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What You Need to Know About GxP Independent Compliance Audits

One of the responsibilities of the Food and Drug Administration (FDA), European, and other national health authorities is to protect the public health by ensuring the safety, efficacy, and security of human drugs. To meet that responsibility, these regulators conduct routine and for-cause inspections of components of a drug sponsor's quality systems.

While sponsors should always do what they can to maintain effective quality systems, including having provisions for internal audits, compliance audits conducted by an independent third party are invaluable. That's because audits conducted by a third party provide sponsors with an unbiased perspective on the state of their quality systems and the level of compliance with applicable regulations and Standard Operating Procedures (SOPs).

The Importance of Effective Quality Systems

Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and Good Pharmacovigilance Practice (GVP) under the umbrella of GxP are sets of standards that envelop procedures put in place to ensure that products are tested and manufactured properly. However, simply having the appropriate SOPs in place is not good enough.

These procedures must be followed to the letter, or the sponsor may have to deal with the consequences of one or more of its quality systems being noncompliant.

The essence of FDA, European Medicines Agency (EMA), or other national health authority regulations regarding quality is the need to have a quality assurance unit of some type. Obviously, different types and sizes of firms will have differing quality functions. The key is to make sure that internal

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processes are controlled. That's what an audit does – it verifies that control exists. Frequently, adherence to SOPs is the key to this. If those are regularly violated, it is likely noncompliant outcomes will result.

GLP
Good Laboratory Practice

GLP encompasses regulations and guidelines for conducting nonclinical laboratory studies that are intended to support applications for clinical trial or marketing authorization by national regulators, such as the FDA and EMA. Compliance with this regulation is intended to assure the quality and integrity of safety data.

GCP
Good Clinical Practice

GCP is an international and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials. The standard is named ICH-E6 and the aim is to provide a unified standard for clinical trials in the US, EU, and Japan. Collectively, ICH-E6, together with national regulations, serve to protect the integrity of the trials as well as the rights and confidentiality of trial subjects.

GMP
Good Manufactoring Practice

Because the pharmaceutical quality of drugs impacts the health of consumers, the FDA, EMA, and other national health authorities regulate quality very carefully. One of the regulatory standards for ensuring that quality is GMP.

Drug manufacturing is organized into sets of operations and related activities called systems, which are regulated by 21 CFR 211 in the US and EudraLex Volume 4 in the EU. The overarching quality system consists of subsystems that include the facilities and equipment, laboratory, materials, production, and packaging and labeling systems. Proper control of all these systems helps ensure that the manufacturer will produce drugs that are safe and meet the intended efficacy and quality characteristics.

GVP
Good Pharmacovigilance Practice

In addition to medicinal products' benefits, some may also have side effects which may be undesirable and/or unexpected. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse events or any other medicine related problem. GVP are a set of measures drawn up to facilitate the performance of a pharmacovigilance system.

What to Expect When the Health Authorities Inspect

A health authority inspection is an official examination of a facility and its quality systems to determine its compliance with laws and regulations within the jurisdiction.

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Type and length of audit depends on the GxP area to be examined, type of products, and the health authority that perform the inspection. The goal of each type of inspection is to help protect consumers from unsafe products. Inspections are generally conducted for three reasons:

Pre-approval inspection (PAI)

In order for a new medicinal product to be approved, a PAI is required by the country's regulating agency.

Routine inspection of a regulated site/activity

Depending on the authority and risk associated with activity, routine inspections are conducted at initial license application and at intervals of 1-3 years to assure continued regulatory.

"For-cause" inspection

This type of inspection is conducted on short notice or with no notice at all if the regulator receives intelligence or for other reason suspects critical compliance, quality, or safety breaches.

Regardless of the type of inspection, noncompliance with regulations and commitments made to the governing health authority can result in harsh consequences.

Avoidable Consequences of Noncompliance

There is a wide range of consequences for lack of compliance. Specific enforcement activities include actions to correct and prevent violations, remove noncompliant products from the market, and punish offenders. The type of enforcement activity the health authorities uses depends on the nature of the violation.

Why Independent Audits Are so Important

Independent audits shine fresh light on the questions, "Are we doing the right things to stay in compliance and are we following our own SOPs?" They help sponsors take a proactive approach to protecting their drug development program by discovering issues and fixing them before the health authority finds them. If the regulator has already found those issues, then a subsequent independent audit can help the sponsor stay on track toward compliance.

Audits are diagnostic. They point out strengths and flaws in both processes and results. Most audits add to the strengths and fix the flaws.

It is the objectivity of the audit that matters. That's why it isn't enough to conduct internal audits. Audit investigators who are associated with the development program may overlook or downplay the existence of significant issues because it is in their interest to do so.

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ProPharma: The Expert Independent Auditor

Independent compliance audits are a sponsor's best defense against a compliance breakdown. That's why it is crucial that you find the right audit partner.

When you tap the resources of ProPharma, you are leveraging the deep, unparalleled experience of our pharmaceutical industry consultants. To get the best results for our clients, we take a team approach that draws upon the extensive knowledge of subject matter experts. To learn more about how ProPharma helps our clients stay in compliance by conducting independent audits, visit propharmagroup.com.

Improving Patient Health and Safety

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory expectations are met, business goals are achieved, and patient health and safety is improved.

Our team of experts brings a comprehensive portfolio of regulatory and compliance solutions to help solve complex challenges in a dynamic regulatory environment. With our mission to improve the health and safety of patients, we are focused on delivering the highest quality of services throughout the full product lifecycle.

regulatory sciences | clinical research solutions | quality & compliance | pharmacovigilance solutions | medical information | R&D technology

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