Agenda: EMA IRIS – Industry Training for GVP Inspections

7th September 2022, 10:00 – 11:30 Central European Time (CET)
Webinar: WebEx

Good Pharmacovigilance practice (GVP) inspections are conducted to ensure that requirements for monitoring the safety of medicines are met. The responsibility for carrying out the inspections rests with the national competent authorities. The European Medicines Agency (EMA) coordinates GVP inspections requested by the Committee for Medicinal Products for Human Use and the Committee for Medicinal Products for Veterinary Use. Following the go-live of IRIS for Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) inspections, EMA is now onboarding GVP Inspections on the IRIS platform with an expected go-live in Q3 2022.

The benefits relevant to Industry stakeholders will include:

1. **Efficiency gains**
   - Harmonisation across different inspections types;
   - Automation of notifications to Applicants/MAHs;
   - Increased data quality through integration with other EMA systems, making use of already available SPOR (Substances, Products, Organisations and Referentials) master data.

2. **Increased security, reducing the risk of unintentional disclosure of confidential information**
   - Streamlined and secured processes for information exchange.

3. **Better knowledge management**
   - Easier access to and retrieval of all inspections data in the context of Centralised Procedure available from one single platform, also providing users with search functionalities.

This webinar aims to explain the GVP Inspections business process in IRIS highlighting the changes and answer any potential questions from industry users.

Topics that will be addressed in this webinar include:

1. IRIS overview
2. IRIS access management
3. GVP Inspections business process, incl. demo of the Industry Portal
4. Guidance and support

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Chair: Dunja Vukić, EMA

Item	Agenda	Time	
1.	**Welcome/Introductions** *Dunja Vukić, EMA*	10:00-10:05	5 mins
2.	**Introduction to IRIS** *Dunja Vukić, EMA*	10:05-10:10	5 mins
3.	**Access Management** First-time registration and access to IRIS *Dunja Vukić, EMA*	10:10-10:25	15 mins
4.	**GVP Inspections business process** Including the demo of the Industry Portal *Dunja Vukić, EMA*	10:25-10:45	20 mins
5.	**Guidance & Support** • **IRIS guide to registration** • **IRIS guide for applicants** • **Guidance for applicants/MAHs involved in GMP, GCP and GVP inspections coordinated by EMA** • **IRIS Forum** *Cristina Pepato, IRIS Inspections Change Manager*	10:45-10:50	5 mins
6.	**Q&A session** (Written procedure) Moderator: *Cristina Pepato, IRIS Inspections Change Manager*	10:50-11:25	35 mins
7.	**Closing** *Dunja Vukić, EMA*	11:25-11:30	5 mins