

The critical role of REMS measures in ensuring **patient safety**



In the pharmaceuticals and medical device realm, the safety profile of a medicinal drug product, medical device or combination product is paramount. Risk Evaluation and Mitigation Strategy (REMS) measures play a crucial role in investigating and ensuring the safety of these products since they are designed to mitigate and eliminate the risks associated with patient health and safety. This brochure discusses the importance of REMS measures, pharmaceutical and medical device regulatory requirements and the comprehensive services that help pharma and medical device enterprises achieve the best outcomes.



Understanding REMS measures

REMS measures are the requirements imposed by regulatory authorities to ensure that the benefits of a drug or medical device outweigh its risks. These measures are critical in identifying potential safety concerns and implementing strategies to mitigate them. The primary goal of REMS is to protect patients from adverse effects and to ensure their well-being throughout the treatment process.

Regulatory requirements and expertise

Knowledge of regulatory requirements related to REMS implementation is essential for pharmaceutical companies and healthcare providers. Implementing a REMS program involves a thorough understanding of the guidelines set forth by regulatory bodies such as the U.S. Food and Drug Administration (FDA). These guidelines outline the necessary steps to effectively monitor, conduct and report on REMS programs.

HCLTech's Medical Information (MI) department has extensive experience handling REMS programs for multiple pharmaceutical industry clients, including members of the top 20 pharmaceutical companies. Our team adheres to regulatory requirements as well as continuously develops and perfects, the system to achieve fully compliant and efficient outcomes.

Comprehensive REMS services

The implementation and execution of REMS programs require a range of services to ensure patient safety and compliance. These services include:

Registering patients, healthcare providers (HCPs) and other stakeholders: Ensuring that all relevant parties are registered and informed about the REMS program.

Individual/bulk patient transfers: Facilitating the transfer of patients from or to alternative suppliers to maintain continuity of care.

Patient profile changes: Updating patient profiles to reflect any changes in clinical or laboratory parameters.

Clinical and laboratory parameter registration: Registering patients' clinical and lab parameters under REMS requirements.

Support for automated registration devices: Supporting devices that automate the registration of clinical and laboratory parameters.

Credentials reset: Assisting medical and other personnel with resetting their credentials on the electronic REMS system.



Maintaining drug and non-drug supply orders: Ensuring the timely supply of necessary drugs and non-drug items.

Scheduling courier collections: Coordinating the collection of laboratory samples for analysis.

Monitoring clinical and laboratory parameters: Continuously monitoring targeted clinical and laboratory parameters and consulting with the treatment team on further measures.

Monitoring off-treatment safety profiles: Keeping track of patients' safety profiles even after they have completed their treatment.

Handling off-label cases: Managing cases where drugs are used off-label, ensuring compliance with regulatory guidelines.



Additional MI department services from HCLTech

HCLTech's MI department offers comprehensive services for REMS programs that have helped our clients consistently achieve strong results.

In addition to the core REMS services, HCLTech's MI department is fully trained and equipped to handle accompanying requests, including:

- ➔ **Identification and reporting of adverse events (AEs) and product quality complaints (PQCs):** Ensuring that any adverse events or product quality complaints are promptly identified and reported

- ➔ **Medical information inquiries:** Receiving, logging and responding to medical information inquiries, performing literature searches and providing standard response documents (SRDs)

- ➔ **Reconciliation of critical data:** Ensuring the accuracy and consistency of critical data related to REMS programs.

- ➔ **Data cleaning:** Performing data cleaning to maintain the integrity of REMS program data.

Conclusion

REMS measures are indispensable in safeguarding patient health and safety in the pharmaceutical and medical device industries. HCLTech's MI department has a proven track record of successfully implementing, monitoring and reporting REMS programs for top pharmaceutical companies.

Our comprehensive suite of services ensures that all regulatory requirements are met, with patient safety prioritized at every step. By leveraging our expertise and experience, we continue to contribute to the overall success of REMS programs and the well-being of patients worldwide.



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