CCEK – NSQF ALIGNED PROGRAM

COURSE SYLLABUS

FOR

Biologist / Biotechnologist

CCEK - NATIONAL SKILL DEVELOPMENT TRAINING PROGRAM

Biologist / Biotechnologist

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	**Biologist / Biotechnologist** **Brief Job Description**: Biologist/Biotechnologist is a critical role and performs the critical activities in various specialized areas like Manufacturing of Bio-products / Biologics Formulation Products or In-Vitro Micro propagation of Plants or Quality Control of Biological Products / Plant based products. Sometimes the role holder is also involved in research work for computational Biology. He/ she is responsible to ensure documentation, quality assurance and compliance with applicable regulation at workplace. The individual also guides junior staff for manufacturing/ quality control of biological products. He/she is involved in relevant processes as per standard operating procedures (SOP) and is responsible for implementation of quality standards like good manufacturing practices, good documentation practices, good storage practices, 5S system etc.	**LFS/Q4101**	**5**

COURSE DETAILS

Biologist / Biotechnologist

EXAMINATION DETAILS

COURSE NAME	COURSE CODE	ELIGIBILITY	DURATION
Biologist / Biotechnologist	G45	B.Tech (biotechnology), M.Sc/B. Sc. (biology and biotechnology related subject), B. Pharma	270

SL. NO.	EXAM	EXAM CODE	MAXIMUM MARK	INTERNAL	TOTAL MARK
THEORY PAPERS					
1	Basic Biology and Life Sciences	T001	100	50	150
2	Microbiology and Molecular Biology	T002	100	50	150
PRACTICAL PAPERS					
2	Genetic Engineering and Biotechnology Applications and 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**

Biologist / Biotechnologist

INTERNAL MARK CRITERIA FOR EACH

SL NO.	MODULE	MODULE CODE	MAXIMUM MARK	INTERNAL MARK	TOTAL MARK
1	Basic Biology and Life Sciences	T001	100	50	150
2	Microbiology and Molecular Biology	T002	100	50	150
3	Genetic Engineering and Biotechnology Applications and 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

Biologist / Biotechnologist

COURSE	Biologist / Biotechnologist	
TOTAL MARKS	Mark: 450	Internal Mark: 150
TOTAL HOURS	270 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 applicable regulations	2
2	Module 2: Fundamentals of Manufacturing in Life Sciences Sector	
3	Module 3: Managing environmental sustainability and comply EHS rules in production and GMP controlled area	1
4	Module 4: Coordination with Manager, teammates and Auditors	0.5
5	Module 5: Employability Skills	1
6	Module 6: Perform bio-product manufacturing activities	0.5
7	Module 7: Perform upstream processing of biological products	1
8	Module 8: Perform purification of harvested material by downstream processing	
9	Module 9: Perform supervising the manufacturing process for biologics formulation activities p	2
10	Module 10: Perform In Vitro Micro propagation of Plants	

11	Module 11: Perform Quality Control analysis of Biological Products	
12	Module 12: Perform Quality Control analysis of Plant based products	1
13	Module 13: Perform Computational Biology for Research activities	
14	Module 14: Entrepreneurial activities to start and run the business operations	
15	Module 15: Manage the critical documents for business activities and for statutory and regulatory compliance	
	Total	9

Training Outcomes

- Discuss performance of Biologist in compliance with Good Manufacturing Practices (GMP) and other environmental regulatory guidelines.
- Explain the fundamentals of the manufacturing process and its various components.
- Demonstrate how to manage production activities across the product line in a life science manufacturing facility.
- Discuss how to maintain a healthy, safe and secure working environment in the production and GMP controlled area.
- 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.
- Demonstrate the methods of reporting and documentation for regulatory compliance.

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 regulatory authorities, regulations, legislation, and good practices (GMP, GLP, GDP) relevant to the Production operation in a life sciences manufacturing facility.
- Explain the basic skills required to perform the job of Biologist
- Explain the importance of a Biologist in a manufacturing plant
- Explain the opportunities of entrepreneurship for Biologist in Life Sciences Sector

Module 2: Fundamentals of Manufacturing in Life Sciences Sector

THEORY

- Discuss the basic concepts of biology and pharmacology required to interpret the manufacturing specifications.
- Discuss fundamental science in production including size separation, mixing and homogenization process, mass transfer, fluid flow, heat transfer and size reduction.
- Explain the role of API in typical pharmaceutical manufacturing and role of API particle size in formulations.
- Explain the role of assay in biopharmaceutical formulation.
- Explain standard quantity effect in formulation.
- Describe drug manufacturing plant components.
- Demonstrate how to perform job activities of Biologist drug by recalling all the essential concepts of manufacturing in life sciences manufacturing facility

Module 3: Managing environmental sustainability and comply EHS rules in production and GMP controlled area

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.
- Explain the concept of energy conservation by switching off the machine and equipment post operations

- Describe ways to optimize the usage of electricity/energy in various tasks/activities/processes
- Describe recyclable and non-recyclable, and hazardous waste generated
- Explain waste segregation into different categories to achieve minimum pollution of land and water
- Explain relevant legislative requirements and company's procedures for the environment, health and safety including an individual's role and responsibilities.
- Discuss workplace hazards in the manufacturing facility in the life sciences sector including how and when to report hazards.
- Explain all the emergency procedures for different emergencies.
- Identify evacuation procedures for employees, contract staff and visitors
- Discuss health, safety and accident reporting procedures, different types of breaches in the environment, health, safety and security and how and when to report including medical assistance and the emergency services.
- Explain the importance of material segregation and 5S system, WHO guidelines for personal hygiene, handling and storing hazardous material
- Discuss the type of safety gears and procedure to use them

PRACTICAL

- Create a checklist of energy conservation practices during and post-work.
- Classify waste into recyclable, non-recyclable, and hazardous.
- Demonstrate the sustainable waste disposal- process.
- Demonstrate how and when to report hazards at the workplace.
- Demonstrate emergency procedures to be followed in different emergencies.
- Demonstrate how to evacuate employees, contract staff and visitors as per procedures in case of emergency.
- Demonstrate how to act in case of emergencies by following health, safety and accident reporting procedures.
- Recall 5S system, WHO guidelines for personal hygiene, handling and storing hazardous material.
- Demonstrate how to use different types of safety gears by following the procedures to use them.

Module 4: Coordination with Manager, teammates and Auditors

THEORY

- Explain List the functional and cross-functional stakeholders for Biologist
- Explain efficient and clear communication methods for reporting incidents/ deviations.
- Explain the techniques for gaining emotional stability.
- Discuss various ways for conflict resolution.
- Explain the best strategies of collaborating with others.
- Describe the problem-solving techniques for routine work-related issues.
- Explain the process of development of a production plan and shift schedule
- Explain the strategies for efficient manpower management and optimization of team productivity

- Explain the type of audits in the life sciences sector for the manufacturing operations.
- 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 behavior.
- Explain the procedure to report inappropriate behavior 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 how to effectively communicate and collaborate with various stakeholders (e.g. manager, groups etc.) in a simulated environment for multiple scenarios.
- Respond to regulatory audit questions in a mock audit situation.
- Demonstrate how to resolve conflict in multiple scenarios.
- Demonstrate appropriate verbal and nonverbal communication that is respectful of gender, religion, disability, etc.
- Prepare a list of gender-neutral communication terms.

Module 5: Employability Skills

THEORY

- Explain the meaning of Financial Accounting
- Explain difference between financial accounting V/s reporting, cost & management accounting
- Explain purpose of Financial Accounting
- Explain basic terms used in financial accounting, capital and revenue account transactions differences
- Describe measurement, valuation & accounting estimates
- Describe various source documents
- Explain rules for classification of accounts
- Explain double entry accounting system/ accounting equation
- Describe the process of Identifying business transactions and recording journal entries into ledgers
- Describe the process of drafting of a trial balance
- Describe the process of passing rectification entries & year-end adjustment entries to finalization of books of accounts
- Describe the preparation of reconciliation statements for Banks, Receivables, and Payables
- Describe the preparation of the Manufacturing, Trading, Profit & Loss Account

- Explain the preparation of the Income & Expenditure account from receipt and payments account and single-entry system to double entry system.
- Explain IFRS Concepts & it's application and comparison to Indian Accounting Standards.
- Describe the regulatory framework for preparation and presentation of financial statements
- Explain the application of accounting standards to financial statements
- Describe prepare company final accounts (as per Sch III)

PRACTICAL

- Prepare a sample Financial Statements of Sole Trader/HUF In accordance with applicable regulatory framework and accounting standards
- Prepare a sample Financial Statements of Partnership Firms including admission, retirement, death and dissolution scenarios & In accordance with applicable regulatory framework and accounting standards
- Prepare a sample Financial Statements of LLP in accordance with applicable regulatory framework and accounting standards
- Prepare a sample Financial Statements of Trust/NGO's in accordance with applicable regulatory framework and accounting standards in accordance with applicable regulatory framework and accounting standards
- Prepare a sample Financial Statements of Membership Societies/AOP, Cooperative Societies In accordance with applicable regulatory framework and accounting standards
- Prepare a sample Financial Statements of various types of corporate entities in accordance with applicable schedules of companies act 2013 & accounting standards with notes to accounts and cash flow statements.

Module 6: perform bio-product manufacturing activities

THEORY

- Describe Discuss SOP for bio-product manufacturing
- Explain all manufacturing processes, national legislation, obligations of marketing authorization and product license
- Discuss that environmental conditions of the production area are maintained within the limits specified in the respective BMR
- Explain the different types of quality checks
- Explain raw material is processed strictly as per BMR and SOP
- Discuss how to observe production incidents for any deviations from the standard production process and record the same as per SOP.

PRACTICAL

- Demonstrate the bio-product manufacturing
- Demonstrate sterilization of equipment
- Perform aliquots of sample as per SOP and label it.

Module 7: Perform upstream processing of biological products

THEORY

- Discuss standard operating procedures and cleanroom guidelines
- Explain how to culture from cryostorage to the work area, in accordance with SOP
- Demonstrate the cleaning operations and cleaning validation as per GMP
- Demonstrate various sterilization techniques of media and solutions
- Explain how to incubate and grow the culture in growth solution and scale-up as per SOP
- Discuss sampling and storage of bulk material
- Explain various tests to show that the culture has reached the required specification
- Explain the culture and growth media in the correct quantities at required levels in the bioreactor
- Explain how to harvest biomaterials in sealed sterile containers for downstream processing (DSP), in accordance with established practices and procedures.
- Discuss how to harvest biomaterials in sealed sterile containers for downstream processing (DSP), in accordance with established practices and procedures

PRACTICAL

- Demonstrate the upstream process
- Perform cleaning and sanitization activity
- Demonstrate sterilization of equipment
- Perform aliquots of sample as per SOP and label it
- Demonstrate how to check the growth parameters such as pH, stirrer speed, pressure, dissolved oxygen (DO2), temperature.

Module 8: Perform purification of harvested material by downstream processing

THEORY

- Discuss the filter unit and connect to the biomaterial source for downstream processing, in accordance with established practices and procedures
- Explain the filter unit preparation and connect with the downstream processing
- Explain the purification methods like chromatography
- Describe the filter unit integrity test, in accordance with established practices and procedures
- Discuss the Sampling and storage of bulk material

PRACTICAL

- Demonstrate purification of the process by filtration
- Prepare aliquots of sample as per SOP and label it
- Demonstrate to store the bulk material at the designated area as per SOP and record the details of the storage
- Perform cleaning and sanitization activities

Module 9: Perform supervising the manufacturing process for biologics formulation activities

THEORY

- Discuss the working principle of machines and equipment used for manufacturing process for biologics formulation explain their calibration and validation process
- Describe the PPE used while working in the bio-manufacturing environment
- Explain the basic process of biologics formulation manufacturing.
- Discuss the blending equipment set up blending operations for biologics in accordance with standard operating procedures for blending process/operations
- Explain draw sample of final blend and send for quality control analysis
- Explain equipment (filling, packaging line, lyophilize (in case of freeze-dried product etc) set up
- Discuss the aseptic/sterile conditions are maintained during the entire process of filling, containerization and sealing and process is carried out as per the SOP for both liquid and lyophilized products
- Discuss in-process quality checks for volume, leakage and ensure the visual inspections are done as per SOP

PRACTICA

- Demonstrate blending of the active ingredient and bulk
- Demonstrate the aseptic and sterile conditions maintenance
- Prepare SOP for liquid products
- Demonstrate the machines and equipment's used for manufacturing
- Demonstrate the blending equipment for biologics

Module 10: Perform In Vitro Micro propagation of Plants

THEORY

- Discuss the working principle of machines and equipment used for manufacturing process for biologics formulation explain their calibration and validation process
- Describe the PPE used while working in the bio-manufacturing environment
- Explain the basic process of biologics formulation manufacturing.
- Discuss the gowning procedure as per SOP
- Explain how to ensure that the work is carried out in accordance with standard operating procedures for preparation of plant tissue culture media
- Explain the defined procedures for micro propagation and aseptically transfer the culture to the fresh media
- Discuss how to observe the growth at regular intervals as per protocol.
- Discuss in-process quality checks for volume, leakage and ensure the visual inspections are done as per SOP
- Explain the defined procedures for starting and running the equipment operating system as per SOP are followed
- Discuss liquid products the filling, containerization and sealing process for vial /syringe or any other container type are performed as per SOP

PRACTICAL

- Demonstrate the use of PPE while working in the bio-manufacturing environment
- Perform gowning as per SOP
- Demonstrate the micro propagation process
- Demonstrate aseptic transfer of the fresh media
- Perform quality checks while performing the micro propagation
- Demonstrate liquid product filling, containerization and sealing process

Module 11: Perform Quality Control analysis of Biological Products

THEORY

- Discuss how to secure the isolated samples for biological analysis
- Describe the process to prepare buffer, solvent solutions, and reagents for running quality tests
- Explain the basic process of instrument cleaning procedure and sequence available for the analysis before using the instrument
- Discuss raw materials, chemicals and reagents used in sterile quality analysis process are properly capped and stored according to specified conditions to avoid cross contamination
- Discuss how to perform biopharmaceutical sample analysis using specified techniques as per written work instructions
- Explain how to prepare quality reports for the analysed samples.

PRACTICAL

- Demonstrate quality analysis tests on biological samples
- Demonstrate cleaning and sanitization activities
- Demonstrate sterilization of equipment
- Perform quality control tests

Module 12: Perform Quality Control analysis of Plant based products

THEORY

- Discuss how to secure the isolated samples for biological analysis
- Describe the process to prepare buffer, solvent solutions, and reagents for running quality tests
- Explain the basic process of instrument cleaning procedure and sequence available for the analysis before using the instrument
- Explain how to handle plant-based products for quality tests
- Describe how to prepare quality reports for the analysed samples
- Discuss how to handle of raw materials, In process, calibration and maintenance of all quality control related instruments

- Describe plant-based products documentation
- Explain the review and approve the logbook entries and trial run records.

PRACTICAL

- Perform quality tests for plant-based products
- Perform cleaning and sanitization activities
- Demonstrate SOP preparation for quality testing of plant-based products
- Perform documentation of the activities

Module 13: Perform Computational Biology for Research activities

THEORY

- Discuss how to Visualize computational data capability/experience to aid results interpretations
- Describe the softwares used in computational biology analysis
- Discuss the science of drug target identification and validation utilizing large scale multi-dimensional human genetics, real-world, clinical and other proprietary deep-phenotype datasets
- Discuss how to collaborate with colleagues in medicinal chemistry for providing scientific knowledge obtained through molecular modelling, supporting preclinical drug discovery
- Describe how to develop computational hypothesis using molecular modelling tools for small molecule and or large (macro molecules, peptides etc
- Discuss how to design molecules (small and large) using computational models

PRACTICAL

- Perform Identify and work on molecule structure determination suing the computational softwares
- Demonstrate how to work on high end computational softwares
- Collaborate with colleagues on a project
- Design lead for a drug molecule using the computational softwares

Module 14: : Entrepreneurial activities to start and run the business operations

THEORY

- Discuss the strategies and methodologies to perform a market evaluation to identify a business opportunity
- Explain the stages of development of a business proposal and detailed project report.
- Discuss various government schemes and non-government funding sources for investment in a business startup and steps to apply for the same
- Explain various statutory, legal and regulatory framework applicable in life sciences

sector for setting up a business unit

- Explain various promotion trends and strategies for promotion of a product or services in life sciences area
- Discuss the basic concepts of accounting and taxation rules to be followed by a start up in biotechnology sector
- List the elements of a proposal to attract future business opportunities and prospective clients.
- Explain how to conduct entrepreneurial programs to identify new business opportunities, generate employment and increase clientele.
- Discuss the importance of a quality system like ISO and stages for implementation of ISO system in a start-up
- Discuss the importance of a carbon credits for environmental sustainability and earning the goodwill and stages for implementation of an environmental sustainability plan in a start up in Biotechnology sub sector

PRACTICAL

- Perform Role plays the characteristics of an effective biotechnology led entrepreneur and leader
- Demonstrate on how to identify new business opportunities
- Prepare a sample business plan and Detailed Project report (DPR)
- Prepare a detailed sample report consisting of information such as future investments, forecasting, business expansion, etc.
- Demonstrate the procedure to apply for bank finances \
- Prepare a sample plan to solve problems and improve productivity at the workplace.
- Demonstrate the procedure to operate a computer for digital marketing, ecommerce, branding, etc.
- Demonstrate how to sell a product or service on an e-commerce platform with integration of payment gateway
- Show how to use services such as NEFT, IMPS, UPI, RTGS for online banking.
- Demonstrate the steps to maintain the accounts and ledgers and how to perform reconciliation on an open source accounting software
- Perform a role play for giving presentation about business plan, forecasting

Module 15: Manage the critical documents for business activities and for statutory and regulatory compliance

THEORY

- Discuss system of documentation as per ISO/ good documentation practices and method of implementation
- Explain scoring, grading and accreditation system of affiliating bodies and clients
- Explain the guidelines for facing audits and best practices for making organization audit ready

- List various types of documents and records to be maintained in the work process
- Discuss software and latest information technology tools for documentation and record maintenance
- Discuss the use of statistical tools for analysis and monitoring
- Elaborate various recording and documentation needs in managing sales, marketing, supply chain etc.
- Explain the need for and importance of engineering drawing and architectural layouts
- Explain best practices in engineering and maintenance in biotechnology sub sector
- Explain accounting standards and regulations
- Discuss the standard procedure for reporting and documentation pertaining to production facility / a laboratory/ a trading organization
- Discuss the methods of material inspection and vendor audit
- Discuss various supply chain management strategies
- Discuss the importance of cold chain management and environmental condition control and monitoring for products and services in biotechnology sub sector
- Discuss the ways to develop team and leadership always ready for audits and inspection
- Discuss the importance of compliance with Statutory, legal and regulatory framework and importance of documentation for each inspection and communication with authorities

PRACTICAL

- Show how to update all the relevant document for future reference
- Show how to maintain various material records and other documents such as equipment manuals, manufacturers' instructions, etc.
- Demonstrate the documentation for sales and marketing management for a start up
- Demonstrate the documentation for financial management for a start up
- Demonstrate the documentation for efficient supply chain and logistics management for a start up
- Demonstrate the documentation for sales and marketing management for a start up
- Demonstrate through the role play the inspection methods to check and verify the quality of materials received from the vendors as per standards
- Employ a situation on how to report and document the safety and noncompliance issues as per the company standards
- Perform the simulated role play and sample documentation for compliance with Statutory, legal and regulatory framework applicable in life sciences sector
- Demonstrate through role play a simulated audit / inspection by client or regulatory body
- Develop an audit response for a sample client inspection report