Bridge Associates International LLC

"Partners for Quality and Manufacturing Excellence"

Margit Schwalbe-Fehl, Ph.D.

Managing Partner

Dr. Margit Schwalbe-Fehl has more than 25 years of experience in the Pharmaceutical Industry in quality operations, manufacturing, and regulatory compliance.
Margit has held in the last 20 years operational and corporate Quality positions with increasing responsibilities in major global pharmaceutical companies. Her experience includes creating and implementing efficient and effective global quality processes and systems across all Quality areas to ensure on-going regulatory compliance with global regulations. She has interacted extensively with representatives of regulatory authorities in Europe and the US where she has worked and lived.

Margit was heavily involved in continuous process and performance improvement projects and major transformational and strategy initiatives in quality and manufacturing which led to a profound understanding how quality and compliance must be integrated in all processes to be a competitive advantage for an organization. Her knowledge of cross-functional businesses processes combined with her experience in leadership and team development makes her uniquely qualified for organizational transformation projects.
In one of her roles, Margit implemented a Chemistry, Manufacturing and Controls (CMC) function within the Industrial Operations function to create and submit variations for marketed products which resulted in increased speed of implementation of product transfers and continuous improvements projects within manufacturing.

Margit combines in a unique way the strategic viewpoint and understanding of global business processes with a pragmatic hands-on experience as she has also successfully led site Quality Control laboratories and the Quality Assurance organizations of a major manufacturing site with active pharmaceutical ingredient production and drug product manufacturing of aseptic products and solid dosage forms for world wide export.

Her sound technical background and her strong people skills give Margit the capability to coach and develop individuals, create high-performing teams and lead them effectively through times of major change, for example after mergers and acquisitions, and through major transformation projects.

Margit has served as representative in the Manufacturing and Quality Operations group of the European Federation of Pharmaceutical Industries and Associations and is a member of PDA and ISPE. Most recently, she was involved in ISPE´s Quality Metrics initiative as a member of the Quality Culture group.

Margit holds a Ph.D. in Analytical Chemistry and a Diploma in Chemistry. She is also is a certified Management and Team Development Coach thus combining her business experience with the skills to build effective leadership.
She has been a Managing Partner at BAI since 2010.

MARGIT SCHWALBE-FEHL, 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.

Since 07/10 **MANAGING PARTNER**

Responsible for quality/cGMP, manufacturing and management projects for global firms world-wide, specializing in quality and manufacturing transformation projects, organizational effectiveness, team and leadership development and improving the effectiveness of quality systems and processes.

In addition to servicing clients, manages the daily business of the firm, including strategic business planning, marketing, and resource management.

Accomplishments: Successful consulting in large and mid-size organizations in the Pharmaceutical and Chemical Industry with the focus on
- → Organizational development for site and global Quality organizations
- → 3-year quality strategy development and implementation
- → Quality Culture and change management
- → Quality Management System implementation and improvements
- → US FDA readiness assessments and inspection preparation training
- → Audit preparation and follow-up
- → Management coaching incl. career development and change management; supported by the Highlands Program

EXPERIENCE: **PFIZER INC. (through the acquisition of Wyeth INC.)**
Heidesheim, Germany, and Peapack, NJ/USA
The world's largest research-based pharmaceutical company with over 110,000 employees world wide and more than 50 Billion USD in annual sales

10/09 to 06/10 **Vice President Quality Excellence, Global Quality Operations**

Accomplishments: Successful integration coordination of the Global Quality Operations organization after the acquisition of Wyeth ensuring on time delivery of synergies and the implementation of a talent retention program

EXPERIENCE: **WYETH PHARMA GmbH**
Heidesheim/Germany, and Collegeville, PA/USA
Major ethical pharmaceutical firm with over 40,000 employees world wide and more than 25 Billion USD in annual sales.

07/07 to 10/09 **Vice President Operational and Technical Excellence, Global Quality and Compliance**

Accomplishments:

- → Created and supported the implementation of a 3-year Strategic Plan for Global Quality & Compliance to ensure a world class Quality organization with regards to business performance and recognition by Regulatory Authorities
- → Co-led the operational transformation of site and above site Quality organizations in a Industrial Operations wide program **which led to more than 25 % improved efficiency in manufacturing sites within 18 months**
- → Developed an optimized organizational model for the Global Quality & Compliance on site and corporate level
- → Developed and implemented an integrated Talent Management Strategy for the Global Quality organization of Wyeth
- → Represented Wyeth Europe externally in the European Federation of Pharmaceutical Industries and Associations (EFPIA) Manufacturing and Quality Operations ad-hoc group
- → Wyeth Leader of the Quality integration with Pfizer

EXPERIENCE: **SANOFI-AVENTIS SA, PARIS/France**
(after the acquisition of Aventis by Sanofi-Synthélabo)

10/05 to 06/07 **Associate Vice President Industrial Quality & Compliance**
Injectables and Inhalation Products

Accomplishments: Provided functional leadership for the Quality organization of eight strategic manufacturing sites producing injectables, medical devices and inhalation products for worldwide markets (approx. 1000 employees in Germany, France, UK, Italy and Hungary) covering

- → Quality management processes in the sites
- → Successful preparation and conduct of regulatory inspections (US FDA, EU EMEA, ANVISA/Brazil and other regulatory agencies)
- → Review and approval for major investment projects ensuring on-going compliance with regulatory and GMP requirements and expectations
- → Regulatory compliance of marketed products at the respective sites

01/05 – 09/05 **Associate Vice President Technical Quality and Compliance**
Expertise; Industrial Quality & Compliance

Accomplishments: Successful integration of the Sanofi and Aventis Quality Organizations and key processes incl.

- → Harmonization of the Global Quality Manual for all sanofi-aventis manufacturing sites (> 80 Drug Products and API sites)
- → Leadership of the world wide Quality management for suppliers and contract manufacturers
- → Design and implementation of GMP and technical training
- → Assessment and implementation of new analytical technology

EXPERIENCE: **AVENTIS PHARMA SA, FRANKFURT/GERMANY**
(created through the merger of Hoechst-Marion-Roussel and Rhone-Poulenc-Rorer)

10/03 to 12/04 **Vice President Quality Systems and Services and Industrial Operations Chemistry, Manufacturing, Controls**

Accomplishments: In addition of continuing with the previously described responsibilities

- → Successful first time implementation and leadership of the regulatory CMC (Chemistry, Manufacturing, Controls) function for marketed products within Industrial Operations **thus enabling timely change control for Industrial Excellence projects and product transfers resulting in significant project savings and improved regulatory compliance**
- → Co-leader of the Quality Integration Team for Aventis during the acquisition by Sanofi-Synthélabo (2004)

12/99 to 09/03 **Vice President Technical Systems and Services**

Accomplishments: Successful **integration of the corporate Quality functions** by defining and implementing key quality processes and systems in the following areas

- → Design, implementation and management of the Global Quality & Compliance Board to assess and manage critical quality risks across the organization incl. critical issue management
- → First time implementation of a Global complaints process and electronic database which allowed the early identification of product quality improvements
- → Creation of the Aventis Global Quality Manual thus ensuring on-going compliance with all relevant regulatory expectations
- → Implementation of an integrated Supplier Quality management process; Supporting cost saving initiatives together with Procurement with the proper Quality risk management processes for new and existing suppliers. Representative of Global Quality Operations in strategic sourcing decisions
- → Implementation of a Global Regulatory Intelligence function for GMP-regulated activities
- → Identification and implementation of Analytical Processes and Technology which enabled site analytical laboratories to improve efficiency and compliance
- → Global GMP and Technical Training
- → Qualification and Validation of facilities, processes, equipment and computer systems
- → Implementation and management of Quality Key Performance Indicators for compliance and business performance

Involved in the **design and implementation of the Global Industrial Management Strategy** in Aventis Industrial Operations (2001/2002)

Involved in the **design and implementation of the Aventis Industrial Excellence Program** (2002/2003)

EXPERIENCE: **HOECHST MARION ROUSSEL**
(created through the acquisition of Marion-Merrel-Dow by Hoechst)

07/99 to 12/99 **Vice President International Quality Systems, Frankfurt/Germany**

Accomplishments:

- → Design and implementation of Global Quality systems and processes including complaints and recall management
- → Leadership of the Corporate GMP Audits group and processes

07/97 to 07/99 **Vice President Quality Operations North America; Kansas City/US**

Accomplishments: Functional leadership for the Quality organization and Quality systems in eight manufacturing sites in North America (US, Puerto Rico, Canada)

- → Responsible for all quality deliverables during a major consolidation of all North American manufacturing activities with numerous product transfers and regulatory activities
- → Direct interaction with US FDA for critical quality defects

Member of the Quality integration team for the merger of Hoechst-Marion-Roussel and Rhone-Poulenc-Rorer (1999)

05/96 to 06/97 **Vice President Quality Operations Europe, Middle East, Africa; Frankfurt/Germany**

Accomplishments: Successful creation and management of a regional Quality unit for Europe, Middle East, Africa with the Quality oversight for 18 drug products plants with solid dosage forms and sterile products

EXPERIENCE: **HOECHST AG, Frankfurt (FFM) and Wiesbaden (WI)/Germany**

04/94 to 04/96 **Senior Director Pharma Quality Assurance/GMP (FFM)**

Accomplishments: Successful implementation of the Quality Systems and Quality Management in drug products manufacturing and active pharmaceutical ingredients production of the Frankfurt site

- → Creation of the first Quality Manual for the Frankfurt site
- → Management of national and international regulatory agencies inspections (including US FDA)
- → Support of regulatory submissions for New Drug Applications, Drug Master Files and Variations

Quality Lead for the Due Diligence during the acquisition of Marion-Merrell-Dow (1995)

07/92 to 03/94 **Director Pharma Quality Control for Marketed Products (FFM)**

Accomplishments:

- → Responsible for 100+ employees in the Quality Control labs covering all testing and release of finished drug products, active pharmaceutical ingredients and raw materials of the Frankfurt site
- → Responsible for analytical method transfers from Development into Commercial testing labs

01/90 – 06/92 **Head Analytical Laboratory and other Service Departments (WI)**

Accomplishments: Management of a Service Department for the Wiesbaden site including the Analytical Laboratory, Physico-chemical Laboratory and Literature Services (Department of 120 employees and 10 mio DM budget)

01/89 – 12/89 **Assistant to the Board of Directors (FFM) – internal trainee program**

01/84 – 12/88 **Laboratory Group Leader Metabolism and Pharmacokinetics in Pesticide Development**

Accomplishments:
- → Planning and conduct of metabolism and pharmacokinetics studies for new pesticides, successful support of international regulatory submissions
- → First-time implementation of Good Laboratory Practices

ADDITIONAL QUALIFICATIONS

- → **Certified Management Coach since 2003**
  Artop e.V., Institute of the Humboldt University Berlin/Germany; Focus on coaching for senior leaders and team development

- → **Trained in Managing Intercultural Differences with focus on cooperation between French, Germans, Americans, and British**
  Various trainings by Jacques Pateau Consultants, Compiegne/France since 2001

- → **Highlands Affiliate since 2003**
  certified to deliver the Highlands Program, an international program for personal, leadership, and team development, to individuals and teams

EDUCATION: Johannes-Gutenberg-University Mainz, Germany
Ph.D. Analytical Chemistry, November 1983
M.S. Chemistry, October 1980

LANGUAGES: German native
English fluent
French and Spanish basic

PROFESSIONAL AFFILIATIONS: Parenteral Drug Association PDA, International Society for Pharmaceutical Engineering ISPE

PUBLICATIONS AND REFERENCES: Available upon request