



Training and Education Sheet

no.: _____ year: 2025

REFERENCES

Title:	All Lima SOPs including the updated versions		
Objectives:	Understanding the contents of the new documentation (SOP, WINs and FRMs) in order to be in compliance with the new requirements of Regulation 2017/745 MDR and ISO 14155:2020 for clinical investigations.		
Subjects:	Contents of all documents (SOPs, WINs and FRMs)		
Operating Procedures / Instructions of ref.:	<p>SOP 33-1 rev.3 "Clinical Investigation" + SOP 14-2 "Risk Management in Clinical Investigation" rev.0 + WINs and FRMs</p> <p>SOP 33-1 rev.3; SOP 14-2 rev.0; WIN 33-1-XX all and FRM 33-YY all. Including updated version</p> <p>All Lima templates and Forms</p>		
Start/End Date:	04 June 2025 / 05 June 2025	Duration [hours]:	3
Teacher/s:	<p>Last Name and First Name:,:Self-Training</p> <p>Signature: NA</p>		

EFFECTIVENESS ASSESSMENT METHOD

Practical Test (attach) ⁽¹⁾

Observation on the job ⁽¹⁾

Written Test (attach)

Interview

Not required ⁽²⁾

⁽¹⁾ Describe the practical test or the observation in the appropriate "Note" section

⁽²⁾ Exclusively for interventions of an informational nature or awareness interventions.



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Key: E=Effective; NE: Non-Effective; PE: Partially Effective.

EFFECTIVENESS ASSESSMENT

Notes:

Corrective Actions (mandatory in case of NE or PE training)

LAST NAME and First Name:

Date: _____ Signature: _____