# Online Internship Programs

## 1) Drug Safety Internship Program:

### Learning Objective:

- Learn to process (preparation, analysis, and follow-up) of complex adverse event reports
- Learn reporting to appropriate authorities and agencies worldwide. Work on stimulated cases to ensure all reporting paperwork is complete, following up on incomplete information, and recording the receipt of information.

- Will work on stimulated cases and adverse event to check if the event reports are complete.

- Learn to create a query, write a query and resolution.
- Check event code using MedRA code list (learn how to use the MedRA dictionary for event codes)
- Evaluate individual AE reports for 1) Grading
    - 2) Relatedness
    - 3) Expectedness
- Learn to use CTCAE to grade an adverse event.
- Learn to write medical narrative using practical information.
- Work on stimulated cases- discuss individual case both serious and non-serious events.
- Learn to evaluate all information required of a case (product, reporter, event, and patient)
- Learn to identify duplicates and non-cases (Non reportable AEs).

## 2) Pharmacovigilance and Signal Detection Program:

### Learning Objective:

1) Discuss signal; learn methods of signal detection, 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

## 3) Clinical Research Internship Program:

**Learning Objective:**

- Learn the basic studies of a CRA,CRC,PM,DM
- Learn the work flow in a clinical trial.
- Work on stimulated CRF's to identify issues related to clinical data.
- Work on stimulated cases to develop clinical protocol, SOPs,
- Work on stimulated cases to identify issue related to ICH/GCP.
- Work on stimulated cases to identify issues that may impact on the conduct of the study and ensure appropriate closure of all issues.
- Learn all aspects of site management from collaboration on site selection to study closeout.
- Learn and develop corrective and preventative actions to all issues found during a stimulated case work.
- Learn how a clinical study is monitored and the role of CRA.
- Maintain clinical study supplies and ship supplies to sites as needed.
- Work on stimulated clinical site visit with material to work on.
- Learn the various duties of a visiting CRA to a clinical site and work on stimulated clinical site visit ( PATIENT RECUIRTEMENT, DATA CHECK, AE MANAGEMENT , INVENTORYCHECK, SITE CLOSEOUT)