National Occupational Standards

Aggregate Report writing for Regulatory Compliance

Unit Code: LFS/N0708

Version: 1.0

NSQF Level: 5.5

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Description

This NOS gives an overview about how to Prepare and compile Aggregate Reports (PSURs, PBRERs, PADERs) for Regulatory Compliance

Scope

The scope covers the following :

- life sciences industry and Aggregate Reports
- Report Structure and Writing Skills for pharmacovigilance reporting.
- Signal Detection and Evaluation for Pharmacovigilance
- Risk Minimization and Compliance for Pharmacovigilance
- Application and Emerging Technologies For Pharmacovigilance

Elements and Performance Criteria

Life sciences industry and Aggregate Reports

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

PC1. analyze a sample Aggregate Report and discuss a case study on regulatory compliance in pharmacovigilance

PC2. outline data sources and their management in pharmacovigilance

Report Structure and Writing Skills for pharmacovigilance reporting

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

PC3. submit a written assignment with sections of Aggregate Reports based on provided templates to demonstrate their understanding of report structure and regulatory writing.

PC4. Participate in group exercises to collaboratively create a comprehensive Aggregate Report section, which will be evaluated for completeness and regulatory compliance.

PC5. explore best practices in writing skills for regulatory compliance

Signal Detection and Evaluation for Pharmacovigilance

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

PC6. participate in discussions and answer questions related to signal detection methods in pharmacovigilance.

PC7. evaluate their knowledge of benefit-risk assessment in pharmacovigilance

Risk Minimization and Compliance for Pharmacovigilance

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

PC8. Identify and evaluate various risk minimization strategies applicable to different contexts within the pharmaceutical industry.

PC9. Prepare a sample comprehensive risk minimization plans for hypothetical scenarios, considering diverse risk factors and potential mitigations

PC10. Apply theoretical knowledge to real-world scenarios by creating a detailed risk minimization plan for a hypothetical drug

PC11. Engage in a simulated audit scenario to identify and address compliance challenges

Application and Emerging Technologies For Pharmacovigilance

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

PC12. Evaluate the impact of ethical decisions on public health and regulatory compliance.

PC13. Apply CAPA principles through a demonstration study, identifying and addressing compliance issues effectively

PC14. Evaluate the potential benefits and challenges associated with integrating AI and blockchain technologies into aggregate reporting processes.

PC15. Evaluate case studies and examples illustrating the successful integration of AI and blockchain in pharmacovigilance

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. IT policies of company

KU3. data integrity related SOPs

KU4. SOP for accessing the computer systems and emails

KU5. procedures for reporting data, escalation procedures

KU6. quality management SOPs including those for change control, deviations and CAPAs and BCP

KU7. basic of aggregrate reports

KU8. operating procedure of software like MedDRA, WHO Drug dictionary, SAS, various Drug Safety Database like Argus and ArisGlobal, Safety Easy (AB Cube), EudraVigilance and ADR reporting software like VigiFlow and VigiBase

KU9. GCP guidelines and ICH E2B standard

KU10. computer handling (MS Word, Excel, Power Point Presentation, Outlook and Skype)

KU11. software validation procedures

KU12. Changes/new regulations affecting pharmacovigilance activities

KU13. method of writing case narratives and medical writing

KU14. tools and methods of literature search

KU15. process flow and forms of ADR reporting reports

KU16. artificial intelligence future software validation tools (IQ, OQ & PQ) as well as about artificial intelligence

KU17. changes/new regulations affecting pharmacovigilance activities

KU18. assessment of Vaccine Adverse Event Reporting System (VAERS)

KU19. recall International Classification of Diseases (ICD) codes for drugs

KU20. Understanding the challenges and potential solutions for the integration of AI into regulatory compliance processes

KU21. Classifying adverse events into different categories, including serious, non-serious, expected, and unexpected.

KU22. Understanding the various sources of adverse event data, such as spontaneous reports, data from clinical trials, and information from social media.

KU23. Recognizing the importance of data quality and reliability in the context of pharmacovigilance.

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 environment, health, safety and security requirements

GS4. apply customer centricity to remain compliant with data integrity rules and regulatory guideline to evaluate impact of wrongdoings

GS5. apply decision-making skills to make balanced judgments within the authority in different situations while dealing with hazards and breaches

GS6. apply problem-solving skills to find solutions for workflow-related difficulties

GS7. use verbal communication skills to communicate with supervisor/ manager/ Incharge or any other concerned authority clearly for escalating any emergency situation or hazard

GS8. draft letters pertaining to AEs and write detailed reports for pharmacovigilance reporting

GS9. record and communicate details of work done to appropriate people using written/typed report or computer-based record/electronic mail

GS10. use computers, internet, software tools for pharmacovigilance related work

GS11. read and interpret various coding systems, medical terminology as per company norms, GCP, PVPI and WHO guidelines

GS12. read notes/comments from supervisors

GS13. disclose information only to those who have the right and need to know it

GS14. maintain confidentiality of sensitive information

GS15. communicate new or changed regulations to relevant members of the department to initiate any change in process

GS16. build and maintain good relationships across functional units and company affiliates

GS17. analyse data and information for preparing reports

GS18. pay attention to detail

GS19. identify anomalies in data

GS20. suggest improvements (if any) in process/formats for reports/documentation based on experience and observation

GS21. use available data and computer software to create required documentation

GS22. make decisions on a suitable course of action or response

GS23. make decisions to write case narratives in compliance to the regulations and guidelines

GS24. plan and organize assigned work in order to achieve specified deadlines

GS25. multi-task and adapt to meet work timelines

GS26. effectively interact with the various stakeholders to complete assigned tasks

GS27. evaluate the drafted reports in line to data integrity rules

GS28. critically assess the terms/ medical codes for preparing the report

GS29. take help of IT team in case of any login related issues

GS30. escalate critical items or any other issue deemed necessary to concerned managers/ clients

GS31. keep customer guidelines, instructions and the relevant regulatory guidelines in focus while reporting the ADR

GS32. ensure data integrity and confidentiality while entering information

GS33. liaise effectively and maintain excellent relationship with the internal/external contacts

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Life sciences industry and Aggregate Reports	**5**	**5**	**-**	**-**
PC1. analyze a sample Aggregate Report and discuss a case study on regulatory compliance in pharmacovigilance	-	-	-	-
PC2. outline data sources and their management in pharmacovigilance	-	-	-	-
Report Structure and Writing Skills for pharmacovigilance reporting	**10**	**10**	**-**	**-**
PC3. submit a written assignment with sections of Aggregate Reports based on provided templates to demonstrate their understanding of report structure and regulatory writing.	-	-	-	-
PC4. Participate in group exercises to collaboratively create a comprehensive Aggregate Report section, which will be evaluated for completeness and regulatory compliance.	-	-	-	-
PC5. explore best practices in writing skills for regulatory compliance	-	-	-	-
Signal Detection and Evaluation for Pharmacovigilance	**12**	**13**	**-**	**-**
PC6. participate in discussions and answer questions related to signal detection methods in pharmacovigilance.	-	-	-	-
PC7. evaluate their knowledge of benefit-risk assessment in pharmacovigilance	-	-	-	-
Risk Minimization and Compliance for Pharmacovigilance	**13**	**12**	**-**	**-6**
PC8. Identify and evaluate various risk minimization strategies applicable to different contexts within the pharmaceutical industry.	-	-	-	-
PC9. Prepare a sample comprehensive risk minimization plans for hypothetical scenarios, considering diverse risk factors and potential mitigations	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. Apply theoretical knowledge to real-world scenarios by creating a detailed risk minimization plan for a hypothetical drug	-	-	-	-
PC11. Engage in a simulated audit scenario to identify and address compliance challenges	-	-	-	-
Application and Emerging Technologies For Pharmacovigilance	**10**	**10**	**-**	**-**
PC12. Evaluate the impact of ethical decisions on public health and regulatory compliance.	-	-	-	-
PC13. Apply CAPA principles through a demonstration study, identifying and addressing compliance issues effectively	-	-	-	-
PC14. Evaluate the potential benefits and challenges associated with integrating AI and blockchain technologies into aggregate reporting processes.	-	-	-	-
PC15. Evaluate case studies and examples illustrating the successful integration of AI and blockchain in pharmacovigilance	-	-	-	-
NOS Total	**50**	**50**	**-**	**-**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0708
NOS Name	Aggregate Report writing for Regulatory Compliance
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Pharmacovigilance
NSQF Level	5.5
Credits	2.0
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-01296-2023-V1-LSSSDC
NQR Version	1
CCN Category	2