Robert Ferer, President
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Phone: 215•896•5491
www.theferergroup.com

the·ferer·group

26 Trails End
Collingwood, ON
L9Y 5B1
Canada

Summary of Qualifications

Teaching / Training

- Performed numerous classroom teaching / training sessions (specifically for clients as part of their in-house training programs, as well as for industry groups for such as PDA and ISPE).
- Develop custom courses as requested, as well as participate in group offerings with other consulting / teaching operations.
- Present live webinars.

Project Management

- Managed project teams including engineering and design, construction, equipment procurements, installation, commissioning, and validation.

Operations Management

- Managerial role on a project where the successful completion of Phase III clinical trial material was driven by my strong leadership. I assumed responsibility for production start-up and all daily operations.
- Work in the field ('hands-on') throughout the operation including component preparation and sterilizing, formulation, filling, inspection, labeling, and packaging.

Engineering

- Designed and sized critical utility systems, including USP purified water, clean steam, compressed gases, and water for injection systems.
- Participated in team efforts to design new and renovated pharmaceutical manufacturing facilities.
- Started up and commissioned systems for which I was involved in the design.
- Managed the engineering review and construction quality control of new facilities to assure that the design complied with the cGMPs and the user's requirements.

Validation

- Experience with the full spectrum of validation activities from validation master planning through final qualification.
- Managerial experience included the on-site management of employees during validation projects, particularly for facility, critical utility, production equipment, and process validation.
- Experience ranges from developing validation strategies for critical manufacturing processes to the writing and implementation of equipment and system validation protocols.

Quality

- Responsible for ensuring compliance with US, EU, and Japanese regulations on numerous projects.
- Developed quality programs, and verified compliance to those programs through audits as well as reviewing and approving documentation.
- Liaising directly with regulators from the US, UK, and Japan as a standard part of assignments.

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About Bob Ferer

As President and founder of **The Ferer Group Inc.**, my goal is to *transfer knowledge* to the new generation of professionals. Through a variety of means, including customized on-site training courses, seminars, web presentations, mentoring, and consultation, I empower and educate professionals in the pharmaceutical, biotech, beverage, and food industries.

A graduate of the State University of New York at Stony Brook, I am an engineering chemist with 20 plus years direct industry experience including design, build, start-up, and management of facilities specializing in aseptic manufacturing. My experience covers all aspects of pharmaceutical operations from receipt of raw materials through inspection, final packaging, and shipping of finished products.

In addition to operations experience, I have played an instrumental role in multiple new/renovated facility start up projects, which included developing and executing project master plans, schedules, and budgets, performing hands-on validation, design review, and equipment start up and commissioning.

As a consultant, I'm frequently contracted to manage large scale projects and provide high-level strategy and goal definition to clients. This includes due diligence, facility audits, compliance, and regulatory guidance for North America as well as EU markets.

Prior to founding The Ferer Group, I recruited, trained, and mentored staff in developing required expertise to support the industry.

To further expand my awareness of the pharmaceutical and biotechnology industries' advancements, I am a member of the International Society of Pharmaceutical Engineers and the Parenteral Drug Association. I'm also a regular contributor to industry publications.

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Professional History

The Ferer Group Inc. 2008 – Present

President

- Develop and present classroom training for PDA and Pharmaceutical Microbiological Forum
- Managing project quality assurance functions for vaccine manufacturing facility remediation project
- Operate as part of client's team to develop, review, and approve quality procedures and processes, specifications, protocols, and validation test plans and reports
- Mentor quality associates and project team members
- Prepare and present webinars for *FDA System Based Inspections* and *Spreadsheet Usage*
- Consult to investment industry on pharmaceutical manufacturing operations

Vectech Pharmaceutical Consultants, Inc. 1992 – 2008

Vice President - Automated Systems

- Developed and presented classroom training for PDA, ISPE, and various clients
- Recruited and trained staff required to support a wide variety of pharmaceutical projects (direct reports varied from 5 to 18 associates, depending on the assignment)
- Successfully managed $60MM turnkey project for an aseptic injectable facility where Vectech provided design, construction management, equipment procurement, installation, commissioning, validation, and quality assurance
- Designed quality programs: Change Control, Environmental Monitoring, Contamination Control
- Assumed role as Operations Manager to support client's need to manufacture Phase III clinical trial material
- Developed, implemented, and managed Validation Programs including Master Plans, qualification protocols, validation protocols, and standard operating procedures

Naska Pharmacal Co., Inc. 1989-1992

Sterile Facility Manager

- Managed the manufacturing and operation functions for a new sterile facility
- Developed and implemented validation techniques for both process equipment and critical systems

Facility Engineer

- Implemented facility engineering services as required throughout the facility, including preventative maintenance, calibration, repairs, and capital improvements
- Conducted engineering studies for sterile products, OTC and Rx liquids, creams, ointments and lotions in support of process improvements

Chemist

- Responsibility for Quality Control functions for OTC and Rx liquids, creams, ointments and lotions, first as a bench chemist and culminating in Finished Products QC Supervisor

Poly Research Corporation 1988 - 1989

Chemist

- Supervised the production and performed quality control testing of inorganic chemicals.

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Technical and Hands-On Work Experience

DISCIPLINES:	SYSTEMS AND EQUIPMENT:
• Teaching, Training, Mentoring • Project Management • Process Control Automation • PLC, SCADA, DeltaV • Technology Transfer • Management of manufacturing operations • Quality Assurance • Facility layout, design and engineering • Quality Control • Process validation • Cleaning validation • Fermentation, Harvest, and Purification	• Computer Networks • Critical Utilities; Pretreatment, Purified Water, WFI • Sterilization and Depyrogenation • CIP / SIP • Fillers • Cappers • Vial and stopper washers • Compounding / Manufacturing • HVAC and BAS • Inspection, Labeling, and Packaging • Compressed Gas (cryogenic liquid, compressors, dryers)

Education

- BS Engineering Chemistry, State University of New York (SUNY)
- American Chemical Society Certification

Professional Associations

- International Society of Pharmaceutical Engineers
- Parenteral Drug Association

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Courses Presented

- *The Contamination Control Plan*, PMF Conference, Key West, January 2011
- *The Importance of Equipment Qualification for the Microbiology Lab*, PMF Fall Forum – Advanced Workshop in Validation, Rochester NY, October 2010
- *Analytical Instrument Qualification*, PMF Workshop on GMP for the Microbiology Lab, Baltimore May 2010
- *Clean Room Design, Contamination Control, and Environmental Monitoring for Controlled Environments*, PDA Annual Meeting, Orlando March 2010
- *The Contamination Control Plan*, PMF Conference, Key Largo February 2010
- *Clean Room Design, Contamination Control, and Environmental Monitoring for Controlled Environments*, PDA San Francisco Course Series November 2009
- *Systems Based Inspections*, Web Seminar Series (all six systems), 2009
- *Use of Spreadsheets to Report Data in FDA Regulated Industries*, Web Seminar, 2009
- *Validation of Environmental Monitoring and Contamination Control Plans*, PMF Workshop, 2008
- *Elements of PAT*, Client Seminar, 2007
- *Sterile Filtration and Integrity Testing*, Client Seminar, 2007
- *Aseptic Processing*, ISBT (International Society for Beverage Technology), 2007
- *Validation of Software*, Vectech On-Line Seminar Series, 2006
- *Using Spreadsheets In the Laboratory*, PDA, 2006, 2007
- *Design of HVAC Systems for Aseptic Facilities*, ISPE, 2004
- *Sterile Drugs Produced by Aseptic Processing, An Engineering Perspective*, Vectech Seminar Series, 2003
- *Assuring Confidence in Laboratory Data*, IAFP (International Association for Food Packaging), 2003
- *Validation of Hardware and Software*, RMUG® (Rapid Micro Users Group), 2002
- *Designing a Clean Room*, ISPE, 2002
- *Change Control as it Relates to 21 CFR Part 11*, Client Seminar, 2002
- *Implementing an Effective Change Control System*, IIR, 2001, 2002
- *Systems Based Inspections*, The Production System, Vectech Seminar Series, 2001
- *cGMP Training*, 21 CFR Part 211, Client Seminar, 2001
- *Pharmaceutical Water Systems*, Client Seminar, 1999

Publications

Building and Equipping a Microbiology Laboratory: How to Budget Size and Cost, *IN* Laboratory Design, Establishing the Facility and Management Structure. Scott Sutton (ed.). DHI/PDA. pp. 187-214. 2010

The Production System, *IN* Systems-Based Inspection for Pharmaceutical Manufacturers. Jeanne Moldenhauer (ed.). DHI/PDA. pp. 233-258. 2007.

Performance Testing and Qualification, *IN* Steam Sterilization: A Practitioner's Guide. Jeanne Moldenhauer (ed.). DHI/PDA. pp. 463-522. 2003.

Validation of Computer-Related Laboratory Systems, *IN* Laboratory Validation: A Practitioner's Guide. Jeanne Moldenhauer (ed.). DHI/PDA. pp. 77-162. 2003.

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Relevant Work Experience

Client Description	Description of Service Provided
Generic Topical Manufacturer	Audit of facility for client that wished to contract manufacture a pharmaceutical spray dosage form
Specialty API Manufacturer / Supplier	GMP training and consultation to assist client entering the pharmaceutical API business
Generic Manufacturer, multiple dosage forms	Validation of facility and critical utility systems, as well as mock PAI
Investment Consortium	Due diligence for a pharmaceutical company being acquired
Name Brand Inhalation Product Line	Project Manager, construction quality control and validation for sterile respiratory Blow Fill Seal project
Name Brand Aseptic Parenteral Product Line	Preparation of facility SOPs to address FDA 483 observations
Name Brand Aseptic Parenteral Product Line	Transfer sterile, aseptic, dental anesthetic process and equipment to US
Name Brand Aseptic Parenteral Product Line	Transfer sterile, aseptic, dental anesthetic process and equipment to US
Novel Biological Products Manufacturer	Project Manager, validation of new facility for botulinum toxin
Novel Biological Products Manufacturer	HEPA filter integrity testing
Novel Biological Products Manufacturer	Cleaning validation audit in preparation for launching new products
Food Packaging Company	Audit of facility for client wanting to package products in foil pouches at
Name Brand Aseptic Parenteral Manufacturer	Project Manager, turnkey design / build project (sterile aseptic manufacturing of dental anesthetics) that included equipment
Name Brand Aseptic Parenteral Manufacturer	Transfer sterile, aseptic, dental anesthetic process and equipment to US
Novel Drug Delivery System Developer	Assume role of Operations Manager for the phase 3 production of dry powder inhaled drugs
Name Brand Parenteral Product Line	Project Manager, validation of equipment, facility, and utilities in response to FDA 483 observations
Generic Aseptic Parenteral Manufacturer	Validation of equipment for sterile, aseptic, dental anesthetic process
Preprocessed Pharmaceutical Closure Manufacturer	Preparation of Validation documents for equipment for rubber closure manufacturer
Name Brand Parenteral Product Line	Validation of facility, equipment, and critical utility systems for sterile, aseptic antibiotic
Food Processing Trade Group	Presenter of training course, Assuring Confidence in Laboratory Data
Training Seminar Company	Presenter of training course, Change Control
Generic Parenteral Manufacturer, Lyophilized	Validation of Lyophilization equipment and process
Generic Aseptic Parenteral Manufacturer	Validation of facility, equipment, and critical utility systems for sterile, aseptic products
Beverage Packaging Trade Group	Presenter and expert panel participant, Aseptic Processing
Pharmaceutical Engineering Trade Group	Presenter of training courses, Designing a Clean Room and Design of HVAC Systems for Aseptic Facilities
Name Brand Manufacturer, multiple dosage	Consultant; critical utilities for European company seeking US license
Generic Parenteral Manufacturer, Terminally Sterilized	Project Manager, engineering renovations and facility, equipment, and utility systems validation of terminal sterilized liquid filled products.

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Client Description	Description of Service Provided
Biological Reagent Manufacturer	Preparation of validation documents for equipment for in-line mixing of buffer solutions
Transdermal Patch Manufactuer	Audit of facility for client that wished to contract manufacture transdermal patches
Generic Manufacturer, multiple dosage forms	Validation of equipment for facility that manufactured generic drugs
Investment Consortium	Due diligence for a pharmaceutical company being acquired
Novel Drug Delivery System Developer	Project manager, validation of facility, equipment, and critical utility systems for pharmaceutical company developing novel time release drug delivery system
Public Health Department Facility	Support the facility design for clean room facility
Name Brand Manufacturer, multiple dosage forms	Consultation for variety of in house initiatives, predominantly compliance and regulatory services
Radiological Drug Manufacturer	Validation of new IT data center infrastructure, utilities, and network. Continuing support for validation of IT infrastructure
Generic Manufacturer, multiple dosage forms	Validation of software
Pharmaceutical Manufacturer Trade Group	Assisted with layout and design of new training facility for non-profit pharmaceutical training and research institute (PDA-TRI)
Generic Oral Dosage Manufacturer	Validation of various equipment, utilities, and systems for generic oral dosage manufacture
Name Brand Manufacturer, multiple dosage forms	Consultation for compressed gas system contamination issue.
Vaccine Manufacturer	Project Manager, fulfilling Quality Assurance role for start up of new vaccine production facility. Also functioning as a mentor and leader for the Quality team
Hospital Care Products Manufacturer	Project Manager, design, install, validation of pretreatment water system
Hospital Care Products Manufacturer	Taught course on Contamination Control. Was facilitator in helping them develop their own contamination control plan
Test Reagent Manufacturer, Lyophilized	Validation of Lyophilization equipment and process
Name Brand Biopharamceutical Manufacturer	Consultant; critical utilities for European company seeking US license
Name Brand Biopharamceutical Manufacturer	Consultant; warehouse, labeling, and storage audits for European company seeking US license
Generic Aseptic Parenteral Manufacturer	Project Manager, validation of new aseptic processing facility (facility, equipment, and critical utilities)
Generic Aseptic Parenteral Manufacturer	Consultant; remediation issues associated with FDA 483 observations
Novel Drug Delivery System Developer	Prepared equipment validation protocols for dry powder inhaled drugs
Generic Aseptic Parenteral Manufacturer	HEPA filter integrity testing
Generic Topical Manufacturer	Consultation; water system contamination issue
Generic Oral Dosage Manufacturer	Consultation; environmental controls for oral manufacturing process
Generic Oral Dosage Manufacturer	Consultation; new inventory control software
Law Firm	Served as an expert witness in a patent infringement law suit.