



Curriculum Vitae of

CAROL DESAIN

carol@thetamarackgroup.net

The Tamarack Group - North Shore, LLC
6804 West Hwy. 61 ♦ Tofte, MN 55615
218-663-7991 Voice ♦ 218-663-7238 Fax

EXPERIENCE

Academic Research

Biochemist

University of Minnesota; University of Illinois

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

Pharmaceutical Manufacturing

Director of Quality Control; Smith Laboratories, Inc., Chicago, IL.

- development and production of API product for human, parenteral use
- managed 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

Consulting

Independent

- provides organizational design and analysis for companies in transition from:
 - R&D to commercial operations
 - single product to multi-product, multi-national operations
- specializes in the start-up and scale-up of new companies, new facilities or new products - and in the re-design of existing systems that have failed compliance audits
- develops and implements quality systems for documentation, process validation, change control, and product development

WORK HISTORY

1971 -1975, University of Minnesota, Minneapolis

Research Associate in Medical and Dental School

1976 -1977, University of Illinois, Chicago:

Research Associate, Biochemistry

1978, Loyola University, Chicago:

Research Associate, Dental Microbiology

1978 -1980, Envirodyne Engineers, Chicago

Laboratory Supervisor for EPA project; Assistant to Vice President

1980 -1986, Smith Laboratories, Inc., Chicago

Director of Quality Control for a parenteral drug manufacturer

1986 - now The Tamarack Group-North Shore, LLC

President and Independent Consultant

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, 1973-74.
- Elmhurst College; Elmhurst, Illinois; Basic Computer Science, 1982.
- Kepner-Tregoe, Inc.; Princeton, NJ; Troubleshooting Instructor Cert., 1987
- Zenger-Miller, Inc.; Cupertino, CA; Instructor Cert. FrontLine Leadership, 1988

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. 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 (LAST 10 YEARS)

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.

“IVD Manufacturing Issues” by Carol DeSain and Charmaine Sutton, BioMedical Focus ‘97, July 30,1997, Minneapolis, MN

“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.

“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.

“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

“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.

CUSTOMIZED, IN-HOUSE PRESENTATIONS (last 10 years)

- **Pelligo Pharmaceuticals**
Allegan, MI - June, 2004
- **Orange County Regulatory Association**
Irvine, CA - May 2004
- **Allergan, Inc.**
Irvine, CA - November 2003
- **Tapemark**
West St. Paul, MN - all of 2003
- **Genitope**
Redwood City, CA - all of 2003
- **Abgenix, Inc.**
Fremont, CA - June, 2004 , July 2003
- **Pioneer Packaging**
Anoka, MN - September 2003
- **Pharmacia**
St. Louis, MO - June 2002
- **DSM Biologics**
The Netherlands - May 2002
- **Tapemark**
St. Paul, MN - October 2002
- **Aventis**
Knoxville, TN - 2002
- **QLT**
Vancouver, BC - 2002
- **Novartis Consumer Products**
Lincoln, NE - November 2002
- **KS Avicenna**
Edmonton, Alberta - September, 2001
- **Bayer Corporation**
Berkeley, CA - January 25, 2000
- **IMCLONE, Inc.**
Sommerville, NJ - May 12, 1999
- **Cellular and Molecular Technologies, Inc.**
Phillipsburg, NJ - May 11, 1999
- **BioPure**
Cambridge, MA - September 1, 1998
- **Ortho Biologics**
Manatee, Puerto Rico - August, 1998
- **Genetic Therapy, Inc.**
Gaithersburg, MD - April 21, 1998
- **Human Genome Sciences, Inc.**
Rockville, MD - April 20, 1998
- **CV Technologies, Inc.**
Edmonton, Alberta - April 1-2, 1998
- **Hybridon, Inc.**
Cambridge, MA - June 10-11, 1997
- **OMJ Pharmaceuticals**

- St. Germain, Puerto Rico - February 27 - March 1, 1997; June 12, 1996
- **R.W. Johnson Pharmaceutical Research Institute**
SpringHouse, PA - May 20, 1997; March 14, 1996
- **Pfizer Animal Health**
Lincoln, NE - December 12-13, 1995; November 18-20, 1996
- **Biosciences Contract Production Corp.**
Baltimore, MD - September 21-22, 1995
- **Amgen**
Thousand Oaks, CA - August 8-10, 1995
- **R.W. Johnson Pharmaceutical Research Institute**
Raritan, NJ - May 20, 1997; March 29-31, 1995

CLIENT LIST

Drug or Biologic Manufacturers

- Abbott, corporate - Northfield, IL
- Abgenix, Inc. -Fremont, CA
- Allergan, Inc. - Irvine, CA
- 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
- BioPure - Cambridge, MA
- Biomedical Frontiers, Inc. - Minneapolis, MN
- Boots Pharmaceutical, PLC - Nottingham, UK
- Boots Pharmaceutical, USA - Shreveport, LA
- Cardiome - Vancouver, BC
- Cellular and Molecular Technologies - Phillipsburg, NJ
- Cilag - Schaffhausen, Switzerland
- DSM Biologics - The Netherlands
- Endorex - Fargo, ND
- 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
- KS Avicenna - Edmonton Alberta Canada
- Lifescan - Milpitas, CA
- Matrix Pharmaceuticals, Inc. - Menlo Park, CA
- Nanosystems - King of Prussia, PA
- Novartis Consumer Products - Lincoln, NE
- Ortho Biologics - Manatee, Puerto Rico
- Ortho Biotech - Raritan, NJ
- Ortho McNeil Pharmaceuticals - Mayaguez, Puerto Rico
- Pelligo - Allegan, MI
- Pharmacia Biologics - St. Louis, MO

- Pfizer Animal Health - Lincoln, NE
- Roche Pharmaceuticals - Piscataway, NJ
- Rh Pharmaceuticals - Winnipeg, Manitoba Canada
- Schering AG - Berlin, Germany
- 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
- Wyeth-Ayerst Elkin Simms Lederle - Cherry Hill, NJ

Device Manufacturers

- Advanced Diagnostic Systems - Raritan, NJ
- Biomira Diagnostics - Rexdale, Ontario
- Biomira, Inc. - Edmonton, Alberta
- Closure Medical - Raleigh, NC
- CV Technologies - Edmonton, Alberta
- Cyberonics, Inc. - Houston, TX
- Epitope, Inc - Beaverton, OR
- INCStar -Stillwater, MN
- Lifecore Biomedical, Inc. -Chaska, MN
- Organon Teknika - Raleigh-Durham, NC
- Ortho Clinical Diagnostics - Raritan, NJ
- Physio-Control, Inc. - Redmond, WA
- Ricerca, Inc. - Cleveland, OH
- Sanofi Diagnostics Pasteur - Chaska, MN
- Tapemark, Inc. - St. Paul, MN

Industry Suppliers/Vendors

- Angus - Louisiana
- Epicentre Technologies, Inc. - Madison, WI
- Fluoroware, Inc. - Chaska, MN
- Pharmacia LKB Biotechnology - Piscataway, NJ
- 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

- 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