EPiC

ExPharmaceutical Inspectors Consortium

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Providing expert GXP auditing and advice, IAG remediation, consultancy and mock inspections. Performed by Ex-Regulators

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Our Mission

Since the company was formed in 2014 it has been our mission to help pharmaceutical, biotechnology and associated healthcare companies to achieve and maintain regulatory compliance and excellent pharmaceutical quality systems, to best industry standards

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EPiC Expertise

Ex-Regulatory Inspectors

Auditors used by EPiC are former Regulatory Inspectors, typically ex MHRA Inspectors

Pharmaceutical Industry Experts

All auditors have extensive industry experience and many years of experience auditing and inspecting within the pharmaceutical industry

International Coverage

EPiC Inspectors have extensive global experience auditing within Europe, the USA, Puerto Rico, India and China

Compliance

World class compliance consultancy support and advice you can rely on

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Services Include:

- Mock Regulatory Inspections
- GXP Audits
- Supply Chain Audits
- Due Diligence Audits
- ‘For Cause’ Audits
- PQS Audits and Consultancy
- Self-Inspections / Internal Audits
- Audit Programme Management
- MIA /WDA Licence Applications & Variations
- Active Substance Registration Applications & Variations
- Contract Qualified Person (QP) Services
- Non-Compliance Remediation
- Compliance Monitor Support
- In Depth System Reviews
- In House Workshops & Coaching
- Inspection Preparation
- Desk Based Reviews
- Template SOP’s
- Advice, Support & Guidance

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Mock Regulatory Inspections

Former regulatory Inspectors can perform mock EMA, EU, MHRA or FDA inspections to assess the readiness of a company to successfully host a regulatory inspection, or as part of an initial gap analysis as a site embarks on preparation for such an inspection.

Remote Audits

During the Covid 19 pandemic, like the MHRA, and like many other businesses, EPIC Auditors has been providing remote support and auditing. Helping companies to meet the regulatory requirements and to develop the quality systems essential to support much needed clinical trials for various Covid 19 treatments.

Advice, Support & Guidance

A broad range of experience across all aspects of the product lifecycle. This includes supporting new companies during the initial stages of product development into clinical trials, through commercial manufacture and distribution to advising on post marketing commitments and pharmacovigilance.

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Current Projects

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In Depth Systems Reviews

EPiC's consultants have been working with two large UK based pharmaceutical manufacturers conducting in depth reviews of their pharmaceutical quality systems. In contrast to an audit which involves sampling documents and records these reviews focus on a particular system, process or procedure with the goal of assessing it in detail against regulatory guidance and expectations. Each review takes between 2 to 3 days with the programme covering 12 to 18 months.

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Support for Overseas Manufacturers

EPiC's Consultants are currently working with an overseas manufacturer who wants to supply medicinal products to the UK and Europe. Starting with a gap analysis of the companies Pharmaceutical Quality System improvements will be made to meet EU GMP requirements. A mock EU GMP inspection will then be performed prior to the company triggering a regulatory inspection.

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Routine Compliance Audits

A number of clients request regular compliance audits of their facilities and systems in order to supplement their own internal audits and attain an independent assessment. Audits are conducted against EU GMP and GDP with any deficiencies and opportunities for improvement being highlighted. When requested EPiC's consultants assist with the implementation of corrective and preventative actions.

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Do you have any questions?

Feel free to reach out!

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