clarity

compliance solutions

Your compliance partner

single source · cost-effective · pragmatic solutions

Your compliance partner

single source · cost-effective · pragmatic solutions

Clarity Compliance Solutions is a leading international regulatory compliance consultancy operating throughout the regulated industries.

We provide full life cycle consultancy for computerised systems and key compliance areas to ensure our clients have the required knowledge and skills to meet with regulatory expectations.

Providing our clients with:

- Clarity for Business Intelligence
- Compliance for Regulatory Excellence
- Solutions for Commercial Confidence

Strategic Governance & Consulting

Our team of highly skilled consultants and associates are carefully sourced from a variety of backgrounds within the regulated industries.

We can support and guide you through:

- Regulatory Change

  providing updates on the ever changing regulations.

- Validation Strategy

  assessing, reviewing and advising on your overall strategic approach to validation.

- Validation Master Planning

  support or drive the planning for new projects.

- Risk Assessment

  drive or support your risk assessment processes.

We utilise our teams practical knowledge and experience of day to day operational problem solving and best practice to deliver highly efficient tailored solutions.

STEP 1

➤ Review

Understand the current business position against known requirements or specific observations to analyse gaps, associated risks and identify opportunities to improve.

STEP 2

➤ Advise

Identify the root causes of the non-compliance to ensure the fundamental problem is addressed in a sustainable manner that fits the business capability and operation climate.

STEP 3

➤ Deliver

Our pragmatic remediation process uses industry proven risk based approaches to identify and mitigate business and regulatory risk. This approach supplies pragmatic remediation options that deliver results.

From issue to resolution to peace of mind. We provide market leading knowledge and skills to manage compliance issues efficiently and cost effectively, giving confidence for regulatory inspection.

Validation Services

Validation of computer systems is an ongoing challenge and many businesses lack the knowledge, skills and resources to meet the demands that computer systems validation poses.

Clarity provide scalable and pragmatic life cycle validation solutions to help meet these demands, such as:

- Validation Strategy
- Validation Master Planning
- Risk Assessments
- Data Integrity
- GAMP®
- 21CFR Part 11 Electronic Records and Signatures
- Policies and Procedures
- Consultancy and Project Delivery
- ERP/Business Systems Validation
- MES Validation
- LIMS Validation

With an integrated approach we deliver the greatest business benefit in terms of business operation, project outcome, audit exposure, ensuring you have beneficial operation from day one.

Our risk based approach to criticality assessments and associated validation strategy ensures a cost effective approach to CSV system compliance. We focus effort and resources on critical areas resulting in reduced validation costs for the project.

Data Integrity

The world of Data Integrity is becoming clearer, but there are still inconsistencies across organisations in their approach to Data Integrity.

With an integrated approach to Data Integrity, we deliver tailored solutions to ensure you achieve Data Integrity compliance, to include:

Data Integrity Auditing

- DI Site Audit
- DI Program Audit

Data Integrity Training

- DI for Management
- DI for Practitioners
- DI for Operational Staff
- DI for Staff - an online course for training the masses

Data Integrity Toolkit

- Leverage and tailor our tools

Do you understand the threats and issues?

Training is a critical element in the development, implementation and operational delivery of a Data Integrity program. Our courses help ensure you and your staff are suitably trained.

Auditing

Auditing is a key tool to maintaining compliance and demonstrates you are in control of your systems.

Helping you identify any issues early, reduces your compliance exposure and costs of remediation.

Whatever your challenge, we can support the delivery of your projects and strategic compliance plans, to include:

- Data Integrity Audit and Benchmarking

- Periodic Reviews and System Health Checks

- Governance and Framework

- Supplier Audits

- In Project Audits

- Computer Systems

- GMP Pre-Inspection and Remediation

- 21 CFR Part 11 Compliance

- Bespoke Audits

Put yourself in a win-win position with your roadmap to compliance.

Let's face it, not all audits go well, but no matter what the outcome, identifying opportunities for improvement, is a positive step moving forward.

On the flip side, having the green light and thumbs up from good audit findings, puts you and your team in a favourable position.

Training

Training is an absolute regulatory requirement.

Our training courses update you of current regulations, guidance and regulatory expectations.

They aim to improve your internal procedures, leverage change and to deliver more cost effective day to day operations.

Open forum and in-house training courses include:

- Data Integrity

- Computer Systems Validation and GAMP®

- 21 CFR Part 11 Electronic Records & Electronic Signatures

- ERP/Business Systems Validation

- Manufacturing Execution Systems Validation

- Laboratory Information Management Systems Validation

Online training courses include:

- Data Integrity

- GMP

- GDP

- Pharma Quality Management Systems

- QP Quality Management Systems

Quality Management Systems

Developing, revising and monitoring your whole Quality Management System can be a daunting and challenging task.

Your QMS is the foundation of maintaining compliance within your regulated business operations and delivery of projects.

Does your QMS meet regulatory expectations? We can support you by reviewing your current QMS or tailoring our own QMS to meet your needs.
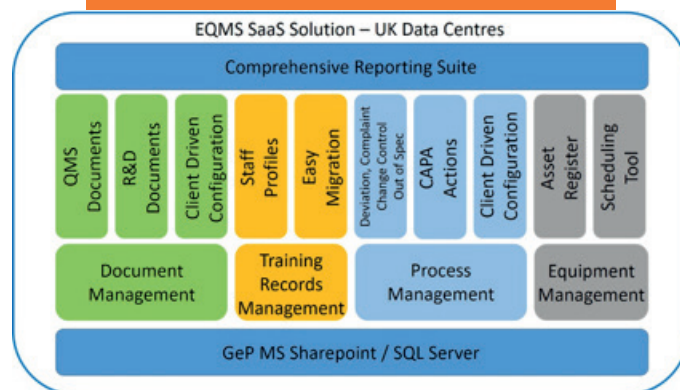
QMS Review Elements:

- Comprehensiveness
  are there any gaps?

- Effectiveness
  are your staff working to the QMS?

- Appropriateness
  is it too detailed or not enough detail?

- Regulatory Alignment
  does your QMS meet regulatory expectations?

- Review Cycles
  are all your QMS components approved?

- Simplification
  are there any duplicated procedures or opportunities for simplification?

Software Solutions

We have partnered with a leading provider of Electronic Quality Management Systems (EQMS), and together we deliver a complete service to the life sciences sector, delivering:

- Quick and easy implementation

- Robust repeatable system to manage quality documents

- Powerful reporting - driving business and quality decisions

- Efficiencies in day to day activities

- Cost savings

- Digital Data Preservation - Long Term Archive

- Compliant and satisfying regulatory requirements

- 21 CFR Part 11 compliant

EQMS Modules

EQMS SaaS Solution – UK Data Centres

Comprehensive Reporting Suite

QMS Documents | R&D Documents | Client Driven Configuration | Staff Profiles | Easy Migration | Deviation, Complaint Change Control Out of Spec | CAPA Actions | Client Driven Configuration | Asset Register | Scheduling Tool

Document Management | Training Records Management | Process Management | Equipment Management

GeP MS Sharepoint / SQL Server

"After reviewing the market, we feel confident that the combination of feature-rich, user-friendly technology and direct life science design and experience makes the perfect fit for our business and our customers."

What to know more?

Please contact us to arrange a demonstration, so you can see for yourself, the benefits an EQMS has to offer.

Specialist Personnel & Project Delivery

Our carefully selected consultants, subject matter experts and project teams deliver tailored solutions to your door.

We support you and your business, so you no longer have to struggle to find the skills and resources.

Working with us is like adding us to your team, freeing you up to focus your energy on the business you know.

Our team are well versed in industry guidance such as GAMP®, several of which have been and are currently involved in the development of GAMP® (GAMP® is a registered trademark of ISPE).

UK & Overseas:
- Contract & Staff

We offer:
- Recruitment Support & Selection
- Project Management Office

Roles include:
- Strategic Governance & Consulting
- Data Integrity Experts
- CSV Experts
- Project Managers
- Project Delivery Teams
- Auditing & Benchmarking

Setting a Positive Quality Culture and avoiding the Fear of Failure

Here at Clarity Compliance Solutions we believe that people are our and your greatest asset.

Embedding a consistent and coherent Positive Quality Culture within organisations plays a vital role in delivering a strong message deep in to the hearts and minds of the people that work within it.

We work with our clients to encourage reporting of instances where quality has been compromised and to build a culture free from the Fear of Failure.

"We are what we repeatedly do.
Excellence then, is not an act but a habit."

Aristotle

"Engaging with Clarity is like adding them to our team, freeing us up to focus on the business, instead of loosing sleep over compliance."

"Clarity have supported our business, providing us with market leading expertise to evaluate, manage and maintain our compliance issues without fuss."

clarity
compliance solutions

www.clarity-compliance.com

enquiries@clarity-compliance.com
Enquiries: +44 (0)1633 400939 | +44 (0)7735 204233

Clarity Compliance Solutions Limited | PO Box 171
Castlewood | Llanvair Discoed | Chepstow | NP16 9BQ