

Independent Audits & Assessments

IEC 62304 Conformity Assessments

Software Validation Audits

FDA Design Control Audits

Internal Quality Systems Audits

Regulatory Risk Evaluations

Consultant Certification Audits

Consent Decree Required Audits

Vendor Qualification Audits

OEM Due Diligence

Software Process Assessments

Part 11 Gap Analysis

Computer System Audit Training

...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 in identifying issues and areas to consider for improvement. Our clients range from large corporations to small start-up companies.

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 recommendation. 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.

Standards conformance – assessments for conformance to **IEC 62304** and other software related standards (e.g., IEC 60601-1 PEMS, ISO 14971 and upcoming IEC 80001 and 80002) and guidances 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 of these standards..

Routine internal audits – These audits can satisfy the 21 CFR 820.22 requirement for internal audits and focus on conformance to internal procedures and adequacy for compliance with 21 CFR 820, 803, 806, and Part 11.

Inspection preparation – Gap analysis and staff training in preparation for FDA inspections. Includes development of short-term strategies to reduce risk in upcoming inspections.

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

Computer System Validation and Part 11– we can perform audits or assessments of computer systems used in production or the quality system for Medical Devices, Pharmaceuticals and Blood Banking.