

Development, Implementation, Validation & Auditing of Systems and Processes

ADB Consulting assists with all portions of the life cycle of regulated systems from pre-development, through to implementation,



ADB Consulting "Team Player": Taking the ball and running for you!

validation and auditing. ADB Consulting offers services for various systems and solutions: R&D, Manufacturing, Quality, Data Management, and Biostatistics.

Throughout the administration of our services, our remains maintaining compliance including but not limited to ICH and FDA regulations: GLPs, GMPs, QSRs, and 21 CFR Part 11. ADB Consulting manages or participates in the servicing of projects involving systems and processes, software and computer hardware, test equipment and manufacturing equipment.

Systems

ADB Consulting manages or supports the development, implementation, validation, and auditing of systems with simple to complex requirements and systems with possible composites of manual processes, software, computer hardware, and test equipment.

Processes

ADB Consulting understands the importance of process designs and validation to improve reliability and repeatability. In achieving our goals, we focus on developing and improving documentation that captures processing methods. In addition and equally important, we focus on the development and improvement of a quality assurance program that ensures accurate knowledge transfers maintaining consistency and validity.

Software

ADB Consulting's services extends to custom built, and commercial off the shelf (COTS) software being used in a regulated environment. ADB Consulting utilizes the most widely accepted methods of the developing, implementing validating and auditing the life of a software from conception to retirement. One of our main goals is achieving compliance in regards to 21 CFR part 11 and associated software regulations.

Test Equipment

Test equipment, whether used in Research and Development or Manufacturing requires as much scrutiny and care from development through use to retirement. Our system and biomedical engineers have the knowledge and experience to assess develop, implement, validate and or audit test systems.

Validation And Auditing

Equipment, Software, and Process validation/auditing are very important when aiming to

produce products and systems that are at less risk for potential hazard and compliance with regulatory requirements. Process validation is a requirement of the Current Good Manufacturing Practices Regulations for Finished Pharmaceuticals, 21 CFR Parts 210 and 211, and of the Good Manufacturing Practice Regulations for Medical Devices, 21 CFR Part 820, and therefore, is applicable to the manufacture of pharmaceuticals and medical devices.

Discounts

ADB Consulting offers discounts on our already low rates for clients that utilizes one or more of our other services.

Other ADB Consulting Services

ADB Consulting provides both Project Management and Project Resources for out-sourced projects and in-services. Some of the most popular services offered are:

- ◆ Clinical Study Setup & Management
- ◆ Data Management
- ◆ Biostatistics, Data Analysis & Reporting
- ◆ Staffing
- ◆ ++++ MORE

ADB Consulting & CRO Inc.

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ADB Consulting, giving the support
you need, when you need it!



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*Serving the Bio-Medical
Research Community
with Pride*

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