EVALUATE-ERR®

What is EVALUATE-ERR?

Exclusive to Med-ERRS®, EVALUATE-ERR is a safety consulting service that examines a unique aspect of a product (such as a dosage form, special packaging, or trademark) and its vulnerability to user error.

Med-ERRS employs Failure Mode and Effects Analysis (FMEA) to determine which path or choice to follow to minimize the risk of error and provide specific recommendations and error-reduction strategies.

EVALUATE-ERR is also performed in response to specific FDA requests or as part of a risk assessment or a Risk Evaluation and Mitigation Strategy (REMS). In late 2012, the FDA released a draft guidance entitled, “Safety Considerations for Product Design to Minimize Medication Errors,” which focuses on the utility of performing proactive risk-assessments in the early stages of pharmaceutical product design. Over the past several years, Med-ERRS has become more involved with providing this type of service in order to help develop risk mitigation strategies.

To view the full draft guidance, please visit:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM331810.pdf

When should EVALUATE-ERR be used?

Pharmaceutical companies use EVALUATE-ERR to assist them with:

- Nomenclature strategy for a product line extension or new indication
- Non-proprietary name evaluation
- Determining appropriate packaging configuration
- Dosage expression (strength, form, schedule or formulation)
- End-user (practitioner or patient) instructions for use (IFU)

What may be included in EVALUATE-ERR?

Our EVALUATE-ERR service is uniquely tailored for each individual client and may consist of:

- Literature review and medication error analysis
- End-user feedback
- Failure Mode and Effects Analysis (FMEA)
- Potential error scenarios and assessment of harm
- Specific risk-mitigation strategies
- Summary of findings and recommendations

What is Failure Mode and Effects Analysis (FMEA)?

FMEA is a risk-assessment method based on the simultaneous analysis of failure modes, their consequences, and their associated risk factors.

Since the 1960s, FMEA has been used most exclusively in areas characterized by high risk, such as nuclear power plant operations, or by high cost, such as the weapons and aerospace industries.

In the pharmaceutical and healthcare industry, FMEA can be used to identify areas of potential failure when products are introduced into the complicated medication use system existing in our healthcare community today.

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Med-ERRS®
ERR on the side of safety℠