Pharmacovigilance Analyst (AI Integrated)

VERSION 1

CURRICULUM / SYLLABUS

SHRM Version	1.0
Date	06.03.2026
Course code	SHRM/LS/02/2026
Mapped to QP Codes	QP Name: Analyst- Drug Safety / Pharmacovigilance QP Code: LFS/N0701 QP Version: 2.0 NSQF Level: 5.5

Preamble

With increase of drug safety concerns as well as enhanced clinical trial and strict regulatory enforcements the role of pharmacovigilance has increased tremendously. IT interface development, software tools, AI tools and data management has made pharmacovigilance turning out to be a professional career. Pharmaceutical industry dependance on pharmacovigilance also providing boost for such a career path

Eligibility

Completed B.Sc (Microbiology) / B. Pharma / B. Tech (Biotech) (Indian / foreign universities)
OR
Completed or Final year MBBS/BDS/BPT/BOT/BAMS/BHMS (in any medical subject)/ (Indian / recognized foreign universities)

Training Outcomes

At the end of the program, the learner should have acquired the listed knowledge and skills

1. Salient aspects of the Life Sciences (especially Pharmaceutical and Bio Pharmaceutical) Industry and its pertinent regulations in order to demonstrate performance that is in line with industry standards.
2. Understanding of the principles, importance, and regulatory framework of pharmacovigilance, including the role of artificial intelligence in drug safety.
3. Perform the collection, processing, and assessment of Individual Case Study Reports (ICSRs).
4. Perform writing aggregate safety reports (PSURs, PADERs, PBRERs, RMPs, Signal management reports).
5. Perform pharmacovigilance literature search activities
6. Perform various pharmacovigilance activities (Case processing, Aggregate safety report, Signal management report writing activities) using software and drug safety databases
7. Ensure regulatory compliance by compiling, identifying, and improving issues in regulatory compliance of ICSRs.
8. Synchronize work with medical reviewer, safety physicians, supervisors and, cross-functional teams and auditors to achieve work goals
9. Competence in integrating artificial intelligence into various aspects of pharmacovigilance, from adverse event identification to regulatory reporting and signal detection efficient and accurate case processing, including data entry, causality assessment, and quality control,
10. Using some AI tools and ability to leverage such AI tools for enhanced productivity

Course Anatomy

Total duration of the course	330 hours (of theory and practical sessions) PLUS Capstone Project 60 hours
	Theory - 180 hours Practical, Project assignments - 150 hours
Course structure	Extensive demo and exercise Several projects on use of various tools Capstone project
Training Delivery	In Hybrid Mode with offline classes from campus with remote access through smart classroom Managed through a LMS platform with separate web page for each batch
Training Input	All digital content available through web page of the batch
Lesson Planning	Flexible structure customised each week while making the weekly roster.

Course Delivery

Program Delivery Pedagogy

- Interactive theoretical sessions to cover fundamental and advanced concepts.
- Practical sessions in a controlled environment to apply theoretical knowledge.
- Real-world scenarios to enhance problem-solving skills.
- A comprehensive project to apply learning in a practical, real-world context.
- Regular quizzes, assignments, and exams to evaluate understanding and progress.

Practical Sessions

Practical sessions will include hands-on exercises with software tools and AI applications connected to Pharmacovigilance, such as:

- Pharmacovigilance System Master File (PSMF), Risk Management Planning (RMP)
- Company Core Data Sheet (CCDS), Reference Safety Information (RSI), Product Information (PI), Summary of Product Characteristics (SmPC)
- Various Drug Safety Databases like Argus, ArisGlobal, Safety Easy (AB Cube), VigiFlow, VigiBase and EudraVigilance
- AI-based tools for regulatory reporting, case processing workflows, signal detection and safety monitoring
- Pharmacovigilance Quality Management System

Software and Hardware Requirements

- Safety database tools (Argus Safety, Aris G, PVNet, Safety Easy (AB Cube), VigiFlow, VigiBase and EudraVigilance etc
- Softwares for Quality Systems in pharmacovigilance
- Excel based replica of drug safety databases

Broad Coverage and Lesson Structure

The table lists the modules and their duration corresponding to the Compulsory NOS of the QP.

NOS and Module Details	Theory (In Hours)	Practical (In Hours)	Total (In Hours)
SECTION A : INTRODUCTION TO LIFESCIENCE, PHARMACEUTICAL SCIENCE, PHARMACOVIGILANCE - (Total Duration - 65 hrs : Theory 38 + Practical 27)			
Module 1 - Orientation to the Life Sciences industry and its job role.	5:00	5:00	10:00
Module 2 :Basic Principles of Clinical Pharmacology and Drug Action : NOS Code LFS/N0509	8:00	2:00	10:00
Module 3 : Introduction to Clinical Research : NOS Code LFS/N0509	10:00	10:00	20:00
Module 4 : Basics of Pharmacovigilance and key activities LFS/N0702, v1	15:00	10:00	25:00
SECTION B : REGULATION, PROCESS, REPORTING IN PHARMACOVIGILANCE (Total Duration - 100 hrs : Theory 55 + Practical 45)			
Module 5 : Regulatory Framework and Reporting Requirements for pharmacovigilance	10:00	5:00	15:00
Module 6 : Adverse Event Identification and Data Sources	10:00	5:00	15:00
Module 7 : Global/Local Medical Literature Surveillance LFS/N0702, v1	10:00	10:00	20:00
Module 8 : Individual Case Safety Reports (ICSRs) processing LFS/N0702, v1	10:00	10:00	20:00
Module 9 : Writing aggregate safety reports including PSURs, PADERs, RMPs, Signal Management Reports LFS/N0706, v1	15:00	15:00	30:00
SECTION C : USING SOFTWARE AND AI TOOLS IN PHARMACOVIGILANCE- (Total Duration - 85 hrs : Theory 35 + Practical 50)			
Module 10 : Pharmacovigilance Software Tools and AI Integration	5:00	10:00	15:00

Module 11 : Safety Databases and Other Associated Tools	5:00	5:00	10:00
Module 12 : Introduction to AI for Pharmacovigilance and Drug Safety	10:00	15:00	25:00
Module 13 : Software Validation and Artificial Intelligence (AI) in Pharmacovigilance LFS/N0705, v1	10:00	10:00	20:00
Module 14 : Regulatory Reporting and Case Processing Workflow with AI	5:00	10:00	15:00
SECTION D : QUALITY CONTROL AND COMPLIANCE (Total Duration - 65 hrs : Theory 43 + Practical 22)			
Module 15 : Pharmacovigilance Quality Management System (PQMS) Mapped to LFS/N0703, v1	10:00	10:00	20:00
Module 16 : Regulatory Compliance in Pharmacovigilance LFS/N0703, v1	15:00	5:00	20:00
Module 17 : Coordination with Medical Coder/ Reviewer, Safety Physicians, Supervisors, and Cross-Functional teams and auditors LFS/N0704, v1	6:00	2:00	8:00
Module 18 : Bio Ethics	4:00	2:00	6:00
Module 19 : Managing environmental sustainability LFS/N0119, v2	4:00	2:00	6:00
Module 20 Display sensitivity towards all genders and people with disability	4:00	1:00	5:00
SECTION E : Employability Skill and PROJECTS			
Module 23 : Employability and basic communicative skills SSC/N9002	4:00	6:00	10:00
Module 25 : Capstone Project (60 hours) To choose one project out of a list to be provided.	5:00		5:00

Total Duration	**180:00**	**150:00**	**330:00**

Module-wise Syllabus and Lesson Plan

Module 1 - Orientation to the Life Sciences industry and its job role.

1. Life Sciences (especially Pharmaceutical and Bio Pharmaceutical) industry, organizational structure and employment benefits
2. Overview pharmaceutical industry, it's functioning and role of various departments in operation of pharmacovigilance activities.
3. Role of a Pharmacovigilance (PV) Associate and practice the required skills. career growth including R&D opportunities in the field of Pharmacovigilance

Module 2 :Basic Principles of Clinical Pharmacology and Drug Action :

NOS Code LFS/N0509

1. Basic of pharmaceutical science
2. Discuss the fundamental concepts of clinical pharmacology encompassing all aspects of the relationship between drugs and humans
3. Describe the relevance of pharmacokinetics and pharmacodynamics in clinical trials
4. Explain the basics of bioavailability and bioequivalence in clinical studies.
5. Discuss the bioassay parameters used in clinical trials

Module 3 : Introduction to Clinical Research :

NOS Code LFS/N0509

1. Define the basic concepts of clinical research
2. Describe the development process of medical products and the related regulations.
3. Explain different type of clinical trial
4. Discuss different phases of clinical trial
5. Understand clinical trial protocols - Objective, different parts, and types
6. How to define eligibility criteria for a trial with inclusion and exclusion criteria, safety and adverse event in protocol, and how to ensure human subjects protection
7. Explain the core ethical principles of clinical research
8. Discuss how the research subject`s safety, rights and welfare are protected in a clinical trial

Module 4 : Basics of Pharmacovigilance and key Processes

Mapped to LFS/N0702, v1

1. Concepts of Pharmacology including Absorption, Distribution, Metabolism, Elimination, and Route of Drug Administration in context of Pharmacovigilance

2. Drug development process including including formulations, sources of APIs, drug safety issues and how such safety ensured
3. Understand the role of pharmacovigilance in ensuring drug safety and public health.
4. Concepts of disease physiology and reason of disease condition
5. Drug related safety events and adverse events and origin of Pharmacovigilance
6. Definition and concepts of Pharmacovigilance as per WHO, GVP & ICH, FDA, PVPI
7. Identify the key challenges and limitations of traditional pharmacovigilance methods.
8. Process to perform the activities related to writing of Pharmacovigilance System Master File (PSMF), Risk Management Planning (RMP) followed by risk/benefit assessment, Periodic Safety Update Reports (PSURs) and Signal detection and Management.
9. PRACTICAL -
    a. List the contents of Pharmacovigilance System Master File (PSMF)
    b. List the content and key components of a Risk Management Plan (RMP)
    c. List the steps followed in risk/benefit assessment and Signal detection
10. Procedure to prepare signal management reports and accordingly calculate proportional reporting ratio (PRR) and IC Value
    a. PRACTICAL - Demonstrate the procedure to calculate proportional reporting ratio (PRR) and IC Value.
11. Minimum requirements to set up a PV system in any organization + PRACTICAL

Module 5 : Regulatory Framework and Reporting Requirements for pharmacovigilance

1. Describe the development process of medical products and the related regulations.
2. Summarize regulatory authorities and guidelines for pharmacovigilance in India like GVP (India & Europe), PvPI, USFDA guidelines, WHO etc.
3. Explain the roles and responsibilities of regulatory authorities in drug safety
4. Explain the pharmacovigilance requirements as per Schedule 5 of New drugs and clinical trials Rules, 2019
5. Role of PVPI in ensuring medicine safety
6. Norms pertaining to Good Documentation Practice (GDP), Good Clinical Practice (GCP) and Indian Council of Medical Research (ICMR)
7. Describe the terms used in pharmacovigilance like Risk Management Plan (RMP), Company Core Data Sheet (CCDS), Reference Safety Information (RSI), Product Information (PI), Summary of Product Characteristics (SmPC)
8. Understand the legal requirements for adverse event reporting to regulatory
9. Describe the differences between reporting in different regions, such as consequences of non-compliance with regulatory reporting

10. Analyze the challenges and solutions for integrating AI into regulatory compliance.

Module 6 : Adverse Event Identification and Data Sources

1. Classify adverse events into various categories, including serious, non-serious, expected, and unexpected.
2. Determine GCP for ensuring the safety of the research subject and the validity of a clinical trial
3. Discuss the source of safety Information and safety evaluation
4. Examine the different sources of adverse event data, such as spontaneous reports, clinical trials, and social media.
5. Understand the importance of data quality and reliability in pharmacovigilance.
6. Analyze the challenges and opportunities associated with mining data for adverse event identification.
7. Evaluate the ethical considerations in using diverse data sources for safety monitoring
8. Steps for corrective actions/ follow up actions at site in case of an event/adverse event/ serious adverse event/ serious adverse reaction in a clinical trial / BA-BE Study to ensure patient/ volunteer safety and Good Clinical Practices (GCP) compliance
9. PRACTICAL
    1. Practice classifying adverse events based on provided case examples.
    2. Analyze real-world data sets containing adverse event reports and identify potential signals.
    3. Conduct a data source assessment for a given adverse event, considering data quality and reliability.
    4. Develop a strategy to leverage AI for efficient adverse event identification using different data sources

Module 7 : Global/Local Medical Literature Surveillance

Mapped to LFS/N0702, v1

1. Explain literature databases like PubMed, Embase, etc.
2. Describe the importance of local literature search
3. Explain the methods and signal search strategies, Search strings using drug safety databases
4. Carry out screening, review, and assessment of search records
    a. PRACTICAL - Demonstrate how to perform a literature search using Different strategies like use of Mesh words, literature search data analysis etc.
5. How to Identify abstracts and full-text articles in the published medical literature databases.

6. List the required permissions to access different search engines with full-text articles + PRACTICAL

Module 8 : Individual Case Safety Reports (ICSRs) processing

Mapped to LFS/N0702, v1

1. Describe general principles in relation to the collection, processing and, reporting of all Adverse Events (AEs)/ Adverse Drug Reactions (ADRs) associated with pharmaceutical products for human use
2. Identify adverse events in special population (Pregnancy, Geriatric and Paediatric)
3. Differentiate between AEs and ADRs, SAEs and SUSARs
    a. PRACTICAL - Identify the seriousness criteria of the AEs and ADRs
4. Explain the importance to analyse the completeness of information, seriousness criteria, severity
5. Explain the process of temporal relationship, causality assessment between event and suspect drug
6. Explain the types of reports in the pharmacovigilance process including spontaneous, clinical trial, registries, post authorisation studies, published scientific and medical literature, regulatory and legal reports
7. Concept of Attributable, Legible, Contemporaneous, Original, and Accurate Plus (ALCOA +) principle and its importance.
8. Explain ICSR reports including expedited (serious reports, at risk reports), non-expedited reports
    a. PRACTICAL - Demonstrate how to write narrative and report writing for medication error and lack of efficacy.
    b. Take part in submission of expedited reports for the pharmacovigilance.
9. Explain the stages of ICSR processing which includes triage, data entry, quality check and, medical review and reporting
    a. PRACTICAL - Perform data entry for ICSRs into safety databases

Module 9 : Writing aggregate safety reports including PSURs, PADERs, RMPs, Signal Management Reports

Mapped to LFS/N0706, v1

1. Describe various types aggregate safety reports including PSURs, PADERs, RMPs, Signal Management Reports and their regulatory timelines.
2. Process of compiling and submitting various safety reports.
3. Principles & Methodologies of Signal Detection and various tools used for processing.

4. Process of Prioritization of Safety Signals and Integrating Safety Information into RMPs.
5. Discuss Compiling Aggregate Safety Reports (PSURs, PADERs) and Writing Risk Management Plans (RMPs)
6. Discuss the importance of Risk Management Plans (RMPs)
7. PRACTICAL
    a. Demonstrate the process of Signal detection, evaluation, and response
    b. Demonstrate compilation of various safety reports

Tools, Equipment and Other Requirements

Softwares for Quality Systems in pharmacovigilance, 8th Edition/IP 2018, Pharmacovigilance

Program of India Guidelines, Good Pharmacovigilance Practices (GVP), Sample SOPs, -QMS,

Deviation and CAPAs, Root cause analysis, Audit and Inspection responses

Module 10 : Pharmacovigilance Software Tools and AI Integration

1. Identify common pharmacovigilance software tools and their functionalities.
2. Explain the advantages of integrating AI into pharmacovigilance software.
3. Understand the underlying architecture and data structures of pharmacovigilance databases.
4. Explore the role of AI algorithms in signal detection and causality assessment.
5. PRACTICAL
    1. Configure a sample pharmacovigilance database and perform basic data entry and retrieval tasks.
    2. Apply AI algorithms to detect safety signals in a provided dataset.
    3. Participate in a group project to design an AI-powered dashboard for real-time safety monitoring

Module 11 : Safety Databases and Other Associated Tools

Mapped to LFS/N0705, v1

1. Explain detailed safety process providing automated global case processing, periodic reporting, E2B intake and submission, comprehensive reporting, detailed analytics, and safety operations from a single system
2. National and other international adverse reporting forms and aggregate report templates
3. Explain differences in ADR reporting for new drugs, vaccines, biologics medical devices and fixed dose combination drugs

   a. PRACTICAL - Perform post-marketing surveillance to store the safety profile and adverse event reports of the drug
   b. List down the differences in ADR reporting for new drugs, vaccines, biologics medical devices and fixed dose combination drugs.
4. Explain the usage guidelines of MedDRA software tools
   a. PRACTICAL - Perform manual data entry from ADR paper forms by using WHO Drug and MedDRA
   b. PRACTICAL - Perform coding of relevant medical terminologies using MedDRA and WHO-drug dictionary
5. Explain usage guidelines of various Drug Safety Databases like Argus, ArisGlobal, Safety Easy (AB Cube), VigiFlow, VigiBase and EudraVigilance
   a. PRACTICAL - Demonstrate the use of softwares like Argus safety, Aris global, VigiFlow and VigiBase for ADR reporting of new drugs, vaccines, biologics medical devices and fixed dose combination drugs.
   b. Demonstrate the use of various Drug Safety Databases like Argus, ArisGlobal, Safety Easy (AB Cube) and EudraVigilance
6. Describe the steps to facilitate compliance with domestic and global safety reporting obligations for drugs, vaccines, biologics, devices, and combination products.
7. PRACTICAL
   a. Demonstrate how to collect and process ICSR data on a validated ICSR software
   b. Demonstrate the procedure for the entry, classification, coding and assessment of adverse event reports, in accordance with international standards and guidelines by using appropriate software tool

Tools, Equipment and Other Requirement

Safety database tools (Argus Safety, Aris G, PVNet etc. Training modules), 8th Edition/IP 2018, Pharmacovigilance Program of India (PVPI) Guidelines, Indian Good Pharmacovigilance Practices (GVP),e-subscription, MedDRA Dictionary (training modules), WHO Drug Dictionary, Sample SOPs, sample Periodic Safety Update Reports (PSURs), Sample Individual Case Safety Report (ICSR),

Module 12 : Introduction to AI for Pharmacovigilance and Drug Safety

1. Explain the fundamental principles of artificial intelligence (AI) and its relevance to pharmacovigilance.
2. Describe the potential benefits and ethical considerations of using AI in drug safety monitoring.

3. Summarize the current regulatory landscape and guidelines related to AI in pharmacovigilance.
4. Evaluate and compare AI-driven pharmacovigilance systems to traditional methods.
5. Awareness about AI techniques, including deep learning, natural language processing (NLP), and predictive modeling.
6. Analyze how AI can enhance signal detection, risk assessment, and predictive analytics in pharmacovigilance.
7. Examine the potential of AI-driven causal inference and benefit-risk assessment.
8. Understand the regulatory considerations for implementing AI applications in pharmacovigilance.
9. Ethical use of AI in pharmacovigilance.
10. Analyze regulatory documents and guidelines that govern the integration of AI in pharmacovigilance.
11. PRACTICAL
    a. Create predictive models for drug safety using AI and real-world data.
    b. Collaboratively conduct a mock benefit- risk assessment using AI-generated insights.

Module 13 : Software Validation and Artificial Intelligence (AI) in Pharmacovigilance

Mapped to LFS/N0705, v1

1. Explain the importance of use of validated software in pharmacovigilance
2. Explain the basics of software validation as per regulatory guidelines
3. Explain AI future software validation tools (IQ, OQ, and PQ) before using the software tool or databases
4. Describe the fundamental basics of artificial intelligence (AI)
5. Explain the relevance of artificial intelligence (AI) in the field of pharmacovigilance
6. PRACTICAL
    a. List the applications of artificial intelligence (AI) for the role of pharmacovigilance associate
    b. Demonstrate the use of artificial intelligence (AI) in ICSR processing

Tools, Equipment and Other Requirements

8th Edition/IP 2018, Pharmacovigilance Program of India Guidelines, Indian and European Good Pharmacovigilance Practices (GVP), USFDA Pharmacovigilance guidelines, e-subscription, excel based replica of drug safety databases,

Module 14 : Regulatory Reporting and Case Processing Workflow with AI

1. Describe the steps involved in the case processing workflow in pharmacovigilance reporting.
2. Explain the concept of signal detection and its significance in safety monitoring in the context of regulatory reporting.
3. Analyze the role of AI in automating regulatory reporting processes.
4. Explore the challenges and solutions for integrating AI into case processing workflows.
5. PRACTICAL
    1. Simulate the case processing workflow with AI assistance using sample cases.
    2. Collaboratively develop a signal detection algorithm and apply it to a dataset.
    3. Create mock regulatory reports for adverse events with AI-supported automation.

Module 15 : Pharmacovigilance Quality Management System (PQMS)

Mapped to LFS/N0703, v1

1. Describe contemporary principles, practical approaches, and regulatory expectations for the Pharmacovigilance Quality Management System (PQMS)
2. Explain how the elements of the Pharmacovigilance and a Quality Management System fit together to achieve regulatory compliance
3. Identify the structures and processes of a quality system and a pharmacovigilance system
4. Explain Audits – Internal & External, Strategic and Regular audits and audit plans
5. PRACTICAL
    a. Develop SOPs for pharmacovigilance.
    b. Develop methodology of Deviations, CAPAs
    c. Application of QMS in Pharmacovigilance System Master File (PSMF)
    d. Pharmacovigilance audit methodology

Module 16 : Regulatory Compliance in Pharmacovigilance

Mapped to LFS/N0703, v1

1. Identify the responsibilities of key pharmacovigilance stakeholders such as Regulatory Authority, Market Authorization Holders (MAHs), Public stakeholders i.e. Physician/ Patient, Qualified Person Responsible for Pharmacovigilance (QPPV), PV Departments
2. Review the submission of ICSRs, PSUR, RMP, signal reports and aggregate reports while ensuring the timeliness and accuracy of reports on a regular basis
3. PRACTICAL

a. Demonstrate how to Review the submission of ICSRs, PSUR, RMP, signal reports and aggregate reports while ensuring the timeliness and accuracy of reports on a regular basis

4. Discuss the ICH-E2 guidelines (Pharmacovigilance- Efficacy guidelines) to address Efficacy-related Safety concerns.
5. Explain 21 CFR Part 11 Compliance (Electronic records and electronic signatures) in pharmacovigilance to ensure electronic signatures Integrity and Security
6. Pharmacovigilance Regulatory Inspections- Dos and don'ts in pharmacovigilance inspections, Inspection agenda, Inspection responses and closures
7. PRACTICAL
    a. Prepare a list of Dos and don'ts in pharmacovigilance inspections, Inspection agenda, Inspection responses and closures
    b. Pharmacovigilance inspection methodology- CAPAs and responses
8. Prepare a response to non-compliance reports by initiating an investigation for the deviations, identify cause
9. Record documentation for each corrective and preventive actions (CAPA) taken to ensure compliance

Module 17 : Coordination with Medical Coder/ Reviewer, Safety Physicians, Supervisors, and Cross-Functional teams and auditors

Mapped to LFS/N0704, v1

1. Explain the basic concepts rules of data integrity as per GCP, GVP,GMP,GDP
2. Discuss the General organogram of PV
3. Demonstrate effective communication in PV department, PvOI, SOPs, job responsibilities of all persons involved in PV activities. Demonstrate in simulated environment
4. Exhibit the core and professional skills like communication, problem-solving, planning and organizing, critical thinking during the coordination related activities
5. Coordinate with the team members during the quality check for the cases, and inform intervention-requiring issues to supervisor
6. Support Patient Support Program Associate/ Data Assistant in mining the spontaneous reports submitted to the national surveillance systems
7. Maintain data integrity while responding to auditors
8. PRACTICAL
    a. Medical coding in pharmacovigilance

b. Medical Review in ICSRs, PSURs, PBRERs, PADERs, RMPs, Signal management report

Module 18 : Bio Ethics

Module 19 : Managing environmental sustainability

Mapped to LFS/N0119, v2

Module 20 : Display sensitivity towards all genders and people with disability

Mapped to LFS/N0119, v2

Module 21 : Employability Skills Mapped to DGT/VSQ/N0102- v1.0