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Benefits of Systematic Failure Analysis as Part of Successful REMS Design

A Case Study

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A novel biologic molecule was being developed for a specific indication, but posed a theoretical (potential) risk for exacerbating an undetected malignancy. Patient access to a potentially life saving molecule had to be counterbalanced with this theoretical, but as yet unobserved, risk.

After convening a multidisciplinary team, a joint effort was initiated to characterize the expected process of medication prescribing, dispensing, and use. Each step of this "blueprint" was assessed to identify failures that could expose patients to the potential risk. A proprietary tool for systematic, evidence based analysis, RxFMEA®, was used to enable facilitation, rank and document the potential failures, identify possible underlying behavioral causes, and define potential interventions.

Observations on the benefits of this process:

- Touch points in the care process became the focus of intense scrutiny as tactics were conceived to assure the right patient got the right drug at the right time and dose.
- The meticulous analysis of the use process identified key failures that, if unmitigated, could lead to compounding events and compromise patient safety.
- The methodology often revealed system flaws, unforeseen weaknesses, as well as system strengths. It confirmed places where tools were relevant and places where others may need to be considered. It also informed the content of educational material to assure failures were addressed.
- The methodology also identified the need for redundancy across interventions, recognizing that relying on only one stakeholder to administer an intervention may not be enough.
- The process provided a robust test of the strategy, with documented evidence to support regulatory submission.

Review of process findings with the company's multidisciplinary group created thoughtful debate. The RxFMEA® process provided the framework to incorporate input from diverse functional perspectives without losing focus on the ultimate objective of creating an effective REMS.

Ultimately, a program including a medication guide, medical community education, and controlled access to the product were defined to prevent exposure to patients for whom the medication may have caused harm. The findings of the analysis were use to prepare final regulatory documents and communication plans. Regulatory approval was granted after the PDUFA date, but without the significant delays associated with a Complete Response.