PREPARING FOR YOUR REMS AUDIT

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ABSTRACT

Seven steps to help vendors prepare for a REMS audit.

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As a vendor providing services or products to sponsors who have drugs subject to a Risk Evaluation and Mitigation Strategy (REMS) program, you can expect periodic audits from individual pharmaceutical companies or consortia. The scope, number of days, number of auditors, and whether remote or on-site will be determined by the services or products provided, and previous audit results.

There are 7 steps that vendors can take to prepare for these audits to make the process as smooth and painless as possible.

1. **Review MSA**
    a. One of the objectives of most REMS audits is to verify that the vendor is meeting their obligations detailed in a Master Services Agreement (MSA) and related Addenda and Statements of Work (SOW). The vendor being audited should review the relevant contractual documents and ask themselves:
        1. Are we meeting our obligations?
        2. What documents, records, SOPs, and other objective evidence can we show the auditor to demonstrate that we are meeting our obligations?

        Have objective evidence of meeting obligations ready to show the auditor if they ask.

2. **Verify Regulations**

    Some REMS-related functions and vendors are FDA regulated and some are not. As a vendor, know your status and be prepared to explain what regulations do and do not apply to the services you are performing or products you are supplying. Regulated REMS functions are those related to

    Assessments of the REMS strategy

    Medication guide or patient package insert

    Communication plan to health care providers

    Elements to assure safe use (EASU)

    Software used to implement regulated REMS functions

    If a service that the vendor performs (for example: program management) is not a regulated REMS function, it is not necessary for that vendor to comply with any particular regulations unless specified contractually.

3. Obtain Agenda

An agenda obtained from the auditor should provide information about:

Dates and times for the audit

Scope of the audit

Relative time allotted to each audit topic

4. Clarify Scope

If, after receiving the agenda, an audit topic is not clear or does not seem relevant, contact the auditor to clarify the scope of the audit. The auditor may have outdated information about the services or product being provided.

5. Prepare Introduction

A presentation to orient the auditor to the REMS functions being performed is very helpful, but it should not be a company marketing presentation. The auditor will be most interested in:

A short summary of the company's services and products, facilities' locations and sizes (number of staff), and corporate structure (especially in REMS-related areas)

Key staff performing REMS-related functions, their titles, roles and responsibilities

Short history of the vendor's participation in the REMS program

History of Regulatory inspections and outcomes

If audited previously, changes made since last audit (including changes in policies, procedures, processes, software, key staff, facilities)

6. Set the Stage

Recommendations for preparation for the actual audit include:

For on-site audits: Lodging and transportation (including airport(s), recommendations for the auditor(s), auditing room reservations, plans for provision of refreshments and lunch (if providing lunch ask auditors for dietary restrictions), parking instructions, and building access instructions.

It is important to give auditor(s) ample room for their laptop, notes, and documents/records being examined. If there are more than one auditor and they are auditing different topics, they may each require a separate room in order to discuss and conduct interviews.

For remote audits: Upload requested documents to a secure, shared site that the auditor(s) can access. Many auditors will ask for an Organization Chart, Table of Contents of procedures, list of software application used in fulfillment of REMS obligations, objective evidence from previous audit observations where the auditor needs to verify completion of the corrective action, relevant MSA, addenda, and SOWs, and other information prior to the start of the audit.

Alert lead staff as to when their participation in the audit may be needed.

7. RELAX!

You got this! Auditors are people. They may misunderstand, make mistakes, or not ask for a critical document that would show your compliance. Have conversations, ask questions, and hopefully, learn something. At least that is how Globiox auditors roll.