APCER LIFE SCIENCES
Together for better health

CASE STUDY

Active remediation measures help mitigate major safety findings

Therapeutic area: All therapy areas

Product type: Drugs and devices

Geography: US

Product life cycle stage: Post-marketing

About the Client

A leading generics company focused on providing specialty products for challenging health disorders.

Business Challenge

This company was inspected by the FDA and received the following serious inspection findings:

- Incorrect capture of initial receipt date of cases and missed to capture data from the source.
- Follow up investigations pertaining to adverse events were not captured appropriately as per the process.
- Inadequate documentation of follow up attempts or incorporation of data in the safety database.
- Incomplete documentation of seriousness assessment in the safety database.
- Inaccurate documentation of causality assessment in some of the cases.

This led to inaccurate analysis in the final data submissions to the regulatory authority, to which, a specific timeline was provided to address these findings.

The company had inadequate resources to address these findings and the key challenge was to submit the corrective measures in a required format within the requisite timeline.

Overview - Importance of Documentation Completeness and Quality

An Individual Case Study Report (ICSR) is a source of information which is documented on the basis of adverse event data received from the reporter and is mandatory to be submitted to the regulatory authorities within the described timelines as an expedited or periodic report. The accuracy and completeness of such information is a critical requirement. Failure to provide this information can trigger an inspection. The inspection findings needs to be individually addressed, with a response adequately reflecting the level of severity, formulated with details and using the correct terminology. If there is an incorrect recording of data, it can lead to misinterpretation or no-identification of risk associated with the drug thereby leading to false or no findings. To improve patient safety, which is of prime importance, error-reporting strategies should be opted, identifying errors, admitting mistakes and making improvements are the basic steps in achieving good documentation practices. Companies should also build as many E2B checkpoints into their database as some issues in the quality of a case can be flagged before getting to the point of submission.

Solution

APCER Life Sciences, as their chosen partner, helped the global pharma company to create a detailed and accelerated project plan for the appropriate corrective and preventive actions.

Corrective Action:

- A detailed follow up process and a detailed training plan for the team was developed.
- A line listing of the cases processed in the last two years was generated.
- Segregation and review of cases in the following categories was performed as per the priority:
  - Regulatory Authority source
  - Serious
  - Non-serious
- Completion of parameters like IRD reconciliation against the source document, identification of any missing data fields, review of seriousness criteria and documentation of causality assessment.
- Review of literature cases to ensure all cases were processed from full text articles which were procured and updated from FTA accordingly.
- Review and update of the email box was ensured for all follow up information in the safety database.

Preventive Action:

- Implementation of process modification plan provided clarity to the existing follow up process. To mitigate the risk, all the follow up attempts were tracked, and open cases were reconciled within the Argus Safety database on a weekly basis.
- Generation of monthly missing field reports was implemented to check for data completeness.
- Bi-weekly IRD reconciliation.
- Strengthened the quality review process by adding an extra layer of review.
- The rationale for seriousness, labelling and causality assessments of adverse events was entered into the safety database.

Outcome

To assess the effectiveness of corrective and preventive action plan, subsequent audits were carried out by client and APCER QA teams which resulted in no observation with respect to the above mentioned findings:

- The follow-up cases were revisited and the data were updated accordingly.
- The safety documents were updated and risk management activities were streamlined.

Our Pharmacovigilance Capabilities

Domain Expertise: 100+ physicians, 90% healthcare professionals supporting drug safety and Pharmacovigilance.

Experience and expertise in different product types including Drugs, Vaccines, Biologics, Biosimilars, Cell and Gene Therapy products / Advanced Therapy Medicinal Products, Medical Devices, and Combination products.

Risk Management Expertise: Risk management solutions provided by our experts and QPPVs are core to our governance model and project oversight.

Efficient Project Management: Our unique "two-in-a-box model" deploys a Client Partner and Delivery Head to ensure timely execution on deliverables and inculcate strong governance to monitor compliance at each stage through the life of the project.

Proactive Approach: Service-level adherence (SLA) and quality deliverables, coupled with strategic alignment to provide business value, makes us a trusted partner for PV for this pharmaceutical company.

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Part of APC Group

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2013, and ISO 27701:2019 certified company.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 11 4650 0802

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