Bridge Associates International LLC

"Partners for Quality and Manufacturing Excellence"

Greg Guthrie

Managing Partner

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I have 43 years of experience in the pharmaceutical industry, primarily in manufacturing operations. My management experience has included the positions of first line Supervisor, Department Manager, Production Superintendent and Site Manager. My staff positions have included global project management, manufacturing strategy development and implementation. Since 2006 I have been a Managing Partner at Bridge Associates International (a pharmaceutical consulting company).

In my various management roles I have been involved with the design and implementation of several organizational improvement initiatives such as Team Based Systems, Primary Process Units (sites within a site) and 12 hour shift schedules. As a Primary Process Unit Leader in the late 90's my production organization designed and implemented several leading edge projects including the construction, equipping and commissioning of a "cellular" manufacturing area and lights out tablet compression. The same group was responsible for several new product transfer/validation projects from R&D into production.

In global staff roles, I have had a variety of responsibilities including project leader for a team that designed, developed, validated and implemented global Information Technology systems at several manufacturing sites. The IT systems included: Enterprise Resource Planning System (SAP), Manufacturing Execution System (MES), Laboratory Information Management System (LIMS) and Data Analysis Tools (DAT).

As Senior Director Manufacturing Strategy, I was responsible for development and execution of a synergy plan for the region of Americas Asia Pacific which included 35 manufacturing plants and for the development of the Technology Strategy for those plants. It was in this role that I developed and implemented a global strategy roadmap for how the organization was going to develop and implement improvement initiatives in the area of Process Analytical Technology (PAT).

As a Pharmaceutical Consulting I have helped a number of clients in such areas as: strategy development, strategy implementation, process improvements, project leadership, Project Management Office activities, Computer System Validation audits, etc.

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EXPERIENCE:

BRIDGE ASSOCIATES INTERNATIONAL, LLC , Princeton, New Jersey

Pharmaceutical consulting in all areas of Manufacturing/Quality Operations, Operations Excellence initiatives and Information Technology system implementation and project management.

MANAGING PARTNER
(2006 – Present)

Recent engagements have included:

- Provided PMO support and guidance for a global effort to identify a strategy for Product Knowledge Management (tools, processes, governance, etc.) for a top five pharma company
- Provided PMO support for a multi-site compliance and remediation project for a Division of a top five pharma company
- Conducted a GxP CSV audit of multiple IT systems for a top five pharma company
- Provided PMO support for a multi-site project to build, test and implement a global LIMS system
- Work stream leadership role on a project to design an automated process for the compilation of Annual Product Reviews
- Work stream leadership role on a project to design and implement a global regulatory product information system
- Participated in the development of an Information Technology strategy for capturing product and process data across an enterprise
- Performed a Quality and Engineering risk assessment at 5 nutritional manufacturing plants and worked with global leadership team to develop mitigation strategies
- Facilitated process with a global manufacturing leadership team to develop a vision and strategy…this included the development of a 3 year strategic plan and identification of strategic initiatives and tactical projects to move towards the vision
- Completed a GxP audit of the Software Development Life Cycle processes at a German ERP software provider wanting to enter the U.S. market
- Provided PMO support for a team that developed a Governance model for Integration Middleware Technology and Processes
- Worked with various clients to identify process and GxP improvement areas and to develop mitigation plans

SANOFI-AVENTIS (and predecessor companies) 1971– 2005

SENIOR DIRECTOR MANUFACTURING STRATEGY
(2000– 2005)

Named as the Head of Competitive Intelligence & PAT (Process Analytical Technology) within the Industrial Technology group at the time of the formation of sanofi-aventis in 2004.

Worked in various roles prior to the merger:

- Led a global project to design, develop, test and implement a common Electronic Batch Record System (EBRS), Laboratory Information Management System (LIMS), Data Analysis Tool (DAT), Data Historian (DHS) and install them at 5 sites
- Directed the overall synergy plan for 35 plants in the Americas Asia Pacific (AAP) area. Facilitated development of overall manufacturing vision and strategy for the AAP group and developed (and gained approval for) a global strategy for PAT

DIRECTOR DRY PRODUCTS PPU (PRIMARY PROCESS UNIT)
(1996 – 2000)

Head of the manufacturing unit producing 3 Global Strategic Products (180 associates…3 billion doses per year…launched 2 new products).

Developed overall capital strategy for the PPU and managed projects that included: construction of a new manufacturing area utilizing "cellular manufacturing technology"…"lights out" tablet compression suite…renovation of existing granulation area

Implemented a new organizational concept of PPUs based on a "plant within a plant" model

PRISM IMPLEMENTATION LEADER FOR NORTH AMERICAN
(1993 – 1996)

Led a multifunctional project team to design, develop, test and implement an Enterprise Resource Planning System (SAP), EBRS, LIMS and Laboratory Acquisition System (LAS) for 3 sites.

SITE MANAGER – RICHMOND HILL PLANT – TORONTO CANADA
(1990 – 1993)

Represented Industrial Operations on the Executive Committee for Marion Merrell Dow Canada. Participated in an analysis of the plant network for MMD Canada and eventually implemented a decision to close the Richmond Hill facility. During the 18 months leading to the plant closure the site maintained an excellent safety record, maintained production schedules, launched two new products, transferred production to other sites, maintained employee morale, sold and closed the facility.

VARIOUS MANUFACTRING POSITIONS
(1971 – 1990)

Dry Products Superintendent at Cincinnati Plant

Capsule Production Manager at Kansas City Plant

Manufacturing Manager at St. Louis Plant

EDUCATION: MBA Finance - 1986 - Avila College - Kansas City, MO
BA Chemistry – 1983 - University of Missouri at Kansas City

PROFESSIONAL AFFILIATIONS AND INTERESTES:
Greg has been active in a number of industry and professional groups and has served on many working groups and steering teams within ISPE, CAMP and ASTM