JERRY DALFORS

Mr. Dalfors has had extensive (33 years) consultative, technical and managerial experience in the development and manufacture of highly regulated biopharmaceutical products including injectables, biologics, medical devices and oral dosages demonstrating increased responsibility, technical innovation and accountability.

The diversity of previous positions and projects are indicative of his capabilities to provide solutions that are practically sound, technically state-of-the-art, and in step with regulatory agencies. His efforts can be shown to have moved each of his prior companies and clients forward. His successes are due to an ever increasing technical background, a knowledge and appreciation for effective team building and fundamental, principle centered leadership.

Title: Principal, JD Technologies

Function: Responsible for the technical and regulatory review to assure projects are compliant with cGMP, and to organize the appropriate expertise and resources to meet project deadlines and budget requirements by:

1. Carefully and thoroughly identifying Client requirements.
2. Assembling an appropriate design team consisting of Client members, process and systems engineers, and other resources as necessary.
3. Obtaining Client understanding and approvals to expedite timely, cost effective project execution.
4. Assuring compliant and satisfactory completion of project tasks through documentation and process operation.

RECENT AND CURRENT PROJECTS

Process and Product Definition, Contract Mfg. Audit	**AGOURON PHARMACEUTICALS**
Management and Re-organization of the Validation Dept.	**GENSIA LABORATORIES, LTD**
Building Management System Validation	**GENSIA LABORATORIES, LTD**
Conceptual cGMP Design review for a Novel Liquid/Liquid Centrifuge System	**CINC**
Mrktg Mgr., Establishment of a BioPharmaceutical Division	**LANDIS & STAEFFA**
Create Manufacturing Filing Strategy for Ph. III Drug Prod.	**CARRINGTON LABORATORIES**
Establish the Controlled Document System in Costa Rica including Change Control, Calibration, Engineering Documentation	**CARRINGTON LABORATORIES**
Design and Execution Automatic Pipetting Systems Validation	**BAYER**
Operations and Compliance Assessments for Facility Purchases	**DLJ**
Validation Master Plan and Protocols (self-directed)	**STASON PHARMACEUTICALS**
Creation of a Controlled Documents / SOP System	**PACIFIC RIM MECHANICAL**
Microbiological Audit (Objectionable Organisms)	**FERNDALE LABORATORIES**
Design, Mgmt and Execution of the Validation program for New/Existing Facilities	**BAYER**
Technical Services, Reengineering and Management	**WYETH AYERST**
Reengineering of the QA Product Release Process	**BAXTER**
Major Project Organization and Lyo Validation	**BAXTER**

21 CFR Part 11 Remediation Strategy **ELI LILLY**

EXPERIENCE PRIOR TO THE FORMATION JD TECHNOLOGIES

ALLIANCE PHARMACEUTICAL CORP. - SAN DIEGO, CA - 1988-1994

Title: Div. Dir., Pharmaceutical Operations

Function: Responsible for the construction, startup and operation of the Corporate Headquarters, two pilot facilities (with clean rooms and hot WFI Loops), laboratories and vivarium. Processes fully integrated using PC/PLC based automation and document generation.

Organized and set-up temporary manufacturing (clean room, filling and rotary terminal sterilization) facilities in Ireland and Germany to produce clinical materials for evaluation in Europe.

Responsible for the development and implementation of new methods and procedures for manufacturing, sterilization and microbiological testing of unique new emulsion products and oral imaging agents.

Managed the equipment procurement and transfer of technical manufacturing operations to sister venture operation in Germany for European production, clinical evaluation and marketing.

Directed 5 departments (Pilot Operations, Microbiological Operations, Transfer Operations, Facility Operations and Validation Operations) with staffing of 30+ people and an annual operating budget in excess of $3 million.

CETUS - EMERYVILLE, CA - 1988

Title: Manager, Validation

Function: Responsible for establishing a validation department to support the new manufacturing facility as well as completing the validation efforts in a contractual arrangement with the design/build construction company.

Participated in the development of purification and cleaning procedures for the production of relatively complex fermentation products (IL-2 and TNF)

Provided direction for the compilation of the Functional Requirements for the fermentation process control systems (loops, alarms, data acquisition, etc.) which included production, CIP/SIP and waste sterilization.

Organized and directed efforts of multidisciplinary professionals, using in-house as well as outsourced resources, for the successful validation of the pilot plants and manufacturing facility. A $1.5 million project.

Successfully prepared and presented the Validation Master Plan and corresponding program to the FDA prior to completion of construction and assisted with the presentation of the construction plans.

KABI-VITRUM - CLAYTON, NC - 1984 - 1988

Title: Validation/Instrumentation Manager

Function: Organized and directed the formation of the technical engineering group responsible for all process automation, evaluation of new equipment, validation and instrumentation.

Guided a vendor, production and electronics team through a total redesign and replacement of the control and documentation systems used for the critical sterilization of emulsion products. Served as a major contributor in the design and construction of a new production facility which includes R&D laboratories, administration, utilities, shipping and receiving, etc.

Developed statistical models using experimental design methods to be used in place of 'traditional' methods often found to be inadequate in demonstrating appropriate probabilities of sterility assurance.

Prepared and maintained department budgets which included control of timelines and significant capital spending.

CUTTER LABORATORIES - OGDEN, UT and CLAYTON, NC - 1972 - 1984

Title: Process Engineer, Sterilization - Validation (NC)
Project Engineer, Qualification - Validation (UT)
Quality Assurance Testing Manager - (UT)

Function: Developed a variety of unique devices for monitoring temperatures, performing more accurate sterility tests, gathering and analyzing data, and implementing the applications at a highly practical level on the shop floor.

Responsible for the establishment and organization of the industry's first sterilization validation program (continuous sterilization of LVP's) in conjunction with the instrumentation and biological monitoring of the process to arrive at the what later became known as the Process F_o – the correlation between the D-value of the spore and the temperature profile of the process. Served as the lead member of a sterilization development program which later became an industry standard to be used by the FDA as a field training exercise for inspectors. Developed and implemented the use of continuous monitoring of ETO concentration during the sterilization of medical devices

As QC/QA Testing and Release Manager had the responsibility for managing the testing and final release of all incoming raw materials, final products (LVPs and Medical Devices) and environmental monitoring of the manufacturing facility. Our laboratory was instrumental in ushering in the LAL testing for final product release and the participated in the industry forum establishing the particulate standards for parenteral solutions and medical devices. Managed a staff of approximately 35.

EDUCATION

B.S., Microbiology - Weber State College - 1969
Business Administration - 55 hours (incomplete MBA due to relocation to NC)
Extensive course work in;
Statistics, Process Control / Automation, Experimental Design and SQL
Participated and Taught a variety of industry related short courses

FACULTY

Johnston Technical College, Smithfield, NC
Production Planning
Univ. Of California, San Diego (UCSD)
BioMedical Manufacturing Technology
Steering Committee, Engineering and Science - UCSD Extension

PUBLICATIONS

Terminal Sterilization of Perflourocarbon (PFC) Emulsions: Difficulties and Possible Solutions

"We Can Fix the Documentation Later", ISPE, 1999

PRESENTATIONS

Novel Sterilization of PFC Emulsions
PDA Annual Meeting - 1993
In-house versus Contract Manufacturing, BioTechnology Transfer Seminar
Biomanufacturing Issues in the University Cirriculum
Biotechnology Symposium - California State University - 8th Annual
Validation - Practical Strategies and Methodologies - 1996
Pharmaceutical & Biotechnology Contract Manufacturing - 1996
Mfg. Execution Systems (MES) - A Strategy for ISO-9000 Compliance
Western Manufacturing Automation Show - 1996
Validating BioPharmaceutical Utilities, IIR Conference - 2000
Organization and Management of Controlled Document Systems, Chairman, IIR Conference – 2000
Statistical Tools for Validation – IIR Conference 2001

MEMBER

Parenteral Drug Association (PDA)
International Society of Pharmaceutical Engineer (ISPE)
Instrument Society of America (ISA)