

ADAMAS

clarity · integrity · excellence

Global QA Services

- GCP - GVP - GLP - GMP Audits
- Computer System Compliance
- Mock Inspections
- SOP Development
- Benchmarking and Risk Management
- QMS Consultancy
- Due Diligence
- Gap Analysis
- Training



ADAMAS is one of the largest Quality Assurance consultancy organisations 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 to one product start-up companies. 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 retains the agility to manage the smallest and most unique of projects. ADAMAS's consultants are great to work with, highly experienced and knowledgeable and know 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.

Good Pharmacovigilance Practice (GVP)

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 of the below 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.

- 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)

“I would also like to say again how valuable the Pharmacovigilance mock inspection was for all who participated. The auditor was a formidable inspector and really allowed many individuals naive to the EU inspection process to experience what it could be like. The auditor was both comprehensive but gracious with the feedback on the individual sessions allowing folks to understand the good and not so good with individual performances. Finally, the close out session together with the many offline discussions helped with our overall understanding of where we are with inspection readiness.”

D.H., Vice President, US R&D, Pharma Company 10-Mar-17

Computer Systems Compliance Practice (CSC)

Computerised systems and new Information Technology (IT) driven clinical applications are now an everyday part of the Clinical Trial process and, if not managed appropriately, can represent significant regulatory risk to critical data points, the integrity of Essential Documents and the security of your network and applications.

ADAMAS's Computer System Compliance (CSC) experts can help by working with you to ensure your organisation and vendors have a robust System Development Life Cycle (SDLC) in place, or design and implement an entire SDLC for your organisation. We can assist in ensuring that the range of validation audits your organisation performs adds value and help identify the issues that matter. ADAMAS can conduct these audits on your behalf, both internally and at your vendors' facilities.

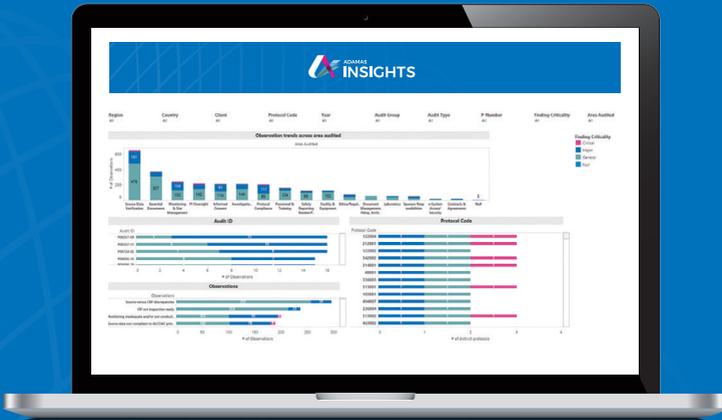
Reflecting the increases in sophistication (and prevalence) of networks and applications, it is now a common regulatory expectation that organisations also have a comprehensive programme of CSC process audits in addition to validation audits. ADAMAS can advise on and/or perform the full range of CSC and IT process audits, including IT Security Audits and 21CFR11 compliance, to ensure all aspects of CSC have been explored, understood and remediated where necessary.

- **Computer System Compliance Auditing**
- **Computerised System Development Life Cycle (SDLC) Process Audits**
 - System-specific Computer System Validation Audits
 - Datacenters
 - Back up and Data Recovery
 - Business Continuity & Disaster Recovery
 - IT Security
- **Computer System Compliance Consulting**
- **Computer System Compliance Analysis**

Introducing ADAMAS Insights

ADAMAS has expanded our services to provide a comprehensive view of data collected from all GxP audits allowing our clients to benchmark the quality of their compliance against anonymised 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, visualised and organised 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 organisation.

The Power to Shape Your Success

Discover how ADAMAS Insights can make your organisation better.



Identify Trends

See how data quality varies and aligns across regions, countries, clients, 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 organisation, 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

Americas

EMEA

APAC



Contact Details

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

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