Bridge Associates International LLC

"Partners for Quality and Manufacturing Excellence"

Doreen Newhouse

Partner

Doreen Newhouse has over 25 years experience in pharmaceutical quality assurance in both local and global roles, including FDA, MHRA, CFDA, ANVISA and other health authority inspection readiness programs, GMP compliance remediation programs, continuous improvement initiatives, quality operations for early stage biotechnology products, technology transfers and facility start-ups, and computer systems validation. Ms. Newhouse's experience includes regulated quality assurance in both GLP and GMP businesses. She has a comprehensive working knowledge of quality business processes and the management of quality risk in operational, remediation and continuous improvement activities. She strives for pragmatic approaches to problem-solving that effectively balance product quality, compliance and business requirements. Her people skills have enabled her to lead local teams as well as virtual teams in a multi-cultural environment to deliver on strategic objectives.

Ms. Newhouse's most recent global quality role for a large pharmaceutical company involved implementation of a corporate data integrity program. In this role, she led a cross-functional initiative to enhance organizational capacities and culture, policies, procedures and tools, to enable robust data integrity of GMP-related processes in the global manufacturing network. Ms. Newhouse's activities included strategic program management as well as direct engagement with cross-functional SMEs at sites throughout the global network for coaching, training, problem-solving and assessments.

Ms. Newhouse is passionate about collaboration and continuous improvement. She champions quality excellence and behavioral change management in all aspects of her work to facilitate improvement and learning. She holds a highest honors degree in Zoology from the University of New Hampshire and a Master of Science degree in Oceanography from Dalhousie University in Canada. She joined Bridge Associates in 2017 as a Partner.

PROFESSIONAL EXPERIENCE

Novartis (based at Sandoz GmbH, Holzkirchen, Germany)

Global Head, Data Integrity Program, Sandoz and Novartis Technical Operations March 2015 – July 2017 (Retired)

- Drove implementation of a Novartis-wide data integrity excellence program at GMP manufacturing sites to strengthen systems, processes and quality culture
- Led efforts to foster change of associated human behaviors and culture relevant to ensuring data integrity
- Supported data integrity remediation activities at a site that had received a Warning Letter
- Served on the global compliance committee for management escalation of quality events with potential to impact data integrity, including reviewing investigations and challenging rigor of scope, potential impacts, root cause analysis and appropriateness of proposed CAPAs
- Consulted with site leadership, quality unit and manufacturing site SMEs and global functional heads to support their understanding, prioritization and mitigation of data integrity risks
- Coached, trained, and contributed to the development of a network of SMEs embedded at manufacturing sites world-wide to strengthen GMP data management practices

Head Compliance, Global QA BioPharmaceuticals (Sandoz Biosimilars) & Oncology Injectables - April 2011- February 2015

- Provided GMP compliance oversight to biosimilar and oncology injectable manufacturing sites engaged in development and production, including implementation of quality council governance structure for the business unit network
- Drove improvements in compliance metrics, inspection readiness and other strategic compliance activities.
- Provided global compliance oversight of a Warning Letter remediation program and successful re-inspection preparation at a strategic sterile manufacturing site
- Led FDA inspection readiness and hosting for two laboratory-focused inspections during the approval process of the first biosimilar product licensed by FDA

Self Employed Writer and Non-Profit Volunteer 2009-2011

Quality Director, Global Quality Operations, Pfizer (formerly Wyeth Pharmaceuticals) 2005-2008

- As member of site quality leadership team at a large biotech manufacturing facility, led several site quality functions including quality systems, quality IT projects, quality compliance and audit and quality operations with responsiblity for management of up to 50 associates
- Implemented and led a site Inspection Readiness PMO of 15 working teams that delivered remediation CAPAs and multiple successful health authority inspections following an FDA Warning Letter at a sterile manufacturing site

- Led QA/QC team of 35 associates and drove compliance requirements for a facility start-up and technology transfer for bulk manufacture of an oncology product. The project was completed on time (15 months) and in budget. FDA waived the PAI due to recent history of compliance excellence for the involved companies.

Quality Associate Director

Pfizer (formerly Wyeth Pharmaceuticals) 2002-2005

Directed quality project management function at a large biotechnology manufacturing facility with responsibility for operational and budget planning, personnel mentoring, coaching and development and collaboration with global quality leads

- Led cross-site teams in development of quality systems standards for investigations, CAPA and technology transfer to align with corporate requirements.
- Maintained compliance of LIMS-related systems with corporate policies and procedures.
- Member of strategic planning and project oversight committees.
- Hired and mentored quality systems management team for facility start-up in Ireland.
- Facilitated change adoption and cross-site business process alignment within the biotech division for initial phase of enterprise LIMS deployment
- Championed alignment of specific quality systems with corporate policies, built consensus and drove teams to aggressive project timelines for implementation
- Championed adoption of operational excellence concepts and tools

Quality Assurance Specialist/Genetics Institute 1997-2001

Supervised QA activities for Phase III and commercial biologics bulk manufacturing, including product lot disposition activities, computer systems validation and technology transfers from development

Responsible for:

- Review and approval of manufacturing batch records, product certificates of analysis and batch disposition decisions
- Review and approval of system life cycle documentation, and manufacturing and QC operational SOPs
- Performing laboratory audits and assessments at internal and third-party facilities in the US, Scotland and Ireland
- Meeting aggressive lot disposition timelines by valuing collaboration, excellence and relentless customer-focus
- Assumed roles of increasing responsibility within the function and site

1972 - 1997

Various SME and managerial roles in environmental consulting and quality assurance in regulated science including:

1972 - 1982: Marine Plankton Specialist, Lab Supervisor and Technical Writer with Normandeau Associates, Inc., and environmental consulting company (1972-1982)

1977 - Staff Scientist with Canadian International Development Agency (1977) on research project in Samanco Peru to establish a field laboratory for the study of larval anchovy

1982 - 1986 - Full-time family focus

1987 - 1997 - Quality Assurance Specialist/Manager/ at two CRO's engaged in GLP/ISO/GMP/and other EPA/FDA/OECD regulated activities:

- Springborn Laboratories (now Smithers Viscient; 1991 – 1997)
- Resource Analysts, Inc. (1987-1991)

EDUCATION

University of New Hampshire, Durham, NH USA
B.A., Zoology, 1972, summa cum laude
Phi Beta Kappa

Dalhousie University, Halifax, Nova Scotia, Canada
M.Sc., Oceanography, 1977

AFFILIATIONS
ISPE - International Society for Pharmaceutical Engineering - Member
ASTM - Participant in Workgroup for Revision of ASTM E 1578 Standard Guide for Laboratory Informatics
PDA - Participant in PDA Data Integrity Working Group