

Minutes of Board of Studied Meeting
Department of Biotechnology
School of Energy Technology (SoET)
Pandit Deendayal Energy University
Gandhinagar, Gujarat-382 4267

Date: 28/06/2023
Time: 11:30 AM to 12:40 PM
Venue: Board Room, First Floor, C-Block
Mode: Hybrid Mode
Microsoft Meeting ID:
451 527 539 799

A. Members of Board of Studies

Name of BoS Member	Name of Organization and Designation	Present / Absent	Remarks
Prof Anirbid Sircar	Director of School of Energy Technology, PDEU	Present	
Dr Praghresh Bhatt	Dean of School of Energy Technology, , PDEU	Present	
Dr.Swapnil A. Dharaskar	Chairman-BoS , Head of Department of Chemical Engineering,I/C Department of Biotechnology, PDEU	Present	
Prof. Surendra Singh Kachhwaha	Dean of School of Technology, PDEU	Present	
Dr.Sivaraman Dhanasekaran	Assistant Professor, Department of Biotechnology, PDEU	Present	
Dr.P.S.Pradeep	Assistant Professor, Department of Biotechnology, PDEU	Present	
Dr.Manoj Pandey	Head of Department of Chemistry, PDEU	Absent	
Dr. Surya Ramachandran (External Academic member)	Associate Professor, Medical Biotechnology Gujarat Biotechnology University, Gujarat, India	Present	
Dr.Pallab Bhattacharya (External professional member)	Associate Professor, National Institute of Pharmaceutical Education and Research, Ahmedabad, Gujarat, India	Present	
Dr.Bhoomika Patel (External professional member)	Associate Professor, School of Medico-Legal Studies, National Forensic sciences university, Gujarat, India	Present	
Dr. Devi Rajeswari (External Academic member)	Associate Professor & Head School of Biosciences and Technology, VIT University, Vellore, Tamil Nadu, India.	Present	
Dr. Yogesh Murkunde (Industrial Expert- Recruiter)	Director , Intox Pvt Ltd, Pune, India	Present	
Dr. Vishal Patel (Industrial Expert- Recruiter)	Sun Pharma Advanced Research Company, Vadodara, India	Present	
Dr. Jignesh (Industrial Expert- Recruiter)	Research and Development Wing Torrent Pharmaceuticals Ltd, Ahmedabad, Gujarat, India	Absent	

B. Agenda of the Meeting

1. Welcome address by Prof. Anirbid Sircar – Director of the School of Energy Technology, PDEU.
2. Preamble about Biotechnology course by Dr. Swapnil Dharaskar- Chairman-BoS, Head of Department of Chemical Engineering, I/C Department of Biotechnology, PDEU.
3. Presentation and briefing of proposed B. Tech program in Biotechnology by Dr.Sivaraman Dhanasekaran, Assistant Professor, Department of Biotechnology, PDEU.
4. Approval of Program Name Change (From Biotechnology & Bioengineering to B.Tech in Biotechnology)
5. Introduction of new bridge courses in Mathematics and Life science in the first two semesters of B. Tech in Biotechnology.
6. Review and discussion on the Proposed Course curriculum for B. Tech in Biotechnology by the committee members

C.Minutes of BoS Meeting and General Discussion/Recommendation by BoS Members:

- **Dr. Swapnil Dharaskar**, Chairman BOS, greeted all BOS members through formal instruction of External and Internal members. Followed by the introduction, he briefed the committee about the proposed agenda and enlightened the vision and mission statement of the program.
- **Professor Anirbid Sircar**, the Director of the School of Engineering and Technology (SoET), highlighted to the committee members the importance of initiating the B.Tech program in Biotechnology at PDEU.
- **Dr.Sivaraman Dhanasekaran**, Assistant Professor, Department of Biotechnology, presented the subject layout matrix and course curriculum before the committee and also briefed about the PDEU's policies in encouraging outcome-based education and funding opportunities for the students in bringing innovations into the real-time product.
- **Dr.Sivaraman Dhanasekaran** provided the glimpses on research and development ecosystem at PDEU and its relevance in nurturing the student idea; he also enlightened the committee about the role of the Innovation and incubation center (I.I.C.) of PDEU in scaling up the product development and its relative bridging activities up to commercialization. The session was then kept open for the discussion about all the agenda points
- **Agenda:** *Approval of program name change from Biotechnology & Bioengineering to B.Tech in Biotechnology*
Discussion: All BoS members (Internal & External) unanimously accepted for revising the program name to B.Tech in Biotechnology.
- **Agenda:** *Introduction of new bridge courses in Mathematics and Life science in the first two semesters of B. Tech in Biotechnology*
Discussion: BoS members appreciated the effort of introducing the two bridging mathematics, that is, bridging mathematics I and II, in the first two semesters of the program, followed by the bridging biology course offered in the name of fundamentals of life sciences during the IInd semester.
- **Agenda:** *Review and discussion on the proposed course curriculum for B. Tech in Biotechnology*

Discussion: Dr.Pallab Bhattacharya (Professional Expert) appreciated the course layout and PDEU initiative in bringing the B.Tech in Biotechnology program. Further, Dr.Pallab suggested including the following (I) Components from artificial intelligence (A.I.) and machine learning (ML) as it's been a demanding skill for biotechnologists, (II) the Feasibility of including chapters on Biomedical devices in addition to Biomedical engineering (III) Provision for including units related to Pharmacovigilance and (IV) Ensure the existence of Cell and Gene therapy related components in the subject "Tissue Engineering & Regenerative Medicine."

Suggestion I: *Inclusion of components from artificial intelligence (A.I.) and machine learning (ML) as it's been a demanding skill for biotechnologists*

Discussion: In line with this suggestion, it has been briefed to the committee that the suggested components were already covered in a course called "Industry 4.0 curriculum" to be taught during IVth Semester.

Suggestion II: *Feasibility of including chapters on Biomedical devices in addition to Biomedical engineering*

Measures Taken: As suggested, two new units (Unit I & IV) were included in the course called "Biomedical Engineering" to be taught during VIIth semester of the program, and the details of the same are listed below

Unit I- Introduction to Medical Devices- emphasizes Classification and Essential Principles of Medical Devices and IVDs. Regulation, Product Lifecycle of Medical Devices, and Classification of Medical Devices (Enclosed Annexure I).

Unit -IV: Regulation in Medical Devices includes Clinical Investigation of Medical Devices—validation and Verification of Medical devices and Adverse Event Reporting of Medical devices (Enclosed Annexure I).

Suggestion III: *Provision for including units related to Pharmacovigilance*

Measures Taken: Considering the importance of Pharmacovigilance a new team (IV) included in the course called "Intellectual Property Rights (I.P.R.) & Regulatory Approval" to be taught during VIIth semester of the program, and the details of the same were listed below

Unit IV- Regulatory aspect of Clinical trial, which emphasizes Pharmacovigilance's significance in safety monitoring in clinical trials (Enclosed Annexure II).

Suggestion IV: *Ensure the existence of Cell and Gene therapy-related components in the subject "Tissue Engineering & Regenerative Medicine"*

Discussion: In line with this suggestion, it has been briefed to the committee that the suggested components were already covered in Unit IV: Clinical Applications of the course "Tissue Engineering & Regenerative Medicine" to be taught during the IVth Semester (Enclosed Annexure III).

- **Agenda:** *Review and discussion on the proposed course curriculum for B. Tech in Biotechnology*

Discussion: Dr. Devi Rajeswari (Academic Expert) appreciated the industry-competent course layout and suggested the following (I) Suggested to include the

course on Industrial Biotechnology and (II) Provision for inclusion of topics relevant to Biosimilars to the existing program.

Suggestion I: *Suggested to include the course on Industrial Biotechnology*

Measures Taken: Considering the industrial relevance and scope of Industrial Biotechnology, a new course named “Industrial Biotechnology” has been included in the Vth Semester (Enclosed Annexure IV).

Suggestion II: *Provision for inclusion of topics relevant to Biosimilars in the existing program*

Measures Taken: Considering the clinical significance and therapeutic application of the Biosimilars, a revision has been made with the inclusion of the chapter on the Application of Biosimilar in Unit 3 (Pharmacotherapy of Protein drugs) of the course called “Pharmaceutical Biotechnology” to be thought during IVth Semester (Enclosed Annexure V).

- **Agenda:** *Review and discussion on the proposed course curriculum for B. Tech in Biotechnology*

Discussion: Dr. Surya Ramachandran (Academic Expert) appreciated the initiatives for introducing birding biology and mathematics and suggested the following (I) Inclusion of the lab work for the subject “Recombinant DNA Technology,” (II) Suggested to include the regulatory aspects with particular reference to I.E.C. & I.A.E.C. and (III) Provision for inclusion of components related to vaccine drug trials.

Suggestion I: *Inclusion of the lab work for “Recombinant DNA Technology.”*

Measures Taken: Gene isolation and manipulation become an essential skill for a future-ready biotechnologist; in this regard, a new lab course named “Genetic Engineering lab” was introduced in the VIIth semester (Enclosed Annexure VI).

Suggestion II: *Suggested to include the regulatory aspects with particular reference to I.E.C. & I.A.E.C.*

Measures Taken: Ethical approval paves greater importance in executing Pre-clinical and clinical trials for drugs and medical devices, in preview of this as suggested by the expert components about the regulatory aspect (I.E.C. & I.A.E.C.) of the product development included in units 3 (Bioethics) and unit 4 (Regulatory part of Clinical trial) of the course called “Intellectual Property Rights (I.P.R.) & Regulatory Approval” to be thought during VIIth semester of the program and the details of the same were listed below

Unit III- Bioethics which emphasizes the Institutional Biosafety Committee, Institutional Animal ethics committee, Institutional review board, Human Genome Project, and ethical issues, etc. (Enclosed Annexure II).

Unit IV- Regulatory aspect of Clinical trial, which emphasizes the Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials (Enclosed Annexure II).

Suggestion III: *Provision for inclusion of components related to vaccine drug trials.*

Measures Taken: As suggested, the methods of preparation of vaccines have been included in Unit 2 (Vaccines) of the course called “Pharmaceutical Biotechnology” to be taught during the IVth Semester (Enclosed Annexure V).

- **Agenda:** *Review and discussion on the proposed course curriculum for B. Tech in Biotechnology*

Discussion: Dr. Bhoomika Patel (Professional Expert) appreciated the mapping of the course matrix, especially the pharmaceutical components and its industrial relevance and scope of the students who aspire for the curriculum. Dr. Bhoomika Patel suggested the following improvisation to the course contents (I) Provision for Inclusion of components about the regulatory aspect of medical devices, (II) Inclusion of topics relevant to biopharmaceuticals and (III) Justification for mapping Tissue engineering followed by biomaterials.

Suggestion I: *Provision for Inclusion of components pertains to the regulatory aspect of medical devices*

Measures Taken: As suggested, a new unit (IV) has been included in the course called “Biomedical Engineering” to be taught during VIIth semester of the program, and the details of the same are listed below

Unit -IV: Regulation in Medical Devices includes Clinical Investigation of Medical Devices, Validation and Verification of Medical Devices and Adverse Event Reporting of Medical Devices (Enclosed Annexure I).

Suggestion II: *Inclusion of topics relevant to biopharmaceuticals*

Measures Taken: As per the suggestion, a revision has been made with the inclusion of the chapter on Application of Biosimilar in Unit 3 (Pharmacotherapy of Protein drugs) of the course called “Pharmaceutical Biotechnology” to be taught during the IVth Semester (Enclosed Annexure V).

Suggestion III: *Justification for mapping the subject's Tissue engineering followed by Biomaterial & Implants in the course layout.*

Discussion: It has been briefed to the committee that understanding tissue biology would ideally sensitize the students while studying the tissue reaction toward biomaterial-based implants and subsequent etiology. Hence tissue engineering subject will be taught during the IVth semester, followed by which the subject Biomaterial & Implants scheduled during the Vth semester of the program.

- **Agenda:** *Review and discussion on the proposed course curriculum for B. Tech in Biotechnology*

Discussion: Dr. Yogesh Murkunde (Industrial Expert) appreciated the industrial coherence and its significance in the subject layout. Dr. Yogesh Murkunde suggested introducing a chapter on the regulatory approval process.

Suggestion: Suggested to introduce a chapter on the regulatory approval process

Measures Taken: As per the suggestion, a revision has been made in the Unit IV (Pharmaceutical product development) of the course called “Pharmaceutical

Technologies" to be taught during the IVth Semester, and the details of the same are listed below

Unit IV- Pharmaceutical product development, which emphasizes CDSCO- Regulatory requirements and approval, Drug distribution cycle, etc. (Enclosed Annexure VII).

- **Agenda:** Review and discussion on the proposed course curriculum for B. Tech in Biotechnology

Discussion: Dr. Vishal Patel (Industrial Expert) appreciated the effort to include pre-clinical and clinical components in the subject layout. Dr. Vishal Patel suggested introducing a chapter on ethics & regulation involved in validating medical devices.

Suggestion: suggested to introduce a chapter on ethics & regulation in medical devices

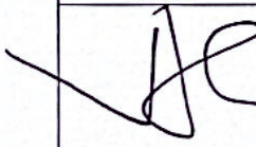
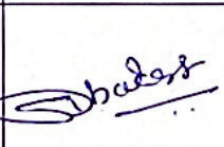
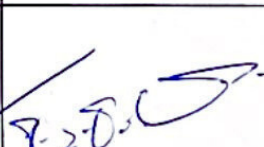
Measures Taken: As suggested, a new unit (IV) was included in the course called "Biomedical Engineering" to be taught during VIIth semester of the program, and the details of the same are listed below

Unit -IV: Regulation in Medical Devices includes Clinical Investigation of Medical Devices. Validation and Verification of Medical device, Adverse Event Reporting of Medical device (Enclosed Annexure I).

- **Agenda:** Review and discussion on the proposed course curriculum for B. Tech in Biotechnology

Discussion: Dr. Praghesh Bhatt, Dean of the School of Energy Technology, expressed his preview and briefed the committee on semester-wise credit mapping adopted for the proposed program.

- **Conclusion:** BoS members provided their valuable inputs and suggestions concerning the improvisation of course layout about B.Tech in Biotechnology and the measures taken against each suggestion listed above in detail, along with corresponding enclosures in the form of annexures enclosed herewith for further clarification.

Prof. Anirbid Sircar Director of School of Energy Technology, PDEU	Dr. Praghesh Bhatt Dean – SOET, PDEU	Dr. Swapnil Dharaskar Chairman-BoS	Prof. Surendra Singh Kachhwaha Internal BoS Member	Dr. Sivaraman Dhanasekaran Internal BoS Member	Dr. P.S. Pradeep Internal BoS Member
					
Dr. Surya Ramachandran (External Academic member) Gujarat Biotechnology University, Gujarat, India	Dr. Pallab Bhattacharya (External professional member) NIPER, Ahmedabad, Gujarat, India	Dr. Bhoomika Patel (External professional member) National Forensic sciences university, Gujarat, India	Dr. Devi Rajeswari (External Academic member) VIT University, Vellore, Tamil Nadu, India.	Dr. Yogesh Murkunde (Industrial Expert- Recruiter) Director , Intox Pvt Ltd, Pune, India	Dr. Vishal Patel (Industrial Expert- Recruiter) Sun Pharma Advanced Research Company, Vadodara, India
