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Global QA Services

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ADAMAS is one of the largest Quality Assurance consultancy organizations in the world and over 20 years has established a reputation for consistently delivering gold standard services to the healthcare industry across the globe.

ADAMAS's core capabilities and expertise are in the provision of expert, independent Quality Assurance (QA) and Quality Management System (QMS) auditing and consulting, worldwide. Our services include all aspects of:

- **Good Clinical Practice (GCP)**
- **Good Pharmacovigilance Practice (GVP)**
- **Computer Systems Compliance (CSC)**
- **Good Laboratory Practice (GLP)**
- **Good Manufacturing Practice (GMP)**
- **Quality Management System (QMS) Consulting**
- **Standard Operating Procedure (SOP) Development**
- **Due Diligence**

By understanding our clients' needs, ADAMAS provides cost-effective, quality and compliance enhancing services.

ADAMAS uses a proven QMS based on established processes, tools, and templates developed using 20 years of know-how and experience. This enables ADAMAS to assist clients in effectively and efficiently determining their compliance readiness, enabling them to meet industry requirements.

VISION | MISSION | VALUES

Working In Over 100 Countries With Over 750 Global Clients

Global Expertise

ADAMAS has conducted projects in over 100 countries worldwide and has assisted over 750 clients globally, ranging from top ten pharmaceutical companies to one product start-ups. With a diverse set of QA capabilities, ADAMAS can leverage the resources to manage the largest and most complex global QA projects, but at the same time retain the agility to manage the smallest and most unique of projects. ADAMAS consultants are great to work with, highly experienced and knowledgeable and understand how to ensure our clients achieve their quality goals.

ADAMAS staff are employed on permanent contracts, enabling us to ensure that they are trained to the same consistently high standards on all processes, SOPs and systems (whether ADAMAS or client-based). All deliverables undergo a two-tier quality peer review internally prior to release. This means at ADAMAS our clients only receive the highest consistency and quality of deliverables.

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Computer Systems Compliance Practice (CSC)

Computerized systems and new IT-driven clinical applications are now an everyday part of the R&D process. If these systems aren't managed appropriately, they can represent significant regulatory risk to critical data, the integrity of essential documents, and the security of your network and applications.

ADAMAS's CSC experts can work with you to ensure that your organization and vendors have a robust System Development Life Cycle (SDLC) in place, or to design and implement an entire SDLC for your organization. We can help you make sure that the range of validation audits your organization performs adds value, satisfy regulatory expectations and identify the issues that matter. We can do this by conducting audits on your behalf, both internally and/or at your vendors' facilities.

Reflecting recent increases in the sophistication and prevalence of networks and applications, it's now a common regulatory expectation that organizations also have a comprehensive program of CSC process audits, in addition to validation audits.

ADAMAS can advise on and perform the full range of CSC and IT process audits—including IT-security and computer system validation audits and 21CFR11 compliance checks—to ensure all aspects of regulated computer system risk have been explored, understood and remediated where necessary. We are experienced in working with emerging technologies such as clinical informatics, blockchain and wearable medical technology.

Our range of CSC services includes:

- **Computer system compliance auditing**
  - System-specific computer system validation audits
  - Data centers
  - Backup and data recovery
  - Business continuity and disaster recovery
  - IT security
- **Computerized System Development Life Cycle (SDLC) process audits**
- **All aspects of system & application development processes, including planning, IQ/OQ/PQ, implementation and change control**
- **Computer System Compliance (CSC) consulting**
- **21 CFR 11 compliance gap analysis**
- **Issue management and remediation**

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Good Manufacturing Practice (GMP)

Assessing your systems

ADAMAS's Good Manufacturing Practice (GMP) experts can work with you to ensure your organization and vendors have a robust system in place to meet your manufacturing needs. We can also determine areas for improvement, or potential compliance risks, in your current systems. We assess a wide range of these—most notably those used in quality, production, packaging and labelling, materials, laboratories, and equipment and facilities. We're able to conduct audits on your behalf, both internally and at your vendors' facilities, so you can focus on what really matters: distributing the best possible products.

Preparing you for inspection

Our GMP expertise means we're perfectly placed to prepare you for inspections. Offering a wealth of services, we can train employees on inspection interview techniques, conduct GAP analysis on your quality systems or facilities, facilitate full mock inspections and more.

Supporting your processes

ADAMAS can partner with your organization to develop or enhance internal process. Through support services such as SOP development, training and facility walkthroughs, our team can strengthen the compliance of your systems. GAP assessment and risk assessments can be conducted to drive process improvements throughout the company, too.

Our range of GMP services includes:

- **GMP compliance auditing**
  - Drug Product (DP) - sterile and non-sterile
  - Combination Products Medical Device
  - Drug Substance (DS) and API
  - Laboratory
  - Cell-bank manufacture
  - Excipients
  - Packaging and labelling
  - Warehousing storage and distribution
  - Printed packaging components
  - Components and consumables
  - Service providers
- **GMP Training**
- **SOP—Development, revision, and evolution**
- **Inspection interview training**
- **GAP analysis**
- **Facility assessments**
- **Facility walkthroughs**

Good Distribution Practice (GDP)

It's critical that your pharmaceutical, biotechnology or medical-device organization provides your customers with a compliant product. At ADAMAS, we offer Good Distribution Practice (GDP) to evaluate the compliance of the final phase in the process of distributing products globally. Our thorough audits include the evaluation of temperature conditions, traceability checks, and an assessment of the distribution chain. We can conduct these audits internally, or at your vendors' facilities.

Our range of GDP services includes:

- **GDP compliance auditing**
  - Cold chain
  - Control substance distribution
  - Serialization
  - Named-patient distribution

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Good Pharmacovigilance Practice (GVP)

At ADAMAS we place significant emphasis on adding value to the GVP service we provide to our clients. In response to industry trends and our clients' needs we are continuously developing our service offerings to ensure we remain at the leading edge of GVP consultancy services worldwide. We believe that from concept to delivery, ADAMAS is uniquely placed to ensure our clients' GVP compliance activities are at the forefront of industry best practice.

In addition to our standard full system GVP auditing services, ADAMAS is in a unique position to offer its clients a tailored GVP auditing service covering one or more areas. This represents an opportunity for our clients to focus their compliance activities where they are most needed. With significant industry, inspection and auditing experience in each of these areas, the ADAMAS GVP in-house team has been strategically developed to ensure our clients receive the highest level of expertise both at the GVP systems and process audit level.

Our range of GVP services include:

- **Reference Safety Information**
- **Signal Detection**
- **Audit Strategy & Planning**
- **MAH Oversight**
- **Non-Interventional Programmes**
- **Pharmacovigilance System Master File (PSMF)**
- **Aggregate Reporting**
- **ICSR Case Processing**
- **CAPA Management**
- **Risk Management Planning**
- **Third Party Service Providers/ Commercial Partners**
- **Risk Evaluation and Mitigation Strategy (REMS)**

ADAMAS INSIGHTS

Introducing ADAMAS Insights

ADAMAS has expanded its services to provide a comprehensive view of data collected from all GxP audits allowing our clients to benchmark the quality of their compliance against anonymized competitors, thus allowing them to improve the strategic focus of their QA activities.

Provision of the ADAMAS audit metrics and benchmarking data to our clients, is just one example of the ADAMAS ethos for informing our clients' decisions, allowing them to achieve the best outcomes when considering their quality assurance strategy.

> Make the right decisions. Driven by data, based on actionable insights.

Visit **www.adamasconsulting.com/insights**

More Data, Less Risk

Exclusively access data from more than 1,500 real-world recent GxP audits, visualized and organized intuitively. You will be able to instantly see data quality trends, identify the strengths and weaknesses of your systems and processes, and take action – reducing risk and safeguarding your organization.

The Power to Shape Your Success

Discover how ADAMAS Insights can make your organization better.

Identify Trends

See how data quality varies and aligns across regions, countries, protocols and audited areas

Reduce Risk

Identify potential risks and put strategies in place to reduce or eliminate them

Benchmark Data

Learn how your data compares to that of over 750 other companies in more than 100 countries

Gain Focus

Pinpoint and address the most pressing potential issues in your organization, allocating time and resource effectively and efficiently

Unlock Success

Achieve your goals with complete peace of mind by putting meaningful risk-mitigation strategies in place

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Good Clinical Practice (GCP)

Our highly experienced, trained and competent team of specialist GCP auditors has conducted thousands of audits in all therapeutic areas, according to international and national regulations, in over 100 countries. Continual positive client feedback is evidence of our professionalism and competency.

The conduct of GCP quality audits is becoming an increasingly challenging process, owing to the complexity of clinical trials and the location of investigator sites. Although the majority of sponsor organizations reside in Europe, the USA and Japan, their clinical trial sites are often located in Asia, Africa, South America, the Middle East and Far East. Not only are auditors challenged with physically reaching the investigator sites, but they also have to deal with the diverse cultures they encounter. ADAMAS has a global reach with staff based across four continents. Not only does this help with language and cultural barriers, but also the travel time and cost for the conduct of these audits.

> "It's surely been a pleasure meeting you. Thanks for conducting the audit with such a professional and competent attitude. Although demanding and to a certain extent even tough, once again my opinion on the audit concept can be nothing but positive and inevitably an educational opportunity."
>
> **N.M. Project Manager, Global Pharma Company**

Our range of GCP services Include:

- **Investigator Site Audits**
  - Routine Investigator Site Audits (Phase I to IV)
  - Targeted Investigator Site Audits (Phases I to IV)
  - For Cause Investigator Site Audits (Phases I to IV)
- **System Audits**
  - System Audits of Sponsor/CRO/ Phase I/BA/BE/ARO Operations
- **Mock Inspections**
  - Inspection Preparation and Training (Investigator Site/Sponsor/CRO)
  - Mock Inspections
  - Inspection Facilitation
- **Data Management**
  - Database Audits
  - Data Management System Audits
- **Trial Master File (TMF)**
  - TMF Audits (paper and electronic)
- **Document Audits**
  - Protocol Audits (all Phases)
  - Case Report Forms
  - Informed Consent Forms
  - Investigator Brochures
  - Clinical Study Reports
  - Development Safety Update Reports
- **Vendor Audits**
  - Monitoring and Project Management
  - Data Management, Biostatistics and Medical Writing
  - Clinical Trial Supply
  - Interactive Response Technology
  - Translation Services
  - Archive Facility
  - Centralized ECG/Imaging Facilities
- **Consultancy Services**
  - SOP Development
  - QMS Evaluation
  - Regulatory Intelligence

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Good Laboratory Practice (GLP)

Our GLP team has the experience and capability to conduct audits of all types including: facilities; process data; study specific data and reports against GLP requirements. We audit central laboratories and bio-analytical laboratories for routine and specialized analysis against both GLP and GCP regulations.

GLP Services

Non-clinical laboratory audits of animal or non-animal facilities:

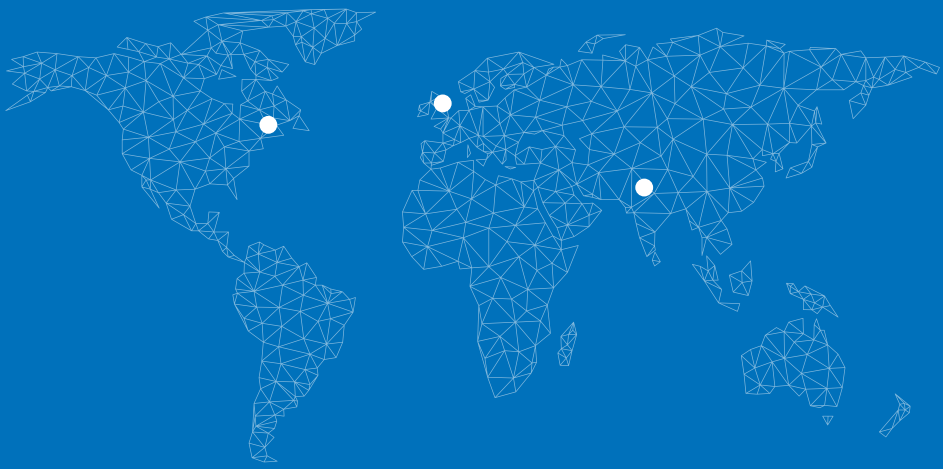
- **Facility audits**
- **Study audits**
- **Critical or in-process phase inspections**
- **Protocol audits**
- **Data audits**
- **Report audits**
- **Procedure/process audits**
- **Bioanalytical laboratory audits**
- **Mock inspections**
- **Document reviews**
- **Archive audits**
- **Qualification or requalification audits**
- **Subcontractor and Vendor Inspections**
- **GLP gap analysis**

GcLP Services

Audits of clinical and bioanalytical laboratories that process human samples for safety parameters, biomarkers, other specialty analysis, bioequivalence etc.

- **Facility audits**
- **Study audits**
- **Protocol audits**
- **Data audits**
- **Procedure/process audits**
- **Report audits**
- **Mock inspections**
- **Document reviews**
- **Archive audits**
- **Qualification or requalification audits**
- **Subcontractor and Vendor Inspections**
- **GcLP gap analysis**
- **Training of clinical staff in the requirements of GLP and GCP (GcLP)**

Americas | EMEA | APAC



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