AQS
AUTOMATION QUALITY SOLUTIONS LTD



AQS is your Compliance and Validation Partner

Each phase of life science companies' product life cycle has associated regulations governing technology that must be clearly interpreted.

AQS leverages the knowledge of our experienced U.S. managed and trained compliance professionals to help our clients obtain U.S. FDA and European EMEA, GLP, cGMP and GCP regulatory compliance, to market their products internationally, attract international customers or investors; while reducing operational costs. Our services incorporate knowledge of industry coupled with strong project management to deliver regulatory compliance solutions to life science companies, from R&D to manufacturing.

Founded by life science professionals, AQS is based in Shanghai China and serves the East Asia biopharmaceutical markets.

The Challenge of Compliance and Validation

U.S. and European life science regulatory bodies have instituted regulations, collectively known as the GxPs (Good x Practices), which have been enacted to govern the development, testing, and manufacturing of drugs, medical devices, and biologics. Life sciences companies must comply with these regulations if they are involved with any of the aforementioned activities.

The GxPs are broken down into:

- Good Laboratory Practices (GLPs): Regulations that apply to the non-clinical studies in the evaluation of a new drug, medical device, or biologic product.
- Good Clinical Practices (GCPs): Regulations that apply to the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials.
- Good Manufacturing Practices (cGMPs): Regulations that apply to the manufacture, testing, and distribution of a new drug, medical device, or biologic for human or veterinary use.

To establish documented evidence that a system meets these standards, and that it will continue to do so over time, requires systems validation. In Addition, there are the U.S. FDA 21 CFR Part 11 and European Annex 11 procedures for technical requirements for systems utilizing electronic records and signatures.

How AQS Can Help

AQS provides skilled resources to assist companies in understanding and interpreting key regulatory concepts in order to make informed decisions in areas such as electronic record keeping, personnel qualifications, training, and validation. Through the use of risk management principles, AQS provides companies with valuable strategies that can be used in all areas of GxP compliance associated with the manufacturing, tracking and distribution of regulated products.

Our flexible delivery method adapts from an entire project to providing expertise and guidance at any phase of the process, from strategy development to data migration and system retirement.

For companies that plan to market their products in the U.S., we provide services for the FDA's Abbreviated New Drug Application (ANDA).

At AQS, we understand it is knowledge which will empower your organization to maintain a validated environment and create a defensible case for the U.S. FDA and European EMEA.

AQS Services

- *Quality Assurance*
- *Computer System Validation*
- *Gap Analysis*
- *cGMP, GLP, GCP, 21 CFR Part 11 assessments*
- *Risk Assessments*
- *Software Remediation*
- *SOPs*
- *Requirements (User / Functional / System)*
- *Design Specifications*
- *Traceability Matrix*
- *Validation Plan*
- *Quality Plan*
- *IQ/ OQ / PQ*
- *Test Plans and Test Protocols*
- *Validation Report*
- *Consultation with FDA on behalf of your firm*
- *Abbreviated New Drug Application (ANDA)*
- *cGMP, GLP, GCP Training*
- *Project Management*

For regulatory compliance of medical devices, pharmaceutical facilities, laboratory instruments, manufacturing automated equipment, LIMS, Documentation Management Systems and others.

Program and Project Management

A major challenge faced by the life science industry is to accelerate and simplify the movement of potential products through multiple stages of discovery, research, development and clinical trials, while adhering to regulatory compliance requirements.

To meet this challenge, companies must put in place enterprise-wide compliance programs and implement and/or upgrade large-scale systems. These programs often cross many company divisions, groups, departments and sites. To successfully deliver these projects or programs on time and within budget requires experienced project and program management. AQS has certified professional project managers (PMP) available to help ensure successful projects.

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