Syllabus
First Semester Courses in
MSc
BIOTECHNOLOGY
(2024-2025)

Contents:

- **Syllabus for Elective Courses:**
  - PSBTY6001EL2 NANOBIOTECHNOLOGY

- Evaluation and Assessment guidelines

APPROVED SYLLABUS

ST. XAVIER'S COLLEGE-AUTONOMOUS MUMBAI-400 001

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MSc I BIOTECHNOLOGY		
Course Title: NANOBIOTECHNOLOGY **Course Code: PSBTY6001EL2**		
Credits 4 Theory -60 hours		
No.	**Course Objectives**	
1.	This course aims to provide students with a comprehensive understanding of nanotechnology principles, including the unique properties and behaviors of materials at the nanoscale. Learners will be initiated to examine the use of nanotechnology in biomedical, agriculture and environment related applications.	
CO	**Course Outcomes** **On completing the course, the learner will be able to**	**Bloom's Taxonomy Level (BT level)**
1	Understand the concepts in nanotechnology , nanomaterials, and its properties	Understanding
2	Understand , apply, and analyze the role of nanomaterials and nanotechnology in healthcare and environment problem mitigations.	Understanding Application
3	Explore the use of nanomaterials in various biotechnological applications such as drug delivery, diagnostics, tissue engineering, and therapeutics.	Application ,analysis and Evaluation

UNIT I	**Introduction to Nanobiotechnology**		**15 L**
	1	Introduction to Nanobiotechnology; Concepts, historical perspective; Cellular Nanostructures; Nanopores; Biomolecular motors; Bio-inspired Nanostructures,	
	2	*Properties of nanomaterials:* Structural properties, chemical properties, surface functionalization, physical properties.	
	3	*Various types of nanomaterials:* Three-dimensional, two dimensional, one-dimensional, and zero-dimensional nanomaterials. Carbon nanotubes, Graphene, Carbon dots, metal nanoparticles, metal oxide-based nanomaterials, semiconductor nanomaterials,	

		quantum dots, hybrid nanoparticles, Bio-nanomaterials, polymer nanoparticles, lipid nanoparticles etc.	
	4	Nanofilms: Thin films; Colloidal nanostructures; Self Assembly, Nanovesicles; Nanospheres; Nano capsules and their characterisation.	
UNIT II		**Synthesis of Nanomaterials**	**15 (T and Practical)**
	1.	Top down and bottom-up approaches for nanomaterial synthesis	
	2.	Physical methods: equipment for mechanical alloying, process variables in milling, Mechanism of alloying,	
	3.	Chemical Approach: Sol gel method, Spray pyrolysis, Electro spraying and spin coating routes, micro emulsion polymerization-	
	4.	.Physical Approaches : Inert gas condensation technique – arc plasma and laser ablation, Vapor deposition and different types of epitaxial growth techniques (CVD,MOCVD, MBE,ALD)- Lithography :Photo/UV/EB/FIB techniques, Dip pen nanolithography, Etching process :Dry and Wet etching, micro contact printing.	
	5.	Nanoparticles: Nanoparticles for drug delivery, concepts, optimization of nanoparticle properties for suitability of administration through various routes of delivery, advantages, strategies for cellular internalization and long circulation, strategies for enhanced permeation through various anatomical barriers	
UNIT III		**Characterization techniques**	
	1.	Microscopy- Optical, SEM, TEM, AFM, High Resolution Imaging techniques	
	2.	Physicochemical Charecterisation:	
	3.	Spectroscopy- Raman, Microwave, Atomic and IR, NMR, DLS,	
	4.	Diffraction methods - DLS, X-RD	
UNIT IV		**Applications and Nanotoxicity**	
	1.	*Nanotechnology in healthcare:* Nanoparticles for diagnostics and imaging (theranostic); Nano nutraceuticals and pharmaceuticals, Targeted Drug Delivery	
	2.	*Nanodevices:* Nano scaffolds ,Nanobots, Sensors	

	3.	*Nanotechnology in agriculture and environment:* Nanotechnology based tools to enhance agricultural productivity, Nano Based Agri and Food Products, Nano pesticides and Nano fertilizers, Nano-enabled technologies and abiotic stress management, Nanobiotechnology for Crop improvement, Biosensors for monitoring environmental changes and bioremediation.	
	4.	• *Nanotoxicity:* Introduction to Safety of nanomaterials, Basics of nanotoxicity, Models and assays for Nanotoxicity assessment; Fate of nanomaterials in different strata of environment; Ecotoxicity models and assays; Life cycle assessment, containment.	

Reference Books:

1. Akçan R, Aydogan HC, Yildirim MŞ, Taştekin B, Sağlam N.(2020) Nanotoxicity: a challenge for future medicine. Turk J Med Sci.50(4):1180-1196.(https://doi: 10.3906/sag-1912-209)
2. Balls, M., Combes, R. D., & Bhogal, N. (2012, March 22). *New Technologies for Toxicity Testing*. Springer Science & Business Media.
3. Cao, G., & Wang, Y. (2011, January 1). *Nanostructures and Nanomaterials*. World Scientific.
4. Chen, Y., Lai, Z., Zhang, X., Fan, Z., He, Q., Tan, C., & Zhang, H. (2020). Phase engineering of nanomaterials. *Nature Reviews Chemistry*, *4*(5), 243-256. (https://doi.org/10.1038/s41570-020-0173-4)
5. Goodsell, D. S. (2004, April 16). *Bionanotechnology*. John Wiley & Sons.
6. Multilayer Thin Films: Sequential Assembly by Gero Decher, Joseph B. Schlenoff, 2003
7. Neelina H. Malsch, Biomedical Nanotechnology, CRC Press
8. Niemeyer, C. M., & Mirkin, C. A. (2006, March 6). *Nanobiotechnology*. John Wiley & Sons.
9. Pedrero, M., Gamella, M. and Serafín, V. (2022) Nanomachines and Nanorobotics: Improving cancer diagnosis and therapy, *The Detection of Biomarkers*, pp. 503–543. (https://doi.org/10.1016/b978-0-12-822859-3.00015-8)
10. Rao, C. N. R., Govindaraj, A., & Panchakarla, L. S. (2021, October 27). *Nanotubes and Nanowires*. Royal Society of Chemistry.
11. Sahu, S. C., & Casciano, D. A. (2014, April 22). *Handbook of Nanotoxicology, Nanomedicine and Stem Cell Use in Toxicology*. John Wiley & Sons.
12. Sutariya, V. B., & Pathak, Y. (2014, July 29). *Biointeractions of Nanomaterials*. CRC Press.

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13. Wavhale, R.D. *et al.* (2021) Water-powered self-propelled magnetic nanobot for rapid and highly efficient capture of circulating tumor cells, *Communications Chemistry*, 4(1). (https://doi.org/10.1038/s42004-021-00598-9)
14. Zhang, Y., Li, M., Gao, X., Chen, Y. and Liu, T., 2019. Nanotechnology in cancer diagnosis: progress, challenges and opportunities. *Journal of Hematology & Oncology*, 12(1). (https://jhoonline.biomedcentral.com/articles/10.1186/s13045-019-0833-3)
15. Zhao, Y., Zhang, Z., & Feng, W. (2016, December 12). *Toxicology of Nanomaterials*. John Wiley & S

Evaluation (PSBTY6001EL2):
Total marks per course – 100.

- Formative Assessment 'for' Learning (continuous internal assessment - CIA to improve learning).
  CIA- 40 marks
  CIA 1: Written test -20 marks
  CIA 2: Assignment -20 marks
- Summative Assessment 'of' Learning (focus on outcomes, quantitative data for outcomes of instruction).
  End Semester Examination – 60 marks
  One question from each unit for 15 marks, with internal choice. Total marks per question with choice -20 to 22.

Distribution of Bloom's Taxonomy levels for the course assessment

Units (1-4)	Remembering	Understanding	Analyzing and Application	Evaluation and Creation
*Percentage	10-15%	25-40%	20-30%	20%

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#.MSc. Part I. Biotechnology Semester I **Course Code: PSBTY6002EL1**

Name of the course: Plant Biotechnology
Credits : 4 (Total number of lectures – 60)
Course Objectives:

- The Course will provide an advanced understanding of the principles, techniques, and applications of biotechnology as applied to plants.
- This course gives an opportunity to students to find out ways of exploiting the plants using biotechnological interventions for value addition or for novel plant products for human use.
- The course aims to introduce the concepts and significance of plant biotechnology in agriculture, food security, and environmental sustainability.
- The course comprehends the importance of tissue culture for mass production of disease-free plants and genetic transformation, production of pharmaceutical proteins and other valuable products using transgenic plants .

Course Outcomes (CO)

Course Title and Code	**Plant Biotechnology**	**PSBTY6002EL1**	
CO No.	**Course Outcomes** ***On completion of the course , the student will be able to***	**PSOs Addressed**	**Cognitive Level**
CO-1	Demonstrate a comprehensive understanding of concepts in plant metabolism and plant tissue culture	PSO-1,3,6,7	U,Ap, E
CO-2	Design experiments using plant tissue culture techniques, including micropropagation, somatic embryogenesis, and protoplast isolation.	PSO-2,3,7	U,Ap
CO-3	Design experimental studies to understand metabolic pathways in order to validate existing and produce new scientific information about the same	PSO-2,3,4,7	U,Ap, E
CO-4	Develop and implement strategies for engineering crop traits, such as stress tolerance, nutrient enhancement, and yield improvement.	PSO-1,3,6,7	U,An,Ap

CO-5	Evaluate the potential benefits and risks of genetically modified crops and assess their societal and environmental impacts.	PSO- 3,4,6,8	U,An,Ap
CO-6	Identify and critically evaluate innovative technologies for their potential applications in plant research and agriculture.	PSO-1,3,6,8	U,An,Ap

CONTENT

Unit1: Plant Metabolism — 15 lectures

- Bioenergetics-basic principles; equilibria and concept of free energy; coupled interconnecting reactions in metabolism, types of metabolic pathways, the main class of metabolic reactions (using few already studied pathways)
- Carbohydrate metabolism and regulation in plants
- Overview of plant secondary metabolism - Main Secondary metabolites, Function of Secondary Metabolites (alkaloid, terpenoids, phenolics)
- Compartmentation of SMs biosynthesis- Cytosol, Mitochondria, Vesicles, Endoplasmic reticulum: chloroplast

Unit II: Plant Tissue Culture — 15 lectures

- Totipotency; Plant growth regulators
- Regeneration and micropropagation of plants: clonal propagation, organogenesis, shoot-tip and meristem culture, haploid culture, triploid culture, protoplast culture; Somaclonal variation;
- Tissue culture and Cell suspension culture system: methodology, growth kinetics and nutrient optimization; Precursors and elicitors
- Plant Transformation methods (emphasis on Agrobacterium mediated transformation); Hairy root culture;

Unit III: Plant Cell Technology — 15 lectures

Secondary Metabolite production: Principles, design and operation of bioreactors: specific design criteria for plant systems; Isolation, characterization and production of secondary metabolites from different plant cell types; Downstream process.

- Plant Biotechnology interventions for mitigating Abiotic -Biotic stress
  - Enhancing cold and heat stress tolerance; secondary effects of abiotic stress – production of ROS; genes involved in scavenging of ROS,
  - Enhancing drought and salt stress tolerance;

  - Enhancing resistance against fungal pathogens; anti-microbial proteins; enhance viral resistance- pathogen derived resistance; herbicide resistance.
- Plant biotechnology in improving fruit ripening and enhancing photosynthesis; Golden rice- nutritionally improved rice through biotechnology; Bt cotton, Bt brinjal and Golden mustard, transgenic sweet potato; Modification of taste and appearance- sweetness, starch and preventing discoloration

Unit IV: Plants as Biofactories **15 lectures**

- Molecular farming, Production of Industrial enzymes, biodegradable plastics, therapeutic proteins, edible vaccines, and antibiotics using transgenic technology.
- Plant-based bioremediation: applications of bioremediation for salinity, heavy metal-contaminated soils, radioactive contamination, etc
- Biofertilizers and Biopesticides- Plant growth promoting bacteria.
- Phytoremediation -Phyto mining
- Plant based Biosensors and Bioindicators for environmental monitoring.

List of Recommended Reference Books

- Cseke L.J., Kirakosyan A., Kaufman P.B., Warber S.L., Duke J.A. and Brielmann H.L. Natural Products from Plants, 2nd edition, Taylor & Francis group, 2006.
- Buchanan B; Gruissem W et al (2nd Ed.) Biochemistry and Molecular Biology of Plants John Wiley & Sons 2015
- Brun T.A. (2006). Gene Cloning and DNA Analysis. An Introduction, Oxford, Blackwell Pub.
- Bernard R. Glick, Jack J. Pasternak, Cheryl L. Patten. (2010) Molecular Biotechnology: Principles and Applications of Recombinant DNA. ASM Press.
- Primrose, S.B. & Twyman, R.M.: Principles of gene manipulation and genomics. (7th ed.) Malden. Blackwell Publishing, 2006. 1-4051-3544-3--(575.1Pri/Twy)
- Chawla, H. S. (2000). Introduction to Plant Biotechnology. Enfield, NH: Science.
- Razdan, M. K. (2003). Introduction to Plant Tissue Culture. Enfield, NH: Science.
- Slater, A., Scott, N. W., & Fowler, M. R. (2008). Plant Biotechnology: an Introduction to Genetic Engineering. Oxford: Oxford University Press.

Evaluation (Theory): Total marks per course - 100

I. Formative Assessment 'for' Learning (continuous internal assessment - CIA to improve learning).
CIA- 40 marks
Continous evaluation using various scientific communication methods

II. Summative Assessment 'of' Learning (focus on outcomes, quantitative data for outcomes of instruction).
End Semester Examination – 60 marks
One question from each unit for 15 marks, with internal choice.

Eg: Template for the Core course End Semester examination in Semester I for the Elective course

UNITS	KNOWLEDGE	UNDERSTANDING	APPLICATION and ANALYSES	TOTAL MARKS- Per unit
1	5	5	5	15
2	5	5	5	15
3		8	7	15
4		8	7	15
-TOTAL - Per objective	10	26	24	60
% WEIGHTAGE	16.67	43.33	40	100%

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Second Semester Courses in MSc-Biotechnology 2023-2024

Contents:

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#.MSc. Part I. Biotechnology Semester II **COURSE: PSBTY6003EL1**

Name of the course: Molecular Oncology
Credits : 4 (Total number of lectures – 60)

Course Objectives:

1. The primary objective of the course is to provide students with a comprehensive understanding of the molecular basis of cancer, including its causes, progression, and potential therapeutic interventions.
2. The course will introduce the learner to advanced technologies and screens, used in cancer research, diagnosis and treatment.

Course Outcomes (COs)

Course Title and Code	**Molecular Oncology**	**PSBTY6003EL1**	
CO No.	**Course Outcomes** *On completion of the course , the student will be able to*	**PSOs Addressed**	**Cognitive Level**
CO-1	Describe the fundamental molecular processes underlying cancer initiation, progression, and metastasis.	PSO-1,2,6	U,Ap
CO-2	Demonstrate knowledge of strategies for cancer diagnosis and therapeutics	PSO-1,6	U,Ap
CO-3	Discuss the concept of personalized medicine in oncology and the development of targeted therapies.	PSO- 2,3	An, Ap
CO-4	Analyse and interpret biological data related to Cancer from accessible databases.	PSO-3,4,6.7	U, An, Ap
CO-5	Apply acquired knowledge to critically analyze and propose strategies for understanding cancer biology, improving therapeutic interventions, and demonstrate readiness for ongoing learning and adaptation to new developments.	PSO-3,4,6.7,8	U, An, Ap

CONTENT

Unit 1: Fundamentals of Cancer — 15 lectures

- Nature of cancer, classification of cancers and tumors, cancer epidemiology
- Etiology: Tobacco and cancer development, cancer susceptibility syndromes, viruses and cancer (RNA and DNA viruses), inflammation and cancer, chemical & physical carcinogens, carcinogenesis, types of carcinogenesis, diet and cancer.
- Cell Cycle regulation and Apoptosis
- Molecular Biology of Cancer
    - Oncogenes, Tumor suppressor genes
    - Role of Telomerases
    - Epigenetics in Cancer
    - Non coding RNAs in Cancer
    - Genomic stability and development of cancer

Unit 2: Invasion, Metastasis and Tumor Immunology — 15 lectures

- Tumorigenesis- Multistep process (stem cell theory, chronic inflammation)
- Angiogenesis and its implication in tumor progression
- Pathogenesis of Metastasis, EMT
- Tumor Immunology-
    - Anti-tumor immune response of regulatory T cells, NK cells,
    - Immune surveillance theory
    - Evasion of immune surveillance by cancer cells
    - Tumor antigens
    - Immunoediting

Unit 3: Cancer Diagnosis and Therapeutics — 15 lectures

- Methods of Diagnosis
    - Blood Chemistry, Cytology, Biopsy
    - Cytogenetics Immunophenotyping, Marker studies
    - Imaging
    - Sequencing technologies in detection of cancer causing alterations
    - Detection of recognized genetic aberrations
- Conventional Cancer treatment – radiation, chemotherapy, and surgery
- Targeted Therapy – Check point inhibitors, Hormone therapy, Monoclonal Antibodies
- Immunotherapy
- Natural Products in Cancer therapeutics
- Current Combination Therapy Approaches
- Therapeutics in Clinical Trials
- Predictive biomarkers for personalized onco-therapy

Unit 4: Cancer - Data analysis **15 lectures**

- Introduction to High Throughput Sequencing and its Application in Cancer
- Introduction and concept of cancer genomics
- Cancer genome analysis project; Cancer genomics data sets visualization
- Cosmic database (catalog of somatic mutations in cancer), data types, features, and data retrieval for analysis
- Gene expression
    - Gene expression databases, Gene expression omnibus as an example for expression data analysis, UCSC genome browser
    - My cancer genome database resources
    - Gene expression analysis/profiling/tools, expression atlas
- Cancer epigenetics and whole genome haplotyping

List of Recommended Reference Books

- Lewin, Benjamin; Krebs, Jocelyn E.; Goldstein, Elliott S. & Kilpatrick, Stephen T.: Genes XI. New Delhi. Jones and Bartlett India Pvt. Ltd., 2015. 978-93-80853-71-0--(575.1Lew)
- Watson, James D., Baker, Tania A., Bell, Stephen P. & Gann, Alexander: Molecular biology of the gene. (6th ed.) New York. Pearson Education Inc., 2008. 0-321-50781-9--(574.88Wat)
- Lodish, Harvey F.; Berk, Arnold; Kaiser, Chris A. & Krieger, Monty: Molecular cell biology. (7th ed.) New York. W.H. Freeman and Company, 2013. 978-1-4641-0981-2--(574.87Lod)
- Alberts, Bruce, Alexander Johnson, Julian Lewis, David Morgan, Martin Raff, Keith Roberts and Peter Walter: Molecular Biology of the cell (6th Ed) Garland Science Publishing., 2015
- Weinberg, R.A. (2013). The Biology of Cancer (2nd ed.). W.W. Norton & Company.
- Databases and Relevant current research articles

Evaluation (Theory): Total marks per course - 100

I. Formative Assessment 'for' Learning (continuous internal assessment - CIA to improve learning).
CIA- 40 marks
Continous evaluation using various scientific communication methods

II. Summative Assessment 'of' Learning (focus on outcomes, quantitative data for outcomes of instruction).
End Semester Examination – 60 marks
One question from each unit for 15 marks, with internal choice.

Eg: Template for the Core course End Semester examination in Semester II for the Elective course

UNITS	KNOWLEDGE	UNDERSTANDING	APPLICATION and ANALYSES	TOTAL MARKS- Per unit
1	5	5	5	15
2	5	5	5	15
3	5	5	5	15
4		8	7	15
-TOTAL - Per objective	15	23	22	70
% WEIGHTAGE	25	38.33	36.67	100%

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Syllabus
Second Semester Courses in
MSc
BIOTECHNOLOGY
(2024-2025)

Contents:

- **Syllabus for Elective Course:**
  - PSBTY6004EL2:

    REGULATIONS AND QUALITY MANAGEMENT SYSTEMS IN BIOTECHNOLOGY

- Evaluation and Assessment guidelines

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MSc I BIOTECHNOLOGY		
Course Title: REGULATIONS AND QUALITY MANAGEMENT SYSTEMS IN BIOTECHNOLOGY **Course Code: PSBTY6004EL2**		
Credits 4 Theory -60 hours		
No.	**Course Objectives**	
1. 2. 3.	The course aims to provide students with a comprehensive understanding of the legal, ethical, and global and regional regulatory frameworks that govern the field of biotechnology. It will help students to understand key legislative bills and guidelines related to biotechnology regulation in India, explore the Quality Control (QC) and Quality Assurance (QA) framework in biotechnology industries. It will help the learner to gain comprehensive knowledge of regulatory frameworks such as FDA, EMA, and ISO, alongside practical understanding of quality audits, regulatory inspections, and Product Lifecycle Management systems essential for ensuring quality assurance in biotechnology.	
CO	**Course Outcomes** **On completing the course, the learner will be able to**	**Bloom's Taxonomy Level (BT level)**
1	Recognize ethical considerations and dilemmas inherent in biotechnological research, product development, and IP protection, analyze case studies to evaluate ethical implications and make informed decisions.	Understanding Analysing Evaluation
2	Comprehend biosafety regulations and guidelines governing the handling, containment, and transport of GMOs and hazardous materials and apply biosafety principles to ensure environmental and public safety.	Understanding Analysing Evaluation
3	Evaluate the significance of Quality Control (QC) and Quality Assurance (QA) departments in biotechnology, emphasizing their pivotal role in maintaining product quality and compliance.	Understanding Analysing Evaluation
4	Apply principles of GXP Quality Systems, including GLP, GCP, and GMP, throughout product development and manufacturing stages, to ensure regulatory compliance and reliability of test results.	Application Analysing Evaluation

5	Apply Quality by Design principles, including identification of critical quality attributes and process parameters, alongside interpretation of FDA and ICH guidelines, to ensure product safety and compliance in biotechnological processes.	Application Analysing Evaluation
6	Analyse regulatory landscape and standards, quality audits, prepare for regulatory inspections, and contribute in development of document management systems in biotechnology, ensuring compliance and continuous improvement.	Application Analysing Evaluation Creation

UNIT I	**Biosafety, Bioethics and Principles of Regulation in Biotechnology**		
	1	Biosafety- introduction; historical background; introduction to biological safety cabinets; primary containment for biohazards; biosafety levels; GRAS organisms, biosafety levels of specific microorganisms; recommended biosafety levels for infectious agents and infected animals; definition of GMOs . LMOs, primary containment of biohazards, BSCs, Clean Room technology	**15 L**
	2	Principles of safety assessment of transgenic plants – sequential steps in risk assessment; concepts of familiarity and substantial equivalence; , Risk assessment- environmental risk assessment and food and feed safety assessment	
	3	Bioethics- Introduction, ethical conflicts in biological sciences - interference with nature, • Bioethics in health care - patient confidentiality, informed consent, euthanasia, artificial reproductive technologies, prenatal diagnosis, genetic screening, gene therapy, transplantation. • Bioethics in research – cloning and stem cell research, Human and animal experimentation, animal rights/welfare, Agricultural biotechnology - Genetically engineered food, environmental risk, labeling and public opinion. Sharing benefits and protecting future generations - Protection of environment and biodiversity – biopiracy	
	4	The U.S. , E.U. and Indian approaches on Biotechnology research, Intentional introduction into environment, GM Food, labelling etc.	

	5	Framework for Regulations: Convention on Biological Diversity, Cartagena Protocol on Biosafety, WTO Agreements, Codex Alimentarius, Plant Genetic Resources for Food and Agriculture. Judicial response to disputes on biotechnology trade and development, Role of IBSC, RCGM, GEAC, and others, National Biotechnology Regulatory Bill 2013, The DNA Technology (Use and Application) Regulation Bill – 2019, Recombinant DNA Research and Biocontainment guidelines-2017	
	6	Field trails – biosafety research trials – standard operating procedures - guidelines of state governments; GM labeling	
UNIT II		**Concepts in Quality Control and Quality Assurance**	**15L**
	1	Role of QC and QA Quality: Quality Control, Quality Assurance, Concepts of quality control and quality assurance functions in Biotechnology based industries. Roles and responsibilities of quality control department, Importance of quality assurance in ensuring product quality and compliance.	
	2	GXP Quality Systems: GLP (Good Laboratory Practice) – Safety / Toxicology Studies (Pre-Clinical) ,GCP (Good Clinical Practice) – Human Studies (Clinical) GMP (Good Manufacturing Practice) – Manufacture of Products Good Laboratory Documentation: SOPs and documentations, EP/BP/JP/USP, Use and Certification of Performance	
	3	ASTM Methods, Method Qualification, Equipment Qualification Equipment Maintenance Equipment Calibration, Selectivity and specificity, Reference standards, Precision, accuracy, and Linearity, Sources of Errors calibration of equipment, Calibration and validation of various instruments	
	4	Quality control system for raw material, process , and finished products, Certificates of Analysis	
	5	Application of process analytical technology (PAT) in quality control, In-process quality control.	
	6	Validation: Facility qualification, vendor qualification, sterilization validation, SOP preparation, Installation Qualifications, Operational Qualifications Performance Qualifications, Qualification validation, Analytical and bioanalytical method validation	

UNIT III		**QbD and Risk management**	**15L**
	1	Quality by Design principles: Importance of QbD in development and manufacturing, Understanding critical quality attributes (CQAs) and critical process parameters (CPPs), Risk assessment and identification of critical process parameters (CPPs)	
	2	*Risk characterization and development of analysis plan (*management and communication)	
	3	*CAPA- Corrective and Preventive action*	
	4	Hazard Analysis Critical Control Points (HACCP) in foods, cosmetics and pharmaceuticals	
	5	FDA and ICH guidelines for QbD implementation	
UNIT IV		**Regulations and Audits**	**15**
	1	Regulatory landscape and standards relevant to quality assurance	
	2	Understanding quality audits: purpose, scope, and types	
	3	Overview of regulatory inspections: FDA, EMA, ISO	
	4	Systems for Document, reporting, audit , learning and Product Life cycle management.	
	5	Documentation examples for Biotechnology Lab: Preparation of SOPs and QC reports: Calibration of pipettes, Autoclave Validation,UV-Vis SPectrophootmeter Equipment Calibration and Qualification,Environmental Monitoring methods, Preparing a checklist of QC documents Demonstration on QA documents	

Recommended Resources :

- Affairs, O. O. R. (2023, March 28). *Corrective and Preventive Actions (CAPA)*. U.S. Food And Drug Administration. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/corrective-and-preventive-actions-
- *Biosafety in Microbiological and Biomedical Laboratories*. (n.d.). https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2009-P.pdf.
- *Biosafety Programme | Department of Biotechnology*. (n.d.). https://dbtindia.gov.in/regulations-guidelines/regulations/biosafety-programme
- *Cartegana Protocol*. (2000) (n.d.). https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.

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- Dent, M. P., Vaillancourt, E., Thomas, R. S., Carmichael, P. L., Ouedraogo, G., Kojima, H., Barroso, J., Ansell, J., Barton-Maclaren, T. S., Bennekou, S. H., Boekelheide, K., Ezendam, J., Field, J., Fitzpatrick, S., Hatao, M., Kreiling, R., Lorencini, M., Mahony, C., Montemayor, B., Mazaro-Costa, R., … Yang, C. (2021). Paving the way for application of next generation risk assessment to safety decision-making for cosmetic ingredients. *Regulatory toxicology and pharmacology : RTP*, *125*, 105026. https://doi.org/10.1016/j.yrtph.2021.105026
- Dudeja, P., Gupta, R. K., & Minhas, A. S. (2016, September 28). *Food Safety in the 21st Century*. Academic Press.
- *FDA.COM*. (n.d.). FDA.COM. https://www.fda.com
- Glick, B. R., Pasternak, J. J., & Patten, C. L. (2010, January 1). Molecular Biotechnology. ASM Press..
- *Good Manufacturing Practices*. (n.d.). https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/gmp
- *ICH Official web site : ICH*. (n.d.). https://www.ich.org/page/quality-guidelines
- *ISO - Biotechnology*. (2020, July 16). ISO. https://www.iso.org/sectors/health/biotechnology
- Luciani, F., Galluzzo, S., Gaggioli, A., Kruse, N. A., Venneugues, P., Schneider, C. K., Pini, C., & Melchiorri, D. (2015). Implementing quality by design for biotech products: Are regulators on track?. *mAbs*, *7*(3), 451–455. https://doi.org/10.1080/19420862.2015.1023058
- *Process validation for the manufacture of biotechnology-derived active substances and data to be provided in the regulatory submission - Scientific guideline | European Medicines Agency*. (n.d.). https://www.ema.europa.eu/en/process-validation-manufacture-biotechnology-derived-active-substances-data-be-provided-regulatory-submission-scientific-guideline
- Radu, E., Dima, A., Dobrota, E. M., Badea, A. M., Madsen, D. Ø., Dobrin, C., & Stanciu, S. (2023). Global trends and research hotspots on HACCP and modern quality management systems in the food industry. *Heliyon*, *9*(7), e18232. https://doi.org/10.1016/j.heliyon.2023.e18232
- Ratledge, C., & Kristiansen, B. (2006, May 25). Basic Biotechnology. Cambridge University Press.

Evaluation (PSBTY6004EL2):
Total marks per course – 100.

- Formative Assessment 'for' Learning (continuous internal assessment - CIA to improve learning).
  - CIA- 40 marks (Assignments/Group Presentations/Document preparation)
- Summative Assessment 'of' Learning (focus on outcomes, quantitative data for outcomes of instruction).

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- End Semester Examination – 60 marks
- One question from each unit for 15 marks, with internal choice. Total marks per question with choice -20 to 22.

Distribution of Bloom's Taxonomy levels for the course assessment

Learning Levels	Remembering	Understanding	Analyzing and Application	Evaluation and Creation
*Percentage	NA	45-50%	30-40%	20-25%