

Independent **Audits** & **Assessments**

Internal Quality Systems Audits

Agile Software Process Assessments

Regulatory Risk Evaluations

Software Validation Audits

Design Control Audits

Internal Quality System Audits

Consultant Certification Audits

Consent Decree Required Audits

Vendor Qualification Audits

OEM Due Diligence

Software Process Assessments

Part 11 Gap Analysis

Computer System Audits

...Turn for details



Independent Audits and Assessments

- **Using industry and FDA recognized experts**
- **Risk-based approach**
- **Audit and best practice assessments**

We will work with you to plan the type of audit or assessment that will fit your needs and budget. Our audits help improve your staff's ability to articulate and defend existing approaches and documentation as well as identify issues and areas to consider for improvement. Our clients range from large corporations to small start-ups.

Our approach is risk-based, focusing on areas of regulatory and product safety risk. Our assessors avoid nitpicking and are flexible in terms of acceptable approaches.

Our reports are designed to clearly distinguish objective findings from subjective concerns and recommendations. Objective evidence of effectiveness of procedures is a key factor in determining their adequacy, rather than using a "one size fits all" criteria. Executive summaries differentiate findings of different significance and communicate overall status and regulatory risk.

Our staff has years of experience including certified auditors and instructors for public training courses on Quality Systems, Design Control and Software Validation with FDA co-instructors. Our staff has been involved in routine internal auditing as well as in response to significant FDA enforcement actions and some have come from FDA. Our staff has performed internal training at FDA and Health Canada and has authored related standards.

Quality System and Regulatory – assessments of premarket submission change history, new submissions, and quality systems for compliance and adequacy.

Inspection preparation – Gap analysis and staff training to prepare for FDA inspections including short-term strategies to reduce risk in inspections.

Standards conformance – assessments for conformance to **IEC 62304** and other software related standards (e.g., IEC 60601-1 PEMS, ISO 14971, and IEC 80001-1, 80002-1) by some of the authors of these standards. These focus on the intent of the standards and allow for the flexibility of approaches inherent in each.

Vendor, OEM, M&A – Assessments of outside companies for vendor capabilities and compliance and due diligence to identify gaps and regulatory risks in acquisitions or OEM arrangements.

Design Control and Software Validation – assessments to identify compliance issues as well as opportunities for process improvement. These assessments range from in depth on-site best practice assessments to off-site document reviews.

Computer System Validation and Part 11—audits of computer systems used in production or the quality system for Medical Devices and Pharmaceuticals.

Agile process Gap Assessment - focused on areas that tend to be "tricky" spots with Agile. We help identify the gaps, but we also help our clients comply **in a manner best suited** to the process they want to use. So our assessment is oriented to ... "here's the gap" and "here's a suggestion for closing that gap in an agile way." We believe this capability is our distinction ... many consultants can identify gaps, and most can suggest an approach to fix it ... but most of the time that suggestion will look like a boiler-plate and be waterfall-oriented. We embrace agile methods and believe they can be more effective, when implemented properly, at achieving true compliance.