AUDITING

Auditing is a key tool to maintaining compliance in the regulated industries. To demonstrate you are in control of your systems an effective audit program is essential. The very highest standards for compliance and quality systems are vital, not only for internal operations but also those of suppliers.

An effective audit program will help you identify issues early, reduce your compliance exposure and reduce your costs of remediation.

While there is a cost to auditing, there is an inherent business benefit of ensuring highly effective operations, systems and high on stream times for your manufacturing or production facilities.

The cost of inadequate auditing can be:

- Inefficient operations
- Loss of reputation with regulatory agencies resulting in more frequent and in-depth inspections
- Cost of a bad batch or bad batches
- Product Recall with resulting lost market share
- Warning Letters or 483's

Ultimately this can cost £millions in lost sales and/or regulatory fines.

Our range of audits include:

Supplier Audits	Check before you purchase a system and manage/mitigate the on-going issues.
In Project Audits	Are projects being implemented and validated according to agreed validation plans and quality procedures?
21 CFR Part 11	Do you and your system comply with 21 CFR Part 11 ERES requirements?
Data Integrity	Do your systems meet data integrity requirements? Can you ensure data integrity for the lifetime of the data and its retention period?
Gap Analysis	Formal review of where you are vs where you want to or expect to be.
Periodic Reviews	Review the operation, change management and validation maintenance of a system then proactively resolve issues and ensure optimum operation.
System Health Checks	Are you operating and maintaining the validated status of your computer systems?
Computer Systems Pre-Inspection	Are your computer systems and your documentation ready for inspection? Are your staff ready to host an inspection?
GMP Audits	We perform internal and external GMP audits against most recognised pharmaceutical standards. We use specialist sector-specific auditors as needed, including experienced IT/ computer system auditors.
CSV and GMP Pre-Inspection and Remediation	We help get sites ready for CSV and GMP regulatory and corporate inspections, including working with groups to get their own areas ready. Not all audits go well, and we can help get sites that have had poor inspections back on their feet.

In addition to the delivery of the audits as above, Clarity Compliance Solutions can also train your staff or QA teams in the art of auditing computerised systems or auditing in general.

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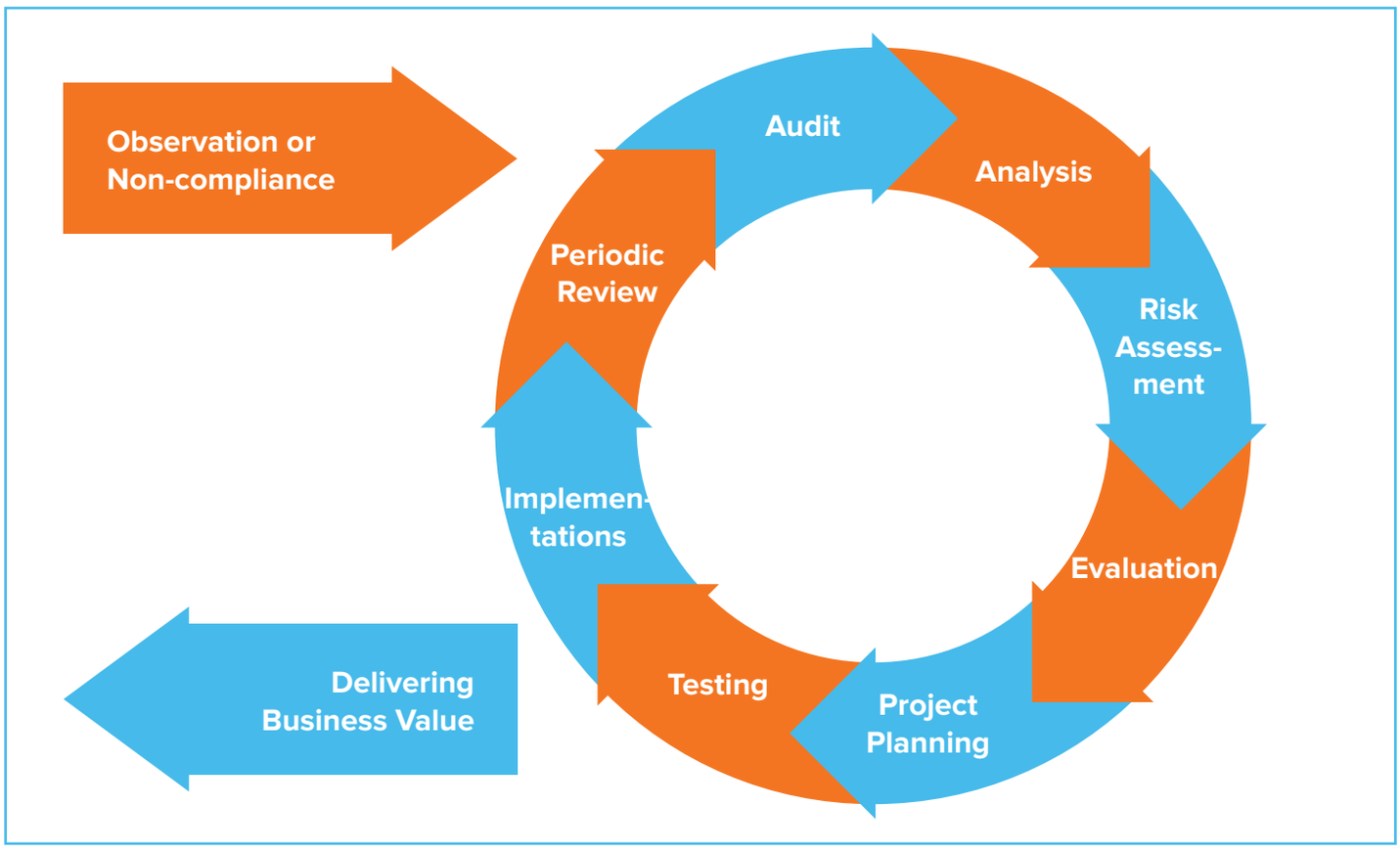
Compliance Lifecycle

The audit is just one segment of the Compliance Lifecycle, however on its own it only identifies issues.



Clarity Compliance Solutions provides a flexible process to support or guide you through from issue to resolution and peace of mind.

Review	Understand the current business position against known requirements or specific observations to analyse gaps, associated risks and identify opportunities to improve.
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. Understand what needs to be done and how it can be achieved efficiently and in the most cost-effective manner. Plan the project and drive to success.
Deliver	Our pragmatic remediation process uses industry prove risk based approaches to identify and mitigate business and regulatory risk. This approach supplies pragmatic remediation options that deliver results.

Our approach generates significant business benefits through time, cost and resource savings throughout the delivery phases of any audit.

Why Clarity Compliance Solutions?

Clarity Compliance Solutions are a leading supplier of consultancy and execution services to the life science industry. Our philosophy is to treat validation of all pharmaceutical systems as a lifecycle process requiring monitoring from cradle to grave to ensure control of the system. Our audit services are a key component of this lifecycle approach comprising in a unique set of tools designed to ensure compliance is effectively evaluated, managed and maintained.

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www.clarity-compliance.com | enquiries@clarity-compliance.com

Consulting: +44(0)7725 744636 | Enquiries: +44(0)7735 204233
Clarity Compliance Solutions Ltd • PO Box 1965 • Newport • NP19 1BQ