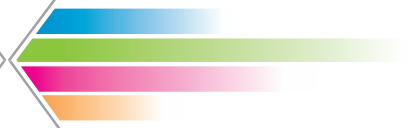


Axiom Understanding REMS

e-Learning Module



As regulations around patient safety continue to evolve in the life science industry, most likely your organization has already considered or moved forward with a plan to establish a *Risk Evaluation and Mitigation Strategy (REMS)*. For many organizations, REMS is a critical requirement that can directly impact the success of their product approval and positioning.



Axiom has developed ***Understanding REMS***, an off-the-shelf e-learning module that will help your organization jumpstart the process of spreading awareness and understanding the impact of REMS. Educating various departments within your organization on risk management, and specifically on REMS, is essential for achieving success in today's highly regulated marketplace. Take the next step forward with ***Understanding REMS***.



In partnership with *Pedagogue Solutions*, this course also offers a reliable, valid, comprehensive knowledge assessment that can be included as part of any training development or certification path.



Module Objectives

After completing the **Understanding REMS** module, learners will be able to:

- Define risk management
- Recognize the evolution of risk management plans leading up to the current requirement of REMS for certain products
- Describe the key differences between REMS and risk minimization action plans (RiskMAPs)
- Describe REMS and its goal
- Identify possible REMS elements
- Recognize possible penalties for violating a REMS

Module Outline

Below is the **Understanding REMS** module high-level outline:

- **Lesson 1:** Introduction to REMS
 - Description of Risk Management
 - Evolution of Risk Management
 - Key Differences Between RiskMAPs and REMS
- **Lesson 2:** Defining REMS
 - General Overview of REMS
 - Goal of a REMS
 - Factors Used to Determine Necessity of REMS
 - Impact of REMS
 - Possible REMS Elements
 - REMS Evaluation Requirements
 - Penalties for REMS Violations
 - Sample REMS

Licensing and Delivery Options

The **Understanding REMS** module offers cost-effective content licensing options for small to large organizations. The module can be delivered in a variety of formats, including:

- CD-ROM
- Web or LMS (SCORM)
- Pedagogue Solutions hosting*

Getting Started

For more information, pricing, or questions regarding this off-the-shelf module, please contact Donna Thomas at **267-757-2101** or donna.thomas@axiomhh.com.

* Hosting and support licensing and costs are not included as part of the REMS module content licensing.

