

## Good Clinical Practice (GCP) Refresher Training: Based on ICH E6(R3)

Online Training

Date: April 10-11, 2025

Hour: 10:00 GMT+2 (Bucharest, Athens)

## Day 1 - 10<sup>th</sup> of April 2025

10:00	Registration
10:00 - 12:00	ICH E6 R3 Unveiled
	What's New, What's Changed, What Matters.
	Discover the "new" GCP and understand its significance.
12:00 - 12:15	Coffee Break
12:15 - 13:15	The Updated Principles
	The "old" ones have been revised, and two additional ones have also been added.

## Day 2 - 11th of April 2025

10:00	Registration
10:00 - 11:15	<ul> <li>The "new" GCP for Investigators, including Informed Consent</li> <li>A detailed walk-through updated Investigator responsibilities</li> </ul>
11:15 - 12:00	<ul> <li>Data governance (for Investigators and Sponsors)</li> <li>Familiarise yourself with this entirely new section of the ICH GCP Guideline.</li> </ul>
12:00 - 12:15	Coffee Break
12:15 - 12:45	<ul> <li>Overview of the fundamental concepts</li> <li>How Quality by Design, Fit for Purpose, Avoidance of Complexity, Proportionality, and more are now more important than ever.</li> </ul>
12:45 - 13:05	Questions and answers  An opportunity for you to clarify any uncertainties you may have.
13:05 - 13:15	Wrap-up
13:15	<b>Test</b> Note: Due to the interactive nature of the Agenda, the timing may change