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| Department of Biotechnology | LP: BT18015 |
| B.E/B.Tech/M.E/M.Tech : Biotechnology Regulation: 2018 | Rev. No: 00 |
| PG Specialisation : NA | Date: 10/07/2023 |
| Sub. Code / Sub. Name : BT18015 - Biosafety And Hazardous Management | |
| Unit : I | |

Unit Syllabus: BIOSAFETY**(9)****Objective: To create awareness and responsibilities about the aspects of biosafety**

| Session No * | Topics to be covered | Ref | Teaching Aids |
|--------------|---|--|---------------------|
| 01 | Introduction and historical background of biosafety concept | TB 1 (Pp. 1-12) | PPT, ICT Tools & BB |
| 02 | Introduction to Biological Safety Cabinets (BSC) | TB 1 (Pp. 1-12) | PPT, ICT Tools & BB |
| 03 | Primary containment for biohazards | TB 1 (Pp. 487-508) | PPT, ICT Tools & BB |
| 04 | Biosafety levels | TB 1 (Pp. 303-323) | PPT, ICT Tools & BB |
| 05 | Biosafety levels for GMOs & environmental risk analysis | TB 1 (Pp. 509-530) TB 2 (Pp. 23-51) | PPT, ICT Tools & BB |
| 06 | Biosafety levels of specific microorganisms | TB 1 (Pp. 90-116) | PPT, ICT Tools & BB |
| 07 | GMPs in various biotech industries | IS 1 | PPT, ICT Tools & BB |
| 08 | Recommended biosafety levels for infectious agents and infected animals | TB 1 (Pp. 579-586) | PPT, ICT Tools & BB |
| 09 | Biosafety guidelines by government of India | TB 1 (Pp. 587-593) | PPT, ICT Tools & BB |
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Content beyond syllabus covered (if any):

COVID diagnosis & Vaccine development case study.

* Session duration: 50 minutes



Sub. Code / Sub. Name: **BT18015 - Biosafety And Hazardous Management**

Unit: **II**

Unit Syllabus : BIOLOGICAL WASTE MANAGEMENT AND DISPOSAL

(9)

Objective : To acquire knowledge on biological waste management and disposal

| Session No * | Topics to be covered | Ref | Teaching Aids |
|--------------|--|---------------------------------------|------------------------|
| 10 | Introduction to biohazard and wastes | TB1 (Pp. 81-97) IS 2 | PPT, ICT Tools & BB |
| 11 | Transfer stations optimizing waste allocation | TB1 (Pp. 292-297) | PPT, ICT Tools & BB |
| 12 | Transfer stations optimizing waste compatibility & storage | IS 3 | PPT, ICT Tools & BB |
| 13 | Labeling and handling of hazardous wastes | TB1 (Pp. 290-297) | PPT, ICT Tools & BB |
| 14 | Hazardous waste manifests | IS 4 | PPT, ICT Tools & BB |
| 15 | hazardous waste transport | TB1 (Pp. 298 -302) TB2 (Pp. 21-26) | PPT, ICT Tools & BB |
| 16 | Bio-medical waste | TB1 (Pp. 433 - 435) IS 4 | PPT, ICT Tools & BB |
| 17 | Hazardous waste management rules | TB2 (Pp. 21-26) IS 4 | PPT, ICT Tools & BB |
| 18 | Hazardous waste documentation | RF 3 | PPT, ICT Tools & BB |
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Content beyond syllabus covered (if any):

Importance of waste management for sustainable environment.

* Session duration: 50 mins



Sub. Code / Sub. Name: **BT18015 - Biosafety And Hazardous Management**

Unit: **III**

Unit Syllabus : GENETICALLY MODIFIED ORGANISMS

(9)

Objective : To make the students aware of the use of GMOS and their associated risks

| Session No * | Topics to be covered | Ref | Teaching Aids |
|--------------|--|--------------------------------------|---------------------|
| 19 | Definition and introduction of GMOs & LMOs | TB3 (Pp. 8-10) | PPT, ICT Tools & BB |
| 20 | Roles of institutional biosafety committee | TB1 (Pp. 417-422) TB3 (Pp. 36-40) | PPT, ICT Tools & BB |
| 21 | RCGM, GEAC etc. for GMO applications in food and agriculture | TB3 (Pp. 35-40) | PPT, ICT Tools & BB |
| 22 | Environmental release of GMOs | TB1 (Pp. 431-435) TB3 (Pp. 05-07) | PPT, ICT Tools & BB |
| 23 | Risk analysis and risk assessment | TB3 (Pp. 22-25) | PPT, ICT Tools & BB |
| 24 | Risk management and communication | TB1 (Pp. 441-445) | PPT, ICT Tools & BB |
| 25 | Overview of national regulations | TB3 (Pp. 33-35) | PPT, ICT Tools & BB |
| 26 | International agreements including Cartagena protocol | TB3 (Pp. 35-55) | PPT, ICT Tools & BB |
| 27 | Advanced research in GMOs and environmental impact | IS 5 | PPT, ICT Tools & BB |
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Content beyond syllabus covered (if any):

Case study on GMOs in food and medicine.

* Session duration: 50 mins



Sub. Code / Sub. Name: **BT18015 - Biosafety And Hazardous Management**

Unit: **IV**

Unit Syllabus : BIORISK ANALYSIS

(9)

Objective : To educate the students in detail about the concept of bio risk

| Session No * | Topics to be covered | Ref | Teaching Aids |
|--------------|---|--|------------------------|
| 28 | Overall risk analysis | TB1 (Pp. 504 – 510) TB2 (Pp. 37-55)) | PPT, ICT Tools & BB |
| 29 | Emergency planning: on site & off site | TB2 (Pp. 21-26) RF 2 (Pp. 05-08)) | PPT, ICT Tools & BB |
| 30 | Risk management ISO 14000 | RF 2 (Pp. 12-14) TB1 (Pp 264 -270) | PPT, ICT Tools & BB |
| 31 | Quantitative risk assessment | TB1 (Pp 266 -270) TB2(Pp. 89-94) | PPT, ICT Tools & BB |
| 32 | Rapid and comprehensive risk analysis | TB2(Pp. 89-94) TB4 (Pp. 104-106) | PPT, ICT Tools & BB |
| 33 | Risk due to radiation and explosion due to over pressure | RF2 (Pp. 26-32) TB 4 (Pp. 191 -197) | PPT, ICT Tools & BB |
| 34 | Potential hazards, extreme operating conditions, toxic chemicals | TB1 (Pp. 305-309) TB 4 (Pp. 283 -287) | PPT, ICT Tools & BB |
| 35 | Safe handling of valuable biological materials | TB1 (Pp. 163-164) TB5 (Pp 35 -39) | PPT, ICT Tools & BB |
| 36 | Potential misuse of bioscience and elements of a laboratory biosecurity | TB1 (Pp. 531 -550) | PPT, ICT Tools & BB |
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Content beyond syllabus covered (if any):

Safety protocols followed in Biotech R&D labs.

* Session duration: 50 mins



Sub. Code / Sub. Name: **BT18015 - Biosafety And Hazardous Management**

Unit: **V**

Unit Syllabus : SAFETY AUDITS

(9)

Objective : To enable students to conduct safety audit and write audit reports effectively in auditing

| Session No * | Topics to be covered | Ref | Teaching Aids |
|--------------|---|--|------------------------|
| 37 | Hazard identification safety audits | RF3, TB2 (Pp. 221-229)) TB5 (Pp. 331-350) | PPT, ICT Tools & BB |
| 38 | Checklist, What if analysis, Vulnerability models | RF 4 | PPT, ICT Tools & BB |
| 39 | Event tree analysis & fault tree analysis | TB2 (Pp. 89-94) TB5 (Pp. 472 -480) | PPT, ICT Tools & BB |
| 40 | Hazan past accident analysis | TB2 (Pp. 14-25) RF1 (Case history 1) | PPT, ICT Tools & BB |
| 41 | Fixborough, Mexico, Madras, | TB2 (Pp. 14-25) RF 1 (Case history 3-5) | PPT, ICT Tools & BB |
| 42 | Vizag, Bhopal analysis | TB2 (Pp. 14-25) RF1 (Case history 1) | PPT, ICT Tools & BB |
| 43 | Personal safety | TB1 (Pp 496-498) | PPT, ICT Tools & BB |
| 44 | Prevention of chemical hazards | TB1 (Pp 278-280) TB5 (Pp. 87-95) | PPT, ICT Tools & BB |
| 45 | Management of spills | TB1 (Pp 67-69) | PPT, ICT Tools & BB |
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Content beyond syllabus covered (if any):

Case studies on risk management and strategies in implementation of plan.

* Session duration: 50 mins



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TEXT BOOKS:

1. Fleming D.O, and Hunt D.L, "Biological Safety: Principles and Practices", 4th Edition, American Society for Microbiology, 2006.
2. 4. Hyatt, N, Guidelines for process hazards analysis, hazards identification & risk analysis, Dyadem Press, 2004
3. Young T, "Genetically Modified Organisms and Biosafety: A Background Paper for Decision-Makers and Others to Assist in Consideration of GMO Issues" 1st Edition, World Conservation Union, 2004.
4. Fawatt H.H, and Wood, W.S, "Safety and Accident Prevention in Chemical Operation", Wiley Interscience, 1965.
5. Industrial Accident Prevention (1941) : Heinrich H. W.

REFERENCES:

1. Handley, W, "Industrial Safety Hand Book ", 2nd Edn., McGraw-Hill Book Company, 1969.
2. Taylor, J.R, "Risk analysis for process plant, pipelines and transport", Chapman and Hall, London, 1994
3. <https://www.des.nh.gov/sites/g/files/ehbemt341/files/documents/2020-01/hw-35.pdf>
4. https://www.researchgate.net/publication/267345303_The_Structured_What_IfChecklist_A_New_Twist_On_An_Old_Approach

INTERNET SOURCES:

1. <https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmp>
2. <https://biosafety.utk.edu/biosafety-program/waste/>
3. <https://cpheeo.gov.in/upload/uploadfiles/files/chap9.pdf>
4. <https://www.epa.gov/hwgenerators/hazardous-waste-manifest-system#:~:text=EPA's%20hazardous%20waste%20manifest%20system,dispose%20of%20the%20hazardous%20waste.>
5. <https://www.fda.gov/food/agricultural-biotechnology/how-gmo-crops-impact-our-world>

| | Prepared by | Approved by |
|-------------|--|-------------------|
| Signature | | |
| Name | Dr M Nareshkumar | Dr E Nakkeeran |
| Designation | Assistant Professor | Professor and HOD |
| Date | 10/07/2023 | 10/07/2023 |
| Remarks *: | This is new lesson plan prepared for this course and not followed from previous lesson plans. | |
| Remarks *: | This lesson plan provides in-depth understanding to the biosafety and risk management systems. | |

* If the same lesson plan is followed in the subsequent semester/year it should be mentioned and signed by the Faculty and the HOD