United States Food and Drug Administration Postmarketing Adverse Drug Experience (PADE) inspections and the most frequently cited deviations from federal regulations

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While many common and preventable drug risks are identified and evaluated before a product is approved and marketed, some risks become evident only after a product is marketed and real-world experience with the product is documented. Postmarketing safety data collection encourages informed decision-making that maximizes benefits and minimizes risks to patients. The United States (US) Food and Drug Administration (FDA)'s Center for Drug Evaluation and Research (CDER) Office of Compliance (OC) Postmarketing Adverse Drug Experience (PADE) team helps promote and protect the public health of the American people by verifying accuracy, reliability and timeline of postmarketing safety-related data submitted to US FDA. Additionally, the PADE team monitors a drug firm's compliance with the PADE reporting requirements (US regulations) set forth by the federal government. During the inspection process, observed deviations from US regulations are documented by the US FDA investigator and tracked by the PADE team. A drug firm's pharmacovigilance or drug safety department should investigate and identify actual and potential causes of PADE non-compliance and implement measures to prevent (re)occurrence by creating corrective actions. The corrective actions should be submitted to FDA, along with the drug firm's response, within 15-days of issuance of a Form FDA 483, Inspectional Observations. The PADE team assesses each observed deviation from the US regulations by reviewing the supporting evidence collected by the US FDA investigator during the inspection, the firm response and any corrective actions.

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Safety database updates: Past and future trends driving the decision to upgrade

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We are often asked the question “When should I upgrade my safety database?” There are obvious answers when it comes to maintaining regulatory compliance and ensuring patient safety. However, companies are often driven to upgrade their systems based on other factors, such as resource efficiency, business harmonization, analytic capabilities and aging technologies. Making the decision to upgrade requires weighing these factors against the cost and effort to implement, and is often a difficult challenge to evaluate. A review of historical information across the industry reveals common upgrade drivers. The upgrade drivers go beyond regulatory compliance and patient safety and uncover the complexities in how companies evaluate business operations and capabilities against cost and effort. Evaluating cost and effort drives the implementation strategy, and is often informed by a company’s past upgrade experience with safety database implementations. Trends in the healthcare and pharmacovigilance industry will cause a shift in the significance of common upgrade drivers. As costs grow disproportionately to the value obtained from each upgrade, life science companies are re-evaluating their approach safety database upgrades. This session will explore this balance between upgrade drivers and the level of cost and effort to implement, as well as how this balance will change in the future.

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