USTR 3668

Co-Sponsored Audits, What Are They?

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What is a Co-Sponsored Audit?

A co-sponsored audit is an audit of a supplier that is sponsored (paid for) by third parties which have an interest in the findings of the audit. An example would be an audit of a Pall manufacturing plant that has been sponsored jointly by three different drug manufacturers.

Biopharmaceutical (biopharm) drug manufacturers need to demonstrate control over their suppliers to ensure that the quality of their products can consistently meet their validated requirements, as set out by the drug registration dossier. These manufacturers achieve this through initial and regular audits of their suppliers to verify the compliance to standards and to provide assurance that the supplier can meet the agreed specifications. This leads to a heavy audit burden on the drug manufacturer's quality team, including arranging audits within the correct time frame; often suppliers have a backlog of audits which mean it can be up to a year before an audit date is available, pre audit reviews, attending the audit, drafting the audit report, and follow up of actions, with the addition of costs associated with each step to consider. This is multiplied for every supplier for their in-bound supply chain. Audits of suppliers are also required as a result of change (both supplier and process driven) and development of new products, which can slow down the adoption of changes to meet market demand.

To alleviate the audit burden, drug manufacturers can co-sponsor an audit of their supplier. When acting as a co-sponsor, they do not engage directly in the auditing process, in fact because of confidentiality among co-sponsors, all communication is handled by an independent auditing company, but as co-sponsor the drug manufacturers can have an input into the audit approach/checklist, and ensure it is aligned with their own supplier audit program. The audits are performed and any corrective actions and/or preventative actions (CAPA) are addressed by the auditing company within an agreed timeframe. The co-sponsor will then receive a copy of the audit report. Whilst the co-sponsor will bear some upfront audit expenses, this upfront cost has the potential to be recuperated, which ultimately means cost savings for the drug manufacturers.

Rx-360's Joint Audit Program♦

As part of a global industry initiative, BioPhorum has facilitated new approaches for the industry to relieve audit burden from suppliers and drug manufacturers. They have collaborated with Rx-360 to increase the awareness of Rx-360's Joint Audit Program. Rx-360 is a non-profit international consortium dedicated to supply chain security and patient safety. They have a long track record for organizing audits and release audit reports under license. Both biopharm suppliers and drug manufacturers can put in an audit request and Rx-360 will proactively seek out co-sponsors through their membership and/or industry customers and reach out to the biopharm supplier to organize the audit. Co-sponsors selected will have an invested interest in the audit reports, with ideally two or three co-sponsors per audit to provide a well-informed and representative, if not more vigorous, audit compared to traditional supplier audits as per the drug manufacturers' own supplier audit program. Once co-sponsors have been identified, the process begins and the audit is conducted not by Rx-360 but by renowned auditing companies such as British Standards Institute (BSI), ASC Associates Ltd , Blue Inspection Body, and SQA Services Inc.

The audits are conducted over two-three days on site ensuring an effective report, with the auditing company managing the CAPA process to address observations, interacting with all stakeholders. Draft reports are reviewed by co-sponsor and auditee then released. When auditing suppliers of single-use systems, Rx-360's Joint Audit Program will use the single-use system audit guide created as part of a collaboration between BioPhorum and Rx-360.

The released audit reports are available for licensing by other drug manufacturers through Rx-360 for a fee. With each licensing of the audit report, the co-sponsor recoups their upfront sponsor fees through the Rx-360 Credit Program. Therefore, not only do the co-sponsors have an input on the audit plan and influence the audit agenda, but their costs also have the potential to be fully recuperated whilst not having to use up the resources of their quality teams.

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