

PharmaBasics, Inc.

Compliance Solutions for the Pharmaceutical Industry

Company Description

PharmaBasics, Inc. is a validation and CGMP consulting company, offering a range of validation and quality system services for your CGMP/GLP facility. PharmaBasics brings to you the experience, knowledge and expertise needed to effectively and efficiently execute your validation projects. Dedication to quality is paramount in all our activities and our personalized support ensures the success of outcome of your projects.

PharmaBasics provides to you:

- Extensive experience with current industry regulations and standards
- Qualified and experienced validation professionals
- Commitment to your satisfaction
- Competitive rates

PharmaBasics, Inc. = Value Added Business and Compliance Solutions

VALIDATION SERVICES

Validation is the core of pharmaceutical business reality in today's regulated environment. Our consultants are dedicated professionals who keep current with validation issues, standards, trends and regulations. The result is a superior level of consulting, writing and execution services that stand up to FDA and EU inspection.

PharmaBasics' range of services includes:

- Validation Project Management
- Validation Master Planning
- Utility and Equipment Specification Development
- Construction Qualification Project Management
- Facility and Utility Commissioning and Validation
- Preventive Maintenance Program Development
- Metrology Program Development
- Best Practices in Quality Management
- CGMP Compliance
- Good Documentation Practices
- Computerized System Validation / Part 11 Compliance
- Process Equipment Validation
- Process Validation
- Cleaning Validation
- Analytical Test Methods Validation
- Standard Operating Procedure (SOP) Preparation
- Stability Monitoring Program Development
- OOS Investigations
- Stability Chamber Selection and Qualification
- Revalidation
- Vendor Assessments and Audits

COMPUTERIZED SYSTEMS / VALIDATION SERVICES

Our consultants have extensive experience in the validation of integrated software and hardware systems. From process control, data acquisition, PLC- or PC-based our computer software consultants are able to verify and document that your system is CGMP compliant.

PharmaBasics' CSV capabilities include the following:

- Software Quality Assurance Program Development and Audits
- System Requirements Document Development
- Functional Specifications Development
- Traceability Matrix Document Development
- Qualification Protocol Preparation and Execution
- Technical Writing and SDLC Document Preparation

LABORATORY SERVICES

Expert consultants in the fields of laboratory auditing and procedure implementation can assist in developing methods and quality control procedures, on site.

- Analytical Method Development and Validation
- Analytical Equipment and Laboratory Computer Systems Qualification
- GxP Auditing
- Laboratory Design, Implementation, Commissioning and Equipment Qualification
- Raw Material Qualification
- Standard Operating Procedures (SOPs) Preparation

REGULATORY COMPLIANCE

PharmaBasics' Quality Assurance and Regulatory Affairs professionals can bring additional expertise and resources to any company. PharmaBasics' professionals can assess existing quality systems for established firms or design new systems for newer firms to assure that your development projects have an easy transition into clinical trials in order to achieve commercial success.

Our staff professionals can provide:

- Common Technical Document (CTD) Dossier Preparation for NDA/ANDA/SNADA
- GAP analysis for compliance with Regulatory CTD documentation requirements
- GAP analysis and remediation for compliance with 21 CFR Part 11 (Electronic Records and Signatures regulation), GLP and CGMP requirements
- Vendor Qualification and inspection of suppliers, contract manufacturing, testing laboratories, equipment vendors and software developers
- Training and education in CGMP, GLP and 21 CFR Part 11 regulations
- SOPs for Quality Systems, Documentation and Software Quality Assurance
- Vendor Assessments / Audits
- CAPA (Corrective Actions and Preventative Actions) Systems
- Agency Inspection Deficiency Corrective Actions
- Quality Assurance Systems Analysis
- Technical Writing, Document Preparation and Review

WHO WE ARE

PharmaBasics' validation professionals have extensive hands-on experience, over many years, with utility systems and equipment used in the pharmaceutical industry. PBI can offer unique solutions to the common staffing, experience, schedule and budget challenges faced in today's market place. For new installations and facilities, PharmaBasics' professionals can perform validation activities concurrent with construction and commissioning, enabling production activities to commence much sooner. For newer companies or departments, we can assist you in establishing protocol formats and content in order to meet FDA expectations. For established companies, we can easily adapt to your established formats. Our combination of flexibility and experience is designed to meet your needs.

PRINCIPAL: Jeffrey M. Singer, Ph.D.

A senior R&D professional with Ph.D. in Organic Chemistry and over 25 years technical, managerial 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.

EDUCATION:

Ph.D., Organic Chemistry, Polytechnic University, Brooklyn, NY; 1987
Thesis Advisor: Mark M. Green
M.A., Chemistry, Queens College, Flushing, NY; 1979
M.S., Geochemistry, Rensselaer Polytechnic Institute, Troy, NY; 1976
B.S., Chemistry, Queens College, Flushing, NY; 1971

BUSINESS STRENGTHS:

Considered "Scientifically Nimble" by virtue of the following factors:

- Broad perspective due to diverse technical background.
- Collaborative in spirit and entrepreneurial by nature.
- Offer a holistic approach to problem solving: able to integrate separate pieces of information in order to formulate a game plan [dissect/work through/arrive at solution].
- Ability to gather hard-to-find information quickly.
- Attention to detail; excellent analytical skills.
- Excel at hard-to-tackle projects.
- Excellent written and oral communications skills; excel at technical writing and preparing technical compliance documents, SOP's, validation reports, CMC stability summary reports
- 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 skills; believe in delegation of tasks to best-suited individuals.
- Computer literate; familiar with development and implementation of Laboratory Information Management Systems and 21 CFR Part 11 Compliance issues.
- Proficient in Analytical Equipment and Laboratory Computer Systems Qualification.

CONTACT INFORMATION:

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