How to be REMS Audit Ready

As part of the BLENREP Risk Evaluation and Mitigation Strategy (REMS) requirement, GlaxoSmithKline (GSK) is required to conduct audits of certified Healthcare Settings (HCS) no later than 180 calendar days after they have dispensed BLENREP, and once every 3 years thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements. HCS Authorized Representative (AR) can be affiliated with more than one HCS and may be involved in more than one audit in a given year. This tool will help the HCS AR be audit ready at all times.

How can a Healthcare Setting be audit ready?

Ensure the current designated AR has completed and signed the Healthcare Setting Enrollment Form.

Maintain a list of staff involved and trained in the REMS.

Ensure REMS training is current for all relevant staff involved in dispensing and administering BLENREP.

Ensure all internal documents are in the most current version and describe current REMS processes and procedures adequately. Documents can include but are not limited to:

- Standard operating procedures (SOPs)
- Policies
- Work instructions (WI)
- Documentation of completion of training

Before each BLENREP infusion at your Healthcare Setting:

Obtain a REMS authorization code prior to infusion to verify the prescriber was certified and the patient was enrolled and authorized to receive BLENREP.

Always maintain accurate records

- Document staff’s completion of REMS training
- Demonstrate all processes and procedures are in place and being followed.

After each BLENREP infusion at your Healthcare Setting:

Submit a REMS Checklist within 5 business days of infusion.

Do not distribute/transfer/loan/sell BLENREP:

Ensure BLENREP has NOT been distributed/ transferred/loaned/sold to another site either (1) outside of your Healthcare Setting or (2) within your Healthcare Setting that is not REMS certified.

If your Healthcare Setting is selected for an audit:

The AR will receive an HCS Audit Questionnaire and HCS REMS Verification History Report for the applicable audit time period. Completion of the Audit Questionnaire is required within 30 calendar days of receipt. Identify any situations where the criteria (see above criteria) were not met during the audit time period and prepare documentation to list the non-compliances, provide rationale, and describe what corrective actions were taken. If no corrective actions were taken, take appropriate action and document. Information on what to expect if your HCS is selected for an audit is detailed on the next page.
What to Expect if Your Healthcare Setting Is Selected for an Audit

The HCS Audit Questionnaire must be completed by the AR for the certified HCS within 30 calendar days of receipt. Compliance with the audit request is a requirement for continued participation in the BLENREP REMS. Failure to complete this audit questionnaire could result in de-certification of your HCS and your HCS no longer being able to dispense BLENREP.

**STEP 1**
Quality Assurance (QA) Auditor provides audit questionnaire and HCS REMS Verification History Report to AR

- Day 1 (Audit Questionnaire Assigned): Audit Notification emailed to AR by QA Auditor
- Day 5 (business): Reminder call from QA Auditor
- Day 14 (calendar): Reminder email notification from QA Auditor. GSK Field Representatives may also contact AR.
- Days 25 - 27 (calendar): Reminder notification from QA Auditor if AR has not sent questionnaire response
- Day 30 (calendar) – Due Date: Final notification from QA Auditor

**STEP 2**
AR submits completed audit questionnaire and supporting documentation

- Within 30 calendar days of receipt of Audit Notification: HCS AR completes the audit questionnaire and submits completed form plus supporting documentation to QA Auditor
- Day of receipt: Notification emailed by QA Auditor confirming documentation received

*If AR does not submit completed audit questionnaire and supporting documentation to QA Auditor by Day 30 (calendar), GSK will determine appropriate action, which may include de-certification of HCS.*

**STEP 3**
QA Auditor performs review within 10 business days of receipt of audit questionnaire and supporting documentation

FURTHER ACTION IS REQUIRED

- QA Auditor requests additional information
- AR submits additional information in 5 business days

NON-COMPLIANT OR COMPLIANT

- QA Auditor reviews additional information and determines HCS to be non-compliant

  After GSK review, QA Auditor sends notification email with non-compliance identified and provides BLENREP Corrective and Preventive Actions (CAPA) Form to HCS AR to complete

  - HCS must institute corrective action(s), and AR submits BLENREP REMS CAPA Form/Evidence within 30 calendar days of receipt
  - QA Auditor will follow up with HCS AR on corrective action(s)/CAPA implementations

  NON-COMPLIANT OR COMPLIANT

  - If CAPA is not submitted or is inadequate, QA Auditor will notify GSK

  COMPLIANT

  GSK will review and make a decision within ten (10) business days on required next steps. Failure to comply with BLENREP REMS Requirements could result in de-certification.

- QA Auditor determines no further clarification required and HCS is determined compliant

  Audit Complete Notification emailed by QA Auditor within 2 business days of QA review

Trademarks are owned by or licensed to the GSK group of companies.

©2021 GSK or licensor.
BLMBND210001 January 2021
Produced in USA.

For additional information on BLENREP REMS, please visit www.BLENREPREMS.com or call the REMS Coordinating Center at 1-855-209-9188, Mon-Fri, 8AM - 8PM ET.