To The Point

An Introduction to Safety Surveillance for Life Sciences

Patients and practitioners expect safety when using a medical product. Their assumptions are based on the premise that the initial product design, clinical testing, manufacturing, and labeling underwent thorough vetting and review prior to the product's release into the market. Responding to unforeseen issues with a product's safety profile efficiently and effectively is key to protecting patient safety and a company's bottom line. This holds true whether the product is a drug, medical device, or dietary supplement.

Product Regulation History

The history of life sciences product regulation demonstrates a trend in product approval processes becoming more stringent. Examples include the FDA's Amendments Act of 2007 and, specifically, the advent of risk evaluation and mitigation strategies (REMS) for drugs. Other examples of heightened safety scrutiny include an increased focus on clinical trial auditing to ensure accurate endpoints for safety and efficacy are met and the creation of good manufacturing practices (GMP) for dietary supplement companies. Most recently the provisions of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) implement serious adverse event reporting. These regulations are telltale indicators that the product safety bar continues to be raised.

Changing Safety Profiles Require Ongoing Review

Once a product enters the stream of commerce, it is subjected to a multitude of patient or user interactions that cannot be fully anticipated in product development. Because of these variables, a robust product safety surveillance program must be created, implemented, and updated regularly.

Safety surveillance programs allow a dedicated group of interdisciplinary company stakeholders to review reported complaints, malfunctions, and injuries (or other adverse events); identify common trends of concern; and provide a platform for senior management to determine appropriate responses and reduce the potential for future harm. Protocols to evaluate product complaints and ensure timely reporting of adverse events to regulatory bodies are another important aspect of safety surveillance programs.

Safety Surveillance Program Structure

A safety surveillance program must have a formal team leader responsible for the activities conducted by the members of the safety surveillance committee, a direct line of communication to senior leadership, and the authority to effect change.

For a product safety surveillance team to be effective, it is imperative that a product manufacturer maintain active two-way communication with product users. Product users may vary based on what the product is, what it does, who sells it, who prescribes it, and who ultimately uses it. Examples of product users include:

- General consumers
- Patients
- Doctors, nurses, and other healthcare practitioners
- Patient advocacy groups

The safety surveillance committee should meet on a routine basis (e.g., monthly) to review the adverse events and complaints received and analyze potential issues surrounding these notices. Meeting minutes should be documented in a clear, objective manner.

Once causal factors are determined as potential safety, quality, or performance issues, the safety surveillance team must have the authority to meet directly with senior management and determine the best action to address the potential situation. A multidisciplinary approach that involves product development, manufacturing, sales, and legal counsel is crucial for an effective, ongoing solution.

Robust Data Analysis and Information Security

The safety surveillance team must have the appropriate technology, training, and staffing to allow for effective data collection and analysis. The system should be set up to ask for set questions such as:

- The person's name, address, phone number, and email address
- The product name, model, lot number, or serial number
- The details of the complaint, illness, and/or injury
- How long the person was taking or using the product
- Other medicines or extenuating circumstances at the time of the incident

Since personal health information will usually be associated with safety surveillance inquiries, the utmost care in privacy protection must be exercised to protect patient confidentiality. Information security controls must be robust and constantly updated to address evolving security threats and regulatory requirements.

The safety surveillance database must have software functionality to track and trend adverse data. In addition to providing reports to the appropriate regulatory bodies, the information can provide knowledge of unforeseen issues. Although sometimes issues are more overt, such as an infection or toxic reaction, the safety surveillance team must also be able to look for "needles in haystacks."

When possible, the product in question should be returned for forensic analysis. A return merchandise authorization (RMA) system should be in place to provide a formal method for tracking returned products. The RMA program should include shipping costs to encourage the customer to return the product for review.

Protecting Patients and the Bottom Line

The ultimate goal is to protect patient safety through conducting structured risk analyses. These efforts can reduce potential litigation expenses and help protect a company's good name and reputation.

When monitoring product safety data, it is important to ensure the information received shows a significant trend while at the same time acting fast enough to protect patient safety. The key is maintaining due diligence throughout the product's lifecycle and ensuring employees know how to write defensively to provide accurate, non-biased data.

Off-label use of approved drugs and devices is also a potential safety concern that can be identified with an effective safety surveillance program. The off-label data entries can also be cross-referenced with the company's sales and marketing records to investigate the potential for off-label promotion.

Companies cannot solely rely on regulators to tell them what to do. If product issues are developing, steps should be taken to address the situation. This is why a systemic, scheduled multi-stakeholder approach is considered best practice for product safety surveillance.

Resources

Food and Drug Administration Amendments Act of 2007, https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/food-and-drug-administration-amendments-act-fdaaa-2007

Food and Drug Administration Adverse Event Reporting: MedWatch, www.fda.gov/safety/medwatch/

Food and Drug Administration Adverse Event Reporting: MDR, www.fda.gov/medicaldevices/safety/reportaproblem/default.htm

ISO 27001 Information Security Management Systems, https://www.iso.org/standard/27001

Healthcare Information Technology for Economic and Clinical Health Act, www.healthit.gov/policy-researchers-implementers/health-it-legislation-and-regulations

Modernization of Cosmetics Regulation Act of 2022, https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra

Learn More & Connect

For more information on protecting your business, contact your local risk engineer, visit the Chubb Risk Consulting Library, or check out www.chubb.com/engineering.

Safety Surveillance Checklist

A company should never be accused of placing profits ahead of patient safety. To help ensure this does not happen, reference this checklist to verify that the following have been addressed.

General	Yes	No	N/A
Are there known or foreseen risks for approved products and products under development?			
Is the safety surveillance program documented in a formal written document?			
Is there a formal safety surveillance committee or team?			
Is there a defined management structure for the safety surveillance team?			
Is there a robust safety surveillance and adverse event database with associated analysis software?			
Are patient privacy issues addressed with an effective and regularly updated information security management system (ISMS) compliant with regulations like HIPAA and HITECH?			
Have appropriate employees (customer service, receptionists, sales representatives, social media managers, etc.) been trained to record customer complaints or adverse events and communicate this information to the safety surveillance committee?			
Is there a formal return merchandise authorization (RMA) program in place?			
Have employees received training from legal counsel or other consultants on best practices for documenting product design, manufacturing, and related safety data with considerations for defensibility?			
Does the database system track off-label adverse events associated with the product?			
Does the safety surveillance committee have a formal process for submitting recommendations to senior management?			
Can senior management provide examples of implemented recommendations based on information provided by the safety surveillance committee?			
Has the safety surveillance committee submitted recommendations to senior management that were not implemented, and can the reasons for non-implementation be substantiated?			
Does a written crisis management plan exist?			
Comments:			

Outsourcing	Yes	No	N/A
Is the contract for outsourced safety surveillance reviewed by legal counsel and regulatory affairs?			
Are there formal, written contractual controls that place responsibilities and timelines for surveillance monitoring, reporting, and analysis on the vendor?			
Are there formal, written contractual controls in place that require additional insured status from the vendor?			
Comments:			

If your answer to any of these questions is "No," correct the condition immediately.