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Effective quality risk management can facilitate better and more informed decisions, provide regulators with greater assurance of a company's ability to deal with potential risks and can beneficially affect the extent and level of direct regulatory oversight.

*ICH Harmonized Tripartite Guideline
Quality Risk Management, 9 November 2005*

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Preview Kendle's capabilities

- Evaluation of the need for risk minimization activities
- Advice on the appropriate or necessary use of an RMP/REMS
- Preparation of Risk Management and Minimization Plans
- Collation and interpretation of data for RMPs
- Liaison with regulatory agencies worldwide
- Development of a Pharmacovigilance Plan

An RMP describes the activities a company will undertake to minimize risks to patients or consumers. The plan should include a safety characterization of the product and details of risk minimization activities. Each plan is unique for the product under consideration.

Effective submissions in a risk-averse culture

Pharmaceutical product manufacturers are required to investigate potential drug safety issues proactively throughout the lifetime of a product, starting early in development. As the pharmaceutical regulatory environment becomes increasingly risk-averse, regulatory agencies across the world are dedicating significant resources to risk management activities.

Since 2005, the European Medicines Agency (EMA) has required a Risk Management Plan (RMP) to be included in Marketing Authorization Applications (MAAs) for new chemical entities, biotechnology products, new dosage forms, new routes of administration, new indications and new patient populations. If additional risk minimization activities are required, a Risk Minimization Plan is required as well.

In the United States, the Food and Drug Administration (FDA) does not require an RMP or Risk Evaluation and Mitigation Strategy (REMS) unless it is specifically requested. However, even when an RMP is neither a legal requirement nor specifically requested, pharmaceutical companies often choose to prepare an RMP for internal purposes or to provide additional reassurance to the regulatory agency and lay the groundwork for future global marketing of the product.

The Kendle difference

Preparing an RMP/REMS is a specialized task demanding the appropriate expertise, experience and detailed knowledge of specific risk management issues across different regulatory regions.

Kendle has this expertise and can prepare effective RMPs for customers ranging from small biotech companies without internal resources to large biopharmaceutical customers lacking specific geographic expertise (e.g., a North American company looking to enter the European market). We develop the optimum strategy for monitoring, gathering and interpreting data to feed the information back into an RMP/REMS.

Although RMPs are a relatively recent requirement, Kendle has an existing infrastructure that is tried and tested and can efficiently fulfill the necessary requirements. Our multidisciplinary team, including regulatory experts, experienced physicians and safety specialists with a proven track record of successfully submitting RMPs, will be involved in developing your plan. Our Medical Affairs personnel will then apply their knowledge of the therapy area and review adverse event profiles and signal detection. In addition, our team will draw on our expertise in pre-clinical development and toxicology to provide the necessary preclinical input.

The global nature of our team means we are able to utilize local expertise to address the specific requirements of the different regulatory regions. At Kendle, we recognize that the risk profile of a product can vary according to the region in which it is prescribed, depending on the standard of care,

prescribing patterns and payer profile of the region. An RMP that is ideal for one region may be totally inappropriate for another. Therefore, an RMP prepared by Kendle takes into account the medical, regulatory and practical considerations of the regions in which the product will be marketed.

In many situations, including RMP preparation, Kendle will have already carried out or been closely involved in the product's clinical development studies, enabling us to apply our intimate knowledge and data to prepare your RMP/REMS efficiently and cost-effectively.

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The [FDA amendment] act authorizes FDA to require persons submitting certain applications to submit and implement a Risk Evaluation and Mitigation Strategy (REMS) if FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks of the drug.

*Food and Drug Administration
[Docket No. FDA-2008-N-0174]*

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European Union legislation requires Applicants and Marketing Authorization Holders to provide Competent Authorities with a description of pharmacovigilance and risk management systems.

Volume 9A, Rules Governing Medicinal Products in the European Union, March 2007

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For more information

about Kendle's capabilities in Risk Management Plans, please contact us at info@kendle.com or at one of the telephone numbers listed below:

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