



Craig Laubacher

Senior engineer with over 11 years experience performing validation services for wide array of pharmaceutical and medical device companies. Successfully developed multiple Risk Based compliance validation programs for Fortune 500 and smaller companies. Broad background in manufacturing processes including: solid material handling, extrusion, filling, bag manufacturing, robotics, material handling, facilities, and purified water systems. Experienced in training and implementing ISO 14971 policies and risk assessments.

EXPERIENCE:

Validation Project Manager, Emergo Group - 2007 to Present

Responsible for providing or leading consulting services in the areas of process validation, software validation, validation of test methods, design validation, technology transfer, training and general consulting. Expert resource for equipment and computer system validation requirements.

Validation Services Manager, Deaton Engineering, Inc. - 1999 to 2007

Senior manager of validation services for clients in the pharmaceutical and medical device industries. Responsible for supporting validation programs by leading the development of Validation Master Plans, Standard Operating Procedures, Risk Assessments, Functional Specifications, Design Specifications, Installation, Operational, and Performance Qualifications, Part 11 Compliance and Summary Reports. Led the successful execution of numerous Part 11 gap assessments and compliance projects. Led or executed validations for chemical processing, material handling, facility systems, computer systems including automated process control systems, equipment assembly, barrier isolation systems and purified water systems. Developed complete validation programs for small to medium sized businesses. Provided quality system procedures, Master Validation Plans, training and internal review boards to manage the program. Provided these clients with on-going validation services and consulting. Responsible for reviewing and quoting validation projects and ensuring customer satisfaction with company services. Conducted multiple training courses on validation compliance.

Environmental Engineer, Environmental Compliance & Engineering, Inc. - 1998 to 1999

Performed environmental audits at industrial facilities including food and beverage, tank car manufacturing, chemical manufacturing, distribution and material handling, as well as other major manufacturing locations. Led projects including air emission inventories and permitting, SARA 313 threshold calculations and Form R reports, Tier II report preparation, hazardous waste management, Storm Water Plan preparation, and Spill Prevention Control and Countermeasure Plan preparation. Conducted Phase I site assessments of several industrial and commercial properties.



Craig Laubacher, continued...

TRAINING:

- Conferences / workshops in validation, Part 11 compliance and pharmaceutical good manufacturing practices.

EDUCATION:

- Bachelor of Science, Electrical Engineering, Baylor University, Waco, TX
- Masters of Business Administration, Baylor University, Austin, TX