PROPHARMA GROUP®

Improving Patient Health and Safety

CASE STUDY

FDA Regulated Drug Audits: Lack of Audit Findings Doesn't Necessarily Indicate Vendor Compliance

When a client's initial qualification audit proved inadequate, our auditing experts stepped in with a plan to meet regulatory compliance.

When performing initial qualification audits, it's important to evaluate all critical systems evenly to ensure compliance. Lack of evaluation of all critical systems can leave Sponsors and their manufactured drug products vulnerable to multiple risks and serious regulatory action.

Lucky for one Sponsor, ProPharma Group was able to step in and provide a thorough surveillance audit that uncovered 20 observations that were missed during the initial qualification audit. By completing a more thorough audit and assisting with the remediation, we were able to provide our client long-term peace of mind that the material produced was safe and effective.

> "The client was notably impressed by ProPharma Group's auditors, who went above and beyond the call to manage the implementation of the CMO's remediation commitments as well as provide review and consultation on the actions taken.

Benjamin Frey
Senior Director Quality Systems

Challenge

A new investigational drug Sponsor who outsources their drug product manufacturing, testing, holding, and distribution to support clinical trials was performing the initial qualification of their contract manufacturing organizations (CMOs) by performing onsite audits. The Sponsor had contracted with a consulting firm that specializes in facilities engineering and cleanroom fabrication to perform the qualifying audit of a CMO who performs aseptic processing and release testing of injectable products.

Naturally, because of the auditing firm's specialization in the facilities and equipment system, this was the primary focus of the audit. Other systems that were critical to the Sponsor's sterile products, such as quality, production, and laboratory controls were either not performed or performed at such a cursory level that there was only a limited understanding of the system performance and controls.

As a result of this "qualification" audit, the facilities and equipment system was found to be operating in a state of control; however, **the lack of evaluation of other critical systems left the Sponsor and the manufactured drug products vulnerable to multiple risks** including increased serious regulatory action and jeopardizing Regulatory Agency approval of drug applications.

Solution

After the system gaps in the initial supplier qualification process were identified and awareness of the associated risks were evaluated by the Sponsors' new quality manager, ProPharma Group was engaged to perform the routine surveillance audits of the qualified suppliers.

Upon review of the initial qualification report, it became apparent that the initial audit was narrowly performed around the facilities and equipment system. We proposed that the surveillance audit (which was performed one year after the initial audit) include additional systems to provide a more robust evaluation.

An on-site GMP audit was performed surrounding the quality, materials, production, and laboratory controls systems. **The outcome of this second audit was disparate with the findings of the first firm contracted by the Sponsor** and resulted in three critical observations, seven major observations, ten minor observations, and numerous recommendations.

In addition to performing a robust audit and providing a comprehensive audit report detailing all observations, recommendations, and regulatory references, **ProPharma Group seamlessly collaborated with the Sponsor and CMO to develop a remediation plan.**

Results

In response to the identification of observations across multiple quality systems, the CMO committed to implementation of ProPharma Group's recommended remediation activities. It was communicated that as a result, **all critical and major observations were found to be adequately addressed prior to the Phase III manufacture of a drug product** on behalf of the Sponsor and appropriate corrective and preventative action timelines were established.

By identifying potential risks and working with the CMO and sponsor to remediate all noted observations, the implementation and optimization of the CMO's systems **provided long-term peace of mind that the material produced was safe and effective for use in clinical trials.** The sponsor was able to rest assured that their drug program compliance risk was lowered due to the knowledge they gained by partnering with ProPharma Group experts.

Since this audit was performed, there have been no discrepancies or non-conformances associated with the sponsor's drug product.

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Improving Patient Health and Safety. **At Every Step.**

The ProPharma Group Advantage

Regulatory Affairs

- Drugs, Biologics, and Medical Devices
- FDA and EMA Expertise
- Full Lifecycle Support

Life Science Consulting

- 1200+ Team of Professionals
- Global Scale and Reach
- Service Excellence

Pharmacovigilance

- QPPV and LPPV Services
- Single-Source Provider
- 24/7 Multilingual Services

Medical Information

- Bilingual Native-Speaking Specialists
- Global MI Partner
- Support at Every Level

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