

ಮೈಸೂರು ವಿಶ್ವವಿದ್ಯಾನಿಲಯ



UNIVERSITY OF MYSORE  
(Estd.1916)

**POST GRADUATE DIPLOMA**  
**in**  
**RESEARCH METHODOLOGY AND**  
**QUANTITATIVE TECHNIQUES FOR**  
**DATA ANALYSIS**



**SYLLABUS AND REGULATIONS FOR  
POST GRADUATE DIPLOMA IN BIOTECHNOLOGY ENTREPRENEURSHIP AND  
COMMERCIALIZATION (PGDBTEC)  
CHOICE BASED CREDIT SCHEME  
(For academic year 2018-19 onwards)**

**Aim of the Course:**

*The aim of this PG diploma course is to impart instruction and training to candidates in specialized field of bioentrepreneurship and commercialization. The course helps the next generation of biotechnology entrepreneurs with an improved chance of achieving success in industry and also is intended to develop capacity building for employment, teaching and research.*

The program shall be called Post Graduate Diploma in Biotechnology Entrepreneurship and Commercialization (PGDBTEC). It is a one-year program consisting of two semesters. It is a fully self financed course. The course shall be governed by the following regulations:

**ELIGIBILITY FOR ADMISSION:**

Candidates applying for admission to Post Graduate Diploma in Biotechnology entrepreneurship and Commercialization (PGDBTEC) must have obtained a minimum of 55% (50% in case of SC/ST and category-I candidates) of total marks put together from all the years of the M.Sc examination from a recognized University in India. Admission procedure including entrance examination shall be governed by the regulations stated by the University of Mysore, Mysuru.

**INTAKE:**

The maximum intake for this course would be limited to 20 seats.

**COURSE OF STUDY:**

- The course of study for the Post Graduate Diploma in Biotechnology Entrepreneurship and Commercialization (PGDBTEC) shall extend over a period of one year consisting of two semesters. Each semester shall be of twenty four weeks duration.
- The academic calendar shall be as notified by the University from time to time. However, a candidate can take a maximum of two years for completion as per the double- norms of the University of Mysore.
- The medium of instructions shall be in English.

NO admission

S.R. [Signature]

Chairman  
BOS in Biotechnology  
University of Mysore  
Mysore-570 000

- First Semester will consist of 4 Hard Core Papers with 4 credits each and 2 project works (to be chosen among 4 minor projects) having 4 credits each, with a total of 24 credits.
- Second Semester will consist of industry internship in start-up companies and is having 24 credits.
- Conduct of the classes will be based on the CBCS regulation of the University of Mysore.

**ATTENDANCE:**

In case a candidate's class attendance in a course is less than 80% or as stipulated by the University, the candidate is said to have DROPPED that course, and such a candidate is not allowed to appear for C3 in that course. Further criteria related to the attendance are as governed by the CBCS regulation of the University of Mysore.

**SCHEME OF EXAMINATION:**

There shall be a University examination at the end of each semester. The evaluation of the candidate shall be based on continuous assessment. The structure for evaluation is as follows:

- Assessment and evaluation processes happen in a continuous mode. However, for reporting purposes, a semester is divided into 3 discrete components identified as C1, C2, and C3.
- The performance of a candidate in a course will be assessed for a maximum of 100 marks as explained below.
  - a. The first component (C1), of assessment is for 15 marks. This will be based on test, assignment and seminar. During the first half of the semester, the first 50% of the syllabus will be completed.
  - b. The second component (C2), of assessment is for 15 marks. This will be based on test, assignment, and seminar. During the second half of the semester the remaining units in the course will be completed.
  - c. During the 22th-24th week of the semester, a semester-end examination of 3 hours duration shall be conducted for each course. This forms the third/final component of assessment (C3) and the maximum marks for the final component will be 70.

*S. R. V. S.*

d. A candidate's performance from all 3 components will be in terms of scores, and the sum of all three scores will be for a maximum of 100 marks (15 + 15 + 70). The details of continuous assessment are summarized in the following Table.

<b>Component</b>	<b>Syllabus in a course</b>	<b>Weightage</b>	<b>Period of Continuous assessment</b>
C1	First 50% (3 units of total units)	15%	First half of the semester To be consolidated by 10 th week
C2	Remaining 50% (Remaining 3 units of the course)	15%	Second half of the semester To be consolidated by 16th week
C3	Semester-end examination (All units of the course)	70%	To be completed during 22nd - 24th Week.

S.R.L.B

**Department of Studies in Biotechnology, Manasagotri, Mysuru 570006**  
**PG Diploma in Biotechnology Entrepreneurship and Commercialization**  
**(Effective from the Academic Year 2018-19, Scheme of Instruction and Examination)**

Paper Code	Title of the paper	Type of Paper	Duration 24 weeks	Duration of examination	Internal Assessment marks (C1 & C2)	Final C3 marks	Max. Marks	Credits
<b>I Semester-Theory</b>								
BTEC 01	Biotechnology Entrepreneurship & Basics of Start-up Finance	Hard Core	3hrs/week	3hrs	30 marks	70 marks	100 marks	4
BTEC 02	Biotechnology Industry Evaluation & Commercialization	Hard Core	3hrs/week	3hrs	30 marks	70 marks	100 marks	4
BTEC 03	Biotechnology Market & Product Development	Hard Core	3hrs/week	3hrs	30 marks	70 marks	100 marks	4
BTEC 04	Electives: Any One 1. Advanced Topics in Entrepreneurship 2. Essentials of Entrepreneurial Planning and Execution	Soft Core	3hrs/week	3hrs	30 marks	70 marks	100 marks	4
<b>Practicals:</b>								
<b>Practical I: BTEC 05/BTEC06 Project work</b>		Practicals	16 hrs/week	4 hrs	30 marks	70 marks	100 marks	4
<b>Practical 2: BTEC07/BTEC 08 Project work</b>		Practicals	16 hrs/week	4 hrs	30 marks	70 marks	100 marks	4
					<b>Total Marks and Credits</b>		600 marks	24
<b>II Semester: Industry Internship</b>								
Paper Code BTEC 09	Internship in start-up companies				200 marks	200 marks		24
	Industry Report, Presentation, Viva					200 marks	600 marks	24
					<b>Total Marks and Credits</b>		600 marks	24
<b>Grand Total</b>							1200	48

**Department of Studies in Biotechnology**  
**Manasgangotri, Mysuru 570006**  
**SYLLABUS FOR**  
**POST GRADUATE DIPLOMA IN BIOTECHNOLOGY ENTREPRENEURSHIP AND**  
**COMMERCIALIZATION (PGDBTEC)**

**First Semester:**

**Paper Code: BTEC 01 (Hard Core)**

**48hrs**

**Title: Basics of Biotechnology Entrepreneurship**

**Unit 1: An introduction to, Biotechnology for unmet market/societal needs** Health Biotechnology: Helping to save and Extend Lives, Food and Agricultural Biotechnology: Helping to Feed the world, Industrial and environmental biotechnology: A Better way to make Things, The Public Policy Environment for Biotech Innovation.

**Unit 2: Basics of Start-up:**

Risks of joining a Biotechnology Company, Genzyme in the Early Days, The Importance of Understanding Business and Finance, Raising Capital, Managing the Uncertainty of Biotechnology Core Values, Integrating the science and Business, The Value of a Business Background and Experience, Driven from within, In touch with Events outside the company, Good Fortune and Success, Company Formation, Ownership structure, and Securities Issue, EntityFormation,OwnershipStructure **8 hrs**

**Unit 3: Biotechnology Entrepreneurship:**

The Significance of the Biotechnology Entrepreneur, The Integration of two Distinctly Different Disciplines, Biotechnology Entrepreneurship versus General Entrepreneurship, Entrepreneurship and Intrapreneurship, The Biotechnology Entrepreneur, Manager, or Leader, Essential Biotechnology Entrepreneurial Characteristics, Being the Entrepreneur for a season, Driving Forces behind a Biotech Entrepreneur's Decisions, Learning from "Failure".

**Unit 4: The Biotechnology Industry: An Engine of Innovation**

The Birth of an Industry, The Industry Takes Root, The Industry Today, The Challenge of Drug Development, Falling R&D Productivity, The Consistent Challenge, Howdy Partner, The End of the Blockbuster Era, The Times they are a changing, Mapping the Human Genome, An Evolving Vision, Changing Economics, A Greater Promise, Investing in Innovation, Partnership of convenience, Promoting Technology Transfer, Not Just About Drugs, Everything Old is New Again, The Challenge of Scale, Improving Yields, The Challenge Today, The moment is now, Value is Transient, Value is Geographic Dependent Value is not a Function of Sales and Earnings, The Challenge for Life Sciences Companies.

**Unit 5: Biotechnology Clusters**

Actively Developing clusters world -wide, Benefits of a Biotechnology Cluster, Essential Elements to Growing a Biotechnology Cluster in a Region, Important Consideration, Enhancers of Biotechnology Cluster Development, Maintenance Factors Vs Drivers, Inhibitors of Biotechnology Cluster Growth, The Role of Government in Developing Biotechnology Clusters.

**Unit 6: Biotechnology Incubators: Indian Context**

Lucknow Biotechnology Park, Uttar Pradesh, Biotechnology Incubation Centre, Genome Valley, Hyderabad, Andhra Pradesh, Biotechnology Core Instrumentation Facility (BTCIF) at TIDCO Centre for Life Sciences (TICEL), Chennai, The Golden Jubilee Biotech Park for Women, Siruseri, Kanchipuram District, Tamilnadu, Guwahati Technology Incubation Centre (GBPIC) at Biotech Park, Assam, Bangalore Biotech Park, Karnataka, KRIBS BioNest, Kochi, Kerala (previously called KINFRA Biotech Park).

**Paper Code: BTEC 02 (Hard Core)**

**48hrs**

**Title: Biotechnology Business Planning and Commercialization**

**Unit 1: Business Models and Business Plans**

Different types of business models, models suitable for BioTechnology firms, which model is best for certain technologies, what is a business plan, building a business plan to support the model, establishing a Mission statement, Executive summary, Market analysis, Product descriptions, Proposed gearing, estimation, financials, Human resources, Intellectual property assessment, Entrepreneurs' role as a leader and risk manager, Critical analysis of case studies of important companies and entrepreneurs

**Unit 2: Financing a startup**

Valuation models for technologies and recognising its stage of development, types of financing options, what 'equity' and 'debt' financing mean, advantages and disadvantages of debt and equity options, financial gearing for the business model, various sources of finance, debt, Bootstrapping, Crowdfunding, Angel investors, Venture Capital, Incubators & Accelerators, Grants, Bank Loans, Business loans from Micro-Financing and NBFC (Non Banking Financial Corporations), Government programmes

**Unit 3: Principles of Marketing**

What is Marketing?, The Marketing Mix "4 P's" (Product, Price, Place and Promotion), 3 other P's (People, Positioning, Packaging), creating utility, types of utility (Form, Place, Time, Possession), Image utility, key features of biotechnology utility, the exchange process

**Unit 4: Human Resource Management and its implications in Biotechnology**

Introduction to Human Resource Management, establishing a suitable organisational structure, HR planning, Organisational culture, employee handbook, recruitment, selection process, strategies to acquiring skilled talent, managing careers, performance appraisals, continual monitoring, employee training and management development, compensation management, occupational safety and health, Grievance handling, disciplinary actions, trade unions, complexities in the biotech industry, technology & training, non-compete agreements, retention, Legalities

**Unit 5: Commercializing Biotechnology**

Proof of concept, SWOT (Strength, Weakness, Opportunity & Threat) Analysis, Intellectual property rights in various industries, patent search, patent protection path, the role of business model, Legal, licensing, Intra-firm cooperation, Mergers and Acquisitions, Clusters and its role, Clusters around the globe, clusters/industries within India, utilizing clusters, access to funding in clusters, Critical analysis of Case studies, Exit Strategies

**Unit 6: Indian Biotechnology Sector**

Investing in Biotechnology sector, compound annual growth rate, statistics of growth of biotech industries in India, Growth drivers, BIRAC and its functions, Foreign direct investment policy, sector policy, Guidelines for stem cell research and biosimilars, National biotechnology developmental strategy, Investment opportunities, Foreign investors,



**Paper Code: BTEC 03 (Hard Core)**

**48 hrs**

**Title: Biotechnology Market & Product Development**

**Unit 1: Biotechnology Products and their Customers:** Development a Successful market strategy, Marketing, Develop a marketing strategy for your future product, Identify the patient, Identify the physician or Healthcare Provider, Identify the payers, Advancement of the Marketing Concepts, Market Research and Assessment Tools, Other Market Tools and Concepts, Starting to Develop a Market Strategy, Identify your market Development Milestones, Biotechnology Product Adoption Curve

**Unit 2: Biotechnology Products Development:**

Therapeutics Drug Development and Human Clinical Trails, Small molecules Drugs, Large Molecules Drugs, Clinical Transition Studies – Investigational New Drug Approval Clinical Trials, Development and Commercialization of In-Vitro Diagnostics: Applications for Companion Diagnostics, Bringing IVD Products to Market, Successful Adoption of IVDS, Reimbursement of IVD Products, Applications of an IVD as a companion Applications, Forging Diagnostic and Therapeutic partnership for companion Diagnostic Application Integrating an IVD Into the Drug Development pathway as a Companion, Diagnostics, Challenges to the Development and Commercialization of CDx Products, Future Applications for IVD Products.

**Unit 3: Regulatory Approval and Compliances for Biotechnology Products**

History of the FDA, Regulations Related to Biomedical Product Development Current Regulatory Pathways, Translational Development, Human Clinical Testing Phases, Biological License Application (BLA)

**Unit 4: The Biomanufacturing of Biotechnology Products**

The History of Biotechnology and Biomanufacturing, A Typical Biomanufacturing Process Biosimilars, Discovery, Process Development, Clinical Manufacturing, Clinical Trials Good Manufacturing Practices, Facility Requirements, The Biomanufacturing Team – Their Typical Roles and Responsibilities in a biologics Manufacturing Facility, Material anagement Biologics Drug Substance Manufacturing, Manufacturing Support Functions, Contract CMO) Versus In-House Manufacturing

**Unit 5: Intellectual Property Protection Strategies for Biotechnology Innovations**

The Intellectual Property Toolbox, Patents, Contracts relating to intellectual Property Joint Research Projects, Copyrights, Trademarks, Pharmaceutical patents and market, Exclusivity, Regulatory Approvals for Biologics and Biosimilars, Diagnostics and personalized medicine, Corporate IP Management, Patent Strategies and Product Lifecycle Management

**Unit 6: Biotechnology Market in India**

Biotechnology companies, major tie-ups, biotech segments, regulatory reforms in different states, emerging business models, generic drugs and Indian biotech industry, major players, future of Indian biotech industries.



**Unit 1: Introduction**

What is valuation?, Profit/Equity Ratio, Discounted Cashflow Method, Asset Based Valuation method, Valuation models and its abstractness in BioTechnology/startup, Comparable Companies Method & its complexities, Free Cash Flow (FCF) Method & forecasting FCF, Product life cycle, assessing the biotechnology's stage in the product life cycle, regulatory approval process, Basic research stage, PreClinical stage, Clinical phases, Market assessment, SWOT (Strength, Weakness, Opportunity, Threat) analysis, Modelling for an appropriate exit strategy

**Unit 2: Methods of funding**

Estimating, Cost Control and escalations, how business model dictates funding options, two main instruments of funding a startup, Equity & Debt, their advantages and disadvantages, Implications of Equity and Debt on a startup and it's growth prospects, levels of risks and prospects of returns with each option, cost of raising capital, impact on Free Cash Flow and operating costs, Venture Debt, Intellectual property valuation

**Unit 3: Early Stage Investments**

Bootstrapping, achieving Proof of Concepts, leveraging retained equity, lean modelling, suitability analysis, Angel Investors, role of angels, managing expected returns, Incubators & accelerators, Grants, Major incubators in India, qualifying for grants

**Unit 4: Crowdsourcing**

The mechanics of crowdsourcing, structuring investors incentives, the international platform, introduction to major crowdsourcing services, cost of listing, importance of a social cause, forecasting payouts, managing an exit, critical analysis of case studies

**Unit 5: Venture Capital**

What is Venture Capital (VC)? Implication on the corporate structure and Free Cash Flow, Modelling for external investors, Growth strategy, Alphabet Rounds of Equity, Protecting Intellectual property, Legality, Intra-Company cooperation in BioTechnology, Strategic investors, Managing investor expectations, Corporate administration in India & Ministry or Corporate Affairs(MCA), later-stage venture debt

**Unit 6: Exit Strategy**

What is Exit Strategy?, Profit Target, Barriers to Exit, Licensing, Royalties in the BioTech sector transferring Intellectual Property, Legal procedure, Investor remuneration, Mergers & Acquisitions, Initial Public Offering (IPO, Stock Market Listing), Buyout, Liquidation, "Friendly" sale, Advantages and disadvantages of options, Critical Case studies

**Tutorials:** student-teacher interaction and discussion



**Paper Code: BTEC 04/2 (Soft Core)**  
**Title: Marketing Strategies**

**48hrs**

### **Unit 1: Principles of Marketing**

What is Marketing?, the role of identifying needs from a BioTech perspective, creating utility, four forms of utility (Form, Place, Time, Possession), the exchange process, current market gaps in BioTech industries (emerging markets and clusters), The Marketing Mix (Product, Place, Price and Promotion), Case Studies in successful synergies

### **Unit 2: Marketing Management Process**

Assessing marketing opportunities, Defining the market, Consumer assessment, Environmental assessment, Demand analysis and sales forecast, Identifying Market Segments and Selecting Target Markets, Selecting the most attractive segments, Developing marketing strategies, Positioning, Modification in the stages of product life cycle, Planning marketing programs, Designing Pricing Strategies, Selecting and Managing Marketing Channels & Distribution Systems, Managing marketing efforts, Organizing resources, Implementation, Monitoring and Control

### **Unit 3: Product Management**

Introducing a new product or service, Sources for identifying a need, Innovation, Product life cycle and its management, four phases (Introduction, Growth, Maturity, Decline), Acquisition as New Product Development, role of researchers and consultants in Biotechnology, Idea generation and screening, Product Mix, product classifications and its considerations in a marketing plan

### **Unit 4: Branding**

What is branding? Its importance in Biotechnology, Public Relations (PR) and its effect on brands, Brand perception, benefits to the retailer, manufacturer and the consumer, brand equity, value contribution to organization, Packaging and labelling, legal responsibilities and limitation, indirect communication with the consumer/client, Case studies to evaluate impact on biotechnology companies

### **Unit 5: Marketing & Bio Technology**

Critical evaluation of Case Studies from various industries in the Biotechnology Sector

### **Unit 6: Tutorials, student-teacher interaction and discussion**

### **Second Semester:**

Industry Internship for 6 months at Startup Industries.

### **References**

1. Regulation of the pharmaceutical industry. Abraham J and Lawton Smith H. 2003. Houndmills, Basingstoke, Hampshire: Palgrave Macmillan.

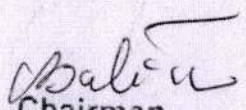


2. Quality assurance and quality management in pharmaceutical industry. Anjaneyulu Y and Marayya R. 2005. Hyderabad, AP.: Pharma Book Syndicate.
3. Biotechnology entrepreneurship: Starting, managing and leading biotech companies. Craig Shimasaki, Academic Press, 2014.
4. Chagturu R and Murad F. 2014. Collaborative Innovation in Drug discovery. New York, NY: John Wiley & Sons.
5. Cohn K and Hough D. 2007. The Business of Health care (3 volumes). Westport: Greenwood Pub. Group.
6. Cottier T and Mavroidis P. 2003. Intellectual property. Ann Arbor.: University of Michigan Press.
7. Croin B. 1984. The citation process. London.
8. Endrenyi L, Declerck D and Chow S. 2017. Biosimilar Drug Product Development. Boca Raton: CRC Press.
9. Everett B and Trijillo N. 2010. Technology transfer and intellectual property issues. New York: Nova Science Publishers.
10. Friedman y. 2008. Best practices in Biotechnology business development . Washington DC: Logos Press.
11. Guirdham M. 1990. Interperosnal skills at work. New York: Prentice-Hall.
12. Haider S and Asif E. 2011. Quality control Training Manual. Boca Raton [Fla.]; CRC Press.
13. Haider S. 2002. Validation standard operating procedures. Boca Raton [Fla.]: St. Lucie Press.
14. Hofmann A. [n.d.]. Scientific writing and Communication.
15. Improving new Product Development: Bausch. 2004. [Place of publication not identified]: American Productivity & Quality Centre (APQC).
16. Jain N. 2011. Pharmaceutical product development. New Delhi: CBS Publishers.
17. Jameel F, Hershenson S, Khan M, and Martin-Moe S. (n.d.). Quality by design for biopharmaceutical drug product development.
18. Kanfer I and Shargel L. 2010. Generic drug product development. New York: Informa Health care.
19. Krattiger A, Mahoney R, Nelsen L, Thomson J, Satyanarayana K, Graff G, Fernandez C, Kowalski S and Benett A. 2007. Intellectual property management in health and agriculture innovation. Oxford, UK. : MIHR.



20. Laouisset D. 2012. Managerial technology transfer. Hauppauge, NY: Nova Science Publishers
21. Lynch M and Woolgar S. 1990. Representation in scientific practice. Cambridge, Mass: MIT Press.
22. Morgon P. 2015. Sustainable development for healthcare industry. Cham: Springer International Publishing.
23. Rekalitis G, Gracia-Munoz S and Seymour C. (n.d.). Comprehensive quality by design for pharmaceutical product development and manufacture.
24. Robbins S. 1989. Training in interpersonal skills. Eaglewood Cliffs. NJ[u.a.]: Prentice Hall.
25. Schroerer D. 200. Technology transfer. Aldershot: Ashgate.
26. Schuhmacher A, Hinder m and Gassmann O. (n.d.). Value creation in the pharmaceutical industry.
27. Shargel L and Kanfer I. 2010. Generic drug product development: New York: Informa Health care, USA.
28. Spiiker B. (n.d.). Guide to drug development.
29. Sriamornsak P, Limmatvapirat S and Piriyaprasart S.(n.d.). Pharmaceutical formulation and development.
30. Sullivan N. 2009. Technology transfer. Cambridge, GBR: Cambridge University Press.
31. The entrepreneur's guide to biotech start up. Peter Kolchinsky
32. S.S. Kanka: Entrepreneurial Development, Sultan Chand.
33. Prasanna Chandra: Project Planning, Analysis, Selection, Implementation and Review, Tata McGraw Hill.
34. Vasantha Desai: Dynamics of Entrepreneurial Development, Himalaya.
35. C.B. Gupta&N.P. Sreenivasan: Entrepreneurial Development, Sultan Chand.
36. Nirmal K. Gupta: Small Industry – Challenges and Perspectives, Anmol Publications.
37. Vasantha Desai: Small Scale Industries and Entrepreneurship, Himalaya.



  
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