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Recent Accomplishments:

- Published an article on Virus testing of Monoclonal Antibodies in “BioPharm”
- Published an article in PDA journal on current trends in endotoxin testing in biotechnology
- Served as chairman of PDA Biotechnology Subcommittee Task Force that developed a training course for PDA titled “Quality Assurance for Biotechnology”
- Presented various training seminars for PDA, CCE, SAM, and individual companies on various topics, including “Quality Assurance for Biotechnology”, “Good Laboratory Practices”, “Validation for the Healthcare Industry”, “Process Validation”, Design Control: Preparing for the New Device GMP Regulations”
- Served as a faculty member on the Loyola University Masters in Quality Management graduate course “Quality Assurance in Regulated and Non-regulated Industries”
- Published a chapter in the Interpharm Press book titled *Separations Technology*
- Completed training program as an ISO 9000 Lead Assessor (Auditor)
- Published a section in the Interpharm Press book titled *Biotechnology: Quality Assurance and Validations*

Professional Positions:

1992 –Present **Validation and Compliance Services**, San Diego, California

Principal Consultant involved in validation and compliance programs for biotechnology, drug and device manufacturing firms, and gene therapy research institutes. Projects include the preparation of compliance programs, writing validation master plans and protocols, and execution of validations of facilities and equipment. Prepared and presented numerous professional training programs on topic such as validation, compliance, QA/QC, GLPs and GMPs. Clients have included international and domestic companies ranging from small star-up companies to major pharmaceutical and device companies.

1981 – 1992 **Hybritech Incorporated**, San Diego, California (A Division of Eli Lilly)

1990 – 1992 **Director of Corporate Validations**

Prepared and implemented Therapeutics division Master Validation Plan for Aseptic Processing facility. Completed facility, equipment and process validation. Managed an interdepartmental validation team to complete the execution of the validation plan. Interfaced with FDA (CBER division) on facility review. Coordinated FDA Inspection of NDA facility for Pre-license Approval with no adverse observations (No 483 issued). Directed efforts of the internal engineering department and external architectural firm on design and specification of aseptic processing facility. Monitored construction for compliance with regulatory requirements.

1986 – 1990 **Director of Therapeutics Quality Control/Quality Assurance**
Directed the activities of the Therapeutic QA/QC Chemistry and QC Biology departments. Programs instituted include documentation, USP Chemistry testing, microbiology, virology, general safety and DNA testing. Completed the installation and implementation of an environmental monitoring program in compliance with aseptic processing guidelines.

1983 – 1986 **Director of Therapeutic Process Development**
Directed the activities of the group responsible for the sterile manufacturing of IND products for clinical trials. Developed processes for protein purification, process scale-up, aseptic filling and packaging of sterile injectable products.

Designed a facility for the sterile manufacturing of clinical trial products. The facility included two clean rooms, isotope processing labs, biological purification labs, and process development labs. The facility was in constant use for over 8 years. Facility was successfully inspected annually by California State FDB during that time.

1981 – 1983 **Director of Process Development**
Responsible for the product transfer from research to manufacturing and for development of scale-up manufacturing of diagnostic products, including Hybritech's first diagnostic test kits (IgE, HCG, Ferritin, and PAP)

1974 – 1980 **Ortho Diagnostics (Bio-Reagents), Irvine, California (A Division of Johnson & Johnson)**

Director of Research and Development

Responsible for the development of new products and for the manufacturing of custom clinical diagnostic products. The products included serum and urine controls and standards, enzyme reagents, RIA controls, clinical chemistry reagents and lyophilized products. Obtained a patent on a blood gas control.

1972 – 1974 **Curtis Nuclear Corporation, Los Angeles, California**

Senior Research Chemist to R&D Group Leader

Responsible for the development of RIA Diagnostic kits. Products included seven RIA kits introduced to the marketplace in 18 months.

Education:

1972	Post Doctorate Fellowship	The University, Southampton, England
1971	Ph. D., Organic Chemistry	University of California, Los Angeles
1966	B. Sc., Chemistry	University of Nevada, Reno