Fields." EMF Health Effects Information Service Project Report.

Public Workshops/Seminars by Carol DeSain

Effectively Implementing Good Manufacturing Practices and Quality System Regulations
Institute for International Research, June 26-27, 2000, Philadelphia, PA.

"Managing the Risk Assessment Process" Institute for International Research, CheckPoint Conference, March 22, 1999, Washington DC.

"Documentation Practices" by Carol DeSain,
Biological Process Technology Institute;
University of Minnesota/Minneapolis; May 20, 1998.

"Design Control and Specification Setting for Device and Diagnostic Products" by Carol DeSain and Charmaine Sutton, Biological Process Technology Institute;
University of Minnesota/Minneapolis; May 22, 1998.

"Validation Planning and Decision Making for Medical Device and Diagnostic Manufacturers: Managing Commitments in a Competitive Market" by Charmaine Sutton,
Medical Alley; Minneapolis, June, 1999

"IVD Manufacturing Issues" by Carol DeSain and Charmaine Sutton, BioMedical Focus '97, July 30, 1997, Minneapolis, MN

"A Nuts and Bolts Look at the 510(k) Process" by Charmaine Sutton, Medical Alley,
Minneapolis, MN; July 9, 1997.

"Product Development Practices for GMP and ISO 9001 Compliance," by Charmaine Sutton and Carol DeSain, Santa Clara, CA, April 9-11, 1997, sponsored by the University of Wisconsin, Madison.

"Design Controls: How to Comply with GMP and ISO 9001 Requirements" by Charmaine Sutton and Carol DeSain,

University of Minnesota, 2/4-5/97.

“Documentation” Tutorial by Carol DeSain at “Surviving the Challenges of Current FDA Pharmaceutical/BioTech Inspections III; Pharma Conferences; Vienna, Austria, 2/10/97.

“Fundamentals of Medical Device Regulatory Requirements”, by Charmaine Sutton, Medical Alley, 11/13/96, Minneapolis, MN.

“GMPs and Clinical Supplies” by Carol DeSain, GMP by the Sea, Newport, RI, Pharma Conferences, 10/9/96
Also presented at “Surviving the Challenges of Current FDA Pharmaceutical/BioTech Inspections III; Pharma Conferences; Vienna, Austria, 2/10/97.

“Pet Peeves of Validation: What Goes Wrong and Why” by Carol DeSain, Medical Device Validation and GMP Compliance Strategies Conference, Minneapolis, MN, 6/5/96.

“Documentation, Audits, Inspection and In-House Training” by Carol DeSain, Biotechnology in the cGMP Environment, University of Minnesota, May 22, 1996,

“Product Development Planning and Documentation”, by Carol DeSain and Charmaine Sutton, BioPharm Conference, Boston, MA. 5/7/96.

“Developing a Quality System”, by Charmaine Sutton, Medical Alley’s 7th Annual Device Seminar, Minneapolis, MN; 12/13/95.

“How to Write SOPs”, by Carol DeSain and Charmaine Sutton, Applied Clinical Trial Conference, East Brunswick, NJ, October 15-18, 1995.

“Documentation and Quality Assurance”, by Carol DeSain and Charmaine Sutton, Biotechnology in the cGMP Environment, University of Minnesota, 10/19/95, 5/22/96, and 10/30/96.

“GMPs in Medical Product Development: Controlling Development Process Without Limiting Innovation,” by Charmaine Sutton and Carol DeSain, University of Wisconsin - Madison, The College of Engineering, April 12-13, 1995.

“Documentation During Product Development” BioPharm Conference, Workshop, Carol DeSain and Charmaine Vercimak, San Francisco, June 15, 1994.

“Current Good Manufacturing Practices: Implementation and Maintenance” by Carol DeSain Center for Continuous Education, 3 day seminar, San Diego, April 25-27, 1994, San Diego, May 8-10, 1995 Boston, October 3-5, 1994 San Diego, December 4-6, 1996

“GMP Update” by Carol DeSain West Coast Trainers Group, Genentech, 4/29/94

“GMP Training” by Carol DeSain, NE Chapter of PDA, Boston, 3/30/94.

“Overview on Product Submissions: 510k”, Medical Alley’s 6th Annual Device Seminar, by Charmaine Vercimak, Minneapolis, MN, 12/7/93.

“Writing Documentation to Support Good Manufacturing Practices and ISO 9000 Standards,” sponsored by Dashe and Thomson, December 5, 1991, Minneapolis, MN; by Carol DeSain and June 18, 1992, Minneapolis, MN; by C. DeSain and C. Vercimak

“GMP Compliance Update, Trends and Predictions for the Future,” presented at **“Risk Reduction for the Medical Device Industry: Regulatory Compliance and Liability**

Prevention", by Carol DeSain, sponsored by National Center for Preventive Law and a consortium of Minnesota companies, April 30, 1992, Minneapolis.

"Developing/Implementing a Validation Master Plan," BioPharm Conference Workshop, June 8-9, 1992, San Francisco, CA, presented by Carol DeSain and Georgiann Keyport.

Clients of Carol DeSain

Drug or Biologic Manufacturers

- Abbott, corporate - Northfield, IL
- Abgenix, Inc. -Fremont, CA
- Allergan, Inc. - Irvine, CA and Westport, Ireland
- ALG Laboratories, Inc. - University of Minnesota - Minneapolis, MN
- Amgen - Thousand Oaks, CA
- American Pharmaceutical Partners - Chicago, IL
- Aventis - Knoxville, TN
- Bayer - Berkeley, CA
- Bayer - Clayton, NC
- Berlex Laboratories, Inc. (U.S. Schering AG) - Cedar Hills, NJ
- Biogen, Inc. - Cambridge, MA and Amsterdam, The Netherlands
- BIOPHARM - Heildburg, Germany
- BioPure - Cambridge, MA
- Biomedical Frontiers, Inc. - Minneapolis, MN
- Boots Pharmaceutical, PLC - Nottingham, UK
- Boots Pharmaceutical, USA - Shreveport, LA
- Cardiome - Vancouver, BC
- Cell Therapeutics Inc. - Seattle, WA
- Cellular and Molecular Technologies - Phillipsburg, NJ
- Chiron Corporation - Emeryville, CA
- Cilag - Schaffhausen, Switzerland
- Colder Products Company - Chaska, MN
- DSM Biologics - The Netherlands
- Eli Lilly and Company - Indianapolis, IN
- Endorex - Fargo, ND
- Fibrogen, Inc. - San Francisco, CA
- GalaGen, Inc., formerly Land O' Lakes - Arden Hills, MN
- Genetic Therapy, Inc. - Gaithersburg, MD
- Genitope Corporation - Redwood City, CA
- Helix Biocore, Inc. - Plymouth, MN
- Hoffman- LaRoche - Nutley, NJ
- Human Genome Sciences - Rockville, MD
- Hybridon - Cambridge, MA
- IBEX - Toronto, Ontario, Canada
- Imclone - Sommerville, NJ
- J&J companies (OCD, OBI, Cilag, Lifescan, Ortho McNeil, Pharmaceutical Research Institute, Advanced Diagnostic Systems)
- KS Avicenna - Edmonton Alberta Canada
- Lifescan - Milpitas, CA
- Matrix Pharmaceuticals, Inc. - Menlo Park, CA
- MedImmune, INc. - Gaithersburg, MD
- MicroBioLogics - St. Cloud, MN
- Miles Pharmaceutical - Berkeley, CA
- Nanosystems - King of Prussia, PA
- NDS Inc. - Chaska, MN
- Northfield Laboratories, Inc. - Mt. Prospect, IL

- Novartis Consumer Products - Lincoln, NE
- Organon Teknika Corporation -
- Ortho Biologics - Manatee, Puerto Rico
- Ortho Biotech - Rairtan, NJ
- Ortho McNeil Pharmaceuticals - Mayaguez, Puerto Rico
- Paddock Laboratories, Inc. - Minneapolis, MN
- Pelligo - Allegan, MI
- Pharmacia Biologics - St. Louis, MO
- Pfizer Animal Health - Lincoln, NE
- Proctor and Gamble - Norwich, NY
- Protein Design Laboratories, Inc. - Plymouth, MN
- Roche Pharmaceuticals - Piscataway, NJ
- Rh Pharmaceuticals - Winnipeg, Manitoba Canada
- Schering AG - Berlin, Germany
- Smith Laboratories, Inc. - San Diego, CA
- Spinal Therapies - St. Paul, MN
- Stryker Biotech, Inc. - Hopkinton, MA
- Surmodics - Minneapolis, MN
- Pacgen Biopharmaceutical - Vancouver BC
- Paddock Laboratories, - Minneapolis, MN
- Palatin - Edison, NJ
- Procter and Gamble Pharmaceuticals - Norwich, NY
- Protein Design Laboratories, Inc. - Plymouth, MN
- QLT - Vancouver, BC
- R.W. Johnson Pharmaceutical Research Institute - SpringHouse, PA
- Ultraceuticals, Inc. -
- VanDenBergh Foods - Joliet, IL
- Wyeth-Ayerst Elkin Simms Lederle - Cherry Hill, NJ
- Zenith Laboratories, Inc. - Rosemont, IL
- Zymogenetics, Inc. - Seattle, WA

Device, Diagnostic and Combination Product Manufacturers

- 3M - St. Paul, MN
- Abbott Diagnostics - Irvine, TX
- Abbott Diagnostics - Abbott Park, IL
- Advanced Diagnostic Systems - Raritan, NJ
- American Medical Systems - Minnetonka, MN
- B. Braun - Germany
- Biomira Diagnostics - Rexdale, Ontario
- Biomimetics - Nashville, TN
- AngeLase, Inc. - Plymouth, MN
- Biomira, Inc. - Edmonton, Alberta
- Closure Medical - Raleigh, NC
- Cooper Lasersonics, Inc. - Santa Clara, CA
- Coloplast - The Netherlands
- Covidien
- Cross Cart - Gainesville, FL
- CV Technologies - Edmonton, Alberta
- Cyberonics, Inc. - Houston, TX
- Diagenx - Canada
- EMPI, Inc. - St. Paul, MN
- Endotronics, Inc..- Coon Rapids, MN
- Epicentre Technologies Corporation - Madison, WI
- Epitope, Inc - Beaverton, OR
- GML, Inc. - St. Paul, MN

- Haemoscope, Inc. -Skokie, IL
- Heartleaf Technologies, Inc. - Minneapolis, MN
- Immunicon - Huntington Valley, PA
- INCStar -Stillwater, MN
- Lifecore Biomedical, Inc. -Chaska, MN
- MicroBioLogics - St. Cloud, MN
- MTS Systems Corporation - Eden Prairie, MN
- Organon Teknika - Raleigh-Durham, NC
- Ortho Clinical Diagnostics - Raritan, NJ
- Physio-Control, Inc. - Redmond, WA
- Pioneer Packaging - Anoka, MN
- Ricerca, Inc. - Cleveland, OH
- Sanofi Diagnostics Pasteur - Chaska, MN
- Sulzer Spine Tech - Minneapolis, MN
- Surmodics, Inc. - Minneapolis, MN
- Tapemark, Inc. - St. Paul, MN
- Travanti - St. Paul, MN
- Uroplasty, Inc. - St. Paul, MN and The Netherlands
- Vascular Solutions, Inc. - Minneapolis, MN
- Venatech, Inc. - Evanston, IL
- Vital Heart Systems, Inc. - Minneapolis, MN

Industry Suppliers/Vendors

- Angus - Louisiana
- Automed, Inc. - Arden Hill, MN
- Biometric Research Institute - Arlington, VA
- Dashe and Thomson
- Decision Management International - Bradenton, FL
- Epicentre Technologies, Inc. - Madison, WI
- Fluoroware, Inc. - Chaska, MN
- Grant Thorton - Minneapolis, MN
- Northfield Laboratories - Chicago, IL
- Pharmacia LKB Biotechnology - Piscataway, NJ
- Spectra Science - Minnetonka, MN
- Rosemount, Inc. - Eden Prairie, MN
- W.R. Grace - Chicago, IL

Educational/Technical Institutes

- Duluth Technical Institute - Duluth, MN
- Faribault Vocational Technical Institute - Faribault, MN
- Orange County Regulatory Association - Irvine, CA
- University of Minnesota; BioProcessing Technology Institute - Minneapolis, MN
- University of Wisconsin - Madison, WI
- Center for Continuous Education - Oceanside, CA

Law Firms Representing Drug, Device, Biologic Clients

- Herzog-Hart Group - Boston, MA
- Lichtsinn, Haensel, Bastian, Erchul and Crocker, S.C. - Milwaukee, WI
- Popham, Haik, Schnobrich & Kaufman, Ltd. - Minneapolis, MN
- Wildman, Harrold, Allen and Dixon - Chicago, IL
- Dorsey & Whitney - Minneapolis, MN