

Pharmacovigilance and Signal Detection Program

Learning Objective:

- 1) Discuss signal, learn methods of signal detection and signal workup,
- 2) Learn how to investigate a signal and communicate a potential signal with the population.
- 3) Learn how to follow up on a potential signal.
- 4) Discuss PSUR- Learn the content of the PSUR report, timelines for submission and renewals.
- 5) Discuss Risk management plans.
- 6) Explain the EU risk management strategy, the new approaches to risk assessment and prevention, and the different steps to be considered in the risk management process
- 7) Describe the components of the EU Guideline on the risk management system, focusing on pharmacovigilance and risk minimization plans.
- 8) Discuss REMS

What will you learn?

1. Why signal detection is needed.
2. Regulatory requirements.
3. Approaches to signal detection.
4. Good pharmacovigilance practices.
5. How signals are generated for drugs following AEs.
6. How to anticipate risks by following a signal.
7. Responsibility of a Pharmaceutical company in monitoring safety of the drug and eliminating risks.
8. How to create Risk management and Risk minimization plans.
9. How to communicate about risks, i.e. adequately informing patients and their doctors about how they can use a drug safely or why their drug is no longer available.
10. Concepts of premarketing risk assessment and its important role in the development of (REMS).
11. How to speak the language of drug safety, signaling, risk management, and pharmacovigilance

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