

# 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.