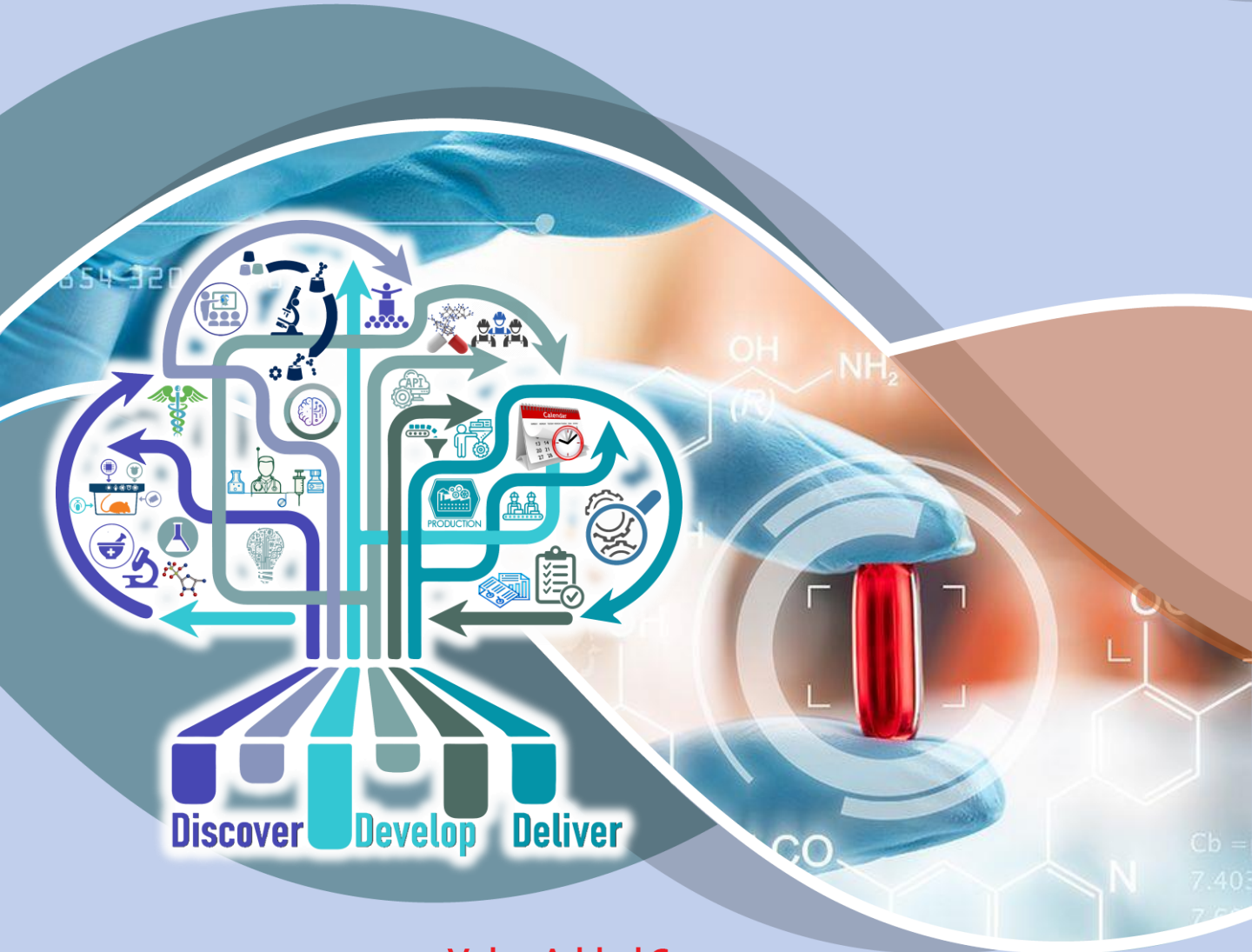




KLE Academy of Higher Education & Research Belagavi

[DEEMED-TO-BE-UNIVERSITY]

REACCREDITED AT THE 'A+' LEVEL BY NAAC (THIRD CYCLE), PLACED IN 'A+' CATEGORY BY MHRD (GoI)



Value Added Course on

PHARMACEUTICAL PRODUCT DEVELOPMENT & TECHNOLOGY TRANSFER - An Industrial Perspective

Offered by

Dept. of Pharmaceutics
KLE COLLEGE OF PHARMACY
Belagavi

JNMC Campus, Nehru Nagar Belagavi - 590010.

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Our B. Pharm Program has been accredited by NBA for a period of 6 years (from July 2019 to June 2025)



BELAGAVI

Courses Preamble:

This course involves scientific value addition approach for the candidates to have knowledge about the Drug product development in pharmaceutical industry. The following modules strengthens the literature search capabilities for the regulatory markets. This shall be value addition for the technology transfer and the automation process during manufacturing.

Courses Objective:

1. To impart knowledge about the Generic Drug development and its requirement.
2. To strengthen the knowledge of literature search for regulatory markets.
3. To provide the scale up parameters and trouble shooting.
4. To introduce to the automation world of manufacturing.

Course Outcomes:**Upon completion of this course, participants will be able to:**

- **CO1:** Relate literature search for various regulatory market for generic product development.
- **CO2:** Appraise skills in handling various stages of Product Development and Tech Transfer
- **CO3:** Design technical Scale-up parameters of Rapid mixer granulator, Blender, Tablet Compression machine.
- **CO4:** Compute strategies for Business Development, Project Management and Automation in Manufacturing.

Modules:

Module 1: Literature search for regulatory market for generic drug development

Sr No	Value added Topic	Duration
1.	Drug Product literature search for Major regulatory market - Demo for Online search with case study 1.1 USA: USFDA (NDC): The Center for Drug Evaluation and Research (CDER) literature and identification of the Reference Listed Drug / reference standard for drug product <ul style="list-style-type: none">• Approved drug product literature• Dissolution method data base• Inactive ingredient search for approved drug products.• Orange Book- Approved Drug Products with Therapeutic Equivalence Evaluations• Product-Specific Biostudy Guidance for Generic Drug Development 1.2 Canada: Health Canada (DIN): Drug Product Database 1.3 Europe: MHRA: SPCs, PILS, PARs <ul style="list-style-type: none">• Centralized and Decentralized procedure 1.4 Australia: TGA	04 Hours
2.	Patents WIPO, USPTO, EPO, IP Australia	01 Hour
3.	Others, Dailymed Pill Identifier Drugs.com	01 Hour
	Total Hours	06 Hours

Upon completion of this module students will able to

MO1: Demonstrate skills in operating various search tools for literature survey of regulatory agencies and Patents.

MO2: Review literature data and relate with regulatory bodies for generic product development.

Module 2: Pharmaceutical Product Development and its stages.

Sr No	Value added Topic	Duration
1.	Application of Test License and Import License for Drug Product	01 Hour
2.	Pre-Formulation of the Active Ingredients. <ul style="list-style-type: none">• Physico chemical properties of the Drug substance• Drug excipient compatibility study• Selection of excipients• Drug classification as per BCS	01 Hour

3.	Drug Development and manufacturing processes 3.1 Brief about Formulation DOE – Factors and Variables 3.2 Brief about Process DOE- Factors and variables	01 Hour
4.	Product Development Report – Heart of Formulation R&D 1. Contents of Model PDR as per QbD format 2. Dissolution Method development 3. Risk assessment and risk mitigation- along with Case study	03 Hours
	Total Hours	06 Hours

Upon completion of this module students will able to

MO1: Compute details for application of test and Import license for product manufacture.

MO2: Select suitable API and excipients for product development and prepare manufacturing documents BMR and MFR.

MO3: Optimize formulation and process variables by DoE.

Module 3: Technology Transfer

Sr No	Value added Topic	Duration
1.	Technology transfer documents – MFR / MPR, PVP, PVR, Blend Uniformity Sampling protocol, Hold time studies, In-Use stability protocol, and Freeze thaw study Protocol.	1 Hour
2.	Technical Scale up parameters for RMG- Calculation wrt Tip speed / Froude Number for RMG- RPM calculation. Case study	1 Hour
3.	Technical Scale up parameters and Calculation wrt Tip speed / Froude Number for Blender – RPM and time calculation. Case study	1 Hour
4.	Technical Scale up parameters for Compression machine – Calculation of Dwell Time for R&D and Production machine. Case study	1 Hour
5.	Challenges and trouble-shooting during scale up from R&D to Production	2 Hours
	Total Hours	06 Hours

Upon completion of this module students will able to

MO1: Design technical Scale-up parameters of Rapid mixer granulator, Blender, Tablet Compression machine.

MO2: Create tech transfer documents in product manufacture.

MO3: Identify trouble shooting during scale-up from R&D to production.

Module 4: Business Development, Project Management and Automation in Manufacturing.

Sr No	Value added Topic	Duration
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1.	Documents related to Product manufacturing. API Assay compensation and calculation.	02 Hour
2.	Automation in manufacturing Integrated systems/Suits Electronic BMR	02 Hour
3.	Business Development	01 Hour
4.	Project Management	01 Hour
	Total Hours	06 Hours
	Assessment (Formative + Summative)	04 Hours

Upon completion of this module students will able to

MO1: Apply automation and integrated systems in product manufacture **MO2:** Compute strategies for business development and Project management.

Module 5: Overview to Advanced Excel

Sr No	Value added Topic	Duration
1.	<p>Section One - Make a Start with Excel</p> <ul style="list-style-type: none"> • What is a Spreadsheet? • Excel Rows and Columns • Enter Text and numbers in a cell • Data Formatting - Font formatting, Number formatting, colour of a cell; centre text and numbers; Table formatting, Conditional formatting, Hide/Unhide; Sort / filter, paste special, Find and select • Text Functions Using: Mid/Search/Left/Right Functions; Using Trim/Clean/Upper/Lower Functions; Using Substitute/Text Functions; Using Trim/Clean/Proper/Dollar Function • Currency symbols in excel • How to save your work in excel <p>Section Two - Excel Formulae</p> <ul style="list-style-type: none"> • The SUM Function • How to multiply in excel • Subtract and Divide • Combine the Arithmetic Operators • Formula Auditing • The Average Function • The Date & Time Function <p>Section Three - Microsoft spreadsheet Features</p>	02 Hour

- Advanced Filters - Extracting Records with Advanced Filter; Using Formulas in Criteria
- Advanced Sorting - Sorting by Top to Bottom/Left to Right; Creating/Deleting Custom List; Sort by using Custom List
- How to Merge cells
- Data Import from Web, Text (Text to columns)
- Removing Duplicates
- How to use Auto fill in excel
- How to Sort data in excel
- Searching with MATCH and INDEX
- How to Create an Excel Template
- Data Forms in Excel
- Drop Down Lists in Excel
- Add your own Error Messages
- Array Formulas Intermediate Excel
- Frequency Distribution Intermediate Excel
- Hyperlinks in Excel

Section Four - Microsoft Excel Pivot Tables & Charts

- Excel Pivot Tables (Creating, Formatting Simple PivotTables), Creating / Modifying a PivotChart
- Create an excel chart
- Formatting Charts: Move and Resize your chart; Charts Styles and Layouts; Adding Chart Titles and Series Titles Legends / Lables
- Formatting / Renaming / Deleting Data Series; Changing the Order of Data Series; Chart Layout Panel in Excel
- Printing Charts
- Adding Data to a Chart;
- Create Pie chart in Excel
- Format Pie chart segments
- Create a 2D line Chart in Excel (Combo Charts – Secondary Axis)
- Format your Axis titles
- Predict the future with a Trendline chart
- Sparkline charts
- Section Five - Conditional Logic
- 'IF' Function
- Conditional Formatting in excel
- Statistical Functions:
- CountIF, Count IFS, SUMIF, SUMIFS, Averagelf, Averagelfs, Nested IF, IFERROR Statement, AND, OR, NOT; LARGER / SMALLER Functions (Colour coding & data rearrangement)
- Absolute Cell References

	<p>Section Five - Advanced Excel – Data Processing & LOOKUP Functions</p> <ul style="list-style-type: none"> • Reference other Worksheets • LOOKUP Function: VLOOKUP/HLOOKUP Function in Excel; Index and Match; Creating Smooth User Interface Using Lookup; Nested VLookup; Reverse Lookup using Choose Function <p>Arrays Functions - Array Formulas, Use of the Array Formulas; Basic Examples of Arrays (Using ctrl+shift+enter); Array with if, len and mid functions formulas; Array with Lookup functions; Advanced Use of formulas with Array.</p>	
	Total Hours	06 Hours

Module Outcomes: Upon completion of this module students will be able to:

1. Create & Edit worksheets
2. Process data sets using Outline, autofilter & pivot tables
3. Process data sets employing Excel Formulae & produce statistical results
4. Extract and modify data with search and replace, use conditional formatting to highlight specific data
5. Creates and format PivotTables & Charts

Validate data using LOOKUP features

Industrial Perspective for Pharmaceutical Product Development and Technology Transfer

Total Course Duration: 30 Hours

TEACHING METHODOLOGY & EVALUATION

- **Professional Activities, Learning Resources and Assessment**
- **Suggested Class Room Activities**
 - MCQ's, Case studies, Problem based learning, Assignment, Group Discussions.
 - Assessment
- **25% Formative assessment:**
 - 20% marks will be award on the basis of average of two assignments given in the course i.e. 05 Marks.
 - 40% marks will be given on the basis of professional activity i.e Problem identification and solving, Report writing and Documentation. 10 Marks.
 - 40% marks will be awarded on the basis of objective/subjective Test i.e. 10 Marks.
- **75% summative assessment:**
 - End term exam of 75 marks will be conducted to award total exam score. Question paper will be set as per the university rules applied to other courses.
 - Exam Score: 40% passing criterion will be based on Formative assessment plus Summative assessment scores. Attendance, Participation and feedback 80% attendance is compulsory to complete this course.

Industrial Perspective for Pharmaceutical Product Development and Technology Transfer

ELIGIBILITY & OTHER RELEVANT INFORMATION

- **Eligibility:** Students pursuing B. Pharm final year and post graduation
- **Duration:** 20hrs of lectures spread over 3 Months
- **Fees/Charges:** The course is offered to the students with a nominal registration fee.
- **Added Benefits for the Participating Students:**
 - Enriched knowledge of Pharmaceutical product development and Tech transfer.
 - Nurturing the technical skills in designing the scale-up parameters for production.
 - Enhanced Patent and market research skills.
 - Enhanced employability skills.

CAREER OPPORTUNITIES

Product Development

Technology Transfer

Research & Development

Quality Assurance

Regulatory Affairs

Industrial Perspective for Pharmaceutical Product Development and Technology Transfer

REFERENCES

- Pharmaceutical Product Development: Insights into Pharmaceutical Processes, Management and Regulatory Affairs. By **Dr. Vandana Patravale and John D'Souza**, CRC Press, Taylor and Francis Group.
- Pharmaceutical Drug Product Development and Process Optimization: Effective use of QbD. By **Sarwar Beg, Mahfoozur Rahman**, Apple Academic Press, Taylor and Francis Group.
- Pharmaceutical Product Development. By **N.K Jain**. CBS Publisher PVT, LTD.
- Pharmaceutical Process Scale- Up. By **Michael Levin**. CRC Press, Taylor and Francis Group.
- Pharmaceutical Project Management. By **Tony Kennedy**. CRC Press, Taylor and Francis Group
- Drug Regulatory Affairs by **Sachin Itkar, Dr. N.S. Vyawahare**, Nirali Prakashan.
- <https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/search-regulatory-references-drugs>
- <https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/pharmaceuticals/current-projects>
- <https://www.nintex.com/blog/the-4-phases-of-project-management-and-how-process-automation-can-help/>

Industrial Perspective for Pharmaceutical Product Development and Technology Transfer



Highlights of the Course

- **Regulatory Market for Generic Drug Development**
- **Stages of Pharmaceutical Product Development**
- **Technology Transfer & Scale-up Parameters for Production - Challenges and trouble-shooting.**
- **Automation in Manufacturing**