BASICS OF PHARMACOVIGILANCE 2023

Training agenda:

1.DAY

09:00 – 10:30

- **Pharmacovigilance basics, introduction**

- Brief introduction to Pharmacovigilance – history, existence, objectives, outcomes
- Description of basic PhV activities, experience with adverse reaction reporting

- **Adverse reactions**

- Definitions, reporting sources
- Evaluation
- Valid/invalid cases
- Special situations
- Literature as a source of adverse effects
- Examples from practice

10:30 – 11:00 – break

11:00 – 12:30

- **Organisation of Pharmacovigilance**

- PhV organisation at European / national level
- Organisations at company level (GVP, EMA, PSMF, SOP)
- Global PhV vs. local PhV
- Pharmacovigilance training
- Monitoring of legislation

- **Pharmacovigilance from a global and local perspective**

- Description of activities of the local person
- Description of activities of the global person
- Differences between countries (legislative requirements)
- Links and differences in activities
- Relevant training

12:30 – 13:30 – lunch break

13:30 – 15:00

- **Relationship between Pharmacovigilance and Registration**

- Pre-registration phase and registration phase, post-registration phase
- Registration dossier – RMP, CO, NCO, ACO, ANCO, Similarity Assessment
- When does Pharmacovigilance start?
- Setting up proper communication between departments
- What should not be forgotten?

- **Control mechanisms in PhV (Quality Management)**

- SOP, PSMF
- Key Performance Indicators (KPIs)
- Risk based approach
- Training and audit plans
- Business continuity
- Corrective and preventive actions management (CAPA)
- Archiving

15:00 – 15:30

- **Discussions and questions**

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2.DAY

09:00 – 10:30

- **Specific PhV Documentation**

- Detailed description of individual pharmacovigilance documents – RMP
- More detailed description of individual pharmacovigilance documents – PSUR
- Brief description of CO, NCO, ACO, ANCO etc.

- **Pharmacovigilance database**

- Working with PhV databases – reporting of AEs (examples, specific cases, quality)
- xEVMPD (Art. 57)
- EVDAS
- SPOR
- Local company databases

10:30 – 11:00 – break

11:00 – 12:30

- **Benefit/Risk assessment, signals**

- B/R evaluation process
- Methods for determining B/R
- Signal
- Distinction between company and EU responsibilities

- **Pharmacovigilance outputs**

- PhV directed to authority, own society and the public

12:30 – 13:30 – lunch break

13:30 – 15:00

- **Audit/inspection experience**

- External/internal
- How to behave during inspection/audit
- Rights, GDPR, administrative law
- Examples and experience from inspections and audits over the last two years

15:00 – 15:30

- **Discussions and questions**