CCEK – NSQF ALIGNED PROGRAM

COURSE SYLLABUS

FOR

Clinical Data Validation and Quality Control

CCEK - NATIONAL SKILL DEVELOPMENT TRAINING PROGRAM

Clinical Data Validation and Quality Control

CCEK – NSDC course package covers the following Qualification Packs and leads to the following NSDC certifications. The students who successfully completed the course programs are entitled to get NSDC certification after undergoing the assessment process of NSDC as per the rules and regulations stipulated by NSDC from time to time.

SL. NO.	QUALIFICATIONS PACK	QUALIFICATIONS PACK CODE	NSQF LEVEL
1	**Clinical Data Validation and Quality Control** **Brief Job Description**: The professional with Clinical Data Validation and Quality Control is able to ensuring the accuracy and reliability of clinical data in clinical research industry. This includes data validation principles, database locking, query management, data reconciliation, and quality control measures in Clinical Data Management (CDM). The professional with Clinical Data Validation and Quality Control has knowledge to manage discrepancies, uphold data integrity, and make informed decisions critical to the success of clinical trials and studies.	**LFS/MCr-0011**	**5.5**

COURSE DETAILS

Clinical Data Validation and Quality Control

EXAMINATION DETAILS

COURSE NAME	COURSE CODE	ELIGIBILITY	DURATION
Clinical Data Validation and Quality Control	G46	Pursuing 3rd year of 3-year/ 4-years UG	30

SL. NO.	EXAM	EXAM CODE	MAXIMUM MARK	INTERNAL	TOTAL MARK
THEORY PAPERS					
1	Introduction to Clinical Data Management	T001	100	50	150
2	Quality Control in Clinical Trials	T002	100	50	150
PRACTICAL PAPERS					
2	Clinical Data Validation Techniques	L001	100	50	150
TOTAL MARKS					
1	Total Examination Marks (Theory Online + Practical Examination)				300
2	Total Internal Marks				150
3	**Total Marks (Total Internal Marks + Total Examination Marks)**				**450**

Clinical Data Validation and Quality Control

INTERNAL MARK CRITERIA FOR EACH

SL NO.	MODULE	MODULE CODE	MAXIMUM MARK	INTERNAL MARK	TOTAL MARK
1	Introduction to Clinical Data Management	T001	100	50	150
2	Quality Control in Clinical Trials	T002	100	50	150
4	Clinical Data Validation Techniques	L001	100	50	150
	TOTAL		300	150	450

ATTENDANCE	GENERAL PERFORMANCE	INTERNAL EXAMINATIONS/ PROJECTS/ ASSIGNMENTS	TOTAL MARKS
5	5	40	50

COURSE SYLLABUS

FOR

Clinical Data Validation and Quality Control

COURSE	Clinical Data Validation and Quality Control	
TOTAL MARKS	Mark: 450	Internal Mark: 150
TOTAL HOURS	30 Hrs	

DEFENITION OF CREDIT

1 Credit	15Hrs Theory/ 30Hrs Practical
Skill Components	60 – 70 % of Total Credit

MODULES INCLUDED IN THIS SUBJECT

SL NO	MODULE NAME	CREDIT BREAKUP
1	Module 1: Data Validation Techniques	0.5
2	Module 2: Database Lock and Freeze	
3	Module 3: Query Management and Resolution	
4	Module 4: Data Reconciliation	0.5
5	Module 5: Quality Control Measures	
	Total	**1**

Training Outcomes

- Apply data validation techniques to ensure data accuracy in CDM.
- Develop and manage database lock processes, ensuring data integrity for clinical trials.
- Effectively generate, track, and resolve queries, fostering clear communication with study sites
- Demonstrate reconciliation data and managing discrepancies, ensuring data consistency.
- Implement quality control measures, conduct data reviews, and prevent data quality issues, upholding data reliability

MODULES

Module 1: Data Validation Techniques

THEORY

- Understand the theoretical principles of data validation in the context of Clinical Data Management (CDM).
- Discuss different types of validation checks and edit rules used in CDM, such as range checks, consistency checks, and format checks.
- Explain process of implementing validation procedures in CDM, including data validation plan creation and execution
- Explain foundations of automating validation checks and incorporating them into data management workflows

PRACTICAL

- Create a comprehensive validation plan for clinical data
- Execute validation procedures based on the plan, including data validation checks, query generation, and resolution

Module 2: Database Lock and Freeze

THEORY

- Explain the process of database lock in Clinical Data Management (CDM) and its significance in the clinical research lifecycle.
- Describe criteria used to determine when to freeze and lock a clinical database, including data completeness, accuracy, and documentation.
- Discuss methods for ensuring data integrity before the database lock.

PRACTICAL

- Demonstrate the practical ability to execute the database lock process in real-world CDM projects, including the creation of a lock plan and coordination with cross-functional teams

Module 3: Query Management and Resolution

THEORY

- Describe principles behind query generation in clinical data management.
- Explain the workflow for query resolution, including how queries are identified, prioritized, and resolved.

- Discuss the steps involved in resolving data discrepancies and discrepancies in clinical trial data.
- Brief importance of effective communication with study sites and investigators in the query resolution process

PRACTICAL

- Apply practical techniques to generate queries based on clinical data discrepancies
- Practice documenting communications and maintaining a professional tone in written and verbal interactions.

Module 4: Data Reconciliation

THEORY

- Explain the significance of data reconciliation in ensuring data accuracy, consistency, and compliance with study protocols.
- Describe the principles of reconciling data between investigator sites and the sponsor in clinical research
- Explain the challenges and processes involved in reconciling data obtained from different laboratories.
- Outline the process of managing discrepancies in clinical trial data, including identification, documentation, and resolution.

PRACTICAL

- Apply practical techniques to reconcile data between investigator sites and the sponsor.
- Engage in hands-on activities to align and harmonize laboratory data for analysis and reporting.

Module 5: Quality Control Measures

THEORY

- Explain the importance of early detection and prevention of data quality issues in clinical data management.
- Describe the principles of implementing quality control measures at various stages of a clinical study.
- Discuss processes of data quality review and data listing review in clinical data management.
- Discuss importance of root cause analysis and corrective actions in data quality management

PRACTICAL

- Apply practical techniques to implement quality control measures at different stages of a clinical study, from data collection to analysis