BioPhorum

GUIDANCE DOCUMENT ON

CONSIDERATIONS RELATED TO ENSURING GOOD OUTCOMES IN BIOPHORUM EXTRACTABLES TESTING WHEN USING A CONTRACT LABORATORY

CONNECT
COLLABORATE
ACCELERATE™

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About BioPhorum

BioPhorum's mission is to create environments where the global biopharmaceutical industry can collaborate and accelerate its rate of progress, for the benefit of all.

Since its inception in 2004, BioPhorum has become the open and trusted environment where senior leaders of the biopharmaceutical industry come together to openly share and discuss the emerging trends and challenges facing their industry.

Growing from an end-user group in 2008, BioPhorum now comprises over 90 manufacturers and suppliers deploying their top 3,500 leaders and subject matter experts to work in seven focused Phorums, articulating the industry's technology roadmap, defining the supply partner practices of the future, and developing and adopting best practices in drug substance, fill finish, process development and manufacturing IT. In each of these Phorums, BioPhorum facilitators bring leaders together to create future visions, mobilize teams of experts on the opportunities, create partnerships that enable change and provide the quickest route to implementation, so that the industry shares, learns and builds the best solutions together.

Per ISO 13485 an organization shall document procedures to ensure that purchased product conforms to specified purchasing information which includes monitoring and re-evaluations of the supplier. In this case, the contract lab is the supplier of BioPhorum extractables data. Performing the evaluation of contract labs should involve a technical review of their capability to generate quality BioPhorum extractables data. The cause and effect diagram below (Figure 1) provides a starting point for suppliers to generate an audit checklist to help satisfy the requirements of ISO 13485 and is intended to improve the likelihood of generating quality data from contract labs.

There are four focus areas for improving the outcomes from quality BioPhorum extractables data including Method, Operator/Lab, Equipment and Materials.

- The Method branch is intended to evaluate how well the lab conforms to the BioPhorum extractables guidance.
- The Operator/Lab branch helps to evaluate the experience level of the personnel and the lab's ability to work under a quality system.
- The Equipment branch helps to determine the capability and validation state of the analytical equipment for generating extractables data.
- The Materials branch focuses in on the quality of reagents and standards used in an extractables study.

It is important to understand that this is not intended to be a comprehensive plan for evaluating a contract lab's capability. It is a starting point to initiate dialog to gain a deeper insight, from which an initial level of confidence is achieved and help satisfy, in part, the requirements of ISO 13485.

Figure 1: Cause and effect diagram for key attributes leading to the generation of quality BioPhorum data