Bridge Associates International LLC

"Partners for Quality and Manufacturing Excellence"

James B. Powers, Jr. MSA, BS-BioChem
Managing Partner

James Powers is a Quality, Compliance and Lean Leader with over 25 years of pharmaceutical experience. His experience includes proactive leadership, designer and implementer of compliance / GMP based solutions across global sites. His professional experience includes directing quality and compliance operations for global pharmaceutical, biotech, aseptic, vaccine, API and generic manufacturing operations including direct remediation of FDA Warning Letters and Consent Decrees at multiple manufacturing sites in North America, Puerto Rico, Europe and Asia.

Experience includes hands on leadership of Data Integrity assessments, remediation, strategy development and risk assessments in response to regulatory inspections for both small and global pharmaceutical, biotech and personal health care organizations. Expertise includes performing detailed assessments of chromatography data systems (CDS) including electronic records, supporting audit trails and user roles. Developing interim measures that can be taken to protect patients and to ensure the quality of drug products. Developing long-term remediation strategies and enhancements to procedures, processes, methods, controls, systems, management oversight, and human resources to ensure data integrity. James has helped clients design and implement company wide Data Integrity programs.

Direct hands on experience in leading and running day to day activities related to quality operations at multiple manufacturing sites is a key strength that James brings to the workplace. Specific areas of expertise includes: quality operations, laboratory operations, investigations, CAPA, aseptic operations, stability programs, direct BOH interactions and audit readiness, customer service / product complaints, enterprise systems, program management office (PMO), change management and communications. This breath of experience includes work in North America, Europe, Asia and South America.

Skills include direct participation in Board of Health inspection and remediation activities related to Quality Systems, Data Integrity and Laboratory Operations. James has provided direct leadership to teams responsible for FDA Consent Decree and Warning Letter remediation efforts.

James experience includes the leadership and implementation of Laboratory Excellence programs across a wide range of laboratory environments.

Laboratory Excellence modules include: mindset & behavior transformations, change management, lean concepts (leveling, flow, standard work, 5S), shift huddles, flexible workforce, reduced testing, method improvement, visual management, performance management and Gemba walks. Laboratory Excellence is further enhanced with paperless laboratory excellence modules including: Full paperless business and laboratory workflows, automation, instrument integration, enhanced analytical technology, e-visual management, QC testing at line and electronic performance management (KPIs). Business benefits of Laboratory Excellence (LE) include: Productivity gains of 20-60%, lead time reduction and Right First Time (RFT) quality improvements. Laboratory Excellence yields compliance improvements and a more balanced and rewarding work environment for laboratory analyst. Laboratories that implement LE concepts yield trained individuals that become future leaders within organizations.

As a certified Lean Six Sigma practitioner, James brings an exceptional mix of GMP compliance, people skills and practical lean business practice knowledge to speed business results. James led the design and implementation of a world class lean laboratory program for both Wyeth and Pfizer Global Supply which has yielded improved quality, customer service and over $13 M in hard budget savings.

James led the implementation of a world class paperless QC laboratory and Quality environments across 17 global sites that have yielded over 63 million dollars in productivity improvements. He provided the vision and leadership in the delivery of standard quality business process and supporting automated systems used to support GMP operations within the Global Supply Chain. James led the Laboratory Automation Compliance Enhancement and Standardization (LACES) global program which includes standard business processes and supporting automation (LIMS, CDS, Data Archive, integration with laboratory instruments and SAP) tools. Direct business benefits included quality improvements, lead time reductions and productivity gains. As a member of ASTM, James chairs the ASTM E13.15 subcommittee responsible for authoring the ASTM Standard LIMS Guide. Current ASTM responsibilities include leading the transformation of existing standards into a new Laboratory Informatics Standard Guide.

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change management and communications. This breath of experience includes work in North America, Europe, Asia and South America.

Direct business support from initial business concepts, selection, implementation, operations, design reviews, optimizations, supporting audits and systems retirements.

PROFESSIONAL EXPERIENCE

1/2012 – Current: Managing Partner, Bridge Associates International, Princeton, NJ

Pharmaceutical and Biotech consulting in all areas of Manufacturing Operations, Quality Operations, Lean Practices and Information Technology system implementation. Assisting clients design and implement company wide Laboratory Excellence Programs and Data Integrity programs including detailed work flow assessments of laboratory computer systems including Chromatography Data Systems (CDS) and LIMS. Working globally to add practical business value in the regulated marketplace.

7/11 – 12/11: Partner, Bridge Associates International, Princeton, NJ

Pharmaceutical consulting in all areas of Manufacturing Operations, Quality Operations, Lean Practices and Information Technology system implementation. Working globally to add practical business value in the regulated marketplace.

1/09 to 3/11: Senior Director, Global Quality Operations, Pfizer, Collegeville, PA

Responsible for providing global vision and leadership in the design and implementation of a world class lean laboratory program for Pfizer Global Supply which has yielded improved quality, customer service and over $13 M in hard budget savings in the 1st 12 months of operation. Responsible for mentor teams in the use of lean six sigma tools and innovation to rapidly transform QC laboratories to achieve significant productivity improvements.

Responsible for leading the Laboratory Automation Compliance Enhancement and Standardization (LACES) global program which includes standard business processes and supporting automation (LIMS, CDS and Data Archive) for 17 manufacturing sites. Responsible for defining standard quality business processes (including laboratory processes, batch disposition and CAPA) across all business units (Animal Health, Biotech, Consumer, Development, Nutritional, Pharmaceutical, global Quality and Compliance operations). Provide business input during FDA and board of health (BOH) audits related to the LACES program and laboratory operations.

Led the formation of Communities of Practice (CoP) for the LACES program and laboratory operations including supporting collaboration tools (eRooms/Web Sites/Sharepoint) to disseminate and share best practice. Responsible for project staffing, performance and budget decisions. Working knowledge of global regulations and guidance documents and how they impact business operations at manufacturing sites and supporting corporate functions.

8/07 to 12/08: Senior Director, Global Quality & Compliance, Wyeth, Collegeville, PA

Responsible for defining standard quality business processes across global Quality and Compliance operations. Responsible for leading major cross-functional compliance programs including the Lean Laboratory program and the Laboratory Automation Compliance Enhancement and Standardization program (LACES, LIMS, CDS, Data Archive, instrument and SAP integration) to achieve significant business productivity gains and compliance

improvements. Responsible for mentoring teams in the use of lean six sigma tools and innovation to achieve significant productivity improvements. Led Communities of Practice (CoP) for the LACES program and laboratory operations including systems (eRooms/Web Sites) to disseminate and share best practice. Provides business input during board of health audits and internal investigations related to the LACES program and laboratory operations. Responsible for project staffing, performance and budget decisions. Working knowledge of global regulations and guidance documents and how they impact business operations at manufacturing sites and supporting corporate functions.

12/06 to 8/07: Senior Director, Global Quality & Compliance, Wyeth, Collegeville, PA and Puerto Rico

Responsible for leading critical Quality and Compliance remediation and enhancement programs for the Global Quality and Compliance organization supporting world wide supply chain operations and laboratory functions. Led compliance efforts related to BOH Observations, Consent Decree and Warning Letter remediation at multiple global sites including Puerto Rico. Led quality assurance and compliance business process improvement efforts to maximize quality and compliance related to manufacturing and laboratory investigations and CAPA. Assist in defining business process standards. Utilizes Operational Excellence / Lean Six Sigma (DMAIC) methodologies and tools to optimize business value. Led Global Quality & Compliance (GQ&C) work teams related to Investigation Quality Assessments (IQA) and quality business process improvements on a global basis including North America, Puerto Rico, Europe, Latin America and Asia Pacific.

2/01 to 12/06: Director, Process Excellence, Wyeth, Great Valley, PA

Responsible for providing global vision and leadership in the delivery of standard quality business process and supporting automated systems used to support GMP operations within the Global Supply Chain. Specific system areas include laboratory information management systems (LIMS), chromatography data acquisition systems training systems, instrument data archive, quality investigations, TrackWise (Manufacturing Investigation Reports (MIR), Laboratory Investigation Reports (LIR)), trending, commitment tracking, change control, and technical specifications. Created and lead the start up of both the LACES and TrackWise global programs. Led compliance response to FDA BOH 483 observations and Consent Decree agreements. Directly participated in authoring responses and implementing commitments in response to FDA Consent Decree. Provide quality leadership and GMP expertise for Business Process Management (BPM) projects including on-going efforts in the area of integration between enterprise systems.

1/00 to 2/01: Associate Director, Quality Assurance & Tech. Services, Wyeth-Vaccines , Marietta, PA

Responsible for restarting a biotech vaccines manufacturing plant after FDA shut down due to GMP inspection observations. Responsible for authoring 483 response to FDA, negotiating with FDA and legal support teams on Consent Decree content. Responsible for developing restart protocol for the resumption of manufacturing and supporting systems for vaccines products. Responsibility for SAP R/3 implementation (MRP II QA / QM team member) for the Wyeth-Ayerst North American Supply Chain. Responsibility for LIMS and validation support for new Information Management systems being implemented in the Wyeth-Ayerst Global Supply Chain. Responsibility for QA oversight for the Technical Specification System. Member corporate oversight committee (bio/vaccine plant) with primary responsibility for directing the implementation of new GMP systems. Member Wyeth Corporate Validation and Part 11 Electronic Records Steering Committees.

2/99 to 1/00: IS – Year 2000 PMO – American Home Products (AHP) / Wyeth Pharmaceuticals, Glenloch, PA

Global responsibility for Year 2000 (Y2K) issues related to Certification, Implementation and Business Continuity Planning. Responsible for laboratory embedded chips, Regulatory, Compliance and Validation for all divisions of American Home Products Corporation (AHP). Relationship Manager – Wyeth-Ayerst Global Pharmaceuticals Supply Chain. Relationship Manager for Wyeth-Ayerst Research (Global responsibility). Tasks included working with senior W-A Supply Chain and Research business leaders in North America, Europe, Asia and Latin America. Direct oversight for 140 million dollar Y2K remediation program for AHPC.

10/97 to 1/99 Associate Director – Product Quality-Policies & Best Practice, Wyeth Pharmaceuticals, Radnor, PA

Responsible for Product Quality Customer Complaint responses, Global Quality Assurance Policy and Best Practice functions for corporate head quarters. Responsible for streamlining workflow and productivity improvements. Designed Product Quality complaint trend report for the Wyeth Pharmaceutical OTC and Rx business units. Directed the Product Quality Training unit including reorganizing the file structure for department cGMP training records.

6/94 – 9/97 Quality Head, Quality Assurance, Wyeth Great Valley and West Chester.

Responsible for all Quality Assurance functions at both the Wyeth-Ayerst Great Valley, PA (oral / solid dosage) and West Chester, PA (sterile / parenteral) facilities. Responsibilities include directing a large multi-faceted laboratory operation including chemistry, microbiology (environmental monitoring, sterility), physical testing, commercial stability, product complaint, annual product reviews, method development / validation, tech transfer and record review with a staff of 130+ individuals. Working hands on experience with FDA GMP, PAI and DEA audits including authoring 483 responses and meetings with FDA District and Center personnel. Successfully managed capital and department budgets of over 5 million dollars. Established new Quality Systems including: cGMP Compliance Council, OOS policy, Change Control policy, Batch Record Design, Annual Product Review (APR) and Statistical trending of stability data. Responsible for strategic planning, productivity workflow redesigns (implemented self-directed work teams), performance metrics development and implementation. Proven leadership, self-motivator, and consensus building skills. Member of the facility Continuous Improvement (CI) -Steering Committee and vendor CI based teams.

12/89 - 6/94 Associate Director - Quality Assurance Computer Applications, Wyeth (Corporate)

Wyeth-Ayerst Laboratories, Inc. Corporate. Responsible for 7 pharmaceutical facilities in the U. S. and Puerto Rico. Responsible for Laboratory Information Management Systems (LIMS), Data Acquisition, Office Automation and Document Imaging applications. Developed productivity enhancements using time and motion studies responsible for reduced cycle time and enhanced profitability. Specific tasks include automation: specification, design, purchase, installation, training, validation, support and maintenance. Successfully directed multiple automation projects (LIMS and data acquisition), on time and under budget using project management tools. Implemented LAN based automation using Lotus Notes and Microsoft Office products.

EDUCATION: University

- Penn State University, B.Sc. Biochemistry
- Temple University - Graduate work - Pharmaceutical QA & SPC
- Drexel University - Graduate work - Environmental Engineering
- West Chester University, Masters of Science (MSA) Administration

EDUCATION: Strong support for continuous on-going education

- Penn State University Graduate Center - Project Management,
- Penn State University Graduate Center - C Programming
- Penn State University Graduate Center - Quality Management
- Information Mapping – Policies & Procedures
- Financial and Business Decisions – SIRCO, Stan Ross (Temple U.)
- SAP R/3 Training (QM, MM, PP-PI) courses
- Penn State University Graduate Center – e-Business – Supply Chain Management
- Information Mapping
- Requirements Management – Telelogic / Doors
- EDMS / Documentum – Document Management
- LabWare LIMS System Administration
- Data Stewardship – Building and Implementing a data model / meta data stewardship program
- LabWare LIMS, Waters Empower Chromatography, Cerity Data Archive
- Lean - Six Sigma – Rath & Strong: Green Belt Certification
- Investigation Training – MIR / LIR
- Root Cause Analysis
- Human Performance Model (HPM) Training
- Lean Laboratory Training – BSM
- Instructor – Analytical Development University (ADU)

INDUSTRY TRAINING:

PDA - Design and Validation of Water Systems, FDA - PDA Work Shops, Pittsburgh Conference, Scientific Computing & Automation, Parenteral Drug Association, International LIMS Conference, PDA Computer Validation, American Chemical Society - Laboratory Management, McCrone Research Institute - Microscopy, PhRMA-Validation of Computerized Systems, Document Management-Optical Imaging, Novell Netware System Administration, Microsoft Project, Good Manufacturing Practices (cGMPs), Good Automated Laboratory Practices (GALPs-EPA), Good Automated Manufacturing Practice (GAMP), Paper / Oral Presentation: Business Benefits of Global LIMS Implementation, LabWare LIMS CEC (presenter).

AFFILIATIONS:

ISPE Member, American Society for Testing and Materials (ASTM), Chairman of ASTM E13.15 Sub committee responsible for publishing the ASTM Laboratory Informatics Standard Guide

COMPUTER SKILLS:

LabWare LIMS, StarLIMS, Waters Empower Chromatography Data Systems (CDS), Agilent Cerity Data Archive, SAP, TrackWise, LAN/Admin, Outlook, SharePoint, EDMS Documentum (GXPharma), Microsoft Office (Word, Excel, Power Point, Access, Project, Visio), Turbo Chrom , Programing (Basic, C++, Web HTML), Web Page Management.

REFERENCES: Available upon request.