CCEK – NSQF ALIGNED PROGRAM

COURSE SYLLABUS

FOR

Associate-Clinical Research Management

CCEK - NATIONAL SKILL DEVELOPMENT TRAINING PROGRAM

Associate-Clinical Research Management

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	**Associate-Clinical Research Management** **Brief Job Description**: Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility) supports clinical trial activities, carries out reporting and documentation for monitoring of research activities to ensure regulatory compliance and Good Clinical Practices (GLP) as per ICH and coordinates with site staff members, investigators, SMO and Sponsor.	**LFS/Q3501**	**5**

COURSE DETAILS

Associate-Clinical Research Management

EXAMINATION DETAILS

COURSE NAME	COURSE CODE	ELIGIBILITY	DURATION
Associate-Clinical Research Management	G41	B. Sc. (Biology,Life Sciences, Biotechnology)/ B.Tech. Biotech/ B. Pharma)	320

SL. NO.	EXAM	EXAM CODE	MAXIMUM MARK	INTERNAL	TOTAL MARK
THEORY PAPERS					
1	Clinical Research Management Systems & Data Management	T001	100	50	150
2	Resource Coordination and Project Planning	T002	100	50	150
PRACTICAL PAPERS					
1	Utilization of Clinical Trial Management Systems	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**

Associate-Clinical Research Management

INTERNAL MARK CRITERIA FOR EACH

SL NO.	MODULE	MODULE CODE	MAXIMUM MARK	INTERNAL MARK	TOTAL MARK
1	Clinical Research Management Systems & Data Management	T001	100	50	150
2	Resource Coordination and Project Planning	T002	100	50	150
3	Utilization of Clinical Trial Management Systems	L001	100	50	150
	TOTAL		300	150	450

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

COURSE SYLLABUS

FOR

Associate-Clinical Research Management

COURSE	Associate-Clinical Research Management	
TOTAL MARKS	Mark: 450	Internal Mark: 150
TOTAL HOURS	320 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: Introduction to Life Sciences industry and the job role	**2**
2	Module 2: Managing environmental sustainability	
3	Module 3: Display sensitivity towards all genders and people with disability	
4	Module 4: Employability Skills	
5	Module 5: Clinical trial site coordination	**2**
6	Module 6: Reporting and documentation for site coordination	**1.5**
7	Module 7: Clinical trial monitoring	**1.5**
8	Module 8: Reporting and documentation for site monitoring	**1.5**
9	Module 9: Clinical data management	**2**
	Total	**10.5**

Training Outcomes

- Discuss performance of Associate-Clinical Research Management in compliance with Good Manufacturing Practices (GMP) and GCP(Good Clinical Practices) and other environmental regulatory guidelines.
- Demonstrate how to conduct clinical trial monitoring and site coordination.
- Demonstrate good documentation practice (GDP) and data integrity while reporting and documentation as per standard operating procedures (SOP), good laboratory practices (GLP), and Good Manufacturing Practices (GMP).
- Demonstrate how to coordinate with supervisor, colleagues and respond to audit queries during GMP/ regulatory audits.
- Demonstrate sensitivity towards genders, cultures and specially-abled persons.

MODULES

Module 1: Introduction to Life Sciences industry and the job role

THEORY

- Discuss the Life Sciences industry in Indian and global context.
- Discuss the regulations, legislation, and good practices to be followed by Associate Clinical Research Management in a life sciences facility.
- Explain the basic skills required to perform the job of Associate-Clinical Research Management.
- Explain the importance of a skilled Associate-Clinical Research Management for efficient clinical trial and patient safety.

Module 2: Managing environmental sustainability

THEORY

- Explain the concept and importance of energy conservation.
- Describe the possible actions to optimize energy consumption and minimize energy wastage.
- Explain the concept of environmental pollution and its impact on the health of self, community, and planet.
- Describe the possible actions to be taken to minimize environmental pollution at work.
- Explain various guidelines to be followed for hazardous waste management and disposal of waste.

PRACTICAL

- Create a checklist of energy conservation practices during and post-work.
- Classify waste into recyclable, nonrecyclable, and hazardous.
- Demonstrate the sustainable waste disposal- process.

Module 3: Display sensitivity towards all genders and people with disability

THEORY

- Discuss the rules laid by the Sexual Harassment of Women at Workplace (Prevention, Prohibition, and Redressal) Act and the provided penalties for violation.
- Explain the importance of gender sensitive behaviour.
- Explain the procedure to report inappropriate behaviour e.g. sexual harassment.
- Describe the importance of an equal opportunity work culture.
- Discuss the importance of respecting other's cultures, religion, and caste.
- Explain the need for sensitivity towards people with disabilities.
- Explain the correct ways of communication and collaboration with people with disabilities in compliance with the legal framework.
- Identify stereotypes and prejudices associated with people with disabilities and the negative consequences of prejudice and stereotypes.

PRACTICAL

- Demonstrate appropriate verbal and nonverbal communication that is respectful of gender, religion, disability, etc.
- Prepare a list of gender-neutral communication terms.

Module 4: Introduction to Employability Skills

THEORY & PRACTICAL

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- understand the significance of employability skills in meeting the current job market requirement and future of work.
- identify and explore learning and employability relevant portals
- research about the different industries, job market trends, latest skills required and the available opportunities.
- Recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.
- Follow environmentally sustainable practices.
- recognize the significance of 21st Century Skills for employment
- practice the 21st Century Skills such as Self-Awareness, Behavior Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn etc. in personal and professional life
- adopt a continuous learning mindset for personal and professional development
- use basic English for everyday conversation in different contexts, in person and over the telephone
- read and understand routine information, notes, instructions, mails, letters etc. written in English
- write short messages, notes, letters, e-mails etc. in English
- Identify career goals based on the skills, interests, knowledge, and personal attributes
- Prepare a career development plan with short- and long-term goals.
- follow verbal and non-verbal communication etiquette while communicating in professional and public settings
- use active listening techniques for effective communication
- communicate in writing using appropriate style and format based on formal or informal requirements
- work collaboratively with others in a team
- communicate and behave appropriately with all genders and PwD
- escalate any issues related to sexual harassment at workplace according to POSH Act
- identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.
- carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook
- identify common components of salary and compute income, expenses, taxes, investments etc.
- identify relevant rights and laws and use legal aids to fight against legal exploitation
- operate digital devices and use their features and applications securely and safely
- carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.
- display responsible online behavior while using various social media platforms
- create a personal email account, send and process received messages as per requirement
- carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications

- utilize virtual collaboration tools to work effectively.
- identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research
- develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion
- identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity
- identify different types of customers and ways to communicate with them
- identify and respond to customer requests and needs in a professional manner
- use appropriate tools to collect customer feedback
- follow appropriate hygiene and grooming standards
- create a professional Curriculum vitae (Résumé)
- search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively
- apply to identified job opening using offline /online methods as per requirement
- identify apprenticeship opportunities and register for it as per guidelines and requirement

Module 5: Clinical trial site coordination

THEORY

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- Discuss roles and responsibilities of sponsors, CRO (Clinical Research Organizations) and SMO (Site Management Organizations)
- List the functional and cross-functional stakeholders in site management/coordination for Associate-Clinical Research Management.
- Explain the best strategies of collaborating with cross functional teams and vendors involved in clinical trials / BA-BE Study.
- Explain 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
- Explain efficient and clear communication methods for reporting events/ deviations in clinical trial / BA-BE Study to principle investigator or co-investigator and CRO/sponsor to ensure patient/ volunteer safety and Good Clinical Practices (GCP) compliance
- Explain the importance and role of a protocol and its training to all site team before execution of a clinical research project at site
- Explain the process of a site monitoring and role of a site coordinator in the same
- Explain the process of site inspection by regulatory agency or by ethics committee
- Explain the techniques for gaining emotional stability.
- Discuss various ways for conflict resolution.
- Describe the problem-solving techniques for routine work-related issues.

PRACTICAL

- Perform documented shift handovers to the next person in the shift at site.
- Demonstrate how to effectively communicate and collaborate with various stakeholders (e.g. cross functional teams, principle investigator or co-investigator and CRO/sponsor etc.) in a simulated environment for multiple scenarios.
- Demonstrate how to manage corrective actions/ follow up actions at site (in a mock environment) 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

- Demonstrate activities of a site coordinator during a mock site monitoring visit
- Respond to regulatory audit questions in a mock audit situation.
- Demonstrate how to resolve conflict in multiple scenarios.

Module 6: Reporting and documentation for site coordination

THEORY

- Describe the types of documentation at a clinical trial site and the importance of maintaining the records.
- Explain the method of reporting and documentation for clinical research site management as per Good Documentation Practices(GDP), Good Clinical Practices (GCP) and other regulatory guidelines.
- Describe the Attributable, Legible, Contemporaneous, Original, and Accurate Plus (ALCOA +) principle and its importance.
- Discuss the use of eCRF and eConsent Form and other digital tools in site related documentation during a Clinical Trial or BA/BE study.
- Discuss the importance of generic data like employment record, qualification certificates, training records, signature logs and attendance/ access control records in meeting compliance with GCP and GDP.
- Discuss the use of AI and Cloud computing softwares for enrolment, selection and tracking of volunteers/ patients during and after the clinical trial or BA/BE Study.
- Discuss the importance of ethics committee and regulatory body's communication and approvals before starting the clinical trial or BA/BE Study.
- Explain the steps for generating an internal audit report and audit response to sponsor/ regulatory audit observations

PRACTICAL

- Demonstrate mock reporting and documentation for various site coordination / management activities and scenarios in compliance with study protocol, GCP and regulatory guidelines.
- Demonstrate the steps to prepare audit reports as per internal audit performed in a simulated environment
- Demonstrate the steps to prepare an audit observation response for a dummy audit report

Module 7: Clinical trial monitoring

THEORY

- Explain concepts of disease physiology and reason of disease condition.
- Discuss licensing requirements for drug import and biological sample exports.
- Explain different phases of the clinical trial.
- Explain the site activation process
- Explain the site monitoring process during a site visit
- Discuss drug related safety events and adverse events.

PRACTICAL

- Perform source data verification for evaluating the participant's eligibility and protection of participant's rights in a mock setting.
- Demonstrate how to conduct clinical site monitoring and audits.

- Demonstrate how to report drug related adverse events to all concerned stakeholders and ethics committee.
- Demonstrate how to review case report forms (CRFs).

Module 8: Reporting and documentation for site monitoring

THEORY

- Explain WHO regulations and ICH- Good Clinical Practices (GCP) guidelines for documentation.
- Explain purpose and methodology of clinical trial reporting.
- Explain the steps of drafting a site initiation/ activation report.
- Discuss the format and steps of writing site monitoring visit reports and Clinical trial progress report
- Discuss the reports required to be developed for any serious adverse event/ serious adverse reaction
- Discuss the operating procedure of eCRFs and e-reporting in an open source clinical research management software
- Discuss various communication requirement with ethics committee and regulatory body by CROs before and during the clinical trial / BA-BE study.

PRACTICAL

- Demonstrate how to develop, draft, and write the trial protocols.
- Perform reporting and documentation for each stage of clinical site monitoring in compliance with regulatory guidelines.
- Demonstrate how to prepare site monitoring visit reports.
- Demonstrate the steps to write the reports for any serious adverse event/ serious adverse reaction
- Demonstrate the operating steps for reviewing eCRFs and submission of e-reports

Module 9: Clinical data management

THEORY

- Explain characteristics of the investigational drug in the clinical study.
- Explain the concepts of medical coding.
- Discuss medical, clinical research, and Data Management process and terminology.
- Discuss clinical data management (CDM) Process and methods to collect, store, and disseminate clinical trial data.
- Discuss the method of eCRF design and basics of Database design
- Discuss the processes for locking the databases and freezing the data extraction
- Discuss the methods and strategies for discrepancy management in CDM
- Discuss the operating steps of a clinical data management software

PRACTICAL

- Demonstrate how to design and develop the eCRF.
- Demonstrate how to fill the data in 2 sample CRF(s) for database testing.
- Demonstrate how to create eCRFs using any of the EDC tools.
- Demonstrate the steps for Data Validation and data cleaning
- Demonstrate the steps for database lock and freezing data extraction
- Demonstrate how to coordinate with Clinical Trial team for any discrepancy or coordination for clinical data management.