
YENEPOYA

(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

# YENEPOYA (DEEMED TO BE UNIVERSITY)

**Deralakatte, Mangaluru - 575018**

## REGULATIONS AND CURRICULUM GOVERNING

## POSTGRADUATE DIPLOMA IN MULTIOMICS TECHNOLOGY

**(CURRICULUM - EFFECTIVE FROM 2018-19)**

ATTESTED

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Ref: No.YU/REG/ACA/Academic Council-31/2018 27.02.2018

**NOTIFICATION – 31/ACM/2018**

Sub: Starting of Post Graduate Diploma course in Multiomics Technologies

Ref: 31st meeting of Academic Council held on 06.02.2018,vide Agenda - 5

****

The Academic Council at its meeting held on 06.02.2018, vide Agenda – 5, approved the proposal to start Post Graduate Diploma course in Multiomics Technologies under Yenepoya University.

The curriculum including syllabus for the said diploma course as drafted and finalized by the Faculty of Allied Health & Basic Sciences has been approved.

The course may be started during the academic year 2018-19.

**(Dr. G. Shreekumar Menon)**
**REGISTRAR**
mj

To:

The Dy. Director
Yenepoya Research Centre

Copy to:
1. P.A. to V.C.
2. P.A. to Registrar
3. Academic Section

# Post-Graduate Diploma in Multiomics Technology

## Preamble

The Post-Graduate Diploma in Multiomics Technologies course is proposed by Center for Systems Biology and Molecular Medicine (CSBMM), Yenepoya Research Centre, Yenepoya deemed to be University. The course is supported under the Biotechnology Skill Enhancement Programme (BiSEP) (Department of Biotechnology, Ministry of Science & Technology, Government of India and Department of IT, BT and S&T, Government of Karnataka).

The students undertaking the course will be trained in cutting-edge areas of genomics, transcriptomics, proteomics and metabolomics. The proposed course curriculum is designed keeping in mind the need of several global and Indian biotechnology-based companies. Upon successful completion, the students will be well-versed in the day-to-day operations of state-of-the-art OMICs technologies and data analysis platforms that will enable them to take up various roles in these companies including the area of research and development.

The broad goal of the course structure is to train graduates to be industry-ready in the competitive biotechnology sector. The duration of the programme shall be for one year with two semesters. Each semester will be of six months duration wherein the first semester shall consist of hands-on-training in sample preparation, operation of instruments, and data interpretation while the second semester shall be spent with industry partners.

# REGULATIONS: THE POST-GRADUATE DIPLOMA IN MULTIOMICS TECHNOLOGY

**1. Title of the programme:**

"Post-Graduate Diploma in Multiomics Technologies"

**2. Eligibility for admission**:

Admission procedure is totally governed by Karnataka Biotechnology and Information Technology Services (KBITS) through Karnataka Biotechnology Aptitude Test (KBAT). Qualified students will be counseled by the University. Selection of candidates shall be based upon merit in the entrance test.

**3. Duration of the programme:**

One year with two semesters. The first semester will consist of theory and practical classes and the second semester will consist of industry internship.

**4. Hours per week:**

Minimum of 32 hours of instructions per week. These hours may be distributed for lectures, seminars, tutorials, practical, and other modes of instructions.

**5. Medium of instruction:**

The medium of instruction shall be English.

**6. Attendance:**

A student shall attend a minimum of 80% of the total instruction hours including lectures, seminars, tutorials, practical and other modes of instructions. There shall be a provision for condoning of 5% shortage of attendance with penalty fee and a student who fails to secure <75% attendance shall not be eligible for examination and shall repeat the semester.

**7. Course objectives:**

i. To impart industry-oriented skill-upgrading training to graduates and post-graduates of biotechnology and life sciences in the area of multiomics technology (including genomics, proteomics and metabolomics) to enhance their employability in biotechnology sector as desired by Karnataka Biotechnology and Information Technology Services (as one of the host institute for their BiSEP course).

ii. To develop industry academic partnerships with leading companies engaged in research and development and service activities in the areas of genomics, proteomics and metabolomics

and bioinformatics by actively seeking their participation in student internship programmes as a part of BiSEP course.

iii. To nurture the local talent and transform the center to enable an ecosystem of entrepreneurship in order to gain entry in the existing New Age Incubation Network (NAIN) programme of Department of IT, BT and S&T.

**8. Expected outcomes of the course:**

i. Strengthening the objectives of BiSEP with a PG Diploma certificate to the BiSEP candidates.

ii. Successful placement of candidate trained under BiSEP in the partner industries.

iii. Successful collaboration with industry partners on BiSEP activities will be expected to bring newer and parallel scientific and commercial collaborations which might result in newer commercial as well as academic collaborations with industries.

iv. The students will learn independent operation of instruments, data analysis, consultancy service, software handling and personal and skill development training.

**9. Course Pattern**

| Paper No. | Title of the paper | Type of Paper | Total Hours/ Semester / Week | Duration of Examination | Internal Assessment Marks | End Semester Assessment Marks | Maximum Marks | Credits |
|---|---|---|---|---|---|---|---|---|
| **I Semester – Theory** | | | | | | | | |
| MOT101 | Proteomics and Metabolomics | Hard Core | 52/4 | 3 Hours | 30 | 70 | 100 | 4 |
| MOT102 | Genomics and Epigenetics | Hard Core | 52/4 | 3 Hours | 30 | 70 | 100 | 4 |
| MOT103 | Bioinformatics and Integrated OMICs Data analysis | Hard Core | 52/4 | 3 Hours | 30 | 70 | 100 | 4 |
| MOT104 | **Electives:**<br>i) Product Development – Biologist | Hard Core | 52/4 | 3 Hours | 30 | 70 | 100 | 4 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | ii) Quality Control/ Quality Assurance Biologist | | | | | | | |
| **I Semester – Practicals** | | | | | | | | |
| MOT105 | Genomics and Proteomics | - | 104/8 | 4 Hours | 30 | 70 | 100 | 4 |
| MOT106 | OMICS Data Analysis | - | 104/8 | 4 Hours | 30 | 70 | 100 | 4 |
| | | | | | | **Total Marks and Credits** | **600** | **24** |

| **II Semester - Industry Internship** | | | | | |
|---|---|---|---|---|---|
| **Paper No.** | **Title of the paper** | **Internal Assessment Marks** | **External Assessment Marks** | **Maximum Marks** | **Credits** |
| MOT107 | Industry Report or Project Report | 200 | 200 | 600 | 24 |
| | Presentation & Viva | - | 200 | | |
| | | | **Total Marks and Credits** | **600** | **24** |
| | | | **Grand Total** | **1200** | **48** |

## 10. Scheme of Examinations

**First Semester Internal Assessment:** 30 marks

Seminar 10 Marks (2 seminars per paper)

Assignment 05 Marks

Internal Test 15 Marks (2 internals)

**Practical**

Continuous assessment – 15 (based on attendance, performance and Record)

Internal Test - 15 Marks (2 internals)

**First semester – End Semester Assessment – 70 Marks**

**Theory**

Part A: 5x3 = 15 Marks (5 questions to be answered out of 6)

Part B: 5x5 = 25 Marks (5 questions to be answered out of 6)

Part C: 2x15= 30 Marks (2 questions to be answered out of 3)

**Practical**

Part A: Minor Experiment : 1x20=20 Marks

Part B: Major Experiment : 1x30=30 Marks

Part C: Viva/Voce : 20 Marks

**Second Semester - Internal Assessment – 400 Maximum Marks**

Progress Reports 200 marks (40 marks per month for 5 months)

Industry Feedback 200 marks (30 marks per month for 5 months)

**Second Semester – Final Assessment – 200 Maximum Marks**

Report/Dissertation 100 marks

Presentation & Viva-Voce 100 marks

Each theory/practical examination (end of the semester) shall be jointly conducted and evaluated by one internal examiner and one external examiner. The panel of examiners prepared by the B.O.S. and approved by the University. Viva- voce shall be conducted by a Common Viva-Board consisting of the Chairman (BOE), internal guide and one external expert as approved by the Controller of Examinations.

**Assessment by LSSSDC (Life Sciences Sector Skill Development Council)**

Electives paper Examination – 50 Marks - 1 ½ Hour duration (MCQs)

Skill Assessment – Viva - 15 Minutes duration by Examiner nominated by LSSSDC

Second Semester Examination conducted by University/Institutes for award of PG Diploma and Assessment by LSSSDC will be undertaken together. LSSSDC nominated Examiner will be a part of Industry Report/Project Report Presentation.

## 11. Classification of successful candidates:

The results of successful candidates at the end of each semester shall be declared in terms of Grade Point Average (GPA) and alpha sign grade.

| Grade Letter | Grade Point | Marks (%) |
|---|---|---|
| O (Outstanding) | 10 | ≥90 |
| A+(Excellent) | 9 | ≥80 |
| A(Very Good) | 8 | ≥70 |
| B+(Good) | 7 | ≥60 |
| B (Above Average) | 6 | ≥50 |

| | | |
|---|---|---|
| C(Average) | 5 | ≥45 |
| P (Pass) | 4 | ≥40 |
| F(Fail) | 0 | <40 |

The results at the end of the second semester shall be classified on the basis of the Cumulative Grade Point Average (CGPA) obtained in both the semesters and the corresponding overall alpha-sign grade. An eight point grading system, alpha-sign grade as described below shall be adopted.

| **Grade Letter** | **Grade Point Average** |
|---|---|
| O (Outstanding) | 10 |
| A+(Excellent) | 9.0 -9.99 |
| A(Very Good) | 8.0-8.99 |
| B+(Good) | 7.0-7.99 |
| B (Above Average) | 6.0-7.99 |
| C(Average) | 5.0-5.99 |
| P (Pass) | 4.0 -4.99 |
| F(Fail) | <4.0 |

Sample illustrations for computing semester grade point averages (GPA), cumulative grade point average (CGPA) and the alpha -sign grades

**Illustration (24 credits) Semester I**

| **Papers** | **MOT101** | **MOT 102** | **MOT 103** | **MOT 104** | **MOT 105** | **MOT 106** | **Total** |
|---|---|---|---|---|---|---|---|
| Maximum marks | 100 | 100 | 100 | 100 | 100 | 100 | 600 |
| Marks obtained | 88 | 88 | 72 | 55 | 65 | 65 | 433 |
| Grade Points Earned (G.P) | 9 | 9 | 8 | 6 | 7 | 7 | 46 |
| Credits (C) /Paper | 4 | 4 | 4 | 4 | 4 | 4 | 24 |
| Total GPW= GPx C | 36 | 36 | 32 | 24 | 28 | 28 | 184 |

The GPA shall be computed by dividing the total GPW of all the subjects of study by the total credits for the semester.
GPA = Total GPW / Total Credits = 184/24 = 7.6

**Calculation of Cumulative Grade Point Average (CGPA):**

The CGPA at the end of the second semester shall be calculated as the weighted average of the semester GPW. The CGPA is obtained by dividing the total of GPW of both the semesters by the total credits for the programme.

The following is the sample illustration of computing semester grade point averages (GPA), cumulative grade point average (CGPA) and the alpha -sign grades assigned for successful candidates.

| **Semester** | **I** | **II** | **Total** |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Semester GPW | 184 | 182 | 366 |
| Semester Credits | 24 | 24 | 48 |
| Semester Alpha Sign Grade | B+ | B+ | B+ |

Cumulative Grade Point Average (CGPA) = Total of Semester GPW / Total Credits for the programme = **366/48 = 7.625 (B+)**

The results of the candidates who have passed the second semester examination but not passed the first semester examinations shall be declared as NCF (Not Completed First semester examinations). Such candidates shall be eligible for the degree only after completion of the first semester examinations.

**12. Tuition Fee:**

Rs. 50,000/-* (Rupees Fifty Thousand only) per student

*For students who are selected through the BiSEP programme, Department of IT, BT and S&T, Government of Karnataka will pay a part of the course fee per candidate to BiSEP Host Institutions.

**13. Detailed syllabus**

Detailed syllabus enclose as Annexure -1

**14. Number of candidates per batch:** 20

**ANNEXURE-I**

## SYLLABUS FOR POST-GRADUATE DIPLOMA IN MULTIOMICS TECHNOLOGY

**SEMESTER-1**

| **Title of the Paper: Proteomics and Metabolomics** | |
|---|---|
| | |
| **Subject Code: MOT101** | **Credits: 4** |
| **Total lecture hours: 52** | **Internal Marks: 30** |
| **Contact hours per week: 4** | **External Marks: 70** |

**Unit 1** **12 hours**

**Proteomics**

Mass spectrometry – ionization methods (MALDI, electrospray), mass analysers, fragmentation modes (CID, HCD and ETD), intact protein analysis, protease digestion, peptide mass fingerprinting, tandem mass spectrometry, , introduction to Data Independent Analysis (DIA), Basics of chromatography and fractionation strategies; Protein sequence and spectral databases/ libraries, *de-novo* sequencing, search algorithms- SEQUEST, X!tandem, MS-Amanda; Proteomic data repositories

**Unit 2** **12 hours**

**Quantitative and Targeted Proteomics**

Introduction to quantitative proteomics- Differential proteomics, post-translational modifications, Targeted proteomics- Parallel reaction monitoring, Multiple reaction monitoring, Targeted proteomics software- Skyline

**Unit 3** **12 hours**

**Proteogenomics**

Concepts and principles of genome annotation, genome search specific peptides, alternative translation initiation, small ORFs, Analysis of transcriptomic and proteomic data for genome annotation; Gene prediction algorithms

**Unit 4** **9 hours**

**Metabolites and Metabolomics**

Metabolomics-an overview, basic sample preparation strategies- extraction, derivatization, Workflow for lipidomics; Introduction to mass spectrometry and modes of data acquisition, data repositories. Targeted Vs Untargeted metabolomics; development of targeted assays for small molecules

**Unit 5** **7 hours**

**Metabolomic Data Analysis**

Peak detection, retention time alignment; identification of molecular features and metabolites; structural confirmation of metabolites. Software- Multiquant, MZmine, XCMS, MarkerView, LipidSearch. Metabolic pathways and inborn errors of metabolism

| Title of the Paper: Genomics and Epigenetics | | | |
|---|---|---|---|
| | | | |
| **Subject Code:** | **MOT102** | **Credits:** | **4** |
| **Total lecture hours:** | **52** | **Internal Marks:** | **30** |
| **Contact hours per week:** | **4** | **External Marks:** | **70** |

**Unit 1** **8 hours**

**Genes and Genomes**

Gene- Eukaryotic and prokaryotic gene structure, genome databases, Coding regions (genes) and Non-coding regions (Intergenic sequences); Gene and related sequences – NTS, ETS and ITS, 3' UTR, 5' UTR, Pseudogenes; Repeat sequences: a) Interspersed repeats: LINES, SINES, LTR elements; SINES types: ALU elements, MIR, MIR3; b) Tandem repeats: Transposons; c) Microsatellites; Genetic mapping; Physical mapping (Contig maps, Restriction maps, DNA sequence maps, FISH); Molecular markers for genome analysis-Restriction enzyme sites, EST, STS, microsatellites

**Unit 2** **10 hours**

**Genomics**

Sanger sequencing-principle, methodology and applications, History of genome sequencing, Human Genome sequencing project; Analysis of gene expression- qPCR, northern blot, southern blot; Transcriptome profiling; DNA microarrays; Copy number variation, sequence repeats, SNV, haplotype, and their relevance in diseases. Comparative genomics. Metagenomics

**Unit 3** **12 hours**

**Next Generation Sequencing (NGS) Technology**

Whole genome - *de novo* sequencing or resequencing; exome sequencing; RNA sequencing; small RNA sequencing; metagenomics; NGS workflow: DNA/RNA isolation and quantitation; Fragmentation (different methods – Physical / Enzymatic/ Chemical); Library preparation-blunt end and adapter ligation, amplification, index addition; single end and paired end reads; Exome/ gene panel capture; Ribosomal RNA depletion (RNA-Seq) and small RNA enrichment; 16S rRNA based sequencing for metgenomics; Platforms for NGS sequencing; Clonal amplification- Bead-based or Emulsion-based PCR amplification, array-based or bridge amplification; Sequencing technologies-(Clone-by-clone sequencing, Shot-gun sequencing, sequencing by hybridization and sequencing by synthesis), Emerging sequencing platforms- PacBio (SMRT technology), Oxford Nanopore systems

**Unit 4** **12 hours**

**NGS data analysis**

Next generation sequence analyses, Data format, Quality control-Phred score; FastQC and FastX tool kits, data analysis tools and pipeline, Read length, read depth, sequence coverage, Homology, clustering, and phylogeny, Genome alignment and analysis tools- BWA (Burrows-Wheeler Aligner), SAMtools, GATK (The Genome Analysis Toolkit), IGV (Integrative Genomics Viewer), HISAT, StringTie, Cuffcompare, Velvet, Oases, Trinity

**Unit 5** **10 hours**

**Gene Expression and Gene Regulation Networks**

RNA-seq analyses. Differential expression, stochasticity, and FDR. Alternate splicing, ENCODE. Epigenomic analyses and cancer/ diseases. Bisulfite sequencing

**Title of the paper: Bioinformatics and Integrated OMICS Data analysis**

| | |
|---|---|
| **Subject Code: MOT103** | **Credits: 4** |
| **Total lecture hours: 52** | **Internal Marks: 30** |
| **Contact hours per week: 4** | **External Marks: 70** |

**Unit 1** **12 hours**

**Introduction to Bioinformatics and Data Generation**

Bioinformatics and its applications to biology, Bioinformatics tools – Web-based and standalone; sequence analysis (BLAST, alignment tools), phylogeny analysis (MEGA7), network analysis (Cytoscape), Gene Ontology

**Unit 2** **7 hours**

**Basics of Linux Operating System**

Introduction to Linux operating system, its distribution and installation; Basic and advanced command line operations; File management and permissions; Overview of scripting languages AWK and shell; Vim text editor

**Unit 3** **10 hours**

**Fundamentals of Programming Languages**

a) PERL

Data structure: scalar, array, hash; Conditional statements: if, else, elsif, unless; Loops: for, foreach, until, while, do..while; String handling: length, lc, uc, substr and regular expression; Array handling: push, pop, shift, unshift; Operators; File handling; References; Subroutine. Bio-PERL.

b) Python

Introduction to python: Overview, Environment setup, Basic syntax; Basic operations; Data types: strings, tuples, lists, dictionaries; Decision making: if, if else, nested if; Loops: while, for, nested, break, continue and pass statement; File handling; Bio-python.

**Unit 4** **12 hours**

**Biological Databases**

Databases and data retrieval systems (DBMS, SQL) – primary and secondary databases, biological databases – NCBI, UniProt, PDB, KEGG, Data annotation strategies; Database development

**Unit 5** **11 hours**

**Integrated OMICS Data Analysis**

Genomic, transcriptomic, proteomic and metabolomics data file format and standards, curation and gene accession mapping, Quality control for data integration, Analysis and visualization, gene set Enrichment analysis, Pathway analysis, Network analysis

| | |
|---|---|
| **Title of the Practical paper: Genomics and Proteomics** | |
| | |
| **Subject Code: MOT105** | **Credits: 4** |
| **Total lecture hours: 104** | **Internal Marks: 30** |
| **Contact hours per week: 8** | **External Marks: 70** |
| | |

**Module 1** **30 hours**

**Next Generation Sequencing**

DNA and RNA extraction and quantitation; quality control, alignment and analysis Introduction to Nanopore Sequencing and library preparation, Nanopore Sequencing; Whole Genome Sequencing; Different data formats for sequencing data including FASTQ, SFF, CSF, CSFASTA, SAM, BAM. Common sequencing and annotation file formats in use for transcriptomics analysis including GTF, GFF, BED

**Module 2** **40 hours**

**Proteomics**

Protein extraction strategies for varied biological samples; in-gel and in-solution digestion; Liquid chromatography-based (SCX/bRPLC); Stop And Go Extraction (C18-based) for mass spectrometry; TMT labeling; Validation of proteomic data

**Module 3** **10 hours**

**Phosphoproteomics**

Extractions of proteins; Enrichment of phosphopeptides using $TiO_2$, Mass spectrometric analysis of phosphopeptide enriched samples

**Module 4** **24 hours**

**Metabolomics**

Extraction techniques for metabolomics; Basics of chromatography; Introduction to lipidomics; Metabolome data resources

| | | | |
|---|---|---|---|
| **Title of the Practical paper: OMICS Data Analysis** | | | |
| | | | |
| **Subject Code:** | **MOT106** | **Credits:** | **4** |
| **Total lecture hours:** | **104** | **Internal Marks:** | **30** |
| **Contact hours per week:** | **8** | **External Marks:** | **70** |
| | | | |
| **Module 1** **28 hours**<br>**Genomics**<br>Quality filter and processing raw data; Mapping tools for WGS using BWA and Bowtie; Demonstration of common SAM tools and BED tools; Transcriptome analysis using Hisat2; Transcriptome analysis using StringTie; Differential expression analysis for transcriptome data using cuffdiff package; Introduction to R and Bioconductor packages | | | |
| | | | |
| **Module 2** **28 hours**<br>**Mass Spectrometry-based Proteomics Data**<br>Data formats of mass spectrometry experiments; Qualitative data analysis; Quantitative data analysis, Normalization techniques for quantitative proteomics; Proteomic data analysis- Search algorithms, False Discovery Rates, Parsimony rules; Data resource based protein identification | | | |
| | | | |
| **Module 3** **24 hours**<br>**Integrated OMICS Data Analysis**<br>Proteogenomic data analysis using Integrative Genomics Viewer; Biological interpretation of OMICs data, Gene set Enrichment analysis, Pathway analysis, Network analysis | | | |
| | | | |
| **Module 4** **24 hours**<br>**Metabolomics**<br>Data formats of mass spectrometry derived metabolomics; Metabolomics data analysis – identification of molecular features, metabolite identification; structural confirmation of metabolites; Data resource based metabolite identification; Using NIST Standard Reference Database, METLIN database; XCMS tool, Human Metabolome Database (HMDB), Compound Discoverer, MZmine | | | |

**Elective papers: (i) Product Development - Biologist**

| | | | |
|---|---|---|---|
| **Subject Code:** | **MOT104** | **Credits:** | **4** |
| **Total lecture hours:** | **52** | **Internal Marks:** | **30** |
| **Contact hours per week:** | **4** | **External Marks:** | **70** |

**Unit 1** **12 hours**

**Essentials of Product Development**

Company protocols for research, privacy policies, institutional and professional code of ethics and standards of practice, IPR guidelines, Knowledge of basic laboratory procedures, GLP and GMP, relevant EOPs, SOPs, process flows in manufacturing, product life cycle and product properties, competitor products. Stability studies – generate stability data & prepare stability reports for innovation products

**Unit 2** **10 hours**

**Reporting and Documentation**

Reporting – different standard reference materials used like drugs, products, side effects, adverse reactions, process details, statistical analysis of test data. Documentation – methods and procedures of writing and maintaining lab, research records, research performance reports, schemes and guidelines, power point presentations, tables, charts, word documents, development of research objectives and proposal writing for funding and contractual purposes, publications and technical writing, Regulatory compliance of the final documents

**Unit 3** **8 hours**

**Planning and Communication**

Research planning – resource, time, timeline & budget considerations, technical feasibility analysis on the NPD ideas by analyzing current development plans, plan day to day activities. Research communications - preparation of progress reports/ research outcomes for steering groups/ bodies, principal investigator, communication with upstream and downstream teams

**Unit 4** **6 hours**

**Problem Solving and Decision Making**

Research initiatives – use new areas of research, techniques and methods, extend research/ product portfolio, creative analysis & interpretation of research data. Decision making – collaborative, appropriate, optimum & best possible solution, Trouble- shoot & Resolve problems to avoid delays

**Unit 5** **8 hours**

**Safety and Security at Workplace**

Different types of occupational health hazards, knowledge of chemical substances, characteristics & safety measures, use of safety gears, masks, gloves & accessories, evacuation procedures for workers & visitors. Health, safety & security issues – types (illness, fire accidents), company policies and procedures, When and how to report, summon medical assistance & emergency services

**Unit 6** **8 hours**

**Interpersonal Skills**

Understand work output requirements, company rules, guidelines & policies related to the process flow, identifying and reporting issues requiring intervention, delivery of quality work on time & report any anticipated reasons for the delay, effective interpersonal communication, conflict-resolution techniques, importance of collaborative working, multi-tasking, training the team members, knowledge of project management

**Elective paper: (ii) Quality Control/Quality Assurance Biologist**

| | | | |
|---|---|---|---|
| **Subject Code:** | **MOT104** | **Credits:** | **4** |
| **Total lecture hours:** | **52** | **Internal Marks:** | **30** |
| **Contact hours per week:** | **4** | **External Marks:** | **70** |

**Unit 1** **16 hours**

**Essentials of Quality Control**

Preparations - buffer, solvents, and solutions for running bio-analytical quality tests

Concepts of pharmacopeia like BP, USP, EP and other applicable guidelines such as WHO, ICH and EMEA, etc., statistical tools and software like combistats, safe handling of infectious materials like cultures, strains and seed strains, procedures for handling infectious spillage control, GLP/GMP, biochemical analysis of proteins, bio analytical methods, working of instruments/apparatus/equipment, biological assays, application of various analytical techniques such as HPLC, capillary electrophoresis including icIEF, FTIR, UV and Fluorescence spectroscopy, ELISAs, enzyme assays and other applicable methods for the testing of biopharmaceuticals, application of microbiological techniques such as air monitoring, water testing, surface monitoring, microbial monitoring, biosafety levels and biosafety hazards

**Unit 2** **10 hours**

**Quality Assurance**

Quality checks - quality assurance samples, master sample, internal controls, statistical analysis of test data, techniques and concepts of statistical quality control and statistical process control, non-conformities. Operational aspects – calibration, accuracy checks of quality control equipments like HPLC, liquid chromatography, mass spectrometry, application software used in quality analysis

**Unit 3** **6 hours**

**Safety and Security at Workplace**

Different types of occupational health hazards, knowledge of chemical substances, characteristics & safety measures, use of safety gears, masks, gloves & accessories, evacuation procedures for workers & visitors. Health, safety & security issues – types (illness, fire accidents), company policies and procedures, When and how to report, summon medical assistance & emergency services

**Unit 4** **6 hours**

**Interpersonal Skills**

Understand work output requirements, company rules, guidelines & policies related to the process flow, identifying and reporting issues requiring intervention, delivery of quality work on time & report any anticipated reasons for the delay, importance of team work, resolution of conflicts, multi-tasking, training the team members, knowledge of project management

**Unit 5** **6 hours**

**Clean Work Station**

Cleaning the work area and equipments, materials and equipments required for cleaning, adequate ventilation for the work area, personal protective equipments, dealing with accidental damage, procuring and storing housekeeping equipment and supplies, disposal of wastes, maintain schedules and records for housekeeping

| **Unit 6** **8 hours** |
|---|
| **Reporting and Documentation in Quality**<br>Reporting – company procedures**,** escalation matrix for reporting identified issues - defects, problem, incidents, quality issues and test results, feedback to production manager and R&D staff. Documentation – procedures and good documentation practices, offline and online mode, accuracy, details, controlled document files and test records, regulatory and compliance requirements**,** inspection - procedures, protocols and checklists, inspection reports |

| **Semester II** | | | |
|---|---|---|---|
| **Subject Code and Title of the Paper** | **Details** | **Credits** | **Duration** |
| **MOT201; Industry Internship Report** | Internship, project report, presentation and viva voce | 24 | 5 months |

**References/Books/Journals**


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