Geneva M. Bowman, M.S., CQA, CMQ/OE

361-676-0661 (c) – gbowman@aiha.org

Profile

Quality assurance professional with experience implementing, maintaining, and managing a quality system in various regulated industries.

Major Strengths

- Lead on external and internal audits, including international evaluations.
- Effective implementation of corrective and preventive actions.
- Experience leading and executing validation projects (test methods and equipment).
- Experience auditing in diverse regulated environments (R&D, GLP, GMP, ISO17025, diagnostic testing).
- Strong working relationship with industry quality managers and directors.
- Ability to work with senior leadership in developing corporate policy, action plans, disseminating information, and implementing plans appropriately.
- Flexible and adept at responding to change.
- Experience in managing diverse teams.

Experience

AIHA Laboratory Accreditation Programs, LLC, Falls Church, VA
Quality Systems & Technical Manager, 03/13-Present

Summary

Responsible for the overall maintenance of the quality management system for AIHA Laboratory Accreditation Programs, LLC. Monitor and ensure laboratory compliance to various accreditation requirements including ISO/IEC 17025, and the EPA-NLLAP. Technical Lead for accreditation and policy implementation inquiries. Actively involved in various industry specific committees to maintain and ensure the appropriate knowledge base to ensure the organizations program suitability.

Duties

- Develops, implements, and manages the quality management system and related documentation, including procedures and work instructions, to ensure continuous improvement, accuracy, and conformance to international standards and national/state program requirements.
- Develops and implements corrective and preventive actions.
- Oversees and conducts internal audits and management reviews
- Prepare and respond to external program evaluations conducted international bodies and government agencies, such as the Asia Pacific Laboratory Accreditation Program (APLAC), the Inter-American Laboratory Accreditation Cooperation (IAAC) and the U.S. Environmental Protection Agency (EPA.)
- Represents the organization at national and international accreditation body meetings.
- Conduct QC reviews of accreditation activities
- Monitors and collects feedback on the performance of site assessors and site assessor trainees to identify opportunities for improvement.
- Collaborate with staff to resolve complaints.
- Trains staff, volunteers and assessors in quality system requirements to enhance the overall performance of the organization.
- Identifies situations adverse to quality and reports these situations to senior leadership and provides recommended resolution plans.
- Serves as the technical contact to laboratories and conducts laboratory assessments.

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ANSI-ASQ National Accreditation Board/ACLASS, Alexandria, VA
Accreditation Manager, 8/10-3/13

Summary
Monitored and ensured laboratory compliance to various accreditation requirements including ISO/IEC 17025, ISO 17043, TNI-NEFAP, TNI-NELAP, EPA-NLLAP, Energy Star, FCC and DoD-ELAP Requirements. Involved in various industry specific committees to maintain and ensure the appropriate knowledge-base to ensure the organizations program suitability.

Duties
- Identified and developed competent assessors for various accreditation
- Developed program specific documents and training programs for various standards. Developed programs, which includes applicable Procedure(s), checklists, assessor training for:
    - TNI-NEFAP (Field Sampling)
    - 21 CFR 211
    - Food Testing (ISO17025/AOAC requirements)
- Conducted customer assessments and manage assessor issues as they arise at assessments
- Ensured all assessments are capable of being executed-Includes review of customer submitted documents for readiness of accreditation assessment
- Ensured all assessments are closed within designated time-frames.
- Managed customer inquiries and assessments on a day-to-day basis

Taconic, Rockville, MD
Senior Quality Assurance Administrator, 2/07-8/10
- Responsible for training all staff on quality systems, policies, and validation/study protocols. Executed validation plans for equipment, animal facility and sterility suite. Lead on internal/external client audits. Conducted critical phase inspections for GLP studies and final report audits for all laboratory testing. Overall responsibility for procedure reviews, quarterly audits of training records, trending of corrective and preventive actions, and ongoing site activities, such as environmental monitoring.

Taconic, Rockville, MD
Sr Specialist, Quality Assurance, 3/2006-2/2007
- Responsible for review of final reports for accuracy, performing audits of GLP studies, maintaining and scheduling service for critical laboratory equipment, performing general laboratory audits and assisting with corrective and preventive actions.

Taconic, Rockville, MD
Specialist, Quality Assurance, 12/2004-3/2006
- Responsible for review of final reports for accuracy; performing audits of GLP studies; maintaining and scheduling service for critical laboratory equipment.

Johnson & Johnson: McNeil Consumer & Specialty Pharmaceuticals, Fort Washington, PA
***Safety & Industrial Hygiene Intern/Co-op*, 9/03-06/04**
- Assisted with statistical analysis of on-site injuries & researched ways to help reduce incidents. Assisted with review of site specific standard operating procedures to comply with Johnson & Johnson worldwide operating procedures. Gained knowledge from industrial hygiene and safety professional in air monitoring, noise surveys, safety inspections and machine guarding.

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Johnson & Johnson Worldwide Safety & Industrial Hygiene, Springhouse, PA
***Hazard Evaluation Specialist*, 3/02-9/02 & 3/03- 9/03**

- Worked to create MSDS (Material Safety Data Sheets) and improved communication skills with colleagues in multiple countries. Proposed & assisted in creation of MSDS Author Training Manual which lead to implemented procedures for better work organization. Provided support & training for ~20 Authors on how to use the database.

Thomas Medical Products, Inc, Malvern, PA *Quality Assurance Intern*, 4/01-9/01

- Waste management reduction team: Researched ways to improve overall production of products. Revised and maintained Standard Operating Procedures. Improved overall knowledge of the medical products and their functions and gained clean room experience while working with products.

Technical Skills

- Microsoft Excel, Microsoft Word, Microsoft Access, Microsoft PowerPoint, Microsoft Outlook, Microsoft Publisher, Microsoft Project, LIMS, Adobe
- Familiar with quality management software such as TrackWise
- Familiar with ISO, FDA, GLP, cGMP, SOP environment
- Familiar with FDA & AAALAC inspections
- Familiar with IAAC/APLAC evaluations
- ISO/IEC 17025 Assessor

Education

California State University, Dominguez Hills, CA
Master of Science in Quality Assurance, December 2011
Concentration Area: Service and Health Care
Thesis: Ensuring Good Quality Practices in an Unregulated Environment Utilizing ISO 26000 as a Guide

Drexel University, Philadelphia, PA
Bachelor of Science in Biomedical Engineering, June 2004

Professional Affiliations

ASQ, American Society for Quality – Senior Member
ASQ-Certified Quality Auditor
ASQ-Certified Manager of Quality/Organizational Excellence