EPiC

ExPharmaceutical Inspectors Consortium

EPiC is a leading pharmaceutical GXP consultancy based in the UK. We offer expert services globally to companies and hospitals involved in clinical trials, marketing, manufacturing, and distributing medicinal products, including cannabis based medicinal products, and their starting materials. Our consulting team is composed of former MHRA Inspectors and industry experts with extensive knowledge and experience of EU, UK and PIC/S regulatory requirements, guidelines, and expectations.

Current Industry Challenges

- **Suboptimal compliance leading to regulatory action** e.g. MHRA IAG referral and/or licence suspension or issue of warning letters.
- **Senior Management not fully aware of licence holder responsibilities** and failing to ensure an effective Pharmaceutical Quality System.
- **Difficulty in interpreting and practically implementing GXP requirements** e.g. EU GMP Annex 1 revision.
- **Backlogs of deviation and complaint investigations.**
- **Poor root cause analysis** leading to repeat deviations.
- **Untimely implementation of Corrective and Preventative Actions** (CAPA).
- **Negative trends in overall quality metrics.**
- **Unmet internal and supplier audit schedules.**
- **Lack of resources, knowledge, and expertise** within the quality function.
- **Increased time since last regulatory inspection** and delayed responses to regulatory queries.
- **Uncertainty about current compliance status.**

How EPiC Can Help You

Mock Regulatory Inspections

We provide a comprehensive assessment of your current compliance status with MHRA, EU & PIC/S regulations, give recommendations to address any deficiencies and prepare your team for regulatory inspections.

GXP Audits

We support your internal and corporate audit programs and audit your supply chain partners as part of your quality oversight obligations.

GXP Gap Assessments

We evaluate your systems, processes, and procedures against specific regulatory requirements to identify gaps and propose solutions to enhance compliance.

Contract QP, RP, RPi and Compliance Monitor Services

We provide qualified and eligible personnel to support you in meeting your regulatory obligations.

Remediation, Advice and Support

We offer bespoke expert support tailored to your specific business, licensing, and GXP regulatory needs, from responding to specific questions and non-conformances to guiding post-inspection remediation. As former regulators we ensure your response to adverse inspection findings is risk based, thorough and effective.

Long-Term Partnerships

We work with clients on major projects e.g. overseeing the design, build, qualification and validation of new facilities, obtaining a manufacturing authorisation, advising on controls for new product introduction, driving compliance improvement and for remediation.

Training and Education

Our experts use their technical knowledge and industry experience to educate your staff, including Senior Managers on GXP requirements and the importance of compliance, ensuring the manufacture and supply of safe and effective products and the generation of reliable clinical trial data. We will mentor staff to view a situation through the eyes of the regulator.

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Why Choose Us?

EPiC's team comprises former regulatory inspectors and industry experts with extensive experience from the MHRA and the pharmaceutical industry. This unique perspective allows us to provide practical insights and guidance aligned with current regulatory expectations.

- Over 10 successful years as the consulting partner of choice for the global pharma & biotech industry
- Over 50 Expert Consultants ready to help
- Over 25 Former MHRA Inspectors at your fingertips
- Over 500 projects completed across the UK, EU, USA, India, China and RoW

"We've employed EPiC in providing advanced risk management training for leadership and management, as well as supervisors, onsite as part of our continuous improvement and personnel development programmes. EPiC was very responsive to our needs, tailoring a programme for us in short order, customising the training to our needs and providing us with the right trainer for the job.

"The fact that EPiC combined within the trainer selected: the ex-regulator's perspective with the practicality and pragmatism of an experienced industry practitioner, I think, provided the participants with the confidence they needed to ask the questions they needed answered. All in all, a very positive and value-adding exercise."

"From the moment I spoke with Richard Andrews my anxiety levels fell and I knew that we were in safe hands. It's difficult to put into words the level of professionalism and expertise that EPiC consultants have provided throughout a very challenging period. The service has been outstanding, and from the initial meeting we have had total confidence in the team. I have no hesitation in recommending EPiC for any business or individual needing GMP support."

"I wanted to thank you for a fantastic audit / inspection process. It was a good blend of deep & detailed challenge with guidance & support on best ways forward. This will put us in a good place as we head towards our application."

READ MORE

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Contact EPiC to discuss your needs, enhance compliance and ultimately safeguard patients.

We offer the following complimentary services:

A one hour presentation to senior management teams on their roles and responsibilities with respect to quality and GMDP compliance.

An EPiC Consultant, who is also a former MHRA GMDP Inspector, to join one of your Quality Management Review meetings and provide feedback.

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