ADAMAS

COLLABORATION. CONFIDENCE. ASSURANCE.

LEADING THE WAY IN GLOBAL CLINICAL QUALITY ASSURANCE FOR OVER 25 YEARS

ADAMAS is one of the largest Quality Assurance consultancy organizations in the world and over two decades it 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 CLINICAL LABORATORY PRACTICE (GCLP)**
- **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 25+ 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, at the same time retaining 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.

All ADAMAS staff are trained to the same high standards on all processes, SOPs and systems with all deliverables undergoing peer review, prior to release. This means that all our clients receive the highest consistency and quality of deliverable.

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ADAMAS REMOTE SERVICE OFFERINGS

Is it possible to monitor compliance, maintain oversight and manage risk remotely? At ADAMAS, we have the solutions to these questions. During uncertain times, we can offer a measure of reassurance.

ADAMAS REMOTE SERVICE OFFERINGS CAN HELP YOU

- **MONITOR COMPLIANCE**
- **MAINTAIN OVERSIGHT**
- **MANAGE RISK**

ADAMAS is ideally placed to assist in this regard via our remote service offerings, not only affording our clients an opportunity to maintain compliance, but also providing peace of mind that while we navigate these challenging times, compliance oversight activities can continue.

WATCH VIDEO AT **WWW.ADAMASCONSULTING.COM/REMOTE-AUDITING-VIDEO**

REMOTE AUDITING
THE ADAMAS APPROACH

At ADAMAS we are committed to supporting our clients and providing the best possible solutions which can be individually tailored. Thanks to many common place technologies, conducting remote audits has become more effective, and offers a viable alternative for maintaining compliance oversight where security, travel or other factors may impose restrictions upon traditional in-person and on-site audits.

For a remote audit to be successful, planning is key. Here at ADAMAS, we implement the neccessary methodology to mitigate any potential challenges and ensure the audit is successful. ADAMAS understand that while we are familiar and experienced in this offering, remote audits may be unfamiliar to some. Over the recent years our Consultants have gained wide experience with their conduct and successful delivery. We are adaptable and flexible, drawing on our extensive experience and knowledge to support you.

MITIGATION AND MANAGEMENT

Regulators have set a clear expectation that compliance and Sponsor oversight are maintained at all times, even if it is not possible to conduct compliance activities on-site as would be normal practice. ADAMAS remote service offerings provide solutions and assurance with credible alternatives.

LISTEN TO PODCAST AT **WWW.ADAMASCONSULTING.COM/PODCASTS**

SERVICE OFFERINGS

Discover how ADAMAS can provide you with remote compliance solutions.

QUALITY INVESTIGATOR SITE ASSESSMENT
QISAs allow the evaluation of key aspects covered during an ISA

VENDOR ASSESSMENTS
Due diligence on behalf of a client in the process of acquiring a new vendor

MOCK INSPECTIONS
Mock GCP and Pharmacovigilance Inspections conducted remotely to specification

SOP DEVELOPMENT
GxP SOP Gap Analysis. New and revised SOP creation and review

QMS CONSULTANCY
Assess the effectiveness of your quality management system

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ADAMAS QUALITY INVESTIGATOR SITE ASSESSMENT (QISA)

The COVID-19 pandemic and its effects on individuals, the health system and nations warranted an alternative approach to how we maintain oversight and compliance during times of uncertainty. Unrestricted travel and future access to clinical sites for monitoring and audit purposes can no longer be guaranteed. ADAMAS have implemented a Quality Investigator Site Assessment (QISA) to ensure our clients can maintain compliance during these times and beyond.

VIEW OUR QISA BROCHURE AT **WWW.ADAMASCONSULTING.COM/QISA/BROCHURE**

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 the 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
- **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

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 global regulatory requirements, 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 on a global level. 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 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:

PV SYSTEM AND PROCESS AUDITS
Pre- and Post-marketing audits at Global HQ and Affiliate level

- Pharmacovigilance System Master File (PSMF)
- Qualified Person for Pharmacovigilance (QPPV)/Local Responsible Person (LRP)
- Global Safety Database
- Case Management (SUSAR/ICSR)
- Aggregate Reporting (PSUR/DSUR)
- Risk Management
- Signal Management
- Medical Coding
- Product Labelling
- Regulatory Intelligence
- Post-authorisation Safety Studies (PASS)
- Patient Support Programs/Non-interventional Programs (NIP)
- Quality Management System (QMS)
- Vendor Management and MAH Oversight
- Audit Strategy Planning and Management

THIRD PARTY AUDITS
Qualification, routine, and for-cause audits

- Commercial Partners
  - Licence Partners
  - Marketing Partners
  - Distributors
- Service Providers and other vendors (global and local)
  - Pharmacovigilance
  - Medical Information
  - Call Centres
  - Market Research Programs (MRP)
  - Patient Support Programs (PSP)
  - Pregnancy Prevention Programs (PPP)
  - Compassionate Use Programs (CUP)
  - US Risk Evaluation Mitigation Strategies (REMS)
  - US Speciality Pharmacy & Infusion Sites
- Consultancy
  - Risk-based Audit Planning (strategic, tactical, operational)
  - Audit Program Management
  - Inspection Readiness Training
  - Mock Inspection
  - Gap Analysis
  - QMS Development
  - CAPA/EC Management

GOOD MANUFACTURING PRACTICE (GMP)

ASSESSING YOUR SYSTEMS

ADAMAS's Good Manufacturing Practice (GMP) experts can work to evaluate systems at your pharmaceutical, biotechnology, medical device organization or at your vendor sites to determine if the systems in place are sufficient to meet your manufacturing needs and the current regulatory standards. As an extension of your GMP Auditing team, we're able to conduct audits on your behalf, using your established audit program or the ADAMAS process, whichever works best for your needs. Our GMP experts have experience auditing systems against applicable regulatory and industry standards. Our experts work with you to apply the correct standards based on your needs, the activities or services provided, and the stage of your project. During our evaluations, we can identify areas for improvement or potential compliance risks. We assess a wide range of systems—most notably those used in quality, production, packaging and labeling, materials, laboratories, distribution, and equipment and facilities.

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 systems, processes, or facilities, and facilitate full mock inspections and more.

SUPPORTING YOUR PROCESSES

ADAMAS can partner with your organization to conduct facility walkthroughs to support process improvements throughout the company. Through support services such as inspection training, gap analysis, or risk assessments, our team can strengthen the compliance of your systems.

OUR RANGE OF GMP SERVICES INCLUDE:

- **GMP COMPLIANCE AUDITING**
  - Drug Product (DP) - sterile and non-sterile
  - Drug Product—Sterile Fill/Finish (i.e. Lyophilized, Liquids (i.e. Vials, Cartridges, Pre-filled Syringes, Ampules))
  - Drug Product—Non-sterile Fill/ Finish (i.e. Tablets, Capsules, Creams, Ointments, Oral)
  - Combination Products
  - Medical Device
  - Drug Substance/Active Pharmaceutical Ingredient
  - Laboratory (Analytical and Microbial)
  - Cell-Bank Manufacture and Storage
  - Excipients
  - Packaging and Labeling
  - Warehouse, Storage and Distribution
  - Printed Packaging Components (i.e. Labels, Cartons, Inserts)
  - Components and Consumables (i.e. Bags, Vials, Filters, Stoppers)
  - Sterilization (i.e. Gamma Irradiation, E-Beam, VHP)
  - Batch Disposition (Qualified Person (QP), Exploitant)
  - Service providers
- **GMP TRAINING/INSPECTION INTERVIEW TRAINING**
  - Greeting and reception, answering questions, avoiding opinion and conjecture, preparation of documents and personnel prior to entering the inspection room
- **GAP ANALYSIS**
  - Interconnection of Quality Systems and compliance with regulatory filings
- **FACILITY ASSESSMENTS**
  - Utilities, equipment, instrumentation, calibration, preventive maintenance, and on-going monitoring of critical systems
- **FACILITY WALKTHROUGHS**
  - Upkeep, clean and use logs, calibration tags, resolution of observed issues

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 a 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 add 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 (CSC) 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**

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)

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**

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MORE DATA, LESS RISK

Exclusively access data from more than 1,500 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

VISIT **WWW.ADAMASCONSULTING.COM/INSIGHTS**

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CONTACT DETAILS

Contact us to see how we could help you and to discuss your individual requirements.

Europe, Middle East & Africa
ADAMAS Consulting Ltd
Building B, Watchmoor Park
Riverside Way, Camberley
Surrey, GU15 3YL
United Kingdom

Contact
Robert Barnes
Business Development Director, EMEA
Carly Davenport
Business Development Director
Tel: +44 (0)1344 751 210
info@adamasconsulting.com

Asia & Pacific
ADAMAS Clinical Quality Consulting Pvt
White Hall
Mezzanine Floor 'B'
143 August Kranti Marg
Mumbai 400036, India

Contact
Shehnaz Vakharia
Vice President, APAC
Tel: +91 (22) 68841501
info@adamasconsulting.com

USA & Canada, Central & South America
ADAMAS Consulting LLC
300 Brickstone Square
Suite 201
Andover, MA 01810
United States of America

ADAMAS Consulting LLC
501 W. Broadway
Suite 800,
San Diego, CA 92101
United States of America

Contact
Katherine Kovac
Business Development Manager, Americas
Tel: +1-619-446-6992
info@adamasconsulting.com

FOLLOW US ON:

@AdamasCQA

/company/adamas-consulting

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