Bridge Associates International LLC

"Partners for Quality and Manufacturing Excellence"

Barbara J. Bassler, Ph.D.

Managing Partner

Dr. Bassler has more than 25 years of pharmaceutical experience in manufacturing, development, and quality operations. Her experience includes retooling and redirecting quality and manufacturing organizations in the US and Europe to improve quality performance and balance/optimize business performance and regulatory compliance. Her corporate career experience includes serving as the Head of Quality Assurance for the Aventis Pharmaceuticals flagship manufacturing site in Frankfurt Germany, where she built the QA organization, obtained FDA approval for the site, and worked extensively with European regulatory agencies. In addition, she has comprehensive experience in sterile drug product, active pharmaceutical ingredient, and medical device manufacturing and quality operations, as well as validation, and pharmaceutical analysis, and pharmaceutical business operations including pharmaceutical licensing and mergers and acquisitions.

Barbara brings a unique combination of pharmaceutical management, GMP/regulatory expertise, savvy analytical ability, and strong people skills to not only diagnose problems, but to design effective solutions and ensure management and shop floor implementation. Barbara has effectively built or revamped quality and manufacturing departments in numerous organizations around the world. In addition, she has experience with a wide range of dosage forms and active ingredients, as well as medical devices and diagnostics, and has worked extensively with regulatory authorities world-wide. She works both in the English and German languages, and has worked with companies in the US/North America, Europe, and Asia.

A member of the PDA, ACS, and Licensing Executive Society, Barbara has spoken frequently at industry/regulatory forums, including the PhRMA, the NJ Health Care Institute, and the German Regulatory Authority Annual Meetings. She has served on the PDA Subcommittee for Cleaning Validation, Aseptic Processing and Sterile API. Barbara holds a Ph.D. and an M.S. in Chemistry, and a B.S. in Biochemistry, and has been a Managing Partner at BAI since 2002.

BARBARA J. BASSLER, Ph.D.

EXPERIENCE: **BRIDGE ASSOCIATES INTERNATIONAL LLC.**
Princeton, NJ USA
Pharmaceutical and medical device manufacturing and quality/cGMP consulting, firm, working internationally to identify and solve manufacturing, quality, and regulatory problems for pharmaceutical/food ingredient companies of all sizes.

5/02 to present **MANAGING PARTNER**

Responsible for quality/cGMP, manufacturing and management projects for global firms world-wide, specializing in change management, quality effectiveness improvement, and manufacturing support for start-ups. In addition to servicing clients, manages the daily business of the firm, including strategic business planning, marketing, and resource management.

Successfully led and completed numerous assignments, many in the EU and Switzerland, focusing on manufacturing change management/ manufacturing-cGMP performance improvement, Quality Systems and QA organization design, FDA/international inspection preparation and management, GMP documentation/fraud investigation and validation strategy, as well as due diligence preparation and manufacturing capability assessments.

EXPERIENCE: **AVENTIS PHARMACEUTICALS, INC**.
Bridgewater, NJ USA
Major ethical pharmaceutical firm with over 80,000 employees world wide and 15 Billion USD in annual sales.

10/99 to 4/02 **DIRECTOR, INDUSTRIAL OPERATIONS ALLIANCES**

Responsible for all licensing deals for AVENTIS Pharma from the Industrial Operations perspective, including negotiating Cost of Goods, manufacturing technology, Quality/Compliance/cGMP for global markets, environmental health and safety issues, and supply chain for dosage forms, medical devices and active ingredients.

Organized and led manufacturing due diligence for company acquisitions.

Successfully negotiated more than one Billion USD in product licensing agreements.

EXPERIENCE: **HOECHST MARION ROUSSEL, INC**.
Frankfurt, Germany
Sterile and semi-solid finished dosage and sterile bulk active facilities with 2 billion dollar annual international sales, including U.S., Japanese and European markets.

4/97 to 10/99

DIRECTOR, QUALITY ASSURANCE DRUG PRODUCTS
Responsible for all non-laboratory quality activities for finished drug products and sterile bulk drug substances, including GMP Compliance, batch record review and releasing, qualification and validation, quality improvement, microbiological support, and marketed CMC activities. Directed staff of 75, including 41 professionals and annual budget of 4 million dollars.

Member of Site Management Team (Drug Products) with annual capital budget responsibility of 30 million dollars.

Accomplishments:

Established quality assurance systems to compete in an international GMP environment, including batch releasing, batch record review, validation, qualification, and continual quality improvement.

Successfully built-up Quality/GMP compliance program for 1500 person manufacturing site, culminating in FDA approval of product transfer from the U.S. and Frankfurt facility renovations. Successfully resolved pre-existing GMP compliance problems with FDA.

Led direction change for the Manufacturing organization toward total quality improvement and cycle time reduction. Catalyzed the formation of cross-functional process-focused teams and performance measurements to pre-established goals.

Hired, developed and trained staff of quality assurance professionals with no previous international QA experience.

Responsible for interactions and commitments on behalf of the company with regulatory authorities (FDA, EU, etc.).

3/96 to 4/97

GROUP LEADER, QUALITY ASSURANCE ANTIBIOTICS
Responsibilities and accomplishments as described above, specifically for sterile antibiotic and fermentation drug substance production and finished product (vial) filling.

EXPERIENCE:

HOECHST-ROUSSEL PHARMACEUTICALS, INC.
Somerville, NJ USA
Solid (including controlled release), semi-solid, liquid dosage facility with 500 million dollars in annual U.S. sales.

11/94 to 3/96

GROUP MANAGER, COMMERCIAL ANALYTICAL SUPPORT (QC)
Directed all quality control laboratory functions for commercial products, including release testing, stability program, method development and validation, and product troubleshooting; staff of 30 professionals and technicians; budget responsibility 3.5 million dollars.

Accomplishments:

Improved Quality Assurance support of Manufacturing by restructuring laboratory functions within QA with product-specific focus, combining release testing, stability testing, and method development.

Developed performance measures around cycle time reduction and analytical data integrity, improved "on-time" performance by more than 50% in less than one year.

2/92 TO 11/94 **MANAGER OF VALIDATION, PROCESS DEVELOPMENT**
Established Company validation policy and group, including manufacturing process validation, cleaning validation, computer validation, and equipment/facility qualification. Managed staff of professionals to develop validation protocols, execute studies, and prepare reports. Reported to Director of Quality Assurance and Operations Management Committee.

Accomplishments: Designed, developed and implemented a comprehensive facility validation program from start-up for a 500 million dollar annual volume manufacturing facility (solid, semi-solid, liquid, parenterals).

Successfully outsourced parenteral manufacturing, including regulatory submission strategy and approval.
Successfully defended four FDA inspections (pre-approval and general).

7/82 TO 2/92 **RESEARCH ASSOCIATE, ANALYTICAL RESEARCH**
Developed and validated analytical methods for drug substances and drug products. Prepared IND and NDA documentation for submission to FDA. Designed and implemented cleaning validation program. Completed Ph.D. during a two year leave of absence.

EDUCATION: Rutgers University
Ph.D. Chemistry, January 1990
Thesis: "Retention Mechanisms of Metallic Stationary Phases in HPLC"

M.S. Chemistry, June 1987

Lehigh University
B.S. Biochemistry, *Magna cum laude graduate*, June 1982

LANGUAGES: English, native
German, fluent

PROFESSIONAL AFFILIATIONS: Licensing Executives Society, Parenteral Drug Association (Cleaning Validation Sub-committee, Aseptic Processing Task Force, Sterile Bulk Task Force), American Association of Pharmaceutical Scientists, Association of Official Analytical Chemists, American Chemical Society.

PUBLICATIONS AND REFERENCES: Available upon request.