National Occupational Standards

Pharmacovigilance Case- Processing (Incidents /adverse event using software including AI tools)

Unit Code: LFS/N0707

Version: 1.0

NSQF Level: 5.5

Life Sciences Sector Skill Development Council || # 14, Rear 2nd Floor, Palam Marg, Vasant Vihar New Delhi-110057 || email:ANSHUL.SAXENA@LSSSDC.IN

Description

This NOS on Pharmacovigilance Case Processing for Incidents/adverse event using software including AI tools will enable individual of adverse event processing, software tools, and advanced AI applications in drug safety. Participants will gain a comprehensive understanding of pharmacovigilance's role in ensuring drug safety and the potential benefits and ethical considerations of AI integration. Regulatory compliance, data source analysis, and the practical application of AI tools are emphasized throughout the course. By the end, participants will be equipped to navigate the evolving field of pharmacovigilance with a strong focus on AI's pivotal role in ensuring drug safety, efficiency, and compliance

Scope

The scope covers the following :

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- Pharmacovigilance and AI in Drug Safety
- Regulatory Framework and Reporting Requirements
- Adverse Event Identification and Data Sources
- Pharmacovigilance Software Tools and AI Integration
- Regulatory Reporting and Case Processing Workflow with AI
- Advanced AI Applications in Pharmacovigilance

Elements and Performance Criteria

Pharmacovigilance and AI in Drug Safety

To be competent, the user/individual on the job must be able to:

PC1. Collaborate in group discussions and debates on the use of AI in pharmacovigilance

PC2. Conduct a review of regulatory documents and guidelines to assess their impact on pharmacovigilance practices

PC3. Evaluate AI-driven pharmacovigilance systems and operating software tools

Regulatory Framework and Reporting Requirements

To be competent, the user/individual on the job must be able to:

PC4. prepare, review, and submit Individual Case Safety Reports (ICSRs) to regulatory agencies.

PC5. Collaborate in conducting a compliance audit to identify areas of non-compliance and proposing corrective actions.

PC6. develop a compliance strategy to incorporate AI components to enhance reporting efficiency and regulatory compliance.

Adverse Event Identification and Data Sources

To be competent, the user/individual on the job must be able to:

PC7. analyze adverse event reports and identify potential safety signals, providing recommendations for further investigation.

PC8. Develop and present a strategy to leverage AI for efficient adverse event identification using a diverse range of data sources, addressing data quality and ethical considerations.

PC9. create a data collection and analysis plan for a pharmacovigilance study, encompassing the selection of data sources, data extraction, and signal detection methods.

Pharmacovigilance Software Tools and AI Integration

To be competent, the user/individual on the job must be able to:

PC10. design AI-powered dashboards for real-time safety monitoring, showcasing how AI-enhanced tools can provide real-time insights for decision-making.

PC11. Create sample of pharmacovigilance database and actively participate in data entry and retrieval tasks, ensuring familiarity with software tools and database management.

PC12. Identify the use of AI-enhanced software for case assessment and data entry, showcasing hands-on proficiency in AI integration.

Regulatory Reporting and Case Processing Workflow with AI

To be competent, the user/individual on the job must be able to:

PC13. Prepare regulatory reports for adverse events, incorporating AI-supported automation for data extraction and report generation.

PC14. Ensure audit of a pharmacovigilance case processing system with AI integration, assessing compliance, data accuracy, and AI-driven efficiencies.

PC15. ensure quality control measures using AI tools in a practical exercise, data accuracy, completeness, and adherence to regulatory guidelines

Advanced AI Applications in Pharmacovigilance

To be competent, the user/individual on the job must be able to:

PC16. Experiment with natural language processing (NLP) techniques for narrative analysis and data extraction from diverse data sources.

PC17. Create predictive models for drug safety using AI and real-world data, and evaluate the predictive accuracy of these models.

PC18. Conduct a benefit-risk assessment using AI-generated insights, showcasing proficiency in advanced AI applications.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. Understanding the roles and responsibilities of regulatory authorities in overseeing drug safety.

KU2. Familiarity with the legal requirements for reporting adverse events to regulatory agencies

KU3. Knowledge of the differences in reporting requirements among various regions, including the FDA, EMA, and WHO.

KU4. Recognizing the consequences of non-compliance with regulatory reporting obligations.

KU5. Understanding the challenges and potential solutions for the integration of AI into regulatory compliance processes.

KU6. Classifying adverse events into different categories, including serious, non-serious, expected, and unexpected.

KU7. Understanding the various sources of adverse event data, such as spontaneous reports, data from clinical trials, and information from social media.

KU8. Recognizing the importance of data quality and reliability in the context of pharmacovigilance.

KU9. Analyzing the challenges and opportunities associated with mining data for adverse event identification.

KU10. Grasping the ethical considerations involved in utilizing diverse data sources for safety monitoring.

Generic Skills (GS)

User/individual on the job needs to know how to:

GS1. use reading and comprehension skills to read instructions, guidelines, procedures, rules, and signages

GS2. use written communication skills to accurately record every information required to be reported as per SOP and regulatory guidelines in the language prescribed by the company's SOP

GS3. apply planning and organizing skills to plan and organize tools and material required for work to fulfil requirements

GS4. use critical thinking skills to ascertain the breach/ compliance of protocols

GS5. apply customer centricity to remain compliant with data integrity rules and regulatory guideline to evaluate impact of wrongdoings

GS6. apply decision-making skills to make balanced judgments within the authority in different situations while dealing with hazards and breaches

GS7. apply problem-solving skills to find solutions for workflow-related difficulties

GS8. use verbal communication skills to communicate with supervisor/ manager/ Incharge or any other concerned authority clearly for escalating any emergency situation or hazard

GS9. Identify and resolve the issues and challenges

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Pharmacovigilance and AI in Drug Safety	**8**	**8**	**-**	**-**
PC1. Collaborate in group discussions and debates on the use of AI in pharmacovigilance	-	-	-	-
PC2. Conduct a review of regulatory documents and guidelines to assess their impact on pharmacovigilance practices	-	-	-	-
PC3. Evaluate AI-driven pharmacovigilance systems and operating software tools	-	-	-	-
Regulatory Framework and Reporting Requirements	**8**	**8**	**-**	**-**
PC4. prepare, review, and submit Individual Case Safety Reports (ICSRs) to regulatory agencies.	-	-	-	-
PC5. Collaborate in conducting a compliance audit to identify areas of non-compliance and proposing corrective actions.	-	-	-	-
PC6. develop a compliance strategy to incorporate AI components to enhance reporting efficiency and regulatory compliance.	-	-	-	-
Adverse Event Identification and Data Sources	**9**	**9**	**-**	**-**
PC7. analyze adverse event reports and identify potential safety signals, providing recommendations for further investigation.	-	-	-	-
PC8. Develop and present a strategy to leverage AI for efficient adverse event identification using a diverse range of data sources, addressing data quality and ethical considerations.	-	-	-	-
PC9. create a data collection and analysis plan for a pharmacovigilance study, encompassing the selection of data sources, data extraction, and signal detection methods.	-	-	-	-
Pharmacovigilance Software Tools and AI Integration	**8**	**8**	**-**	**-**

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. design AI-powered dashboards for real-time safety monitoring, showcasing how AI-enhanced tools can provide real-time insights for decision-making.	-	-	-	-
PC11. Create sample of pharmacovigilance database and actively participate in data entry and retrieval tasks, ensuring familiarity with software tools and database management.	-	-	-	-
PC12. Identify the use of AI-enhanced software for case assessment and data entry, showcasing hands-on proficiency in AI integration.	-	-	-	-
Regulatory Reporting and Case Processing Workflow with AI	**9**	**9**	**-**	**-**
PC13. Prepare regulatory reports for adverse events, incorporating AI-supported automation for data extraction and report generation.	-	-	-	-
PC14. Ensure audit of a pharmacovigilance case processing system with AI integration, assessing compliance, data accuracy, and AI-driven efficiencies.	-	-	-	-
PC15. ensure quality control measures using AI tools in a practical exercise, data accuracy, completeness, and adherence to regulatory guidelines	-	-	-	-
Advanced AI Applications in Pharmacovigilance	**8**	**8**	**-**	**-**
PC16. Experiment with natural language processing (NLP) techniques for narrative analysis and data extraction from diverse data sources.	-	-	-	-
PC17. Create predictive models for drug safety using AI and real-world data, and evaluate the predictive accuracy of these models.	-	-	-	-
PC18. Conduct a benefit-risk assessment using AI-generated insights, showcasing proficiency in advanced AI applications.	-	-	-	-
NOS Total	**50**	**50**	**-**	**-**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0707
NOS Name	Pharmacovigilance Case- Processing (Incidents /adverse event using software including AI tools)
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical and Contract Research, Biotechnology
Occupation	Pharmacovigilance
NSQF Level	5.5
Credits	2.00
Minimum Job Entry Age	NA
Minimum Educational Qualification & Experience	Pursuing 3rd year of UG (B. Sc.(Microbiology)) OR Pursuing 4th year UG (in case of 4-year UG with honours/ honours with research) (B. Pharma / B. Tech (Biotech) (Indian / foreign universities)) OR Medical Graduate (Pursuing Final Year of MBBS/BDS/BPT/BOT/BAMS/BHMS (in any medical subject)/ (Indian / recognized foreign universities))
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023
Reference code on NQR	NG-5.5-LS-01295-2023-V1-LSSSDC
NQR Version	1
CCN Category	2