



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.

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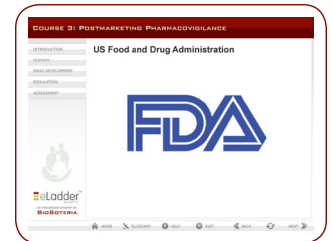
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COURSE 3: POSTMARKETING PHARMACOVIGILANCE

Course 3 delivers key information on the receipt, evaluation, and reporting of postmarketing spontaneous adverse drug reactions (ADRs), including the procedures that marketing authorization holders/license holders must follow to fulfill US and EU regulations. Similarities and differences between postmarketing pharmacovigilance (PV) regulations in the US and EU are covered.

The screenshot shows a software interface for 'COURSE 3: POSTMARKETING PHARMACOVIGILANCE' with a navigation menu on the left. The main content area displays a 'MEDWATCH FORM FDA 3500A (10/05)' from the U.S. Department of Health and Human Services. The form is titled 'Expedited 15-day Safety Report' and includes sections for 'A. PATIENT INFORMATION', 'B. ADVERSE EVENT OR PRODUCT PROBLEM', and 'C. SUSPECT PRODUCT'. The 'B' section has checkboxes for 'Adverse Event' and 'Product Problem', and lists various event types like 'Death', 'Hospitalization', and 'Disability or Permanent Damage'. The 'C' section includes fields for 'Name (List labeled strengths)', 'Dose, Frequency & Route', 'Lot #', and 'NDC# or Unique ID'. A navigation bar at the bottom includes buttons for HOME, GLOSSARY, HELP, EXIT, BACK, and NEXT.



LEARNING OBJECTIVES:

- Understand the purpose and importance of postmarketing PV
- Know the US and EU regulations and guidance for postmarketing PV
- Discuss roles, responsibilities and relationships of internal and external stakeholders with regard to postmarketing PV
- Identify the sources of postmarketing safety reports and distinguish between spontaneous ADR reports and solicited AE reports
- Define the key terms and definitions pertaining to postmarketing PV
- Distinguish between serious and non-serious ADRs
- Distinguish between expected/labeled and unexpected/unlabeled ADRs
- Identify the steps that occur at the Drug Safety Department of the MAH/license holder after ADR report receipt
- Describe how ADRs are triaged and reported to regulatory authorities
- Describe the components of a complete case narrative
- Describe how to evaluate and report ADR reports from the literature

Length: 4 hours

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.