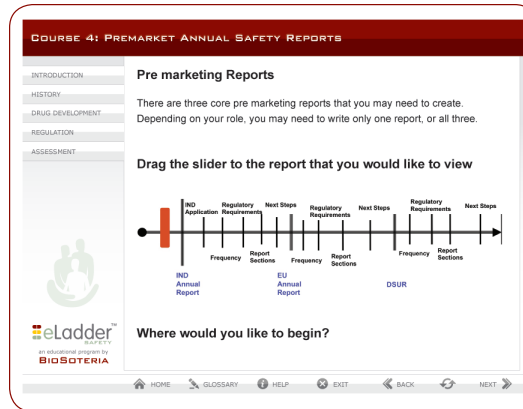


Safety professionals in today's rapidly changing global regulatory environment must have a strong foundation in safety surveillance and pharmacovigilance, which requires ongoing, comprehensive, and up-to-date training and education.

Courses in BioSoteria's engaging, innovative, online eLadder Safety eLearning Program are:

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COURSE 4: PREMARKET ANNUAL SAFETY REPORTS



Periodic safety reporting is required of all manufacturers by regulation and throughout the medicinal product lifecycle. This course intends to provide participants with the knowledge required to develop periodic safety reports that are required by US and EU regulations pre- and postmarketing. By providing instruction on the content and timelines of these reports, and addressing best practices as outlined in ICH and CIOMS guidance documents, learners will be able to understand how to create the various periodic safety reports for investigational and marketed drug and biologic products.

COURSE 5: POSTMARKET PERIODIC SAFETY REPORTS



Length: 6-8 hours
(3-4 per course)

Audience: Individuals interested in entering the field of drug safety and pharmacovigilance; professionals already in the biopharmaceutical industry practicing in the areas of clinical research, drug safety, regulatory affairs, and GCP compliance.

LEARNING OBJECTIVES:

- Describe the regulatory requirements, format, timelines, and components of premarketing safety reports, including:
 - Investigational New Drug Application (IND) Annual Reports
 - Annual Safety Reports (ASRs)
 - Development Safety Update Reports (DSURs)
- Describe the regulatory requirements, format, timelines, and components of postmarketing safety reports, including:
 - Periodic Adverse Drug Experience Reports (PADERS)
 - Periodic Safety Update Report (PSURs)
- Identify sources of information required for each report section



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