



CCEK – NSQF ALIGNED PROGRAM

COURSE SYLLABUS

FOR

Chemist – Production

CCEK - NATIONAL SKILL DEVELOPMENT TRAINING PROGRAM

Chemist – Production

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	<p>Chemist – Production</p> <p>Brief Job Description:</p> <p>Chemist – Production (Pharma, Cosmetics & Biologics) is responsible for monitoring the production processes and maintaining the compliance with regulatory standards. The job role holder carryout the reporting and documentation for regulatory compliance and responsible for maintaining the strict compliance to EHS and GMP guidelines</p>	LFS/Q01201	5

COURSE DETAILS**Chemist – Production****EXAMINATION DETAILS**

COURSE NAME	COURSE CODE	ELIGIBILITY	DURATION
Chemist – Production	G52	UG COMPLETED (SCIENCE)	610

SL. NO.	EXAM	EXAM CODE	MAXIMUM MARK	INTERNAL	TOTAL MARK
THEORY PAPERS					
1	Process Chemistry & Control	T001	100	50	150
PRACTICAL PAPERS					
1	Recrystallization of a Product	L001	100	50	150
TOTAL MARKS					
1	Total Examination Marks (THEORY Online + PRACTICAL Examination)				200
2	Total Internal Marks				100
3	Total Marks (Total Internal Marks + Total Examination Marks)				300

Chemist – Production**INTERNAL MARK CRITERIA FOR EACH**

SL NO.	MODULE	MODULE CODE	MAXIMUM MARK	INTERNAL MARK	TOTAL MARK
1	Process Chemistry & Control	T001	100	50	150
2	Recrystallization of a Product	L001	100	50	150
	TOTAL		200	100	300

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

COURSE SYLLABUS

FOR

Chemist – Production

COURSE	Chemist – Production	
TOTAL MARKS	Mark: 300	Internal Mark: 100
TOTAL HOURS	610 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 POINT
1	Module 1: Introduction to Life Sciences industry and the job role	1
2	Module 2: Fundamentals of Manufacturing in Life Sciences Sector	
3	Module 3: Monitoring the production activities across the product line	2
4	Module 4: Managing environmental Sustainability	1
5	Module 5: Comply EHS rules in production and cGMP-controlled area	2
6	Module 6: Coordination with Manager, teammates and Auditors	1
7	Module 7: Display sensitivity towards all genders and people with disability	
8	Module 8: Generic Reporting and Documentation for Production as per Cgmp	1
9	Module 9: Employability Skills	3
10	Module 10: Manage production activities for API / excipient manufacturing process	

11	Module 11: Manage production activities for sterile manufacturing process	8
12	Module 12: Manage production activities for non-sterile manufacturing process	
13	Module 13: Manage production activities for AYUSH drug manufacturing process	
14	Module 14: Module 14: Manage production activities for sanitary and personal hygiene product manufacturing process	
15	Module 15: Entrepreneurial activities to start and run the business operations	1
16	Module 16: Manage the critical documents for business activities and for statutory and regulatory	
	Total	20

Training Outcomes

- Discuss performance of Chemist - Production (Pharma, Cosmetics & Biologics) in compliance with Good Manufacturing Practices (GMP) and other environmental regulatory guidelines.
- Explain the fundamentals of 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 (cGMP, GLP, GDP) relevant to the Production operation in a life sciences manufacturing facility.
- Explain the basic skills required to perform the job of Chemist- Production (Pharma, Cosmetics & Biologics)
- Explain the importance of a Chemist- Production (Pharma, Cosmetics & Biologics) in a manufacturing plant
- Explain the opportunities of entrepreneurship for Chemist- Production (Pharma, Cosmetics & Biologics) 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.

PRACTICAL

- Demonstrate how to perform job activities of Chemist - Production (Pharma, Cosmetics & Biologics) drug by recalling all the essential concepts of manufacturing in life sciences manufacturing facility.

Module 3: Monitoring the production activities across the product line

THEORY

- Describe about safety gears and PPE to be used during production process.
- Explain cleanroom behaviour and guidelines to be followed at workplace.

- Discuss the standard environmental conditions of the production area.
- explain different types of pre-analysis checks performed in a production unit.
- Explain the different types of production process.
- Describe the chemicals and reagents used in production process, their properties and storage conditions.
- Explain the standard labelling guidelines.
- Explain the purpose of in process checks and their procedures.

PRACTICAL

- Demonstrate the use of PPEs for production process.
- identify out of order, non- calibrated, non- validated equipment are segregated for maintenance
- Demonstrate how to check for the calibration and validation of the equipment and balances used in the manufacturing area
- Perform pre analysis checks as per Standard Operating Procedure (SOP) and cGMP guidelines.
- prepare standard operating procedures, equipment master list, and equipment qualification plan for production process
- Demonstrate the steps of line clearance process.
- Demonstrate how line clearance are conducted on the shop floors for smooth work-flow
- Perform troubleshooting and guide operators during production activities I consideration of critical process parameters and critical quality attributes as per SOP

Module 4: 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.
- Segregate waste into recyclable, non- recyclable, and hazardous.
- Demonstrate the sustainable waste disposal- process.

Module 5: Comply EHS rules in production and cGMP-controlled area

THEORY

- 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

- 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 6: Coordination with Manager, teammates and Auditors

THEORY

- List the functional and cross-functional stakeholders for Chemist - Production (Pharma, Cosmetics & Biologics)
- 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

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

Module 7: 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 8: Generic Reporting and Documentation for Production as per Cgmp

THEORY

- Explain the method of reporting and documentation as per current Good Documentation Practices (GDP) and other regulatory guidelines.
- Describe the Attributable, Legible, Contemporaneous, Original, and Accurate Plus (ALCOA+) principle and its importance.
- Discuss the list of mandatory documentation for maintenance operations.

- Describe the purpose and importance of Standard Operating Procedures
- Explain the steps to develop a standard operating procedure and work instruction
- Describe the purpose and importance of Drug Master File (DMF), Batch Manufacturing Record (BMR) and Batch Packaging Record (BPR)
- Explain the documentation requirement in a change control procedure
- Describe the common formats and processes followed for reporting.
- Explain the procedures of reporting and documentation for manufacturing process.

PRACTICAL

- Demonstrate the use of IT tools for reporting.
- Perform reporting and documentation for drug manufacturing process.
- Record the quality parameters and investigation results in the sample formats and log book.
- Demonstrate adherence of Data integrity and ALCOA+ guidelines during reporting and recording in the production facility.
- Demonstrate documentation of a simulated change control scenario
- Demonstrate how to maintain both electronic and manual records in the log books and other documentation required as per GMP and GDP.

Module 9: Employability Skills

THEORY

- Explain the reporting structure of the organization.
- List the functional and cross-functional stakeholders for Microbiologist-Quality Control
- 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 type of audits in the life sciences sector for the quality operations.

PRACTICAL

- Demonstrate how to effectively communicate and collaborate with various stakeholders (e.g. manager, groups etc.) in a simulated environment for multiple scenarios.
- Demonstrate how to resolve conflict in multiple scenarios.
- Demonstrate how to communicate with auditors and regulatory inspectors during inspections/audits.
- Demonstrate the training procedures to train lab assistants and trainees

Module 10: Manage production activities for API / excipient manufacturing process

THEORY

- Discuss the working principle of machines and equipment used for API / excipient manufacturing process and explain their calibration and validation process
- Describe the PPE used in API / excipient manufacturing and their work instructions.
- Explain the basic process of API manufacturing.
- Discuss the ICH Q7 GMP guidelines for API production.
- Discuss the components of API production equipment's.
- Explain the common scenarios requiring troubleshoot in manufacturing process for machines and equipment
- Discuss the properties and storage conditions of chemicals used in API/ excipient production process.
- Explain various utilities used in API/ excipient production process and their calibration and validation process
- Explain the process of cleaning validation
- Explain the steps of job risk analysis and environmental monitoring at shop floor

PRACTICAL

- Identify and locate various parts of machines used for API/ excipient production.
- Demonstrate various calibration and equipment validation steps in a simulated environment
- Demonstrate the basic troubleshooting for setting/ correcting the parameters of an equipment/ machine
- Demonstrate the cleanroom behaviour and guidelines for API / excipient manufacturing process.
- Demonstrate a simulated cleaning validation process
- Perform the root cause analysis for out-of- specification (OOS) and out-of-trend (OOT) products in case of deviations in production process.
- Demonstrate how to maintain Batch production records for each intermediate and API.
- Demonstrate the documentation in a sample BMR and BPR format
- Perform review of a sample BMR/BPR filled in by an operator
- Demonstrate how to perform a review of a packaging label and carton during primary packaging

Module 11: Manage production activities for sterile manufacturing process

THEORY

- Discuss the working principle of machines and equipment used for sterile product manufacturing process and explain their calibration and validation process
- Describe the PPE used in sterile product manufacturing and their work instructions.
- Explain the basic process of sterile product manufacturing.
- Discuss the ICH Q7 GMP guidelines for sterile product manufacturing.
- Discuss the components of sterile product manufacturing equipments.
- Explain the common scenarios requiring troubleshoot in manufacturing process related to machines and equipment
- Discuss the properties and storage conditions of chemicals used in sterile product manufacturing process.
- Explain various utilities used in sterile product manufacturing process and their calibration and validation process
- Explain the process of cleaning validation for a sterile production area and equipment
- Explain the steps of job risk analysis and environmental monitoring at shop floor

PRACTICAL

- Identify and locate various parts of machines used for sterile product manufacturing.
- Demonstrate various calibration and equipment validation steps in a simulated environment
- Demonstrate the basic troubleshooting for setting/ correcting the parameters of an equipment/ machine used in a sterile product manufacturing
- Demonstrate the cleanroom behaviour and guidelines for sterile product manufacturing process.
- Demonstrate a simulated cleaning validation process
- Perform the root cause analysis for out-of- specification (OOS) and out-of-trend (OOT) products in case of deviations in production process.
- Demonstrate how to maintain Batch production records for each intermediate and sterile product.
- Demonstrate the documentation in a sample BMR and BPR format
- Perform review of a sample BMR/BPR filled in by an operator
- Demonstrate how to perform a review of a label and carton during filling, containerization and primary, secondary and tertiary packaging

Module 12: Manage production activities for non-sterile manufacturing process

THEORY

- Discuss the working principle of machines and equipment used for various non-sterile product manufacturing process like tablet, capsule, liquid oral and explain their calibration and validation process
- Describe the PPE used in non-sterile product manufacturing and their work instructions.
- Explain the basic process of non-sterile product manufacturing.
- Discuss the ICH Q7 GMP guidelines for non- sterile product manufacturing.
- Discuss the components of non-sterile product manufacturing equipment.
- Explain the common scenarios requiring troubleshoot in manufacturing process related to machines and equipment for tablet, capsule, liquid orals
- Discuss the properties and storage conditions of chemicals used in non-sterile product manufacturing process.
- Explain various utilities used in non-sterile product manufacturing process and their calibration and validation process
- Explain the process of cleaning validation for a non-sterile production area and equipment
- Explain the steps of job risk analysis and environmental monitoring at shop floor

PRACTICAL

- Identify and locate various parts of machines used for manufacturing of non-sterile product like tablet, capsule, liquid orals.
- Demonstrate various calibration and equipment validation steps in a simulated environment
- Demonstrate the basic troubleshooting for setting/ correcting the parameters of an equipment/ machine used in a non-sterile product manufacturing like tablet, capsule, liquid orals.
- Demonstrate the cleanroom behaviour and guidelines for non-sterile product manufacturing process.
- Demonstrate a simulated cleaning validation process
- Perform the root cause analysis for out-of- specification (OOS) and out-of-trend (OOT) products in case of deviations in production process.
- Demonstrate how to maintain Batch production records for each intermediate and non-sterile product.
- Demonstrate the documentation in a sample BMR and BPR format
- Perform review of a sample BMR/BPR filled in by an operator
- Demonstrate how to perform a review of a label and carton during each process stage and primary, secondary and tertiary packaging

Module 13: Manage production activities for AYUSH drug manufacturing process

THEORY

- Discuss various production processes for AYUSH drug product manufacturing
- Discuss role of automation in AYUSH drug product manufacturing in terms of production efficiency and product quality
- Discuss the working principle of machines and equipment used for various AYUSH drug product manufacturing process and explain their calibration and validation process
- Describe the PPE used in AYUSH drug product manufacturing and their work instructions.
- Explain the basic process of AYUSH drug product manufacturing.
- Discuss the cGMP guidelines for AYUSH drug product manufacturing.
- Discuss the components of AYUSH drug product manufacturing equipments.
- Explain the common scenarios requiring troubleshoot in manufacturing process related to machines and equipment
- Discuss the properties and storage conditions of chemicals used in AYUSH drug product manufacturing process.
- Explain various utilities used in AYUSH drug product manufacturing process and their calibration and validation process
- Explain the process of cleaning validation for an AYUSH drug production area and equipment
- Explain the steps of job risk analysis and environmental monitoring at shop floor

PRACTICAL

- Demonstrate various calibration and equipment validation steps in a simulated environment
- Demonstrate the basic troubleshooting for setting/ correcting the parameters of an equipment/ machine used in a AYUSH drug product manufacturing
- Demonstrate the cleanroom behaviour and guidelines for AYUSH drug product manufacturing process.
- Demonstrate a simulated cleaning validation process
- Perform the root cause analysis for out-of- specification (OOS) and out-of-trend (OOT) products in case of deviations in production process.
- Demonstrate how to maintain Batch production records for each intermediate and AYUSH drug product.
- Demonstrate the documentation in a sample BMR and BPR format
- Perform review of a sample BMR/BPR filled in by an operator
- Demonstrate how to perform a review of a label and carton during each process stage and primary, secondary and tertiary packaging

Module 14: Manage production activities for sanitary and personal hygiene product manufacturing process

THEORY

- Discuss production processes for various sanitary and personal hygiene product manufacturing
- Discuss role of automation in various sanitary and personal hygiene product manufacturing in terms of production efficiency and product quality
- Discuss the working principle of machines and equipment used for various sanitary and personal hygiene product manufacturing process and explain their calibration and validation process
- Describe the PPE used in various sanitary and personal hygiene product manufacturing and their work instructions.
- Explain the basic process of various sanitary and personal hygiene product manufacturing.
- Discuss the ICH Q7 GMP guidelines for various sanitary and personal hygiene product manufacturing.
- Discuss the components of various sanitary and personal hygiene product manufacturing equipments.
- Explain the common scenarios requiring troubleshoot in manufacturing process related to machines and equipment
- Discuss the properties and storage conditions of raw material used in various sanitary and personal hygiene product manufacturing process.
Explain various utilities used in various sanitary and personal hygiene product manufacturing process and their calibration and validation process
- Explain the process of cleaning validation for a various sanitary and personal hygiene product production area and equipment
- Explain the steps of job risk analysis and environmental monitoring at shop floor

PRACTICAL

- Identify and locate various parts of machines used for manufacturing of various sanitary and personal hygiene product.
- Demonstrate various calibration and equipment validation steps in a simulated environment
- Demonstrate the basic troubleshooting for setting/ correcting the parameters of an equipment/ machine used in various sanitary and personal hygiene product manufacturing
- Demonstrate the cleanroom behaviour and guidelines for various sanitary and personal hygiene product manufacturing process.
- Demonstrate a simulated cleaning validation process
- Perform the root cause analysis for out-of- specification (OOS) and out-of-trend (OOT)

products in case of deviations in production process.

- Demonstrate how to maintain continuous/ Batch production records for each intermediate and sanitary and personal hygiene product.
- Demonstrate the documentation in a sample BMR and BPR format
- Perform review of a sample BMR/BPR filled in by an operator
- Demonstrate how to perform a review of a label and carton during each process stage and primary, secondary and tertiary packaging

Module 15: 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 start up 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 life sciences 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 a environmental sustainability plan in a start up in life sciences sector

PRACTICAL

- Role play the characteristics of an effective 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, e-commerce, 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, business expansion to seek the investment
- Develop a plan to implement a quality system like ISO in a start up.

Module 16: 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 and importance of engineering drawing and architectural layouts
- Explain best practices in engineering and maintenance in life sciences 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 life sciences 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 non-compliance 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