RBVRR WOMEN'S COLLEGE OF PHARMACY

3-4-343, Barkathpura, Hyderabad – 5000 027 (T.S), India

Office: +91 40-27563065, Mobile: +91 9848930555

(Approved by the AICTE, PCI & Affiliated to Osmania University)

Recognized under section 2(f) of the UGC Act 1956

EAMCET Code: RBVW | PGECET Code: RBVW1

www. Rbvrrwcp.org | Email: rbvrrwcoph@rediffmail.com & rbvrrwcp2006@gmail.com

Invites you to the

Certificate course on:

"PROFESSIONAL DEVELOPMENT"

DATE:

3rd Jul 2021

VENUE:

Seminar Hall

Convener: Prof. M. Sumakanth

Principal of RBVRR Women's College of Pharmacy

Guest of Honor: Prof. K. Muthyam Reddy

Hon. Secretary & Correspondent of RBVRR Women's College of Pharmacy

Programme Schedule

DATE	SPEAKER
3rd -5th Jul 2021	**P. Anuradha Reddy** Retd. Professor Osmania University
6th – 7th Jul 2021	**Mrs. P. Swathi** Psychologist
8th – 9th Jul 2021	**Prof. Sumita Roy** Retd. Professor Osmania University
10th - Jul 2021	**Prof. M. Sumakanth** **Principal** RBVRR Women's College Of Pharmacy

Value Added Course		
Course: PROFESSIONAL DEVELOPMENT		
Code: PDC004	**Credits:** 2	**Total No. of Hours** : 36

Introducing Professional development skills as a course to students helps them to succeed in their academic and personal lives, build up strong relationships, and improve their overall well-being. Professional development skills are not only for personal growth but also for professional success. These courses cover a wide range of topics, from leadership skills to technical skills. Below is an outline that covers the basic aspects of various types of Professional Development Skills.

Course Objectives:

The Professional development skills course objective is to create oneself aiming at advancing their career and enhancing their skills and talents in the workplace.

The specific course objectives provides, explores and familiarize the students with insights on Time Management, Advanced writing skills, Interview skills, Leadership skills and Research skills which are important for building up their career.

Professional development skills refer to the abilities and traits that help individuals grow and improve. Here are some reasons why professional development skills matter for individuals:

1. **Improved Self-Awareness**
   Personal development skills help students become more self-aware. This means understanding their strengths, weaknesses, values, and goals. By developing self-awareness, students can make better decisions and find more fulfillment in their lives.
2. **Goal Setting and Time Management**
   College students have a lot on their plates, from coursework to extracurricular activities. By developing goal-setting and time-management skills, students can prioritize their tasks and make the most of their time.
3. **Better Communication**
   By developing communication skills, students can improve their relationships with peers, professors, and future employers.
4. **Adaptability and Resilience**
   Life is unpredictable, and students will inevitably face challenges and setbacks. By developing adaptability and resilience, students can bounce back from setbacks and overcome obstacles.

   By the end of the program, participants will be aware about all that are required for their career development i.e from leadership skills to technical skills.

SYLLABUS

Unit 1	Time Management	6 Hours

Time Management:
What Is Time Management, Why Time Management Is Important.
Planning Tips and Tricks:
Planning Tools
Setting Priorities
Prioritizing Your Tasks
Your To-Do List
Managing Interruptions and DistractionsTips for Controlling Disruptions
Setting Goals:
Goals and Targets, Setting SMART Goals, Your Own SMART Goals

Unit 2	Advanced Writing Skills	7 Hours

The C's of Writing:
Writing Clearly, Writing Concisely, Making Connections, Writing Correctly, Choosing Your Sources
Dealing with Specific Requests:
Types of Letters, Keeping it Real
Writing Mechanics:
Building Paragraphs, Proper Paragraphs, More on Paragraphs, Making Connections
Preparing Business Documents:
Requests for Proposals, The Proposals, The Differences When Writing Proposals, Ten Steps of Proposal Writing, Writing Reports, Documentation

Unit 3	Interview Skills	5 Hours

Interview Skills: Purpose of an interview, Do's and Dont's of an interview , E-Mail etiquette
Group Discussion: Introduction, Communication skills in group discussion, Do's and Dont's of group discussion
Giving Presentations: Dealing with Fears, planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

Unit 4	Leadership Skills	9 Hours

Introduction to Leadership: Roles, functions and characteristics of a leader; evolution and growth of leadership; Leadership traits and ethics; Attitude, Behaviour, Personality traits and leadership; Types and Styles of leadership
Theories of Leadership: Trait Theory, Behavioural theories, Contingency Theories, Transactional Theories and Transformational Leadership Theory
Leadership and Management: Nature, Scope and Significance of Management; Levels of Management; Functions: Planning, Organizing, Staffing, Directing and Controlling; Skills: Conceptual, Human and Technical; Roles: Interpersonal, Informational and Decisional; difference between a leader and a manager
Issues and Challenges for Leaders: Immerging trends in leadership; Servant leadership, Situational leadership; Gender and leadership; Effective Leadership Communication; Emotional intelligence and leadership

Unit 5	Research Skills	9 Hours

Introduction to Research and Research Design
Nature and scope of research, information based decision making and source of knowledge. The research process; basic approaches and terminologies used in research. Defining research question and framing of hypotheses, Preparing a research plan, qualitative and quantitative research designs, Experimentation, Observational studies, Exploring secondary data.

Measurement and Scaling, Data Source and Data Collection

Field research; primary data collection from observations, surveys and experimentation. Measurement and scaling; commonly used scales in reliability and validity of scales. Designing instrument for data collection; testing the instrument, data collection process, Sampling methods and procedures and samplesize decisions.

Data Analysis

Editing and coding of data, tabulation, graphic presentation of data, cross tabulation, Testing of hypotheses; type I and II errors, one tailed and two tailed tests of significance, Parametric and nonparametric tests for Univariate and Bivariate data. Tests of association; simple linear regression and other nonparametric tests.

Report Writing and Presentation

Professional Development Course Outcomes:

After the successful completion of this module the learners will be able to inspire individuals, manage talent, influence, lead teams, resolve conflict, build trust, increase cooperation and enhance productivity.

1. Demonstrate knowledge of and apply the basic principles of productivity to their own life.
2. Identify personal priorities and goals.
3. Identify how to maximize their time in order to accomplish their goals both personally and professionally
4. Students can effectively manage the team as a team player.

Develop interview skills and Leadership qualities which Helps to develop critical appreciation

RBVRR WOMEN'S COLLEGE OF PHARMACY

(Approved by AICTE & PCI, Affiliated to Osmania University)

Barkatpura, Hyderabad- 500 027

CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 1&2 (Session 1&2)

1. Name of the participant and institute: Sri vidya
2. Name of the institute: Rbvrr women's College of pharmacy
3. Email id of the participant: Srividya@gmail.com
4. How was the content delivered by the speaker? (P. Anuradha Reddy)
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
6. Smart goals are to provide better understand all very good
7. Goal setting include-
   a) Process
   b) Performance
   c) Outcome
   d) ✓ All of the above
8. Goal setting helps in
   a) Setting a realistic timeline for the goal accomplishment
   b) ✓ Provide a better understanding of expectations
   c) Give clarity to decision making
   d) All of the above
9. Setting goals is important because it allows to be creative
10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - o No
    - o Maybe

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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 1&2 (Session 1&2)

1. Name of the participant and institute: Sindhuja Yadav
2. Name of the institute: Rbvrr Women's College of Pharmacy
3. Email id of the participant: Sindhuja Yadav 19@gmail.com
4. How was the content delivered by the speaker? (P. Anuradha Reddy)
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
6. Smart goals are to provide better understanding are very good.
7. Goal setting include-
   a) Process
   b) Performance
   c) Outcome
   d) ✓ All of the above
8. Goal setting helps in
   a) Setting a realistic timeline for the goal accomplishment
   b) Provide a better understanding of expectations
   c) Give clarity to decision making
   d) ✓ All of the above
9. Setting goals is important because it allows us to be greater
10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - o No
    - o Maybe

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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 3&4 (Session 1&2)

1. Name of the participant and institute : D neha
2. Name of the institute: RBVRR women's college of pharmacy
3. Email id of the participant : nehad.ka@gmail.com
4. How was the content delivered by the speaker? (Prof. Sumita Roy)
   - Excellent
   - Very Good
   - Good
   - Average
5. How do you rate the session?
   - Excellent
   - Very Good
   - Good
   - Average
6. Leadership is the ability of directing the group to achieve goals
7. What are the most important roles of a good leader?
   a) Motivational Team Members
   b) A Good Communicator
   c) Unity
   d) All of the above
8. What are the qualities of a good leader?
   a) High level intelligence
   b) Emotional Stability
   c) Motivating others
   d) All of the above
9. A leaders most important function is to achieve disered goals
10. Was the session helpful and would you like to attend more sessions like this?
    - Yes
    - No
    - Maybe

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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 3&4 (Session 1&2)

1. Name of the participant and institute : Laxmi Hasu
2. Name of the institute: Rbvrr Women's College of Pharmacy
3. Email id of the participant : laxmiharu21@gmail.com
4. How was the content delivered by the speaker? (Prof. Sumita Roy)
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
6. Leadership is the ability of directing the group to achieve goals
7. What are the most important roles of a good leader?
   a) Motivational Team Members
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   c) Unity
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   a) High level intelligence
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   c) Motivating others
   d) All of the above
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10. Was the session helpful and would you like to attend more sessions like this?
    - o Yes
    - o No
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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 5&6 (Session 1&2)

1. Name of the participant and institute: Hrushitha
2. Name of the institute: RBVRRWCOP.
3. Email id of the participant: Hrushitha@gmail.com
4. How was the content delivered by the speaker? (Mrs.P.Swathi)
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - ✓ Very Good
   - o Good
   - o Average
6. Writing skills are important as it serves as medium through which we communicate – ✓ True / False
7. Clear and effective communication of ideas includes
   a) Purpose relevance and justification of writing
   b) Content relevance and clarity
   c) Word choice and idioms usage
   ✓ d) All of the above
8. Different types of writings include
   a) Expository Writing
   b) Descriptive Writing
   c) Persuasive Writing
   ✓ d) All the Above
9. Resume is a summary of one's information
10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - o No
    - o Maybe

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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 5&6 (Session 1&2)

1. Name of the participant and institute: B. Pavani
2. Name of the institute: RBVRR Women's College of pharmacy
3. Email id of the participant: Pavani@gmail.com
4. How was the content delivered by the speaker? (Mrs.P.Swathi)
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
6. Writing skills are important as it serves as medium through which we communicate – True / False
7. Clear and effective communication of ideas includes
   a) Purpose relevance and justification of writing
   b) Content relevance and clarity
   c) Word choice and idioms usage
   d) All of the above
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CERTIFICATE COURSE ON – PROFESSIONAL DEVELOPMENT

FEEDBACK FORM DAY – 7 (Session 1&2)

1. Name of the participant and institute: Alisha
2. Name of the institute: RBVRR womens college of pharmacy
3. Email id of the participant: Alisha.rodrun@gmail.com
4. How was the content delivered by the speaker? (Prof. M. Sumakanth)
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - ✓ Very Good
   - o Good
   - o Average
6. Observational Studies include -
   a) Cohort studies
   b) Case control studies
   c) Cross control studies
   d) ✓ All the above
7. By controlling the conditions, experimental studies establish Independ
8. Key features of Experimental studies are-
   a) Randomized Controlled trials
   b) ✓ Control groups
   c) None of the above
   d) All of the above
9. Observational research studies involve gathering data
10. Was the session helpful and would you like to attend more sessions like this?
    - ✓ Yes
    - o No
    - o Maybe

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FEEDBACK FORM DAY – 7 (Session 1&2)

1. Name of the participant and institute: Thorineni
2. Name of the institute: RBVRR Women's college of pharmacy
3. Email id of the participant: Thorenivankamma@gmail.com
4. How was the content delivered by the speaker? (Prof. M. Sumakanth)
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
6. Observational Studies include -
   a) Cohort studies
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A 10 DAY CERTIFICATE COURSE IN PHARMACOVIGILANCE 2021

COURSE BENEFITS

- **Career Guidance and Resume Writing Skills**
- **Intensive 36-Hour Training by Industry Experts**
- **Hands-on Real-Time Practice Completion Certificate.**

In Association with our Training Partner:

CLINOSOL™

Registration Fee - Rs 1000/-

Last Date for Registration:

25th Oct 2021

Payment: Gpay to 7416614919

About RBVRR Women's College of Pharmacy:

RBVRR Women's College of Pharmacy, founded in the year 2006, operates successfully under Hyderabad Mahila Vidhya Sangam, guided by the visionary leadership of its Founder Principal, Prof. M. Sumakanth, with a core mission of offering education to young women. The college has spacious classrooms, well-equipped laboratories with the latest equipment, and well-furnished seminar hall, conference room and library with a good number of the latest editions of both textbooks and reference books. The college is recognized as research centre by Osmania University. The college is offering the following courses:

- B.Pharmacy (100seats)
- Pharm.D (32)
- M.Pharmacy (Pharma.Chemistry, Pharmaceutics,Pharm.Analysis and Pharmacology).

About ClinoSol:

Founded in 2019, ClinoSol is a dynamic and forward-thinking healthcare company dedicated to transforming the way medical solutions are delivered. With a strong focus on innovation, ClinoSol has emerged as a pioneer in the industry, continuously striving to improve patient outcome and enhance healthcare systems globally. ClinoSol's products and services are tailored to serve the industry needs, thus, students can benefit from engaging with ClinoSol's professional tone of voice as they explore the innovative advancements in healthcare.

About the Course

- The 10-Day Hands-on Certificate course in Pharmacovigilance aims to provide participants with a comprehensive understanding of pharmacovigilance principles and practices.
- Through interactive sessions and practical exercises, attendees will learn about the importance of drug safety monitoring, adverse event reporting, and risk management strategies.
- The workshop will also cover the regulatory framework surrounding Pharmacovigilance and the role of various stakeholders in ensuring drug safety.
- Assist students in selecting a career path in pharmacovigilance.

SCHEDULE

DATE	MODULE #	TOPIC	SPEAKER	DURATION
28th OCT 2021	Module 1	Introduction to Clinical Research and Pharmacovigilance	C.S Mujeebuddin	4 Hours
29th OCT 2021	Module 2	Case processing workflow	C.S Mujeebuddin	4 Hours
30th oct 2021	Module 3	Causality Assessment	Uma Priya	4 Hours
01st Nov 2021	Module 4	Expedited Reporting	Uma Priya	3 Hours
02nd Nov 2021	Module 5	Narrative Writing	C.S Mujeebuddin	4 Hours
03rd Nov 2021	Module 6	Medical Coding in PV	C.S Mujeebuddin	3 Hours
04th Nov 2021	Module 7	Signal Management	Uma Priya	3 Hours
05th Nov 2021	Module 8	Aggregate Reporting	Uma Priya	4 Hours
06th Nov 2021	Module 9	Hands on Exercises	Dr.Mitesh Reddy	4 Hours
08th Nov 2021	Module 10	Hands on Exercises and Assessment	Dr.Mitesh Reddy	4 Hours

COURSE OUT COMES

After completion of this course Participants can

1. Understand the basics of Pharmacovigilance and current status of Indian and Global Pharmacovigilance.
2. Explain Qualitative and Quantitative signal detection and perform Signal detection and management.
3. Gain insights into the significance of adverse event reporting and effective risk management strategies in the pharmaceutical industry
4. Equip with valuable knowledge and skills, fostering understanding of pharmacovigilance principles and preparing them for potential careers in this field.
5. Familiarize with real-world pharmacovigilance scenarios through Hands-on training sessions.

An Intensive Practice based Certification Course on		
PHARMACOVIGILANCE		
Code:PVCC004	Credits: 2	Course duration:36hrs

This certificate course is designed to equip participants with a deep understanding of pharmacovigilance principles, methodologies, and practical applications. This course is an unique blend of theoretical knowledge and practical skills, providing participants with a solid foundation for a successful career in pharmacovigilance.

OBJECTIVE: This course is exclusively designed for Graduates in Pharmacy and Bio-Sciences, Medical Professionals, junior professionals in Pharmaceutical and IT Industry and also for B.Pharm, Pharm D, M.Pharm pursuing students and to embrace the tactical aspects of Pharmacovigilance .

SYLLABUS

Module I	**Introduction to Pharmacovigilance**	**4hrs**
Introduction to Clinical Research and Pharmacovigilance. Historical perspectives and Current Status of pharmacovigilance. National and international aspects of PV .		
Module II	**Case Processing Workflow**	**4hrs**
Adverse Drug Reactions - Types, detection and reporting methods. Sources of Cases: Unsolicited Reports, Solicited reports, contractual agreements, Regulatory Authorities, Steps in case processing.		
Module III	**Causality Assessment**	**4hrs**
Factors Considered in Causality Assessment, Methods and Tools for Causality Assessment, Methods and Tools for Causality Assessment, Case studies.		
Module IV	**Expedited Reporting**	**3hrs**
Types of Regulatory reporting, Criteria for Expedited Reporting, Time Frames, Channels of reporting, Regulatory obligations.		
Module V:	**Narrative Writing**	**4hrs**
Narrative Writing objectives, regulatory frame work, Template of narrative writing. Case Studies.		
Module VI	**Medical Coding in PV**	**3hrs**
Medical coding: Introduction, WHO adverse reactions, terminologies, Med DRA and Standardized Med DRA.		
Module VII	**Signal Management**	**3hrs**
Signal terminologies, Methods of signal detection. Signal Management process flow, Qualitative and Quantitative signal detection, Analysis of different data sources.		

Module VIII	**Aggregate Reporting**	**4hrs**
Types of aggregate reporting , Reporting intervals, communication to regulatory authorities		
Module IX	**Practical session on Narrative Writing.**	**4hrs**
Exercises on Spontaneous reports,		
Module X	**Practical session on Causality assessment and Med DRA**	**4hrs**
Assessment of Causality based on Naranjo scale for the given cases, Med DRA Coding Demo		

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Barkatpura, Hyderabad- 500 027

CERTIFICATE COURSE ON PHARMACOVIGILANCE 2021

FEEDBACK FORM DAY

1. Name of the participant and institute : Rabia Rimsha
2. Name of the institute: RBVRR Women's College of Pharmacy.
3. Email id of the participant : Rabiarimsha13@gmail.com.
4. How was the content delivered by the speaker?
   - ○ Excellent
   - ✓ Very Good
   - ○ Good
   - ○ Average
5. How do you rate the session?
   - ○ Excellent
   - ○ Very Good
   - ✓ Good
   - ○ Average
6. The atom New treatments that have been tested in laboratory have ?
   a) 72-82% No risk whatsoever when used in clinical trials.
   b) 40-50% Risk when used in clinical trials.
   c) 90-100% Efficacy and effectiveness
   d) Efficacy and safety as well.
7. Controlled clinical trials are essential for assessing ?
   a) CO_2 Compound screening
   ✓ b) CFC The safety and efficacy of new treatment.
   c) Safety and dosage
   d) New drug approval
8. Which is not the principle of GCP as per ICH ?
   a) It should be initiated only if anticipated benefits just the risk.
   b) It should be scientifically signed and described in a clear detail procedure
   c) Its protocol must have received prior approval from the ethics committee
   ✓ d) The confidentiality of the subjects should not be protected all the time.
9. Time line to complete all the three phases of clinical trials before the licensing stage of COVID-19

   a)12-14yrs b) 9-10 yrs ✓ c) 6-7 yrs d) 2-3yrs.

11. Would you like to have more sessions like this ?
    - ✓ Yes
    - ○ No

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CERTIFICATE COURSE ON PHARMACOVIGILANCE 2021

FEEDBACK FORM DAY

1. Name of the participant and institute: Hania Fareen
2. Name of the institute: RBVRR Women's College of Pharmacy
3. Email id of the participant: Fareehaniya22@gmail.com
4. How was the content delivered by the speaker?
   - ○ Excellent
   - ○ Very Good
   - ✓ Good
   - ○ Average
5. How do you rate the session?
   - ○ Excellent
   - ○ Very Good
   - ✓ Good
   - ○ Average
6. The atom New treatments that have been tested in laboratory have ?
   a) 72-82% No risk whatsoever when used in clinical trials.
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   d) The confidentiality of the subjects should not be protected all the time.
9. Time line to complete all the three phases of clinical trials before the licensing stage of COVID-19

   a)12-14yrs b) 9-10 yrs c) 6-7 yrs d) 2-3yrs.

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www. Rbvrrwcp.org | Email: rbvrrwcoph@rediffmail.com **&** rbvrrwcp2006@gmail.com

Certificate course on

GREEN CHEMISTRY IN DRUG DISCOVERY-2021

03rd -10th Dec 2021

COURSE BENEFITS:

- Learn about principles of green chemistry.
- Gain hands on training on microwave synthesizer
- Learn about design of nano-catalysts and significance of phase transfer catalysts and Biocatalysts in drug discovery.

Registration Link:
https://forms.gle/Yu9WvuzVo2LvQbjV8

Registration Fee: 1000/-

Last Date for Registration: 30 Nov 2021

Gpay Number : 7702236567

ABOUT RBVRR WOMEN'S COLLEGE OF PHARMACY

Established in 2006, RBVRR Women's College of Pharmacy functions effectively under *Hyderabad Mahila Vidhya Sangam*, under the visionary direction of Prof. M. Sumakanth, the college's founder principal. The primary objective of the college is to provide education to young women. The institution features large classrooms, modern, well-equipped laboratories, a well-furnished seminar hall, a conference room, and a library with a good selection of the most recent editions of reference and textbook materials.

The college is offering the following courses:

1. B.Pharmacy (100seats)
2. Pharm.D (32seats)
3. M.Pharmacy (Pharma. chemistry, Pharmaceutics, Pharm. Analysis and Pharmacology)

VISION

To lead the way in impacting lives via a creative, tenacious, and caring approach to pharmacy education as a National Women's Pharmacy Professional.

MISSION

Besides from the traditional curriculum, RBVRRWCP empowers and prepares female students for success in a changing society through on-going awareness programs.

OBJECTIVES

- To familiarize with green chemistry.
- To learn about green reagents, green solvents, green catalysts and reaction conditions.
- To know about greener technologies and alternative energy sources.
- To learn about renewable resources and greenhouse effect.
- To know the importance of catalysis in green synthesis.
- To know various techniques in green chemistry based on current needs.
- To learn the various green techniques and the technology behind them.

Value added course		
Course: Green chemistry in drug discovery		
Code: GCDCC004	Credits: 4	Total No. of Hours: 36hrs.

AIM:

This certificate course aims to enhance understanding about the importance of green chemistry in medication design and development. The course focuses on the fundamentals of green chemistry, design, alternative energy sources, green synthesis catalysis, and contemporary green chemistry developments.

SYLLABUS

UNIT I: PRINCIPLES AND CONCEPTS OF GREEN CHEMISTRY 6 HRS

Introduction, principles of green chemistry, sustainable development and green chemistry. Atom economic reactions - rearrangement and addition reactions. Atom un-economic reactions - substitution, elimination reactions.

UNIT II: DESIGNING A GREEN SYNTHESIS 7 HRS

Role of green synthesis in drug discovery Green discoveries; greener reagents, role of green catalysts in organic synthesis, Sustainable synthesis of pharmaceuticals. Development of Photo enzymatic Strategies for Selective Organic Synthesis—Focus on Advantages and Challenges

UNIT III: GREENER TECHNOLOGIES AND ALTERNATIVE ENERGY SOURCES 7 HRS

Chemistry using Microwaves: Microwave heating and microwave-assisted reactions in water, reactions in organic solvents, solvent free reactions. Sonochemistry & Electrochemical synthesis with examples.

UNIT IV: RENEWABLE RESOURCES AND GREENHOUSE EFFECT 8 HRS

Biomass as a renewable resource: Fossil fuels, biomass, solar power, fuel cells and other forms of renewable energy. Chemicals and polymers from renewable feedstock. Greenhouse effect and Global Warming - Introduction - How the greenhouse effect is produced - Major sources of greenhouse gasses - Emissions of CO_2 - Impact of greenhouse effect on global climate. Control and remedial measures of greenhouse effect. Global warming- A serious threat to life on earth.

UNIT V: CATALYSIS IN GREEN SYNTHESIS. 8 HRS

The design of Nano-catalysts for energy and environmental applications. Phase Transfer Catalysts: Introduction, mechanism of catalytic action, type of catalysts and its advantages, Application of Phase transfer catalysis in green synthesis. Biocatalysts: Introduction, Biochemical oxidations and reductions.

PROGRAM SCHEDULE:

DATE	MORNING SESSION (10.30AM-1.00PM)	AFTERNOON SESSION (2.00PM-4.30PM)
03rd Dec 2021	**Dr. V. Naveen Reddy** Assistant Professor, Department of Chemistry, Nizam College, Hyderabad.	**Dr. K. Premalatha** Assistant Professor Department of Chemistry, University College for Women, Osmania University.
04th Dec 2021	**Dr. Bhoomi Reddy Rama Devi** Professor & Head of the Department, Chemistry JNTUH University College of Engineering, Science & Technology, Hyderabad.	**Dr. Srinivas Nanduri** Professor, Department of Chemical Sciences, NIPER Hyderabad.
06th Dec 2021	**Dr. K. Premalatha** Assistant Professor Department of Chemistry, University College for Women, Osmania University.	**Dr. Srinivas Nanduri** Professor, Department of Chemical Sciences, NIPER Hyderabad.
07th Dec 2021	**Dr. Bhoomi Reddy Rama Devi** Professor & Head of the Department, Chemistry JNTUH University College of Engineering, Science & Technology, Hyderabad.	**Dr. V. Naveen Reddy** Assistant Professor, Department of Chemistry, Nizam College, Hyderabad.
08th Dec 2021	**Dr. K. Premalatha** Assistant Professor Department of Chemistry, University College for Women, Osmania University.	**Dr. Srinivas Nanduri** Professor, Department of Chemical Sciences, NIPER Hyderabad.
09th Dec 2021	**Dr. V. Naveen Reddy** Assistant Professor, Department of Chemistry, Nizam College, Hyderabad.	**Dr. Bhoomi Reddy Rama Devi** Professor & Head of the Department, Chemistry JNTUH University College of Engineering, Science & Technology, Hyderabad.
10th Dec 2021	**Dr. Srinivas Nanduri** Professor, Department of Chemical Sciences, NIPER Hyderabad.	**Dr. Bhoomi Reddy Rama Devi** Professor & Head of the Department, Chemistry JNTUH University College of Engineering, Science & Technology, Hyderabad.

Program Coordinator:

Dr. M.Vijaya Bhargavi

Associate Professor& Head

Department of Pharmaceutical Chemistry

RBVRR Women's College of Pharmacy.

Contact no.: 98480 54391

For Queries Contact

Mrs V. Padmaja: 9849583030

Mrs P. Archana: 8660723852

Mrs Sajida Afreen: 7702236567

RBVRR WOMEN'S COLLEGE OF PHARMACY

(Approved by AICTE & PCI, Affiliated to Osmania University)

Barkatpura, Hyderabad- 500 027

CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 1 SESSION – 1& 2 :

1. Name of the participant: G. Manogna
2. Name of the institute: RBVRR Women's College of Pharmacy
3. Email id of the participant : -

4. How was the content delivered by the speaker?
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - ✓ Very Good
   - o Good
   - o Average

6. The most potent greenhouse gas in terms of efficiency is
   a) N_2O
   b) CO_2
   c) ✓ CFC
   d) CH_4

7. The atom economy obtained for green synthesis in the range of
   a) 62-70%
   b) 72-82%
   c) 40-50%
   d) ✓ 90-100%

8. Green synthesis method is _____than the conventional method.
   a) Most costlier b) ✓ More efficient c) Slower d) Less efficient.

9. Which of the following reaction is atom economic reaction?
   a) Addition b) Substitution c) ✓ Rearrangement d) Elimination.

10. Would you like to have more sessions like this ?
    - ✓ Yes
    - o No

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Barkatpura, Hyderabad- 500 027

CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 1 SESSION – 1& 2 :

1. Name of the participant: K. Divya
2. Name of the institute: RBVRR Womens college of Pharmacy
3. Email id of the participant : _____

4. How was the content delivered by the speaker?
   - o Excellent
   - o Very Good
   - ✓ Good
   - o Average
5. How do you rate the session?
   - ✓ Excellent
   - o Very Good
   - o Good
   - o Average
6. The most potent greenhouse gas in terms of efficiency is
   a) N_2O
   b) CO_2
   ✓ c) CFC
   d) CH_4
7. The atom economy obtained for green synthesis in the range of
   a) 62-70%
   ✓ b) 72-82%
   c) 40-50%
   d) 90-100%
8. Green synthesis method is _____than the conventional method.
   a) Most costlier ✓ b) More efficient c) Slower d) Less efficient.

9. Which of the following reaction is atom economic reaction?
   a) Addition b) Substitution ✓ c) Rearrangement d) Elimination.

10. Would you like to have more sessions like this ?
    - ✓ Yes
    - o No

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Barkatpura, Hyderabad- 500 027

CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 2 :

1. Name of the participant and institute : Hadia
2. Name of the institute: RBVRR women's college of pharmacy
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - o Very Good
   - ✓ Good
   - o Average
6. At which part of the enzyme does the substrate fit in?
   - a) Left end
   - b) Right end
   - c) Active site
   - d) Binding site
7. The metal ions that binds the substrate and active site of the enzyme is called
   - a) Inhibitors
   - b) Coenzyme
   - c) Prosthetic group
   - d) Cofactors
8. Active site occupy less than 5 % of total surface of enzyme.
9. How are enzymes different from catalysts?
   - a) Enzymes are active at high temperatures
   - b) Catalysts are active at sub-zero temperatures
   - c) Catalysts are efficient at high temperatures and high pressures.
   - d) Enzymes are denatured at room temperature.
10. How many classes are enzymes divided into?

    a) 6 b)7 c)5 d) 8
11. Would you like to have more sessions like this ?
    - o Yes
    - o No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 2 :

1. Name of the participant and institute : Khadiya hasan
2. Name of the institute: RBVRR women's college of pharmacy
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   - o Excellent
   - ✓ Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - ✓ Very Good
   - o Good
   - o Average
6. At which part of the enzyme does the substrate fit in?
   - a) Left end
   - b) Right end
   - ✓ c) Active site
   - d) Binding site
7. The metal ions that binds the substrate and active site of the enzyme is called
   - a) Inhibitors
   - b) Coenzyme
   - ✓ c) Prosthetic group
   - d) Cofactors
8. Active site occupy less than 10 % of total surface of enzyme.
9. How are enzymes different from catalysts?
   - a) Enzymes are active at high temperatures
   - b) Catalysts are active at sub-zero temperatures
   - ✓ c) Catalysts are efficient at high temperatures and high pressures.
   - d) Enzymes are denatured at room temperature.
10. How many classes are enzymes divided into?

    ✓ a) 6 b) 7 c) 5 d) 8

11. Would you like to have more sessions like this ?
    - ✓ Yes
    - o No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 3

1. Name of the participant and institute : Shruthi vyas
2. Name of the institute: RBVRR women's college of pharmacy
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   - o Excellent
   - o Very Good
   - ✓ Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - ✓ Very Good
   - o Good
   - o Average
6. The selection of reagent is made on basis of
   a) Efficiency
   b) Availability
   c) its effect on environment
   ✓ d) All the above
7. What is Microencapsulated Lewis acid can be reused upto 10 times.
8. Enzymatic fermentation is used for production of antibiotics.
9. When Biochemical reactions are
   a) Chemo selective
   b) Regio selective
   c) Stereo selective
   ✓ d) All the above.
10. Would you like to attend more sessions like this?
    - ✓ Yes
    - o No

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Barkatpura, Hyderabad-500027

CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 3

1. Name of the participant and institute: Nishath fatima
2. Name of the institute: RBVRR women's college of pharmacy
3. Email id of the participant:
4. How was the content delivered by the speaker?
   - o Excellent
   - o Very Good
   - o Good
   - o Average
5. How do you rate the session?
   - o Excellent
   - ✓ Very Good
   - o Good
   - o Average
6. The selection of reagent is made on basis of
   - a) Efficiency
   - b) Availability
   - c) its effect on environment
   - ✓ d) All the above
7. What is Microencapsulated Lewis acid can be reused upto 12 times.
8. Enzymatic fermentation is used for production of Antibiotics.
9. When Biochemical reactions are
   - a) Chemo selective
   - b) Regio selective
   - c) Stereo selective
   - ✓ d) All the above.
10. Would you like to attend more sessions like this?
    - ✓ Yes
    - o No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 4

1. Name of the participant: Saipragna
2. Name of the institute: Rbvrr women's college of pharmacy.
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   a. Excellent
   b. Very Good
   c. ✓ Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. ✓ Very Good
   c. Good
   d. Average
6. The father of green chemistry
   a. Born Haber
   b. Nario Taniguchi
   c. Richard Feynman
   d. ✓ Paul T. Anastas
7. Green solvents are derived from the processing of Agricultural crops
8. Ultrasound assisted reactions generally occur in the range of _____
   a. 20Hz to 20K Hz
   b. Less than 20 Hz
   c. ✓ 20K Hz to 10G Hz
   d. More than 10G Hz
9. Which of the following is the greenest solvent?
   a. Formaldehyde
   b. Benzene
   c. ethanol
   d. ✓ liquid Water
10. Would you like to attend more sessions like this?
    a. ✓ Yes
    b. No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 4

1. Name of the participant: Shruthi vyas
2. Name of the institute: RBVRR women's college of pharmacy.
3. Email id of the participant: _____
4. How was the content delivered by the speaker?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
6. The father of green chemistry
   a. Born Haber
   b. Nario Taniguchi
   c. Richard Feynman
   d. Paul T. Anastas
7. Green solvents are derived from the processing of _____.
8. Ultrasound assisted reactions generally occur in the range of _____
   a. 20Hz to 20K Hz
   b. Less than 20 Hz
   c. 20K Hz to 10G Hz
   d. More than 10G Hz
9. Which of the following is the greenest solvent?
   a. Formaldehyde
   b. Benzene
   c. ethanol
   d. liquid Water
10. Would you like to attend more sessions like this?
    a. Yes
    b. No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 5

1. Name of the participant : C. Pragnya
2. Name of the institute: RBVRR Women's college of pharmacy
3. Email id of the participant : –
4. How was the content delivered by the speaker?
   - a. Excellent
   - b. Very Good
   - c. Good
   - d. Average
5. How do you rate the session?
   - a. Excellent
   - b. Very Good
   - c. Good
   - d. Average
6. Which of the following source of energy can be replenished after a short period of time?
   - a. Solar energy
   - b. Hydro energy
   - c. Coal
   - d. Both a and b
7. Greenhouse effect is due to _____ layer in the atmosphere?
   - a. Ozone
   - b. Infrared
   - c. Moisture
   - d. Carbon dioxide
8. Which Burning of fossil fuels results in
   - a. Increased oxygen levels
   - b. Decreased greenhouse gases
   - c. Increased greenhouse gases
   - d. Increased ethane level
9. Which of the following has maximum global warming potential?
   - a. Methane
   - b. Carbon dioxide
   - c. Nitrous oxide
   - d. Carbon monoxide.
10. Would you like to attend more sessions like this?
    - a. Yes
    - b. No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 5

1. Name of the participant : Hadia khanam
2. Name of the institute: RBVRR womens college of pharmacy
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
6. Which of the following source of energy can be replenished after a short period of time?
   a. Solar energy
   b. Hydro energy
   c. Coal
   d. Both a and b
7. Greenhouse effect is due to _____ layer in the atmosphere?
   a. Ozone
   b. Infrared
   c. Moisture
   d. Carbon dioxide
8. Which Burning of fossil fuels results in
   a. Increased oxygen levels
   b. Decreased greenhouse gases
   c. Increased greenhouse gases
   d. Increased ethane level
9. Which of the following has maximum global warming potential?
   a. Methane
   b. Carbon dioxide
   c. Nitrous oxide
   d. Carbon monoxide.
10. Would you like to attend more sessions like this?
    a. Yes
    b. No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 6

1. Name of the participant: Gaddam gayathri
2. Name of the institute: Rbvrrwcop
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
6. What are cofactors?
   A nonprotein compound & small organic and inorganic molecule.
7. Which of these enzymes are not proteinaceous?
   a. Kinases
   b. Endonucleases
   c. Ligases
   d. Ribozymes
8. Which enzyme is used in the production of sitagliptin?
   a. Ligases
   b. Isomerases
   c. Transaminases
   d. Transferases
9. Enc-reductase. are used to reduce activated alkene bonds in chiral fashion.
10. Would you like to attend more sessions like this?
    a. Yes
    b. No
    c. Maybe

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 6

1. Name of the participant: Zeba fatima
2. Name of the institute: RBVRRWCOP
3. Email id of the participant : –
4. How was the content delivered by the speaker?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
6. What are cofactors?
   An organic & inorganic molecules helps in biomolecular transformation.
7. Which of these enzymes are not proteinaceous?
   a. Kinases
   b. Endonucleases
   c. Ligases
   d. Ribozymes
8. Which enzyme is used in the production of sitagliptin?
   a. Ligases
   b. Isomerases
   c. Transaminases
   d. Transferases
9. Reductases are used to reduce activated alkene bonds in chiral fashion.
10. Would you like to attend more sessions like this?
    a. Yes
    b. No
    c. Maybe

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 7

1. Name of the participant: T. Varsha.
2. Name of the institute: rbvrrwcop.
3. Email id of the participant : —
4. How was the content delivered by the speaker?
   a. ✓ Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. ✓ Very Good
   c. Good
   d. Average
6. What is a catalyst?
   The substance which alters the speed of chemical reaction.
7. Nanomaterial's are the materials with at least one dimension measuring less than ?
   a. 1nm
   b. 10nm
   c. ✓ 100nm
   d. 1000nm.
8. What are different dopants used for ceria
   a. Zr^{4+}
   b. Hf^{4+}
   c. Ti^{4+}
   d. ✓ All of them.
9. Which gas combines with the haemoglobin and hinders the oxygen transport
   a. Carbon dioxide
   b. ✓ Carbon monoxide
   c. SO_2
   d. N_2O
10. Would you like to attend more sessions like this?
    a. ✓ Yes
    b. No

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CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY 03rd-10th Dec 2021

FEEDBACK FORM DAY – 7

1. Name of the participant: Brunda Sree
2. Name of the institute: rbvrr, wcp
3. Email id of the participant : _____
4. How was the content delivered by the speaker?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
5. How do you rate the session?
   a. Excellent
   b. Very Good
   c. Good
   d. Average
6. What is a catalyst?
   This alters the speed of chemical reaction.
7. Nanomaterial's are the materials with at least one dimension measuring less than ?
   a. 1nm
   b. 10nm
   c. 100nm
   d. 1000nm.
8. What are different dopants used for ceria
   a. Zr^{4+}
   b. Hf^{4+}
   c. Ti^{4+}
   d. All of them.
9. Which gas combines with the haemoglobin and hinders the oxygen transport
   a. Carbon dioxide
   b. Carbon monoxide
   c. SO_2
   d. N_2O
10. Would you like to attend more sessions like this?
    a. Yes
    b. No

College Code: 1706

RBVRR WOMEN'S COLLEGE OF PHARMACY

3-4-343, Barkathpura, Hyderabad - 500 027 (T.S), India

Office: +91 40-27563065, Mobile: +91 9848930555

(Approved by the AICTE, PCI & Affiliated to Osmania University)

Recognized under Section 2(f) of the UGC Act 1956

EAMCET Code: RBVW | PGECET Code: RBVW1

www.rbvrrwcp.org | Email: rbvrrwcoph@rediffmail.com & rbvrrwcp2006@gmail.com

Certificate Course on

REGULATORY AFFAIRS

7TH-12TH March 2022

RBVRR Womens college of pharmacy - SEMINAR HALL

INAUGURAL SESSION:

Dr. A. Krishna Shailaja

Prof. Head of Dept of Pharmaceutics,
RBVRR Womens college of pharmacy

Patron

Prof. K. Muthyam Reddy

Hon. Secretary cum correspondent

RBVRR Women's College of pharmacy

CONVENER

Prof. M. Sumakanth

Principal

RBVRR Women's College of pharmacy

SPEAKERS	DATE & TIME
1. Dr. A. Krishna Sailaja Professor & Head, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy	7TH March 2022 & 8th March 2022 at 2.00 pm
2. Raju Bhupathi Raja IP Attorney, Hyderabad	9TH March 2022 & 10th March 2022 at 2.00 pm
3. Dr. Priya Anish Mathews Scientist E, Project Monitoring & IPR Cell ARCA, Hyderabad	11TH March 2022 & 12th March 2022 at 2.00 pm

RBVRR WOMEN'S COLLEGE OF PHARMACY
3-4-343, Barkathpura, Hyderabad – 500027, Ph: 040-27563065
(Approved by AICTE & PCI, Accreditated by NBA (B Pharmacy Course) Affiliated Osmania University)
EAMCET Code: RBVW | PGECET Code: RBVW1

Value Added Course		
Course: Certificate course in Pharmaceutical Regulatory affairs		
Code: PRA C001	**Credits:** 2	**Total No. of Hours** : 36

CERTIFICATE COURSE IN PHARMACEUTICAL REGULATORY AFFAIRS

Regulatory affairs is a profession developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines, and by the companies responsible for the discovery, testing, manufacture and marketing of these products wanting to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare.

COURSE OBJECTIVES

The course is designed to teach all the regulations and rules of the industry. The curriculum of the certification is designed as a comparative analysis of Pharma regulatory systems of different nations integrated with concrete management tools of the supply chain like, Certification schemes, Regulatory compliance with government guidelines, product approval procedures etc. The study resources have been carefully designed to introduce the participant to various aspects and basics of industrial applications, its need, and benefits in assuring quality production.

SYLLABUS

Unit 1	Overview of regulatory affairs	6 Hours
Introduction to Global Regulatory Authorities in Pharmaceutical Industries, Drug Development Process, Regulatory Toxicology GMP and other good practices Introduction and the need for intellectual property right (IPR) - Kinds of Intellectual Property Rights: Patent, Copyright, Trade Mark, Design, Geographical Indication, Plant Varieties and Layout Design		

Unit 2	Pharmaceutical Industry and IPR	8 Hours
IPR in India : Genesis and development – IPR in abroad - Major International Instruments concerning Intellectual Property Rights: Paris Convention, 1883, the Berne Convention, 1886, the Universal Copyright Convention, 1952, the WIPO Convention, 1967,the Patent Co-operation Treaty, 1970, the TRIPS Agreement, 1994 Patents - Elements of Patentability: Novelty , Non Obviousness (Inventive Steps), Industrial Application - Non - Patentable Subject Matter - Registration Procedure, Rights and Duties of Patentee, Assignment and licence , Restoration of lapsed Patents, Surrender andRevocation of Patents, Infringement, Remedies & Penalties – Patent office and Appellate Board		

Unit 3	ICH and WHO guidelines	6 Hours
A comprehensive training on the integrated implementation of Q8, Q9 and Q10 in pharmaceutical development and manufacturing, regulatory assessment, scale up, implementation into commercial manufacturing operations and GMP-inspection. A specific case study was used demonstrating opportunities when using the combination of Q8, Q9, Q10. A comprehensive training on regulatory aspects (regulatory expectations, dossier preparation, assessment and GMP-inspections) in addition to technical development and manufacturing details		

Unit 4	Dossier preparation in CTD format, eCTD submissions and drug registration	6 Hours
It aims to introduce tools to assist the participants in formulating effective strategies in the development, compilation, and submission of US-compliant eCTDs Market authorization & electronic submission in major markets. Market authorization & submission in ROW markets (GCC, Africa), Dossier preparation in CTD Format, eCTD Submissions, Drug Registration in African Countries, Drug Registration in Gulf countries		

Unit 5	AYUSH Regulatory Affairs and Industry Based Case Studies	8 Hours
Introduction to GMP and Traditional Systems of Medicine, importance of quality control and standardization of ayurvedic, siddha, unani and homeopathic systems of medicines of global acceptability. The source and quality of raw materials, storage, post-harvest handling and manufacturing process and stability studies,GMP requirements for AYUSH (International perspective) **Industry Based Case Studies**		

Regulatory Course Outcomes:

After completion of this course

1) After completion of the programme, participant is expected to have in-depth knowledge and understanding of concept of generic drug and innovator, drug discovery and development , Regulatory strategy, approval process of all regulatory filings in various countries,
2) Students are thorough with the procedures and requirements and assist the participants in formulating effective strategies in the development, compilation, and submission of US-compliant eCTDs
3) This certification focuses on Good Manufacturing Practices (GMP), and to implement sensitive and practical analytical methods for standardization and quality control.
4) Participants may develop interdisciplinary knowledge and gain knowledge in filing process of IND, NDA and ANDA, IMPD, and Investigator Brochure (IB), DMF, US Hatch-Waxmn Act and code of federal regulations (CFR),
5) Participants will be exposed to global developments in the field of traditional systems based drugs; quality, safety and efficacy concern of the international community; and ways and methods to improve their manufacturing processes and techniques to assess quality of their products using modem techniques of analysis.

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EAMCET Code: RBVW | PGECET Code: RBVW1

Certificate course on regulatory affairs

FEEDBACK FORM DAY 1

1.Name of the participant:.... Anand Alekhya
2.Name of the institute:.RBVRR WCOP.....
3.Email address:.Anand111@gmail.com.....
4.How was the content delivered by the speaker..
- ☑ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session
- ☑ excellent
- ☐ very good
- ☐ Good

6.Which type of intellectual property right protects inventions, providing exclusive rights for a limited period?
A) Patent
B) Copyright
C) Trade Mark
D) Design

7.Copyright primarily protects:
A) Inventions and discoveries
B) Literary, artistic, and musical works
C) Brand names and logos
D) Industrial designs

8.A trademark is a distinctive sign that identifies:
A) A product or service
B) A manufacturing process
C) A copyrighted work
D) An invention

9.Geographical Indication (GI) tags are primarily used to:
A) Protect plant varieties
B) Protect traditional knowledge
C) Indicate the origin of goods
D) Register trade secrets

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Certificate course on regulatory affairs

FEEDBACK FORM DAY 1

1.Name of the participant: Buyani Jejasree

2.Name of the institute: RBVRR WICOP

3.Email address: Tejasreeka@gmail.com

4.How was the content delivered by the speaker..

☑ excellent

□ very good

□ Good

5. How do you rate the session

☑ excellent

□ very good

□ Good

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Certificate course on ~~IPR~~ Regulatory Affairs

FEEDBACK FORM DAY 2

1.Name of the participant: D.T Keerthana Sanjitha
2.Name of the institute: RBVRR WCOP
3.Email address:" DT.keerthana.10@gmail.com
4.How was the content delivered by the speaker..
□ excellent
✓ very good
□ Good
5. How do you rate the session
□ excellent
✓ very good
□ Good

6.What is the primary purpose of obtaining a patent?
A) To protect a product's brand name
✓ B) To prevent others from making, using, or selling an invention
C) To register a copyrighted work
D) To secure a trade secret

7.What is one of the primary requirements for a patent to be granted?
a) Novelty
✓ b) Simplicity
c) Popularity
d) Flexibility

8.What is the term used to describe the requirement that an invention must not be obvious to a person skilled in the relevant field?
a) Complexity
b) Ingenuity
✓ c) Non-obviousness
d) Commonality

9.Which of the following is NOT a requirement for patentability?
a) Industrial Application
b) Uniqueness
✓ c) Novelty
d) Non-obviousness

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Certificate course on ~~IPR~~ Regulatory Affairs

FEEDBACK FORM DAY 2

1.Name of the participant: Ganaparaju Vaishnavi
2.Name of the institute: Vaishnavi16@gmail.com
3.Email address: RR.VRRWOCP
4.How was the content delivered by the speaker..
□ excellent
☑ very good
□ Good
5. How do you rate the session
□ excellent
□ very good
☑ Good

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Certificate course on ~~IPR~~ Regulatory Affairs

FEEDBACK FORM DAY 3

1.Name of the participant:.. Lakkakula Sravanthi
2.Name of the institute:.. RBVRRWCOP
3.Email address:..Sravanthi1@gmail.com.
4.How was the content delivered by the speaker..
□ excellent
□ very good
□ Good
5. How do you rate the session
□ excellent
□ very good
□ Good

6.What is the primary purpose of copyright law?
a) To protect ideas
b) To protect tangible expressions of ideas
c) To promote fair competition
d) To prevent creativity
7.Which of the following works is NOT eligible for copyright protection?
a) Literary works
b) Musical compositions
c) Ideas or concepts
d) Computer programs
8.What is the duration of copyright protection for works created by an individual author in most countries?
a) Lifetime of the author plus 50 years
b) Lifetime of the author plus 70 years
c) 50 years from the date of creation
d) 70 years from the date of creation
9.Which of the following rights is NOT typically granted to copyright holders?
a) The right to reproduce the work
b) The right to distribute copies of the work
c) The right to perform the work publicly
d) The right to patent the work.

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Certificate course on IPR & Regulatory Affairs

FEEDBACK FORM DAY 3

1.Name of the participant: Mandhaera Monalisa
2.Name of the institute: RBVRRWCOP
3.Email address: Monalisa@gmail.com
4.How was the content delivered by the speaker..
□ excellent
☑ very good
□ Good
5. How do you rate the session
□ excellent
□ very good
☑ Good

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a) Lifetime of the author plus 50 years
b) Lifetime of the author plus 70 years
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Certificate course on ~~IPR~~ Regulatory Affairs

FEEDBACK FORM DAY 4

1.Name of the participant: Mogulooru Sai Soumya.
2.Name of the institute: RBVRR WCOP
3.Email address: saimm10@gmail.com
4.How was the content delivered by the speaker..
□ excellent
☑ very good
□ Good
5. How do you rate the session
□ excellent
□ very good
☑ Good

6.What is the primary purpose of a trademark?
a) To protect inventions
b) To protect tangible expressions of ideas
c) To identify the source of goods or services
d) To prevent competition

7.Which of the following is NOT a type of trademark?
a) Word mark
b) Logo mark
c) Sound mark
d) Trade secret mark

8.What does the ™ symbol typically indicate when used with a trademark?
a) That the trademark is registered with the government
b) That the trademark is being used with permission
c) That the trademark is pending registration or is claimed by its owner
d) That the trademark is in the public domain

9.Which of the following is NOT a requirement for trademark protection?
a) Originality
b) Distinctiveness
c) Genericness
d) Uniqueness

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Certificate course on ~~IPR~~ & Regulatory Affairs

FEEDBACK FORM DAY 4

1.Name of the participant: Mubassheera Maham
2.Name of the institute: RBVRRW COP
3.Email address:.....Maham212@gmail.com
4.How was the content delivered by the speaker..
□ excellent
□ very good
☑ Good
5. How do you rate the session
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□ Good

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FEEDBACK FORM DAY 5

1..Name of the participant: Nanigandla Vasavi
2.Name of the institute: RBVRRWCOP
3.Email address: Vasavi120@gmail.com
4.How was the content delivered by the speaker..
☑ excellent
□ very good
□ Good
5. How do you rate the session
□ excellent
□ very good
☑ Good

6.What does Layout Design protection refer to?
a) Protection of the aesthetic elements of a website
b) Protection of the arrangement of integrated circuits
c) Protection of architectural designs
d) Protection of typography and font designs

7.What is the procedure for registration of Layout Designs?
a) Filing an application with the World Intellectual Property Organization (WIPO)
b) Filing an application with the International Bureau of Intellectual Property (IBIP)
c) Filing an application with the national intellectual property office
d) Filing an application with the United Nations Office for Outer Space Affairs (UNOOSA)

8.What is the effect of registration of Layout Designs?
a) Immediate protection worldwide
b) Exclusive rights to reproduce and distribute the layout design
c) Protection against any use of the layout design, regardless of intent
d) Protection for a limited time without renewal.

9.What is the term of protection for Layout Designs?
a) 10 years from the date of registration
b) 15 years from the date of registration
c) 20 years from the date of creation
d) Lifetime protection for the creator

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FEEDBACK FORM DAY 5

1..Name of the participant: Narkuda Manisha
2.Name of the institute: RBVRR WCOP
3.Email address: MRmisha 14@gmail.com
4.How was the content delivered by the speaker..
□ excellent
□ very good
□ Good
5. How do you rate the session
□ excellent
□ very good
□ Good

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Certificate course on ~~IPR~~ Regulatory Affairs

FEEDBACK FORM DAY 6

1..Name of the participant: Palle Annie Jeswitha
2.Name of the institute: RBVRRWCOP
3.Email address: Annie@gmail.com
4.How was the content delivered by the speaker..
☑ excellent
□ very good
□ Good
5. How do you rate the session
□ excellent
☑ very good
□ Good

6.What is the main difference between Geographical Indication (GI) and trademarks?
a) GI protects product names, while trademarks protect geographical locations
b) GI indicates the origin of a product, while trademarks indicate the source of goods or services
c) GI protects inventions, while trademarks protect artistic creations
d) GI is only applicable to agricultural products, while trademarks apply to all industries

7.What is the procedure for registering a Geographical Indication in India?
a) Filing an application with the Indian Patent Office
b) Filing an application with the Indian Trademark Registry
c) Filing an application with the Geographical Indications Registry
d) Filing an application with the Indian Copyright Office

8.What is the effect of registration of a Geographical Indication?
a) It grants exclusive rights to use the geographical indication to the registrant
b) It prevents anyone from using the geographical indication, even if they were using it before registration
c) It allows for the geographical indication to be used by anyone without restrictions
d) It provides protection for an unlimited duration

9.What is the term of protection for a registered Geographical Indication in India?
a) 10 years from the date of registration
b) 15 years from the date of registration
c) 20 years from the date of registration
d) Indefinite protection, as long as the conditions are met

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Certificate course on ~~IPR~~ Regulatory Affairs

FEEDBACK FORM DAY 6

1..Name of the participant: Pappireddy Lahari
2.Name of the institute: RBVRR WCOP
3.Email address: Lahari.11@gmail.com
4.How was the content delivered by the speaker..
□ excellent
☑ very good
□ Good
5. How do you rate the session
□ excellent
☑ very good
□ Good

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Recognized under section 2(f) of the UGC Act 1956

EAMCET Code: RBVW | PGECET Code: RBVW1

Two-week certificate course on

"Advance Analytical Techniques"

05th april 2022-15th april 2022

INAUGRAL SESSION:

Mr. M. Soundarapandian,

Assistant Director,

Clearsynth Pvt, ltd,

Hyderabad.

FOR QUERIES:

Contact-

1. D.Sowjanya (9494800885)
2. P. Kavya (8919889059)

Registration details:

Free Registration

Last date to register~~: 03rd april 2020~~

SCHEDULE

DAY	DATE	SPEAKER	TOPIC
DAY 1&2	4rd & 6th April 2022	Mr. M. Soundarapandian, Assistant Director, Clearsynth Pvt, ltd, Hyderabad.	Advancements in Chromatography
Day 3&4	7th & 8th April 2022	Mr. A Venkata Rao Manager, LC-MS Department, Aurobindo Pharma Ltd, Hyderabad.	LC-MS & GC-MS
DAY 5&6	9th & 11th April 2022	Dr. K. Bhavya Sri, Associate Professor, Head, Dept of Pharma Analysis, RBVRR Womens College	Analytical Method Validation
Day 7&8	12 7th & 13th April 2022	Mr. Lalit kumar, Research Associate-IV, Aurobindo LTD, Hderabad	X- Ray Diffraction
Day 9&10	14th & 15th April 2022	Industrial Visit;Mr. B. Sreekanth, AGM, HeadQuality Assurance, Caponex Labs Pvt Ltd, Hyderabad.	Inductive Coupled Plasma with Mass Spectroscopy.

Day 1&2: Introduction to the programme (overview), welcoming principal mam and Speaker on to diase (giving bouquet) ,Inauguration, lightening of light, prayer song by students, principal mam addressing the gathering, giving introduction to speaker, at the end momento and vote of thanks

Day 3&4: welcome to day 3 and 4 Session, welcoming the speaker and introduction to speaker and session starts and at the end momento & vote of thanks.

Day 5&6: welcome to day 5 and 6 Session, welcoming the speaker and introduction to speaker and session starts and at the end momento & vote of thanks.

Day 7&8: welcome to day 7 and 8 Session, welcoming the speaker and introduction to speaker and session starts and at the end momento & vote of thanks.

Day 9 &10: welcome to day 9 and 10 Session, welcoming the Guest and introduction and session starts with industrial visit

Value Added Course		
Course: Advance Analytical Techniques		
Code:AATCC004	**Credits:**2	**Total No.of Hours**:36

The aim of conducting this certificate course is to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing in Analytical and Bioanlytical laboratories

Objectives:-Objectives:- The Course Program in Advance Analytical Techniques is designed to provide participants with a comprehensive understanding of Analytical tools available and their advancements for the analysis of pharmaceutical products

SYLLABUS

Unit 1	**Spectroscopic Techniques and their Advancements**	**8 Hours**
NMR Spectroscopy:-Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double Resonance, Spin Spin and spin lattice relaxation phenomenon. 1D- NMR and 13CNMR. **Mass Spectroscopy:**-Principle, theory, instrumentation of mass spectrometry, different types of Ionization Techniques like Electron Impact, Chemical, Field, FAB and MALD, APCI, ESI, APPI, Mass fragmentation mechanism and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry.		
Unit 2	**Chromatographic Techniques and their Advancements**	**6 Hours**
Principle, Instrumentation and Pharmaceutical applications:- HPLC,UPLC, Nano LC, HILIC, GC, SFC		

Unit 3	Hyphenated Techniques	6 Hours
Principle, Instrumentation, Interfaces, Pharmaceutical applications:- LC-MS,GC-MS,ICP-MS, Tandem Mass systems		

Unit 4	X-ray Crystallography	4 Hours
Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction		

Unit 5	Qualification of Analytical Instruments	6 Hours
NMR, MS,HPLC,UPLC,X-ray diffraction		

Advance Analytical Techniques Course Outcomes:

After completion of this course

1) The students will get adequate knowledge on recent advancement and basics of NMR and MS.
2) Students will know the principle and advanced applications of Nano LC, UPLC and HILIC.
3) Students aware of different hyphenated techniques like ICP-MS, LC-MS GC-MS etc.
4) Students are permitted to know in detail about the X- ray crystallography methods and application.
5) Students are familiar with the methods used for calibration and validations of Instruments

College Code: 1706

RBVRR WOMEN'S COLLEGE OF PHARMACY

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Recognized under Section 2(f) of the UGC Act 1956
EAMCET Code: RBVW | PGECET Code: RBVW1
www.rbvrrwcp.org | Email: rbvrrwcoph@rediffmail.com & rbvrrwcp2006@gmail.com

CERTIFICATE COURSE ON
QUALITY BY DESIGN IN FORMULATION DEVELOPMENT

7th-11th April,2022
RBVRR Womens college of pharmacy
SEMINAR HALL

INAUGURAL SESSION:
Dr. A. Krishna Sailaja
Professor & Head, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy

Patron
Prof. K. Muthyam Reddy
Hon. Secretary cum correspondent
RBVRR Women's College of pharmacy

CONVENER
Prof. M. Sumakanth
Principal
RBVRR Women's College of pharmacy

SPEAKERS	DATE & TIME
1. Dr. A. Krishna Sailaja Professor & Head, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy	7TH April 2022 & 8TH April 2022 at 2.00 pm
2. Dr. G. Uma Rani Associate Professor, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy	9TH April 2022 & 10TH April 2022 at 2.00 pm
3. Dr. K.V. Ratnamala Associate Professor, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy	11TH April 2022 & 12TH April 2022 at 2.00 pm

Value Added Course		
Course: Certificate course on quality by design in formulation development		
Code: QBD C001	**Credits:** 2	**Total No. of Hours** : 36

This certification will provide insight into the key principles of QbD covering quality risk management and formal experimental design. The certification is intended as continuing professional development (CPD) for professionals in the pharmaceutical industry, particularly in production, regulatory affairs and quality functions. The certification will offer an excellent introduction for those less familiar with QbD and provide new ideas on how to further implement the QbD concept in research. The case study based approach in certification programme is designed for working professionals in full time employment who want to update their knowledge and gain required skills and attitude in the area in order to become a certified GMP professional in the domain. This certification is also beneficial for professionals from different streams to help them intensify their knowledge. This is an advanced certification having rigorous case studies based methodology throughout the duration.

Objectives:- Objectives:- The Course Program in Quality by design in formulation development is designed to provide participants with a comprehensive understanding of the various aspects of QbD, such as Quallity test product performance, Critical quality attributes, Critical process parameters. QbD tools and studies include prior knowledge, risk assessment, mechanistic models, design of experiments (DoE) and data analysis, and process analytical technology (PAT). including patents, copyrights, trademarks, trade secrets, and Industrial Designs

SYLLABUS

Unit 1	**Overview of QbD**	**8 Hours**

Introduction and the need for QbD in formulation development- objectives of QbD, Various components of QbD such as Quality test product performance, Identifcation of critical process parameters. Ctitical quality attributes, Critical manufacturing attributes in formulation development, risk assessment, risk management. The concept of Design of experiments, Factorial design in formulation optimization. How the DoE fit into the QbD concept.

Unit 2	**Introduction to QTPP**	**8 Hours**

Quality Target Product Profile that Identifies the Critical Quality Attributes of the Drug Product QTPP is a prospective summary of the quality characteristics of a drug product that ideally will be achieved to ensure the desired quality, taking into account safety and efficacy of the drug product. QTPP forms the basis of design for the development of the product. Considerations for inclusion in the QTPP could include the following Intended use in a clinical setting, route of administration, dosage form, and delivery system(s)Dosage strength(s),Container closure system, Therapeutic moiety release or delivery and attributes affecting pharmacokinetic characteristics (*e.g.*, dissolution and aerodynamic performance) appropriate to the drug product dosage form being developed, Drug product quality criteria (*e.g.*, sterility, purity, stability, and drug release) appropriate for the intended marketed product

Unit 3	QbD Methodology and its Implementation	**6 Hours**

Elements of QbD, Importance of Critical Process parameters in formulation optimization, Critical Material attributes and its significance in optimization process. Selection of Critical quality attributes in various dosage forms. Regulatory and Industry views on QbD, Scientifically based examples of application of QbD.

Unit 4	ICH Q8 Guidelines and factorial design	**8 Hours**

Introduction to ICHQ8 Guidelines, risk management and risk analysis.Concept of optimization, optimization parameters, Screening techniques and optimization techniques. Factorial design, 2 level and 3 level factorial design, Formulation of various dosage forms such as microemulsions, Nanoparticles by applying factorial design. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Population modeling sensitivity analyis

Unit 5	Controlling strategy and product life cycle management	**6 Hours**

Design

Introduction to ICH Q10 , A control strategy for input material controls, process controls and monitoring, design space around individual or multiple unit operations, and/or final product specifications which ensure consistent quality. Testing of finished drug products for quality by assessing their specifications. A QbD based control strategy for various dosage forms such as tablets, capsules and novel drug delivery systems

QbD Course Outcomes:

After completion of this course

1) The students will get adequate knowledge on concepts and applications of QbD, objectives, the QbD approach in formulation development
2) Students are thorough with the implementation of QbD in formulation development, method development, and manufacturing
3) Students Gain knowledge regarding identification of Critical Process parameters, Critical quality attributes and critical material attributes.
4) Participants may develop knowledge regarding risk identification, risk analysis and risk reduction
5) Participants develop knowledge on QbD based control strategy for various dosage forms as tablets, capsules and novel drug delivery systems

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Certificate course on quality by design in formulation development

FEEDBACK FORM DAY 1

1.Name of the participant: G. Hareshitha
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4.How was the content delivered by the speaker..
□ excellent
✓ very good
□ Good
5. How do you rate the session
□ excellent
□ very good
✓ Good

6.What is the primary objective of Quality by Design (QbD) in pharmaceutical formulation development?

✓ A) Maximizing production efficiency

B) Minimizing regulatory scrutiny

C) Enhancing product quality and performance

D) Reducing research and development costs

7.Which regulatory agency emphasizes the implementation of Quality by Design (QbD) principles in pharmaceutical development?

A) Food and Drug Administration (FDA)

✓ B) European Medicines Agency (EMA)

C) World Health Organization (WHO)

D) All of the above

8.What is the primary focus of QbD in the pharmaceutical industry?

A) Speeding up the development process

✓ B) Achieving maximum product yield

C) Ensuring consistent product quality

D) Reducing manufacturing costs

9.In QbD, what does the acronym CPP stand for?

✓ A) Critical Pathway Parameters

B) Critical Production Processes

C) Critical Product Properties

D) Critical Process Parameters

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Certificate course on quality by design in formulation development

FEEDBACK FORM DAY 1

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□ excellent
□ very good
☑ Good
5. How do you rate the session
□ excellent
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Certificate course on quality by design in formulation development

FEEDBACK FORM DAY 2

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□ excellent
✓ very good
□ Good
5. How do you rate the session
□ excellent
✓ very good
□ Good

6. What does QTPP stand for in pharmaceutical development?
A) Quality Testing Product Protocol
✓ B) Quality Target Product Profile
C) Quantitative Testing Process Plan
D) Quality Target Process Parameters

7.Which of the following best describes the purpose of QTPP?

A) To define the quality control procedures for manufacturing
B) To establish the target price for the pharmaceutical product
✓ C) To identify the critical quality attributes (CQAs) of the product
D) To specify the timeline for regulatory submissions

8.Who is primarily responsible for defining the QTPP?

✓ A) Regulatory authorities
B) Marketing department
C) Quality control team
D) Cross-functional development team

9.What role does the QTPP play in the pharmaceutical development process?

A) It guides formulation optimization techniques.
✓ B) It determines the patentability of the product.
C) It dictates the manufacturing location.
D) It sets the schedule for clinical trials.

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Certificate course on quality by design in formulation development

FEEDBACK FORM DAY 2

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4.How was the content delivered by the speaker.

- ✓ excellent
- □ very good
- □ Good

5. How do you rate the session

- ✓ excellent
- □ very good
- □ Good

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Certificate course on quality by design in formulation development

FEEDBACK FORM DAY 3

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□ excellent
☑ very good
□ Good
5. How do you rate the session
□ excellent
☑ very good
□ Good

6.What is the primary objective of the Quality by Design (QbD) methodology in pharmaceutical development?
A) Maximizing production efficiency
B) Minimizing regulatory scrutiny
C) Enhancing product quality and performance
D) Reducing research and development costs

7.Which of the following is NOT a key component of QbD methodology?
A) Design of Experiments (DoE)
B) Risk assessment and management
C) Trial-and-error experimentation
D) Quality risk management

8.What is the role of Design of Experiments (DoE) in QbD implementation?
A) To reduce the need for experimentation
B) To explore the design space and optimize formulations
C) To eliminate the need for risk assessment
D) To establish regulatory compliance

9.Which regulatory agency emphasizes the use of QbD in pharmaceutical development?
A) World Health Organization (WHO)
B) European Medicines Agency (EMA)
C) International Conference on Harmonization (ICH)
D) Food and Drug Administration (FDA)

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- ☑ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session
- ☑ excellent
- ☐ very good
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Certificate course on quality by design in formulation development

FEEDBACK FORM DAY 4

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4.How was the content delivered by the speaker..
☑ excellent
☐ very good
☐ Good
5. How do you rate the session
☑ excellent
☐ very good
☐ Good
6.What is the primary purpose of ICH Q8 guidelines in pharmaceutical development?

A) To establish quality control procedures

B) To optimize manufacturing processes

C) To facilitate regulatory submissions

D) To promote the implementation of Quality by Design (QbD) principles

7.Which of the following is NOT a key element of the ICH Q8 guidelines?

A) Quality Target Product Profile (QTPP)

B) Design Space

C) Critical Quality Attributes (CQAs)

D) Traditional trial-and-error experimentation

8.What is the main advantage of using factorial design in pharmaceutical development?

A) It reduces the need for experimentation

B) It allows for the exploration of multiple factors simultaneously

C) It simplifies regulatory submissions

D) It eliminates the need for risk assessment

9.In factorial design, what does each factor represent?

A) A critical quality attribute (CQA)

B) A critical process parameter (CPP)

C) An independent variable being studied

D) A dependent variable being optimized

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Certificate course on quality by design in formulation development

FEEDBACK FORM DAY 4

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4.How was the content delivered by the speaker..
□ excellent
☑ very good
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FEEDBACK FORM DAY 5

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4.How was the content delivered by the speaker:
- ☑ excellent
- □ very good
- □ Good

5. How do you rate the session
- ☑ excellent
- □ very good
- □ Good

6.What is the primary objective of controlling strategy in product life cycle management?

A) Maximizing production efficiency

B) Minimizing regulatory scrutiny

C) Ensuring consistent product quality

D) Reducing research and development costs

7.Which of the following is NOT a key aspect of controlling strategy?

A) Monitoring process parameters

B) Implementing corrective actions

C) Maximizing profit margins

D) Conducting risk assessments

8.What role does statistical process control (SPC) play in controlling strategy?

A) Identifying potential market opportunities

B) Monitoring and controlling manufacturing processes

C) Determining product pricing strategies

D) Conducting market research

9.How does product life cycle management contribute to controlling strategy?

A) By extending the patent life of the product

B) By optimizing production schedules

C) By identifying opportunities for product improvement

D) By reducing the need for regulatory compliance

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FEEDBACK FORM DAY 5

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2.Name of the institute: RBVRRWCOP

3.Email address: Samiksha@gmail.com

4.How was the content delivered by the speaker..

□ excellent

□ very good

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5. How do you rate the session

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Certificate course on quality by design in formulation development

FEEDBACK FORM DAY 6

1.Name of the participant: Cyhooli Indu
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3.Email address: indu@gmail.com
4.How was the content delivered by the speaker..
□ excellent
☑ very good
□ Good
5. How do you rate the session
□ excellent
☑ very good
□ Good

6 What does ICH Q10 stand for?
A) International Conference on Harmonization Quality 10
B) Integrated Communication Hub Question 10
C) International Council for Harmonization Quality 10
D) Integrated Quality Management.
7.What is the primary objective of ICH Q10?
A) To develop new pharmaceutical products
B) To establish guidelines for clinical trials
C) To provide guidance on quality management systems for pharmaceutical manufacturing
D) To regulate drug pricing.
8.Which of the following is NOT a key element of the ICH Q10 model?
A) Quality risk management
B) Quality control
C) Continual improvement
D) Process performance and product quality monitoring system
9.What is the purpose of the "Pharmaceutical Quality System" in ICH Q10?
A) To ensure compliance with regulatory agencies
B) To identify and mitigate risks to product quality
C) To establish pricing strategies for pharmaceutical products
D) To conduct market analysis

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Certificate course on quality by design in formulation development

FEEDBACK FORM DAY 6

1.Name of the participant: Pentela Mohana Lakshmi
2.Name of the institute: RBVRR W.C.O.P
3.Email address: lakshmi40506@gmail.com
4.How was the content delivered by the speaker..
□ excellent
☑ very good
□ Good
5. How do you rate the session
□ excellent
☑ very good
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College Code: 1706

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Recognized under Section 2(f) of the UGC Act 1956

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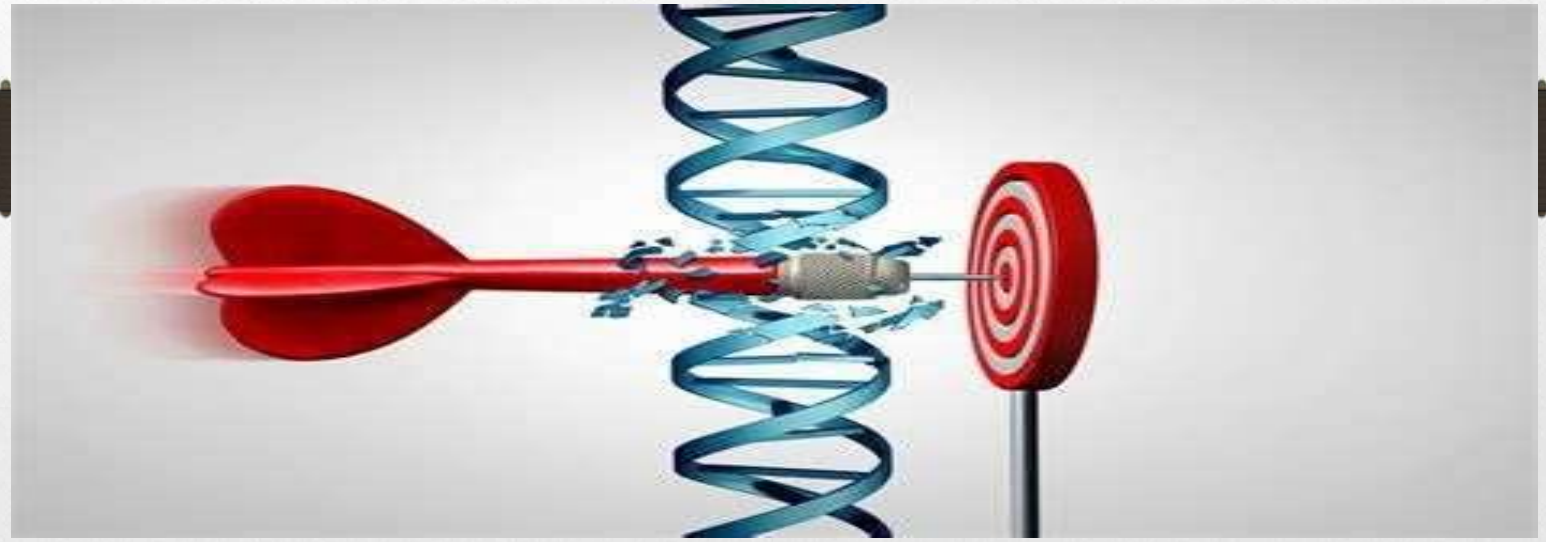
CERTIFICATE COURSE on

TARGETED DRUG DELIVERY SYSTEM



Date and Time:
6TH - 11TH JUNE ,2022
RBVRR Womens college of pharmacy - SEMINAR HALL

INAUGURAL SESSION:
Dr. A. Krishna Shailaja
Prof. Head of Dept of Pharmaceutics, RBVRR Womens college of pharmacy

Patron
Prof. K. Muthyam Reddy
Hon. Secretary cum correspondent
RBVRR Women's College of pharmacy

CONVENER
Prof. M. Sumakanth
Principal
RBVRR Women's College of pharmacy

SPEAKERS	DATE & TIME
1. Dr. A. Krishna Sailaja Professor & Head, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy	6TH June 2022 & 7th June 2022 at 2.00 pm
2. Dr. K.V. Ratnamala Associate Professor, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy	8TH June 2022 & 9th June 2022 at 2.00 pm
3. Dr. Shyam Lal M Associate Professor, Department of Animal Biology, School of Life Sciences, University of Hyderabad	10TH June 2022 & 11th June 2022 at 2.00 pm

Value Added Course		
Course: Certificate course on targeted drug delivery systems		
Code: TDS C001	**Credits:** 2	**Total No. of Hours** : 36

This certification will provide insight into the various approaches for development of novel drug delivery systems. It helps the scientist to understand the criteria for selection of drugs and polymers for the development of delivering system. It explains about the formulation and evaluation of Novel drug delivery systems

Objectives:- Objectives:- The Course Program in on targeted drug delivery systems is designed to provide participants with a comprehensive understanding of the targeted drug delivery systems such as nanoparticles, micropartcles. This course explains about recent advancements in Transdermal drug delivery systems such as iontophoresis and sonophoresis techniques. It helps the participants to have in depth knowledge on different types of vesicular drug delivery systems

SYLLABUS

Unit 1	**Overview of targeted drug delivery**	**8 Hours**
Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.		

Unit 2	**Particulate drug delivery systems**	**8 Hours**
Introduction to nanoparticles, Different techniques for the preparation of nanoparticles, Evaluation of nanoparticles, Various applications of nanoparticles, Introduction to microspheres and Microcapsules. Advantages and limitations of microspheres and microcapsules. Various techniques for the formulation and evaluation of microspheres, Microballons- A novel carrier for drug delivery		

Different techniques for the fotmulation of microcapsules, Evaluation and applications of microcapsules

Unit 3	**Vesicular drug delivery systems**	**8 Hours**
Introduction to vesicular drug delivery systems. Classification and general applications of vesicular drug delivery systems. Introduction to liposomes. Different techniques, evaluation procedures for the formulation of liposomes. Niosomes, classification and evaluation Formulation and evaluation of ethosomes, transferosomes, invasomes, electrosomes, aquasomes, cubosomes. Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.Recent advancements in Transdermal drug delivery systems		

Unit 4	**Protein and peptide drug delivery**	**6 Hours**
Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.		

Unit 5	**Gene therapy**	**6 Hours**
Introduction to gene therapy. Exvivo and invivo gene therapy. Potential target diseases for gene therapy .Gene expression systems. Vectors for gene delivery. Virosomes a novel carrier Liposomal gene delivery systems. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.		

TDDS Course Outcomes:

After completion of this course

1) The students will get adequate knowledge on concepts and applications of nanoparticle drug delivery systems in brain and cancer targeting
2) Students are thorough with the procedures and applications of different vesicular drug delivery systems such as liposomes and niosomes
3) Students Gain insights into the gene delivery procedures and potential targets for gene delivery
4) Participants may develop interdisciplinary knowledge by understating the concept of protein and peptde drug delivery systems
5) Participants develop knowledge on recent advancements in Transdermal drug delivery systems and permeation enhancers applications

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Certificate course on Targeted Drug Delivery Systems

FEEDBACK FORM DAY 1

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2.Name of the institute: RBVRRWCP
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4.How was the content delivered by the speaker..
- ☑ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session
- ☐ excellent
- ☑ very good
- ☐ Good

6.Which of the following best describes targeted drug delivery?
A) Administering drugs without any specific target
B) Directing drugs to a specific site in the body
C) Randomly distributing drugs throughout the body
D) Increasing drug dosage without considering the target

7.What is the primary goal of targeted drug delivery?
A) Maximizing side effects
B) Minimizing drug effectiveness
C) Enhancing drug specificity and efficacy
D) Randomly distributing drugs in the body

8 Which of the following is NOT a potential benefit of targeted drug delivery?
A) Reduced side effects
B) Increased drug concentration in diseased tissues
C) Faster elimination of drugs from the body
D) Improved therapeutic outcomes

9.Which of the following is a common targeting strategy in drug delivery?
A) Administering drugs intravenously
B) Attaching drugs to nanoparticles
C) Delivering drugs orally
D) Injecting drugs into muscles

10 Which of the following is an example of an active targeting mechanism in drug delivery?
A) Passive diffusion of drugs across cell membranes
B) Coating drug particles with a biocompatible polymer
C) Attaching a ligand to a drug carrier for receptor-mediated uptake
D) Releasing drugs slowly over time from a depot injection.

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Certificate course on Targeted Drug Delivery Systems

FEEDBACK FORM DAY 1

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☐ very good

☐ Good

5. How do you rate the session

☐ excellent

☑ very good

☐ Good

6.Which of the following best describes targeted drug delivery?

A) Administering drugs without any specific target

B) Directing drugs to a specific site in the body

C) Randomly distributing drugs throughout the body

D) Increasing drug dosage without considering the target

7.What is the primary goal of targeted drug delivery?

A) Maximizing side effects

B) Minimizing drug effectiveness

C) Enhancing drug specificity and efficacy

D) Randomly distributing drugs in the body

8 Which of the following is NOT a potential benefit of targeted drug delivery?

A) Reduced side effects

B) Increased drug concentration in diseased tissues

C) Faster elimination of drugs from the body

D) Improved therapeutic outcomes

9.Which of the following is a common targeting strategy in drug delivery?

A) Administering drugs intravenously

B) Attaching drugs to nanoparticles

C) Delivering drugs orally

D) Injecting drugs into muscles

10.Which of the following is an example of an active targeting mechanism in drug delivery?

A) Passive diffusion of drugs across cell membranes

B) Coating drug particles with a biocompatible polymer

C) Attaching a ligand to a drug carrier for receptor-mediated uptake

D) Releasing drugs slowly over time from a depot injection.

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Certificate course on Targeted Drug Delivery Systems

FEEDBACK FORM DAY 2

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4.How was the content delivered by the speaker..

- ☑ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session

- ☐ excellent
- ☐ very good
- ☑ Good

6.Which of the following is a common challenge in delivering drugs to brain tumors?

A) Rapid drug metabolism

B) Limited blood-brain barrier penetration

C) High tissue permeability

D) Excessive drug accumulation

7.What is the primary function of the blood-brain barrier (BBB) in drug delivery to the brain?

A) Preventing drug absorption

B) Facilitating drug distribution

C) Protecting the brain from toxins

D) Enhancing drug metabolism

8.Which of the following strategies is commonly used to overcome the blood-brain barrier for drug delivery?

A) Increasing drug hydrophobicity

B) Decreasing drug lipophilicity

C) Using receptor-mediated transcytosis

D) Avoiding drug modification

9.Which of the following imaging techniques is commonly utilized for brain tumor targeting?

A) X-ray

B) Ultrasound

C) Magnetic resonance imaging (MRI)

D) Electroencephalography (EEG)

10 What is the significance of targeting ligands in brain tumor drug delivery?

A) They decrease drug stability

B) They inhibit drug diffusion

C) They facilitate drug transport across the blood-brain barrier

D) They increase drug excretion from the brain

C) Reduced systemic toxicity

D) Prolonged drug elimination from the brain .

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4.How was the content delivered by the speaker..

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FEEDBACK FORM DAY 3

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4.How was the content delivered by the speaker..
- ☐ excellent
- ☐ very good
- ☑ Good

5. How do you rate the session
- ☐ excellent
- ☑ very good
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6.What are particulate drug delivery systems primarily composed of?
A) Lipids and proteins
B) Polymers and nanoparticles
C) DNA and RNA
D) Sugars and vitamins.

7.Which of the following is a common example of a particulate drug delivery system?
A) Antibiotics
B) Antacids
C) Liposomes
D) Antihistamines.

8.What is the primary advantage of using particulate drug delivery systems?
A) Rapid drug clearance from the body
B) Limited drug stability
C) Enhanced drug solubility
D) Controlled drug release and targeting.

9.Which of the following is a characteristic feature of nanoparticles in drug delivery systems?
A) Large size
B) Rapid degradation
C) High surface area-to-volume ratio
D) Low drug loading capacity.

10.How do particulate drug delivery systems facilitate targeted drug delivery?
A) By increasing drug metabolism
B) By decreasing drug specificity
C) By enabling passive or active targeting mechanisms
D) By accelerating drug excretion.

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- ☐ excellent
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FEEDBACK FORM DAY 4

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4.How was the content delivered by the speaker..
□ excellent
□ very good
□ Good
5. How do you rate the session
□ excellent
□ very good
□ Good

6.What is the primary component of niosomes?
A) Phospholipids
B) Cholesterol
C) Non-ionic surfactants
D) Ethanol

7.Which classification system is commonly used for niosomes?
A) Size-based classification
B) Composition-based classification
C) Charge-based classification
D) All of the above

8.Which evaluation parameter is not commonly used for niosomes?
A) Size and size distribution
B) Entrapment efficiency
C) Surface charge
D) Gelation capacity

9.Ethosomes are primarily composed of:
A) Phospholipids
B) Cholesterol
C) Ethanol
D) Non-ionic surfactants.

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4.How was the content delivered by the speaker..

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4.How was the content delivered by the speaker..

- ☐ excellent
- ☑ very good
- ☐ Good

5. How do you rate the session

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- ☐ very good
- ☐ Good

6.Which of the following is a common challenge in the delivery of proteins and macromolecules?

A) Rapid degradation
B) Poor solubility
C) Low molecular weight
D) High stability

7.Which type of delivery system is commonly used for the controlled release of proteins?

A) Liposomes
B) Microspheres
C) Micelles
D) Emulsions

8.The encapsulation of proteins within liposomes helps to:

A) Increase protein stability
B) Decrease protein bioavailability
C) Enhance protein degradation
D) Reduce protein solubility

9.Which evaluation parameter is critical for assessing the efficacy of protein delivery systems?

A) Particle size
B) Drug loading capacity
C) Hemolytic activity
D) Protein release kinetics

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4.How was the content delivered by the speaker..

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FEEDBACK FORM DAY 6

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4.How was the content delivered by the speaker..
- ☑ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session
- ☐ excellent
- ☐ very good
- ☑ Good

6.Which of the following is not a common vector for gene delivery?
A) Viruses
B) Liposomes
C) Plasmids
D) Polymer nanoparticles

7.Which vector is known for its high transduction efficiency but poses safety concerns due to immunogenicity?
A) Adenovirus
B) Plasmid DNA
C) Liposomes
D) Polymer nanoparticles

8.Virosomes are derived from:
A) Retroviruses
B) Inactivated viruses
C) Bacterial vectors
D) Plant viruses

9.Virosomes are unique carriers for gene delivery because they:
A) Are highly immunogenic
B) Can replicate in host cells
C) Mimic viral structure and fusion properties
D) Have low transduction efficiency

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FEEDBACK FORM DAY 6

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3.Email address: lalithalahanika@gmail.com
4.How was the content delivered by the speaker..
☑ excellent
☐ very good
☐ Good
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