| No. of<br>Hours | TOPIC   | Days | Expected date | Conducted date | Remark |
|-----------------|---|------|---------------|----------------|--------|
| 1               | Introduction to Pharmacovigilance                             | MON  | 16-06-25      |                |        |
| 2               | History and development of Pharmacovigilance                  | TUE  | 17-06-25      |                |        |
| 3               | Importance of safety monitoring of Medicine                   | MON  | 23-06-25      |                |        |
| 4               | WHO international drug monitoring programme                   | TUE  | 24-06-25      |                |        |
| 5               | Pharmacovigilance Program of India(PvPI)                      | WED  | 25-06-25      |                |        |
| 6               | Introduction to adverse drug reactions                        | MON  | 30-06-25      |                |        |
| 7               | Definitions and classification of ADRs                        | WED  | 02-07-25      |                |        |
| 8               | Detection and reporting                                       | MON  | 07-07-25      |                |        |
| 9               | Methods in Causalityassessment                                | TUE  | 08-07-25      |                |        |
| 10              | Severity and seriousness assessment                           | WED  | 09-07-25      |                |        |
| 11              | Predictability and preventability assessment                  | MON  | 14-07-25      |                |        |
| 12              | Management of adversedrug reactions                           | TUE  | 15-07-25      |                |        |
| 13              | Basic terminologies used in pharmacovigilance                 | WED  | 16-07-25      |                |        |
| 14              | Terminologies of adverse medication related events            | MON  | 21-07-25      |                |        |
| 15              | Regulatory terminologies. Drug and disease classification     | TUE  | 22-07-25      |                |        |
| 16              | Anatomical, classification of drugs                           | WED  | 23-07-25      |                |        |
| 17              | Therapeutic and chemical classification of drugs              | MON  | 28-07-25      |                |        |
| 18              | International classification of diseases, Daily defined doses | TUE  | 29-07-25      |                |        |
| 19              | International Non proprietary Names for drugs                 | WED  | 30-07-25      |                |        |
| 20              | Drug dictionaries and coding in pharmacovigilance             | MON  | 04-08-25      |                |        |
| 21              | WHO adversereaction terminologies                             | TUE  | 05-08-25      |                |        |
| 22              | MedDRA and Standardised MedDRA queries                        | WED  | 06-08-25      |                |        |
| 23              | WHOdrugdictionary   | MON  | 18-08-25      |                |        |
| 24              | Eudravigilance medicinal product dictionary                   | TUE  | 19-08-25      |                |        |
| 25              | Information resources in pharmacovigilance                    | WED  | 20-08-25      |                |        |

| No. of<br>Hours | TOPIC  | Days | Expected date | Conducted date | Remark |
|-----------------|--|------|---------------|----------------|--------|
| 26              | Basic drug information resources. Specialised resources for ADRs                               | MON  | 25-08-25      |                |        |
| 27              | Establishing pharmacovigilance programme Establishing in a hospital                            | TUE  | 26-08-25      |                |        |
| 28              | Establishment & operation of drug safety department in industry                                | MON  | 01-09-25      |                |        |
| 29              | Contract Research Organisations (CROs)   | TUE  | 02-09-25      |                |        |
| 30              | Establishing Nanational programme  | WED  | 03-09-25      |                |        |
| 31              | Vaccine safety surveillance Vaccine  | MON  | 08-09-25      |                |        |
| 32              | Pharmacovigilance Vaccination failure  | TUE  | 09-09-25      |                |        |
| 33              | Adverse events following immunization  | WED  | 10-09-25      |                |        |
| 34              | Pharmacovigilance methods  | MON  | 15-09-25      |                |        |
| 35              | Passive surveillance –Spontaneous reports and case series. Stimulated reporting                | TUE  | 16-09-25      |                |        |
| 36              | Active surveillance–Sentinelsites, drug event monitoring and registries                        | WED  | 17-09-25      |                |        |
| 37              | Comparative observational studies –Cross sectional study, casecontrol study and cohort study   | MON  | 22-09-25      |                |        |
| 38              | Targeted clinical investigations.  Communication in pharmacovigilance                          | TUE  | 23-09-25      |                |        |
| 39              | Effective communication in Pharmacovigilance   | WED  | 24-09-25      |                |        |
| 40              | Communication in Drug Safety Crisis management   | MON  | 29-09-25      |                |        |
| 41              | Communicating with Regulatory Agencies,<br>Business Partners, Healthcare facilities &<br>Media | TUE  | 30-09-25      |                |        |
| 42              | Safety datageneration, Pre clinical phase,<br>Clinical phase, Post approval phase (PMS)        | WED  | 01-10-25      |                |        |
| 43              | ICH Guidelines for Pharmacovigilance   | MON  | 06-10-25      |                |        |
| 44              | Organization and objectives of ICH   | WED  | 08-10-25      |                |        |
| 45              | Expedited reporting, Individual case safety reports & Periodic safety update reports           |      |               |                |        |