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EXECUTIVE SUMMARY

A senior R&D professional with a Ph.D. in Organic Chemistry and 25 years technical, managerial, business process and scientific experience, gained with major pharmaceutical, multi-national companies and start-up, development stage biotech companies. Over 20 years in the pharmaceutical industry, including parenterals, liquids, solids and semi-solids. An innovative problem-solver who has overseen the development of robotic methods for the analysis of small molecules, such as Coumadin®, engineered the technology transfer of release and cleaning validation methods for the production of an Alzheimer's drug, troubleshooting production problems for pain management drugs such as Percodan®, Naloxone®, Numorphan® and Naltrexone® and the development of new analytical methodologies for flavorants, such as vanillin. Expertise in GxPs, GMP audits, analytical methods validation, technology transfer, computer validation, 21 CFR Part 11 compliance and CTD Dossier preparation for NDA/ANDA's and Supplements.

- Excellent written and oral communications skills; excel at technical writing and preparing technical compliance documents, SOP's, validation reports, CMC stability summary reports and CTD Modules 2,3
- Mutual-Benefit Leadership skills: foster a team-oriented work environment based on mutual cooperation for mutual benefit; look for Win-Win partnering outcomes
- Excellent organizational and Project Management skills (Kepner-Tregoe Project Management training)
- Computer literate; familiar with development, implementation of LIMS and computer/software validation

TECHNICAL EXPERTISE:

- Analytical Techniques: GC, HPLC, GC/LC/MS, FTIR, UV-Vis
- Analytical Equipment Validation: IQ, OQ, PQ
- Stability-Indicating Method Development / Validation / Transfer
- Part 11 Compliance and GAP Analysis
- Best Practices in Quality Management: Quality Systems and CGMPs
- GMP Audits (Audit Preparedness, GMP Inspections (Internal Audits))
- CTD Dossier Preparation
- Validation Master Plan Development
- Stability Protocol Development
- LIMS and Laboratory Data Acquisition Computer Systems
- Computerized Systems Validation Deliverables (UFRS, CRS, FAT, SAT, IQ/OQ/PQ, RTM, VSR)
- Proficient in Microsoft Office software, MS Project, MS Visio, Adobe Acrobat,
- Software Applications worked with: Documentum, Trackwise, ISOtrain, ERP/MRP, EDMS, Maximo

PROFESSIONAL EXPERIENCE

PHARMABASICS, INC., New York
Senior Validation Consultant

2003 – Present

- Created CTD Module 3 Dossiers for registering OTC products in domestic and new overseas markets
- Prepared CTD GAP Analyses for needed materials for drug substances, products and excipients
- Provided QA/QC for clinical documentation at a biopharmaceutical company by revising and editing PK/PD reports CTD Module 5 and Module 2 clinical sections for an NDA registration package
- Authored 100% Effectiveness Recall Script for a repackaging operation of a firm that serves long-term care facilities; drafted an SOP for Destruction of Controlled Substances incorporating DEA Form 41
- Authored stability system SOPs for a clinical supplies repackaging facility.

- Audited LC/MS method validations at a clinical trials CRO in support of clinical trials testing; provided GAP analyses comparing “validated” methods validation against currently accepted ICH validation criteria; investigated risk assessments and documented findings in response to FDA Warning Letters
- Prepared, executed and/or conducted reviews of CSV deliverables including but not limited to compliance assessments, corrective action plans, CSV and SLC documentation (validation plans, user/functional requirements, configuration specifications, protocols (IQ/OQ/PQ, UAT, traceability matrices, etc.), test scripts, test summary logs, and validation summary reports) in support of Computer System Validation
- Conducted GMP Audits for Operational Compliance and developed responses to FDA Compliance Problems, Notices of Observations, Warning Letters and Consent Decrees
- Performed independent assessment of the business process, roles, responsibilities and functions of Quality Unit operations for Product Development R&D groups for conformance to CGMPs
- Reviewed Stability Programs, protocols, studies and supporting documentation for data integrity, accuracy and completeness; assessed handling Out-Of-Specification results, Deviations and CAPAs
- In-depth business process reviews of product development activities, quality and regulatory audits, recommendations for development efficiencies and cost-effective elimination of redundant activities
- Reviewed CAPA investigations for laboratory and manufacturing operations for outstanding issues
- Developed documentation as required for assigned projects (SOPs, guidelines, summaries, etc.)

PHARMABASICS, INC., New York

2002 – 2003

Computer Validation Consultant – Consent Decree Consultant

- Reviewed and certified computer performance qualification documents for enterprise-wide applications, spreadsheets, operating systems, user interfaces, etc., under the terms specified in the Consent Decree document and compliance with CGMP’s and 21 CFR Part 11
- Requested corrections to validation documentation, as required
- Audited unexecuted protocols and executed computer system validation studies for applications such as (but not limited to) SAP, Documentum, TrackWise, CMMS, EDMS, WMS, ISOrtrain, Maximo, etc., for conformance to predetermined acceptance criteria and compliance with CGMP’s and 21 CFR Part 11
- Assured all documentation, such as Change Control, SOP’s, training records, etc., conformed with the terms specified in the Consent Decree and compliance with CGMP’s
- Authored reports summarizing any deficiencies of protocols and/or study results for subsequent FDA review
- Issued approval certificates for subsequent protocol execution and/or study results following resolution of all issues and compliance with CGMP’s and 21 CFR Part 11
- Trained three (3) additional consultants to support computer validation efforts and meet the Consent Decree commitment project timelines
- Subject matter expert on computer system validation / Part 11 questions and issues
- Reviewed current SOPs and work instructions for predicate rule compliance, security requirements, disaster recovery, and data retention plans

EMISPHERE TECHNOLOGIES, INC., Tarrytown, New York

2000 – 2002

Associate Director, Quality Support Services

- Managed the operation of a quality control unit including the GMP Laboratory Documentation Control and Stability, with supervision of technical personnel supporting new product research and development
- Prepared department budget of \$3,000,000 for staffing and \$500,000 for capital equipment
- Designed new analytical testing laboratories in conjunction with facilities expansion
- Prepared commissioning and validation documentation for major laboratory equipment (e.g., GC, HPLC)
- Reviewed and approved all IQ/OQ/PQ validation protocols and executed protocols for CGMP compliance
- Technical Writing included authoring of compliance documents, stability reports for CMC sections, SOP’s specification documents & certificates of analysis (COA’s), stability portions of the CMC section for NDA filings, Out of Specification (OOS) investigation reports, GLP toxicology sample analysis summary reports and reporting of clinical pharmacokinetic data; implemented change control procedures
- Authored primary ICH harmonized stability protocols for transfer to contract research organizations and reviewed all data received for product quality assurance

- Authored Change Control SOP and established company Change Control Review Board
- Completed computer validation report for laboratory Turbochrom Workstation
- Contributed to writing Requirements and Functional Specifications documents in compliance with 21 CFR Part 11 for Turbochrom Client Server as a member of corporate Turbochrom Validation Team
- Interacted with FDA during routine inspection and eliminated potential 483 observations
- Conducted training on new and revised SOPs
- Member of corporate Global Disaster Recovery Team; contributed to development and implementation of company disaster recovery plan; Member of Process and Equipment Validation Committee

G&W LABORATORIES, INC., South Plainfield, New Jersey
Manager, Analytical Research and Methods Development

1997 – 2000

- Managed the operation of an R&D lab with 8 technical personnel for new semi-solid generic OTC product development in support of the overall business process
- Prepared Cleaning Validation Master Plan for all products, to adequately address Warning Letter deficiencies which resulted in product withdrawals
- Team Leader of Cleaning Validation Project responsible for coordinating and tracking all cleaning validation testing activities to ensure compliance
- Prepared 13 product cleaning validation protocols, managed successful execution and authored all reports within 6 months without any FDA 483 observations upon re-inspection
- Investigated vendors and coordinated demonstrations of new laboratory chromatography data systems in order to comply with up-coming 21 CFR Part 11 requirements
- Reviewed all in-coming method validation reports from contract research organizations (CROs) for accuracy, completeness and compliance with USP and FDA method validation guidelines
- Coordinated transfer of all new methods to Quality Control from developing groups; prepared technology transfer reports certifying acceptable methods transfers

CLAY-PARK LABS, INC., Bronx, New York
Manager, Contract Product Development (1996-97)

1995 – 1997

- Managed the business process of project planning and coordination for new semi-solid product development with contract manufacturing and research firms and ensured compliance with QC criteria, SOPs, GMPs and contractual guidelines
- Managed contract-developed business process product Life Cycle, from initial confidentiality agreement to technology transfer, clinical studies through regulatory filings

Analytical Laboratory Manager (1995-96)

- Directed the successful and on-time start-up and operation of a new R&D lab with 6 technical personnel supporting semi-solid generic, OTC and cosmetic new product development
- Negotiated with vendors for cost effective purchase of supplies and equipment (computers, printers, GCs, HPLCs) approved laboratory design specs, wrote job descriptions recruited laboratory staff
- Developed company-wide Technology Transfer strategy for a 33% time reduction
- Authored 25+ SOPs and conducted staff training to rectify all laboratory FDA 483 compliance observations
- Conducted staff training on CGMPs and new / revised SOPs
- Authored and published new, validated HPLC methods for Nitrofurazone products in USP PF (5/97)
- Successfully completed 3 product transfers from international parent company in Israel to CPL
- Designed and successfully implemented an Excel spreadsheet generating QC Stability Test and Spec Protocols to meet FDA compliance initiatives

DUPONT MERCK PHARMACEUTICAL CO., MFG. DIV., Garden City, New York
Principal Scientist, Analytical Technology (1993-94), Manager, Analytical Technical Support (1990-93)

1990 – 1994

- Provided direct analytical troubleshooting expertise supporting products and processes for parenteral, oral liquid and solid dosage forms; reviewed and edited stability and analytical sections of CMC for NDA filings
- Provided direct technical support to proprietary development projects, such as robotics, Warfarin API, Coumadin analytical/process validation and product transfer
- Directed the startup and operation of a new global analytical technical support lab with 19 Chemists, and a \$1,250,000 annual budget; designed new analytical lab facilities to support technical activities

- Received "Accomplishment Award" for preventing \$5,000,000 monthly revenue loss of major product line
- Coordinated technology transfers for Technical Operations between QC and R&D to Italy, Ireland and Puerto Rico; reviewed and approved all method transfer documents
- Project Leader for Site LIMS Implementation; contributed to writing requirements and specifications documents for implementation of Fisons VG Multichrom LIMS
- Served on Corporate Analytical Steering Committee; Corporate Stability/LIMS Implementation Team

PALL CORPORATION, Glen Cove, New York

1989 – 1990

Laboratory Manager, Scientific and Lab Services

- Supervised 15 Analysts performing wet chemical and instrumental testing of filtration products supporting R&D, manufacturing, sales and marketing
- Authored Laboratory SOP Manual
- Prepared requirements and specifications justifications for purchase of new HPLC and FTIR

PEPSICO, INC., Valhalla, New York

1987 – 1989

Senior Chemist, Concentrate Operations

- Responsible for analytical instrumentation purchases and \$500,000 capital analytical instrument budget
- Coordinated R&D, validation, documentation and specifications of new test methods
- Successfully developed and conducted Analytical Round Robin Auditing Program for 11 global plants

LEDERLE LABS, Div., AMERICAN CYANAMID, Pearl River, New York

1986 – 1987

Analytical Development Chemist

- Performed analytical methods development of new proprietary and standard products and established testing protocols for stability monitoring; Member of Company Annual Product Review Committee

REVLON HEALTH CARE, Tuckahoe, New York

1981– 1986

Senior Chemist/Laboratory Supervisor (1982-86); Assoc. Senior Chemist (1981-82)

- Supervised 2 Research Assistants performing USP test methods on new products and raw materials
- Successfully Managed Company Reference Standards Program; Member of Radiation Safety Committee

CHEMTECH CONSULTING GROUP, INC., New York, New York

1980– 1981

Group Leader

- Supervised 2-3 analysts performing EPA test methods by GC on water and wastewater samples for pesticides, herbicides, PCBs and EPA Priority Pollutants
- Reviewed all laboratory data and prepared reports for clients
- Major purchases of new equipment (GCs, Headspace Analyzers, Hall Detector, Class A Fume Hoods)

EQUITABLE ENVIRONMENTAL HEALTH, INC., Woodbury, NY

1979– 1980

Analytical Chemist

- Performed EPA, NIOSH, DoA test methods on water, air, soil, and wastewater samples for pesticides, herbicides, PCBs, EPA Priority Pollutants by GC and GC/MS, for TSCA, RCRA and OSHA projects
- Methods Development for GC/MS PCB analysis and Headspace analysis of airborne contaminants
- Prepared sections of Company Quality Control Manual relating to organic pollutant analysis

EDUCATION

POLYTECHNIC UNIVERSITY, Brooklyn, New York

Ph.D., Organic Chemistry (1987): Specialization: Natural Products Chemistry

QUEENS COLLEGE, Flushing, New York

Master of Arts, Chemistry (1979), Bachelor of Science cum laude, Chemistry (1971)

RENSSELAER POLYTECHNIC INSTITUTE, Troy, New York

Master of Science, Geochemistry (1976)