


## Our Vision ▼

“ To be recognized and respected as the leading authority working with pharmaceutical and other healthcare industries to prevent medication errors. ”

## About Med-E.R.R.S.® ▼

 Med-E.R.R.S., Inc.®, a wholly owned for-profit subsidiary of the nonprofit Institute for Safe Medication Practices (ISMP), was established in 1997 when it was realized that there was a growing need within the pharmaceutical industry to develop trademarks, packaging and labels that minimize the potential for medication errors by users. Since its inception, Med-E.R.R.S. has worked with more than 100 pharmaceutical companies worldwide to provide services that have helped clients make decisions regarding their products with a focus on safety.

The Med-E.R.R.S. staff consists of healthcare professionals with extensive experience in clinical practice. These clinicians understand the real-life situations that occur when products are used in the healthcare environment. Med-E.R.R.S. integrates this knowledge and experience with the input of practicing clinicians in the field to systematically analyze potential trademarks, packages and package labels as well as technology involved in medication use to provide clients with an understanding of their products' risks related to safety.



Trademark Safety Evaluation

**SCREEN-ERR®**

**ERRS MODEL™**



Post-Marketing Services Related to Medication Errors

**MONIT-ERR™**

**EVALUATE-ERR™**



Package and Label Evaluation



Medication Safety Consulting

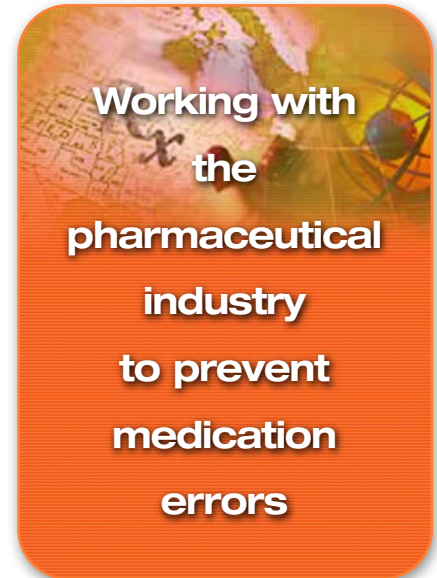
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Working with  
the  
pharmaceutical  
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**Med-E.R.R.S.:**

## Trademark Evaluation Services



Med-E.R.R.S. works globally with pharmaceutical companies in the pre-market phase to determine the likelihood that proposed trademarks may be vulnerable to confusion, possibly contributing to medication errors. Also included in pre-market evaluations is an assessment of any regulatory issues that may affect a trademark's acceptance by regulatory authorities. Below are the two trademark safety evaluation services that Med-E.R.R.S. offers.

### SCREEN-ERR®

SCREEN-ERR® is a service designed to help companies evaluate multiple pharmaceutical trademark candidates at an early stage in the trademark development process. It is used to determine whether any regulatory or other concerns exist which may result in a name not being acceptable to regulatory health authorities. SCREEN-ERR should be used as a tool to help eliminate unacceptable trademark candidates and narrow the list to trademark "finalists" that would undergo further research, using the ERRS MODEL™.

### The ERRS MODEL™

The ERRS MODEL incorporates various techniques recommended by the FDA to evaluate the safety and potential risk of confusion of trademarks, including Failure Mode and Effects Analysis (FMEA). The ERRS MODEL can be used to evaluate the trademark "finalists" that have been narrowed down using the SCREEN-ERR service.

The ERRS MODEL uncovers potential problems arising from look-alike and sound-alike medication names. It also reveals other potential nomenclature problems with trademarks, such as confusion with medical terminology and abbreviations.

Med-E.R.R.S. also reviews each trademark candidate from the perspective of worldwide regulatory authorities. The evaluation also includes consideration of USAN and WHO criteria to identify potential confusion with nonproprietary drug names.

**Results of SCREEN-ERR and ERRS MODEL testing can help clients choose a trademark that has a high probability of acceptance from the regulatory and safety standpoints.**

## Post-Marketing Services Related to Medication Errors



With the release of proposed FDA guidances related to risk assessment, risk management, and pharmacovigilance, pharmaceutical companies are expanding their post-marketing surveillance systems to detect adverse drug events related to medication errors, including events related to nomenclature problems.

Med-E.R.R.S. has created services that range from helping to fulfill a Phase IV commitment for a specific product, to taking a proactive approach for monitoring an entire product line. Med-E.R.R.S. experts in medication error identification and prevention have the tools and experience needed to monitor, classify, and analyze actual or "near-miss" medication errors.

### MONIT-ERR™

The MONIT-ERR™ service offers pharmaceutical companies the opportunity to monitor a specific drug product or groups of products for any occurrence of a medication error. Med-E.R.R.S. can monitor reports of potential and actual medication errors received through various error reporting mechanisms. Events are categorized according to the National Coordinating Council on Medication Error Reporting and Prevention (NCC MERP) Index, collated, and compiled into client reports at regular intervals.

### EVALUATE-ERR™

Using the EVALUATE-ERR™ service, Med-E.R.R.S. can provide an in-depth analysis of error reports using data from various sources, including incidents reported to the client and error reporting databases. The analysis is performed using the Ten Key Elements of the medication use process, a conceptual model developed by ISMP used to describe the components of the medication use process that most often are involved in medication errors. Due to the fact that medication errors are multi-factorial in nature, a review of each of the elements is necessary to assure that all of the components of the medication use process are considered. Based on the analysis, recommendations are made to the client to help reduce the risk of medication errors.

## Package and Label Evaluation



The Med-E.R.R.S. staff uses the experience gained through interactions with other companies, as well as knowledge of medication error causality, to perform expert reviews of drug product packaging and labels. This expertise helps clients create packaging and package labels that are easy to understand and consistent with the most current FDA regulations. The overall goal is to reduce the risk of error in whatever clinical setting the product is used.

Med-E.R.R.S. collaborates with the client to obtain background information about the product and to discuss the proposed packaging and/or label. Factors that are evaluated from the safety standpoint include:

- overall appearance of the label,
- readability and placement of the product name and information,
- presence of confusing terminology, abbreviations, and other extraneous information, and
- visibility and positioning of critical information.

Recommendations and mock-up labels are presented to the client in a summary report.

Med-E.R.R.S. also is available to re-evaluate any packaging or package labels once the recommendations are implemented.

## Medication Safety Consulting



Med-E.R.R.S. is available to perform consultative services for a variety of medication safety-related issues. From the trademark safety evaluation standpoint, issues may include opinions on issues such as specific name pair confusion (side-by-side comparison), trademark modifiers (i.e., suffixes), trademark rejections by regulatory bodies (FDA, EMEA, etc.), or the use of dual trademarks for the same chemical entity.

Other consultative services include evaluation of educational material from the medication safety standpoint as well as the facilitation of focus group or advisory board meetings to discuss a medication safety-related issue for a particular product. Med-E.R.R.S. also is available to assist companies specializing in medication-related technology to improve the functionality and safety of their product(s). Review of device functionality and efficiency using the expertise of an interdisciplinary team can lead to a reduction in device-related medication errors.