

# TRAINING: SAFETYEASY 2 DAYS

## Duration

2 days (09:00 – 17:00)

## Agenda day 1: SafetyEasy Administration

09:00 - 10:30	Adm1	Administrative Features of Safety Easy – Part 1 <ul style="list-style-type: none"> <li>➤ Administrator’s daily tasks – Change Password, Manage Users</li> <li>➤ User’s Management</li> <li>➤ Software’s Management</li> <li>➤ Products Management</li> </ul>
10:30 - 10:45		Coffee Break
10:45 - 12:30	Adm2	Administrative Features of Safety Easy – Part 2 <ul style="list-style-type: none"> <li>➤ Workflow Admin</li> <li>➤ List Management</li> <li>➤ Case Management</li> <li>➤ Clinical studies Management</li> </ul>
12:30 - 13:30		Lunch

## Agenda day 1: SafetyEasy Users

13:30 - 14:15	WS 1	SafetyEasy Introduction – Basic Operations <ul style="list-style-type: none"> <li>➤ Starting SafetyEasy</li> <li>➤ Learn about the SafetyEasy Graphical User Interface (GUI)</li> <li>➤ How to use the views</li> <li>➤ Log Out of SafetyEasy</li> </ul>
14:15 - 15:15	WS 2	SafetyEasy Data Entry: my first case <ul style="list-style-type: none"> <li>➤ Creating a new case, Data Entry</li> <li>➤ Add Attachment to Case</li> </ul>
15:15 - 15:30		Coffee Break
15:30 - 16:45	WS 3	SafetyEasy Data Entry: completing the first ICSR <ul style="list-style-type: none"> <li>➤ Contacts and Query Form</li> <li>➤ Classification &amp; MedDRA Coding: Case Coding View: MedDRA Coding</li> <li>➤ Case Narrative and Medical Assessment</li> <li>➤ Case Validation / Task View + Tracking</li> <li>➤ Use the workflow</li> <li>➤ Promote / demote workflows through the life cycle</li> </ul>
16:45 - 17:00		Question and Answers

## Agenda day 2: SafetyEasy Users

09:00 - 09:45		Wrap-up Day 1
09:45 - 10:30	WS 4	SafetyEasy Case reporting ➤ Transmitting the case via gateway ➤ Exporting E2B XML Cases ➤ Other ways to send a Case ➤ Work on a Case, Follow-Up's ➤ Case Audit Trail
10:30 - 10:45		<i>Coffee Break</i>
10:45 - 11:15	WS 5	SafetyEasy – Working with Workflows ➤ Workflow View ➤ Workflow Status
11:15 - 12:30	WS 6	SafetyEasy - Creating a „special“ case ➤ Literature Cases ➤ SUSAR's from clinical trials ➤ Pregancy / parent-child cases ➤ How to deal with Non-serious cases from clinical trials
12:30 - 13:30		<i>Lunch</i>
13:30 - 14:30	WS 6	<i>WS 6 continued</i>
14:30 - 15:15	WS 7	SafetyEasy – Import ➤ Import a single Case ➤ Import Batches of Cases
15:15 - 15:30		<i>Coffee Break</i>
15:30 - 16:00	WS 8	SafetyEasy - Search and Reports ➤ creating a report ➤ Performing Complex Search Operations using the Reports Engine ➤ Creating a Chart
16:00 - 16:45	WS 9	SafetyEasy - Data Mining ➤ Advanced Search and Reporting Options ➤ Regulatory Reports
16:45 - 17:00		Points to consider, Question and Answers