CCEK – NSQF ALIGNED PROGRAM

COURSE SYLLABUS

FOR

Microbiologist-Quality Control

CCEK - NATIONAL SKILL DEVELOPMENT TRAINING PROGRAM

Microbiologist-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	**Microbiologist-Quality Control** **Brief Job Description:** Microbiologist-Quality Control carries out various microbial analysis of raw materials and finished products in the quality control laboratory as per laid down methods and specifications and performs research work to support the development of new testing protocols. The person is responsible for preparing the documents for reporting the test results and ensures cGMP, GLP and workplace safety. The role holder also carries out the validation of testing protocols and sterilization methods used.	**LFS/Q0308**	**5**

COURSE DETAILS

Microbiologist-Quality Control

EXAMINATION DETAILS

COURSE NAME	COURSE CODE	ELIGIBILITY	DURATION
Microbiologist-Quality Control	G45	UG COMPLETED	570

SL. NO.	EXAM	EXAM CODE	MAXIMUM MARK	INTERNAL	TOTAL MARK
THEORY PAPERS					
1	Microbiological Quality Control Resource Guide	T001	100	50	150
PRACTICAL PAPERS					
1	Identification & Biochemical Tests	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**

Microbiologist-Quality Control

INTERNAL MARK CRITERIA FOR EACH

SL NO.	MODULE	MODULE CODE	MAXIMUM MARK	INTERNAL MARK	TOTAL MARK
1	Microbiological Quality Control Resource Guide	T001	100	50	150
2	Identification & Biochemical Tests	L001	100	50	150
	TOTAL		200	100	300

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

COURSE SYLLABUS

FOR

Microbiologist-Quality Control

COURSE	Microbiologist-Quality Control	
TOTAL MARKS	Mark: 300	Internal Mark: 100
TOTAL HOURS	570 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: Essential concepts of Microbiology for quality control	**2**
3	Module 3: Laboratory specific routine checks	**2**
4	Module 4: Managing environmental sustainability	**1**
5	Module 5: Microbial analysis tests	**2**
6	Module 6: Research and development for new products	**2**
7	Module 7: Comply with EHS rules in production and GMP controlled area	**2**
8	Module 8: Reporting & documentation	**1**
9	Module 9: Coordinate with manager, colleagues and auditors	**1**

10	Module 10: Display sensitivity towards all genders and people with disability	**1**
11	Module 11: Employability Skills	**3**
	Total	**19**

Training Outcomes

- Discuss performance of quality control microbiology operations in compliance with Good Manufacturing Practices (GMP)/ Good Laboratory Practices (GLP) and other environmental regulatory guidelines.
- Explain the fundamental concepts of Microbiology and its various process.
- Demonstrate how to conduct routine quality control checks in a Microbiology lab.
- Discuss the techniques and process of microbiological analysis.
- Demonstrate the operating procedures for various equipments used in microbiological analysis.
- Investigate and analyze laboratory in line with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP).
- Discuss how to maintain a healthy, safe and secure working environment at the pharmaceutical manufacturing shop floor, laboratory and area around in conformance with Environment Health and Safety (EHS) rules.
- 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 regulatory authorities, regulations, legislation, and good practices relevant to the quality assurance in a life sciences manufacturing facility.
- Explain the basic skills required to perform the job of Microbiologist-Quality Control.
- Explain the impact of non-compliance on the quality of the product and the environment.

Module 2: Essential concepts of Microbiology for quality control

THEORY

- Discuss quality principles and concepts applied in the life sciences sector.
- Explain the basic concept of Quality by Design (QbD) and its application in quality control, quality risk management.
- Explain the fundamental concepts of Microbiology.
- Explain the principle of biochemical characterization of microbes by Gram stain and biochemical cards and their standard detection limits.
- Explain the units of measurements of microbial growth.
- Describe sampling plans for microbiological sampling.

PRACTICAL

- Demonstrate sampling methods for conducting microbial test according to SOP.
- Demonstrate sample handling and preparation of microbial samples.
- Demonstrate the use of Good Storage Practices (GSP) guidelines for storage of samples.
- Identify microbes using phenotypic and genotypic methods.

Module 3: Laboratory specific routine checks

THEORY

- List all the Personal Protective Equipment (PPE) used in the microbiology lab.
- Explain the different quality management systems, quality specifications and policy of the company.
- Explain the properties and storage conditions of different chemicals and reagents used in a microbiology lab.
- Discuss the principle of calibration and validation of equipment/glassware used in the lab.

- Discuss the strategies to minimize the risks of cross-contamination, false-positive and false- negative results.
- Describe different strategies used for decontamination in a microbiology laboratory.
- Explain different sterilization processes used in a microbiology laboratory.

PRACTICAL

- Demonstrate the use of PPE in a Microbiology lab.
- Conduct regular checks for lab equipment and instrument for their calibration and validation state.
- Identify out of order/ non-calibrated/ non- validated equipment.
- Demonstrate how to apply the decontamination strategies for contamination control in a microbiology laboratory.
- Demonstrate the steps of sterility testing.
- Demonstrate how to maintain positive and negative controls during testing.
- Demonstrate how to perform laboratory specific checks as per Standard Operating Procedures (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: Microbial analysis tests

THEORY

- Describe the properties of different microbial culture.
- Explain the basic techniques used for microbiological analysis.
- Explain the working principle and application of equipment used in a microbiology lab.
- Describe the optimum growth conditions for different microorganisms.
- Explain the method and importance of containment of microorganisms within the

laboratory facility.
- Discuss about Out of Trend (OOT) and Out of Specification (OOS) samples.

PRACTICAL

- Demonstrate how to prepare media to conduct quality analysis on the samples.
- Demonstrate how to prepare and maintain standard cultures.
- Perform microbial isolation, plate pouring, serial dilutions and screening of microbes.
- Demonstrate how to operate equipment in a microbiology lab.
- Demonstrate how to perform sample- specific microbial tests for detection of different microorganisms in samples.
- Demonstrate the how to identify the reason for unwanted growth of microorganisms.
- Demonstrate how to record and report the observations of the microbial test performed.

Module 6: Research and development for new products

THEORY

- Describe the different scientific literature search tools.
- Explain how to develop new testing protocols for microbiological analysis.
- Explain the procedure to grow different strains of bacteria in various conditions for their molecular and cellular characterization

PRACTICAL

- Demonstrate how to perform the literature search for culture/media development for different microbial strains.
- Demonstrate how to grow different microbial strains in various conditions to understand their reactions.

Module 7: Comply with EHS rules in production and GMP controlled area

THEORY

- Describe the relevant legislative requirements and company's procedures for the environment and health.
- Discuss the workplace hazards and their reporting in a manufacturing facility in the life sciences sector.
- Recall the guidelines and procedures for hazards, accidents, safety signs and signals, and Heinrich pyramid used in a manufacturing plant.
- Explain health, safety, and accident reporting procedures.
- Describe the importance of the gowning, medical assistance and emergency services.
- Discuss the procedures for evacuation for employees, contract staff, and visitors in controlled areas.
- Discuss the types of safety gears and procedure to use them.
- Discuss WHO guidelines for personal hygiene, handling, and storage of hazardous material.

- Explain the importance of material segregation and 5S system.

PRACTICAL

- Demonstrate how to ascertain the breach of EHS protocols in a given situation.
- Demonstrate how to communicate hazards, safety instructions and accidents to teammates and cross-functional teams.
- Demonstrate how and when to follow instructions, guidelines, procedures, rules, signage, codes for different situations and processes.

Module 8: Reporting & documentation

THEORY

- Describe the types of documentation in an organization and the importance of maintaining the same.
- Explain the method of reporting and documentation as per Good Documentation Practices (GDP) and other regulatory guidelines.
- Describe the Attributable, Legible, Contemporaneous, Original, and Accurate Plus (ALCOA +) principle and its importance.
- Discuss how to use lab information management system.
- Explain statistical concepts and application of statistical tools.
- Discuss guidelines for Electronic Records & Electronic Signatures, Audit Trails, Date and Time Stamps, Data Integrity in the life sciences sector.

PRACTICAL

- Demonstrate how to perform reporting and documentation as per GDP and other regulatory guidelines.
- Prepare inspection reports as per inspection activity performed.
- Demonstrate the use of computer/ and software like MS Office, or its alternative for reporting.

Module 9: Coordinate with manager, colleagues and auditors

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

Module 11: Employability Skills

THEORY

- Show how to use basic English sentences for everyday conversation in different contexts, in person and over the telephone
- Read and interpret text written in basic English
- Write a short note/paragraph / letter/e -mail using basic English

Module 12: Apprenticeship Training

THEORY

- Perform checks in a microbiology lab before the start of the microbiological test.
- Perform test for microbial analysis in compliance to regulatory guidelines and support R&D activities.
- Follow Environment, health and safety guidelines in GMP/GLP controlled areas and Lab by ensuring the same is followed by subordinates as well.

- Perform reporting and documentation for Quality Control analysis.