

**CURRICULUM
FOR
ONE YEAR CERTIFICATE COURSE
IN
PRODUCTION OF IMMUNOBIOLOGICALS
AND
ANIMAL CARE**



**CENTRAL RESEARCH INSTITUTE, KASALI
HIMACHAL PRADESH - 173204**

APPROVED BY

**DIRECTORATE OF TECHNICAL EDUCATION, VOCATIONAL AND INDUSTRIAL TRAINING,
SUNDERNAGAR (H.P.)**

IMPLEMENTED W.E.F. SESSION 2016-17

**ONE YEAR CERTIFICATE COURSE IN
PRODUCTION OF IMMUNOBIOLOGICALS AND ANIMAL CARE**

1. SALIENT FEATURES

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|-----------------------------------|---|
| I. Name of the course | : One year certificate course in "Production of Immunobiologicals and Animal Care" |
| II. Duration of the course | : One year |
| III. Type of the course | : Full-time, Institutional |
| IV. Entry qualification | : Matriculation or equivalent pass from recognized board |
| V. Intake | : As approved by H.P. Takniki Shiksha Board
(25 seats for the session 2016-17; reservation as per S.C.V.T. guidelines) <i>50 seat.</i> |
| VI. Pattern of the course | : Annual system |
| VII. Admission criteria | : On the basis of Merit of Matriculation or equivalent examination |
| VIII. Certificate | : Certification shall be done under S.C.V.T. |
| IX. Medium of instruction | : Bilingual (English & Hindi) |

2. GUIDELINES

I. GUIDELINES FOR INTERNAL ASSESSMENT

The Internal Assessment will be of 30 marks. The distribution of marks shall be made as per the following guidelines:

- a. 20 marks shall be awarded on the basis of performance in the internal tests, to be held twice during course as 1st term examination and 2nd term examination containing 10 marks each as internal assessment (10 objective type questions from each paper and each question shall carry 1 marks in each test). For scoring equal weightage shall be given to each test.
- b. 5 marks shall be awarded for discipline and extracurricular activities.
- c. 5 marks shall be given for attendance/punctuality in the classes. 5 Marks for attendance shall be based on the following distribution:
 - i. <75% Nil
 - ii. ≥75%-<80% 3 Marks
 - iii. ≥80%-<90% 4 Marks
 - iv. ≥90% 5 Marks
- d. For internal assessment, The Head of the institute/Chairman of the Department/Coordinator of the Programme will notify the date sheet for Internal Assessment test(s) at the beginning of the academic calendar.
- e. In case a student is absent in the internal assessment test(s), the student will explain in writing the reason for absence to the Chairman of the Department /Coordinator of the programme. Such case(s), if any will be discussed in the board formed with Director or head of the Institute, Administrative Officer, Course Coordinator, one senior course teacher and if it finds the reason given by the student valid, it will be recommended to the Chairman/Coordinator of the programme to allow the student to sit in such test separately. The decision of such special board will be consider as the ultimate judgment of the Institute.
- f. The candidate who regularly attends teaching and practical classes and maintains at least 75% attendance shall be permitted to sit in the final board examinations.

Note: Head of the Institute, CRI, kasauli shall ensure that these marks are conveyed to the H.P. Takniki Shiksha Board, Dharamsala at the end of semester.

STUDY AND EVALUATION SCHEME FOR TRAINING COURSE ON PRODUCTION OF IMMUNOBIOLOGICALS AND ANIMAL CARE

PAPER NO	SUBJECTS	STUDY SCHEME (Weeks)	MARKS IN EVALUATION SCHEME		Total Marks
			INTERNAL ASSESSMENT	EXTERNAL ASSESSMENT	
Theory papers					
OTPIAC-01	Basic Introduction to Microbiology	8	30	70	100
OTPIAC-02	Basic Bacteriology	8	30	70	100
OTPIAC-03	Basic Virology	7	30	70	100
OTPIAC-04	Basic Immunology	5	30	70	100
OTPIAC-05	Immunoprophylaxis	11	30	70	100
OTPIAC-06	Animal Care and Management	7	30	70	100
OTPIAC-07	Basic Introduction to Current Good Manufacturing Practices (cGMP)	4	30	70	100
Theory total					700
Practical papers					
OTPIAC-08	Practical paper-I	-	-	50	50
OTPIAC-09	Practical paper-II	-	-	50	50
Practical total					100
Total marks of the course (Theory+Practical)					800

* Additional 2 weeks is reserved for conducting theory and practical examinations.

N.B. :

1. The examination will be annual. The passing criteria will be 40% in individual theory paper (external), 60% in individual practical examination (external) and 40% in internal assessment (40% of total subjects).
2. External examination shall be conducted by H.P.T.S.B. Dharamshala.
3. Practical examination shall be conducted at Institute level by appointing examiners as per SCVT pattern.
4. Each external theory paper will contain 70 objective type questions having 1 mark each. The maximum time will be 1h 10m (70 m).
5. The marks distribution of each practical paper will be as follows-
 - i. Two experimental questions having 15 marks each.
 - ii. 10 marks will be given to identification of spots to be decided by the examiner.
 - iii. 5 marks on viva-voce
 - iv. 5 marks on practical note book.

**DETAILED CONTENTS
OF
PRODUCTION OF IMMUNOBIOLOGICALS
AND
ANIMAL CARE
SUBJECTS**

Paper- OTPIAC-01: Basic Introduction to Microbiology	
Duration	<p>History and scope of microbiology.</p> <p>Basic introduction to the subject of microbiology and principles involved.</p> <p>Basic introduction of the equipment used in microbiology Laboratory.</p> <p>Cleaning of glassware.</p> <p>Principles of Sterilization and Disinfection.</p> <p>Various methods of sterilization and disinfection.</p> <p>Importance of decontamination.</p> <p>Introduction to biomedical waste management rules and their importance.</p> <p>Introduction to segregation of biomedical waste and color coding of the bags</p> <p>Disposal of biomedical waste.</p> <p>Introduction to importance and working of Effluent treatment plant and incinerator.</p> <p>Biosafety in microbiology laboratory.</p> <p>Basic introduction to different biosafety levels.</p> <p>Working with microorganisms in laboratory – Do's and Don'ts.</p> <p>Aseptic techniques.</p> <p>Working in laminar air flow and biosafety cabinets.</p> <p>Risk of working with microorganisms – to worker and environment.</p>
8Weeks	
Paper- OTPIAC-02: Basic Bacteriology	
8 Weeks	<p>Microscopy-</p> <p>Introduction to Microscopy.</p> <p>Introduction to various types of microscopes used in microbiology.</p> <p>Bacterial morphology – structure and appendages.</p> <p>Bacterial motility – Role of flagella and different methods for detection of motility.</p> <p>Staining techniques – principles and procedures</p> <p>Simple staining.</p> <p>Differential staining.</p> <p>Special staining.</p> <p>Bacterial cultivation-</p> <p>Microbial growth.</p> <p>Growth requirements for bacteria.</p> <p>Culture media - types, uses, composition and general aspects of media preparation.</p> <p>Sterilization and dispensing of different types of media.</p> <p>Culture methods – introduction to the importance of pure cultures.</p> <p>Bacterial Identification-</p> <p>Growth characteristics, colony characteristics, morphology and motility.</p> <p>Basic principles of biochemical reactions.</p> <p>Identification of bacteria using biochemical media.</p> <p>Basic principles of serological Identification.</p> <p>Preservation of bacteria.</p> <p>Importance of preservation of bacterial cultures and principles involved.</p> <p>Methods for preservation of bacterial culture.</p> <p>Long term preservation methods.</p>

Paper- OTPIAC-03: Basic virology	
7 Weeks	<p>Basic introduction to virology, structure and classification. Historical overview. Biosafety in virology Laboratory. Basic introduction of the equipment used in virology Laboratory. Electron microscopy & Fluorescence Antibody Technique. Cultivation of viruses – in-vivo and in-vitro. Animal cell culture. Types of different types of cell culture. Cytopathic effects (CPE.) Virus isolation. Virus quantitation using cell culture based and animal based assays. Basics introduction to virus purification. Immunoassays for virus detection and quantitation. Basic introduction to the growth requirements of cells – growth media and supplements. Working with cell cultures in a laboratory. Propagation and maintenance of different types of cell culture – Basic introduction. Cryopreservation of cells.</p>
Paper- OTPIAC-04: Basic Immunology	
5 Weeks	<p>Basic introduction to Immunology. Historical perspective. Innate and adaptive immunity – Defense system of human body. Introduction to antigens. Introduction to antibodies. Function and importance of antigens and antibodies. Introduction to antigen-antibody interaction and their importance in microbiology. Principles and applications in microbiology.</p>
Paper- OTPIAC-05: Immunoprophylaxis	
11 Weeks	<p>Basics of Immunity – Active and Passive Immunity. Role of Immune system in protection against diseases. Introduction to vaccines and antisera. Introduction to various types of vaccines. Bacterial Vaccines. Viral vaccines.</p>

	<p>Introduction to passive immunization and its importance.</p> <p>Basic introduction to different steps in production of antisera.</p> <p>Basic introduction to cold chain maintenance and its importance.</p> <p>Introduction to quality control testing of vaccine and antisera.</p> <p>Importance of quality control.</p> <p>Introduction to various quality control tests for bacterial vaccines.</p> <p>Introduction to various quality control tests for viral vaccines.</p> <p>Introduction to various quality control tests for antisera.</p> <p>Sampling and testing of different pharmaceutical grades of water.</p> <p>Environmental monitoring in classified area of production and quality control.</p> <p>Introduction to quality assurance and its importance.</p> <p>Quality system and its functioning.</p>
Paper- OTPIAC-06: Animal Care and Management	
7 Weeks	<p>Use of laboratory animals in microbiology.</p> <p>Introduction to animal ethics.</p> <p>Handling of different types of laboratory animals.</p> <p>Care and management of different types of animals.</p> <p>Cleaning of animal house.</p> <p>Introduction to different types of animal houses.</p> <p>Introduction to breeding colonies and experimental animal house.</p> <p>Anesthesia.</p> <p>Introduction to different injection techniques.</p> <p>Introduction to blood collection techniques.</p> <p>Euthanasia.</p> <p>Safe disposal of dead animals and waste generated from animal house.</p> <p>Biosafety while working in experimental animal house.</p>
Paper- OTPIAC-07: Basic introduction to Current Good manufacturing Practices (cGMP)	
4 Weeks	<p>Basic introduction to cGMP concept.</p> <p>Basic introduction to quality management system.</p> <p>Personnel hygiene.</p> <p>Entry and exit procedures.</p> <p>Do's and Don'ts in GMP facility.</p> <p>Brief introduction to qualification and validation.</p> <p>Brief introduction to Self-inspection and Quality Audits.</p> <p>Man and material flow.</p> <p>Good documentation practices.</p>

**Practical classes will be conducted side by side of the theory sessions
(50 weeks)**

Paper- OTPIAC-08: Practical paper-I

Visit to the microbiology laboratory and overview of its working.
 Handling and operation of equipment/instruments used in the microbiology Laboratory.
 Handling and packing of material to be sterilized.
 Handling and operation of different types of autoclaves.
 Handling and operation of Hot air oven.
 Segregation of the biomedical waste and its disposal.
 Demonstration of the Effluent treatment plant and incinerator.
 Working with microorganism with universal precautions.
 Working in laminar air flow bench.
 Working in biosafety cabinet.
 Visit to the virology laboratory and overview of its working.
 Handling and operation of equipment/instruments used in the microbiology Laboratory.
 Propagation of viruses in animals.
 Inoculation of virus into embryonated eggs through various routes.
 Inoculation of virus into different cell cultures and observation for CPE.
 Virus quantitation using cell culture and animals.
 Immunoassays for virus quantitation.
 Preparation of cell culture media with supplements.
 Propagation of cell culture in cell culture flasks.
 Cell counting.
 Maintenance of cell culture.
 Visit to the laboratory using immunological techniques.
 Demonstration of the Instrumentation used in various immunological techniques.
 Preparation of antigens and inoculation into animals.
 Sera separation and preservation.
 Antibody titration.
 Different antigen antibody interaction and handling and operation of instrumentation used .

Paper- OTPIAC-09: Practical paper-II

Handling and use of microscope for observation of microorganism.
 Study of various bacterial morphology under light microscope.
 Detection of bacterial motility using different methods.
 Preparation of smear, simple staining, differential staining and special staining of bacterial cultures. Observation of the stained samples under microscope.
 Preparation, dispensing and sterilization of various media.
 Inoculation of microorganisms into various types of liquid and solid media.
 Inoculation of bacteria using different culture methods.
 Identification of bacteria using biochemical tests.
 Identification of antigens using antisera.
 Preservation of bacterial cultures using different methods.
 Cryopreservation and freeze drying.
 Visit to the vaccine production unit.
 Introduction to equipment/instruments used in vaccine manufacturing unit.

	<p>Demonstration of different steps for production of bacterial vaccines. Demonstration of different steps for production of bacterial vaccines. Demonstration of different steps for production of antisera. Demonstration of cold chain maintenance of vaccines and antisera. Visit of quality control department. Practical demonstration of various quality control tests for bacterial vaccines, viral vaccines and antisera. Working of Quality Assurance Department. Visit of animal house. Hands-on class on handling, care and management of different types of animals – feeding, caging, bedding etc. Cleaning procedures for animal house. Working in experimental animal house and breeding colonies. Different injection techniques in different laboratory animals. Different blood collection techniques in different laboratory animals. Different techniques of euthanasia. Disposal of animal waste. Hands-on practice of each aspect to cGMP concept.</p>
2 Weeks	Theory and Practical Examinations.

- > Total duration – 52 weeks, including Theory and Practical Examinations
- > Time of theory classes is proposed to be in the morning before duty hours and practical classes are to be conducted during duty hours.