Managing Expedited Reporting in Argus Safety

Duration: 1 Day

What you will learn

This Argus Standard Edition 8 Managing Expedited Reporting training is recommended for pharmacovigilance professionals who will be involved with expedited regulatory reporting activities.
Learn To:

Schedule, generate, submit and track regulatory reports.

Auto-schedule expedited reports.

Perform bulk reporting.

Import E2B reports.

Configure and transmit E2B(R3) expedited reports to agencies.

Identify the updates to MedWatch Reports in Argus Safety.

Configure and transmit eVAERS report to FDA CBER.

Monitor compliance.

Benefits to You
By taking this course, you'll know how to manage submission of ICSR reports to regulatory authorities by using configuration options of Argus Standard Edition. You'll be able to automate the expedited reporting process and improve your organization’s compliance.

Audience

End Users
Implementation Consultant
Pharmacovigilance Professionals
Safety Professionals
Technical Administrator

Related Training

Required Prerequisites

Experience with pharmacovigilance concepts and terminiologies

Argus Standard Edition Processing Safety Cases

Argus Standard Edition Jumpstart – Online Course

Course Objectives

Manage expedited reports in the Argus Standard Edition 8

Course Topics

Overview of Regulatory Reports
Overview of Expedited regulatory reporting
Regulatory reports available in Argus Safety
Report delivery methods
Examining the reports in worklists
Examining expedited reporting activities

Scheduling Expedited Regulatory Reports
Overview of scheduling expedited regulatory reports
Viewing a list of expedited reports due soon
Scheduling expedited regulatory reports

Generating Expedited Regulatory Reports
Overview of generating regulatory reports
Generating regulatory reports

Transmitting Expedited Regulatory Reports
Overview of transmitting regulatory reports
Transmitting regulatory reports.

Tracking Expedited Regulatory Reports
Overview of tracking regulatory reports
Tracking Regulatory Reports

Schedule Expedited Regulatory Reports through Reporting Rules
Overview of Expedited reporting rules
Configure Expedited Reporting Rule
Auto-Schedule expedited reports

Performing Bulk Reporting
Overview of bulk reporting
AG Services
Auto-Generate expedited reports
Auto-Distribute expedited reports
Force-Distribute expedited reports
Batch Report Generation

Importing E2B Reports
Overview of importing E2B reports
Import pending E2B reports
Accept or Reject E2B report
Differences report
Auto-Accept incoming E2B reports

E2B(R3)
ICH-ICSR Data Element Structure
Case Form Changes
Null Flavors
Amendments to Case and Amendment Reports
Database and Common Profile Switch Changes
Configuring E2B R3 Destination
Transmission and Acknowledgement of E2B(R3) reports

MedWatch Updates
Argus Console Changes
Case Form Changes
MedWatch 3500 A Drug Report Changes
MedWatch 3500 A Device Report Changes

eVAERS
Argus Console Changes
Case Form Changes
Configure eVAERS Destination
Transmission and Acknowledgement of eVAERS reports

Monitoring Regulatory Compliance
Overview of monitoring compliance
Monitor E2B status and compliance
Dashboards features