GVP Module V Review and Impact of EMA Decision to Publish Full RMPs

A drug safety training by Cvigilance

AGENDA

Wednesday, Oct 18, 2023 – 9am EST/2pm GMT/3pm CET
Format: Live online training

3-3.50pm CET	Introduction and Training Overview: - Risk Management Terminology - Risk Management responsibilities of the MAH in the EU - Associated processes
3.50-4pm CET	*Break*
4-4.50pm CET	Sections of the EU RMP: - Part I: Product Overview - Part II: Safety Specification - Part III: PV Plan - Part IV: Plans for PAES - Part V: RM Measures - Part VI: Public Summary - Part VII: Annexes
4.50-5pm CET	*Break*
5-5.45pm CET	Most recent and upcoming developments: - Short comparison between EU RMP and US REMS - Current GVP Module V Revision 2 and its changes - Upcoming requirement to publish full RMPs and its potential chances and pitfalls
5.45-6pm CET	*Q&A session*