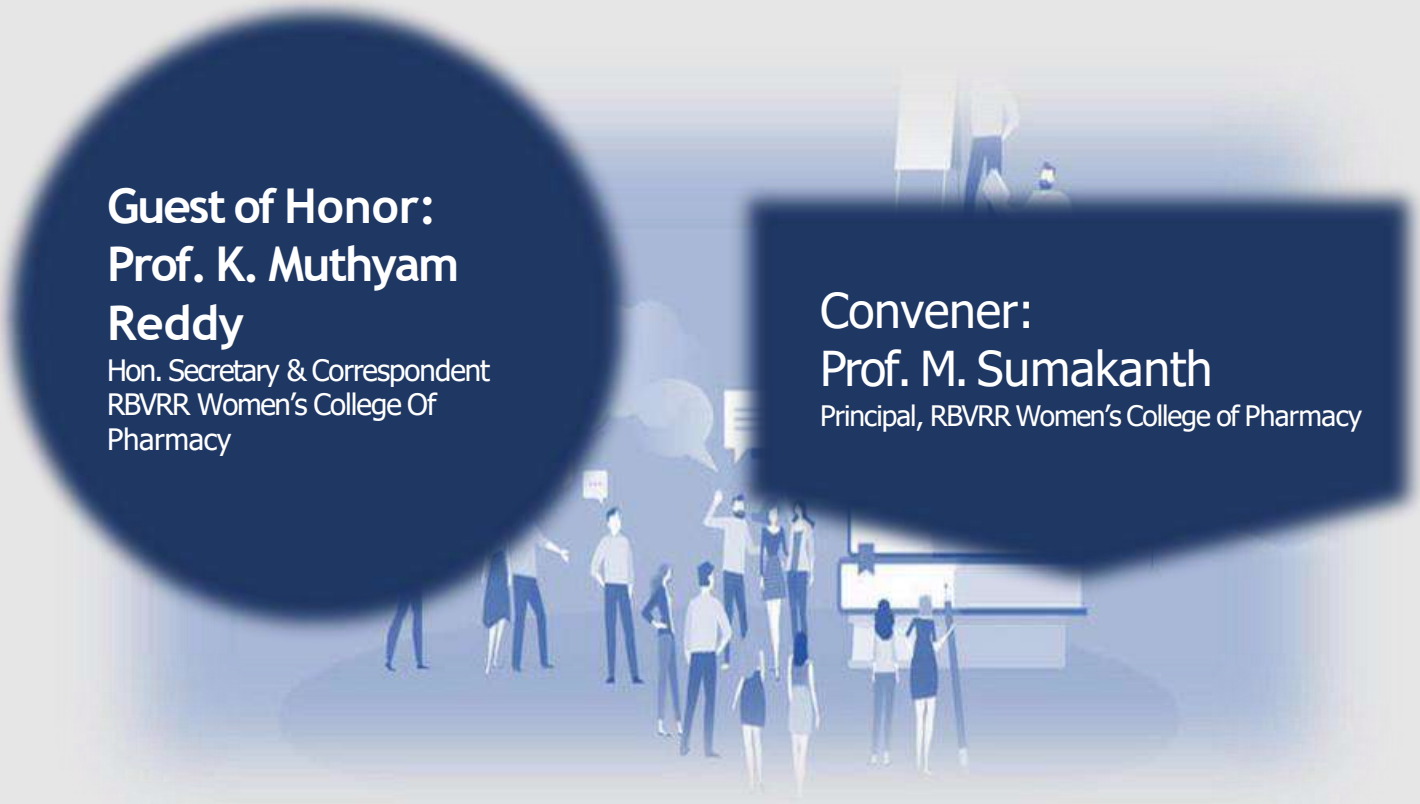
College Code: 1706

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

Invites you to the
Certificate Course on

''PROFESSIONAL DEVELOPMENT''

2nd July 2022, 10:30 AM



Guest of Honor:
Prof. K. Muthyam Reddy
Hon. Secretary & Correspondent
RBVRR Women's College Of Pharmacy

Convener:
Prof. M. Sumakanth
Principal, RBVRR Women's College of Pharmacy

Programme Schedule

DATE	SPEAKER
2nd & 4thJul 2022	**Prof. Purushottam Reddy** Retd. Professor Osmania University
5th & 6th Jul 2022	**Ramakrishna Sistla** Senior Scientist IICT
7th& 8th Jul 2022	**Prof. M. Sumakanth** Principal RBVRR Women's College Of Pharmacy
9th Jul 2022	**P. Anuradha Reddy**

Value Added Course		
Course: PROFESSIONAL DEVELOPMENT		
Code: PDC005	**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. Better Communication

   By developing communication skills, students can improve their relationships with peers, professors, and future employers.

3. 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.

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.
Setting Goals:
Goals and Targets, Setting SMART Goals, Your Own SMART Goals
Planning Tips and Tricks:
Planning Tools
Setting Priorities
Prioritizing Your Tasks
Your To-Do List
Managing Interruptions and Distractions
Tips for Controlling Disruptions

Unit 2	Advanced Writing Skills	7 Hours

The C's of Writing:
Writing Clearly, Writing Concisely, Making Connections ,Writing Correctly, Choosing Your Sources
Writing Mechanics:
Building Paragraphs, Proper Paragraphs, More on Paragraphs, Making Connections
Dealing with Specific Requests:
Types of Letters, Keeping it Real
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

Giving Presentations: Dealing with Fears, planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

Group Discussion: Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

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

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

Theories of Leadership: Trait Theory, Behavioural theories, Contingency Theories, Transactional Theories and Transformational Leadership Theory

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. Measureme 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 sa size 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 a 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 criticalappreciation

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TWO WEEK CERTIFICATE COURSE ON

"ADVANCE ANALYTICAL TECHNIQUES"

APRIL 3rd to 13th 2023

INAUGURAL SESSION :

Mr.A.Venkata Rao

Manager, LC-MS Department, Aurobindo Pharma Ltd, Hyderabad

Free Registration
Last date
30 th March, 2023
Link for Registration
https://forms.gle/nMkAcgS76xsNHEG8A

For Queries:
Contact:

P. Kavya-
891 9889059
D. Sowjanya-
9494800885

Click Here

INSTITUTION'S INNOVATION COUNCIL (Ministry of HRD Initiative)

College Code: 1706

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

Value Added Course		
Course: Advance Analytical Techniques		
Code:AATCC005	**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

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TWO WEEK CERTIFICATE COURSE ON
"ADVANCE ANALYTICAL TECHNIQUES"

October 3rd - 13 th, 2023

Program schedule:

Day	Date	Speaker	Topic
Day 1	Tuesday; 3rd April 2023	Mr. A Venkata Rao Manager, LC-MS Department, Aurobindo Pharma Ltd, Hyderabad.	LC-MS & GC-MS
Day 2	Wednesday 4th April 2023	Dr. G . Jithender Reddy, Senior Scientist, NMR Division, CSIR-IICT, Tarnaka, Hyderabad.	NMR Spectroscopic Techniques and their advancements
Day 3	Thursday; 5th April 2023	Dr. K. Bhavya Sri, Associate Professor, Head, Dept of Pharma Analysis, RBVRR Womens College of Pharmacy, Hyderabad	Analytical Method Validation
Day 4	Friday; 6th April 2023	Industrial Visit;Mr. B . Sreekanth, AGM, Head-Quality Assurance, Caponex Labs Pvt Ltd, Hyderabad.	Qualification of Analytical instruments (NMR, MS, HPLC, UPLC & X-RAY Diffraction)
Day 5	Saturday; 7th April 2023	Dr. G. Chandrasekhar Reddy, SeniorScientific Manager, Analytical Research and Development, Aragen life Sciences, Hyderabad.	Super Critical Fluid Chromatography
Day 6	Monday; 9th April 2023	Mr. Y. Ramakoti Reddy, Technical Head, Avasya Labs, Hyderabad.	Mass Spectroscopy
Day 7	Tuesday; 10th Apr 2023 il	Mr. Lalit kumar, Research Associate-IV, Aurobindo LTD, Hderabad.	Inductive Coupled Plasma with Mass Spectroscopy.
Day 8	Wednesday;	Mr. R. Jagadeesh,	

	11thApril 2023	Scientist-IV, FAR&D, Aurobindo Pharma Ltd, Hyderabad.	X- Ray Diffraction
Day 9	Thursday; 12thApril 2023	Industrial Visit, Mr. B. Sreekanth, AGM, Head-Quality Assurance, Caponex Labs Pvt Ltd, Hyderabad.	Qualification of Analytical instruments (NMR, MS, HPLC, UPLC & X-RAY Diffraction)
Day 10	Friday; 13th April 2023	Mr. M. Soundarapandian, Assistant Director, Clearsynth Pvt, ltd, Hyderabad.	Advancements in Chromatography

Day 1: 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 2: welcome to day 2 Session, welcoming the speaker and introduction to speaker and session starts and at the end momento & vote of thanks.

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

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

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

Day 6: Industrial visit

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

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

Day 9: Industrial Visit.

Day 10: welcome to day 10 Session, welcoming the speaker and introduction to speaker and session starts and at the end momento & Valedictory.

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PV CERTIFICATE COURSE

2023

A 10-DAY CERTIFICATE COURSE IN PHARMACOVIGILANCE

Registration Link:

link:https://forms.gle/vQKyLLUskq28YWpZ8

Registration Fee - Rs 1500/-

COURSE BENEFITS

- Intensive 30-Hour Training by Industry Experts
- Hands-on Real-Time Practice Completion Certificate
- Career Guidance and Resume Writing Skills

In Association With Our Training Partner

CLINOSOL™

A CLINICAL RESEARCH CAREER CATALYST

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:

1. B.Pharmacy (100seats)
2. Pharm.D (32)
3. 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.

OBJECTIVE:

This course is exclusively designed for B.Pharm, Pharm D, M. Pharm students and faculties to embrace the practical aspects of Pharmacovigilance.

Duration: 36 Hrs

SCHEDULE AND SYLLABUS

Date	Module #	Topic	Speaker	Duration
30-04-2023	Module - 1	Introduction to Clinical Research and Pharmacovigilance	C.S Mujeebuddin	3 Hours
1-05-2023	Module - 2	Case Processing Workflow	C.S Mujeebuddin	3 Hours
02-05-2023	Module - 3	Narrative Wrting	C.S Mujeebuddin	3 Hours
03-05-2023	Module - 4	Medical Coding in PV	C.S Mujeebuddin	3 Hours
04-05-2023	Module - 5	Causality Assessment	Dr. Mitesh Reddy	4 Hours
05-05-2023	Module - 6	Expidited Reporting	Dr. Mitesh Reddy	5 Hours
Sunday				
06-05-2023	Module - 7	Signal Management	Uma Priya	4 Hours
07-05-2023	Module - 8	Aggregate Reporting	Uma Priya	4 Hours
08-05-2023	Module - 9	Hands on Exercises	Uma Priya	5 Hours
09-05-2023	Module - 10	Hands on Exercises and Assessment	Uma Priya	5 Hours

Facilitators

MR. C.S MUJEEBUDDIN
Founder & CEO,
ClinoSol Research Pvt. Ltd.

UMA PRIYA
Co-Founder & Director,
ClinoSol Research Pvt. Ltd.

DR. D.MITESH REDDY
Head of Training,
ClinoSol Research Pvt. Ltd.

Dr. SRIDHAR YESHAMAINA
Head , Global Pharmacovigilance, Hetero

RAJA VASUDEV A,
Head , Pharmacovigilance at Indoco Remedies

SCAN THE QR CODE TO GET REGISTERED!!

Last Date to Register
28th October, 2023

Program Coordinator Details:

Dr. J. Archana
Professor and Head, Department of Pharmacology
RBVRR Womens' College of Pharmacy Barkatpura, Hyderabad
For Queries Contact
Dr J Archana- 9985697677
Mrs. M. Kavitha - 9010513142
Ms. Fatima Umaira - 9392301704

Training Partner:
ClinoSol Research Private Limited
India | Canada

An Intensive Practice based Certification Course on		
PHARMACOVIGILANCE		
Code:PVCC005	Credits: 2	Course duration:36 Hrs

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**	**3hrs**
Introduction to Clinical Research and Pharmacovigilance. Historical perspectives and Current Status of pharmacovigilance. National and international aspects of PV .		
Module II	**Case Processing Workflow**	**3hrs**
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	**Narrative Writing**	**3hrs**
Narrative Writing objectives, regulatory frame work, Template of narrative writing. Case studies.		
Module IV	**Medical Coding in PV**	**3hrs**
Medical coding Introduction.WHO adverse reaction terminologies MedDRA and Standardised MedDRA queries.		
Module V:	**Causality Assessment**	**4hrs**
Factors Considered in Causality Assessment, Methods and Tools for Causality Assessment, Methods and Tools for Causality Assessment, Case studies.		
Module VI	**Expedited Reporting**	**5hrs**
Types of Regulatory reporting, Criteria for Expedited Reporting, Time Frames, Channels of reporting , Regulatory obligations.		
Module VII	**Signal Management**	**4hrs**
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.**	**5hrs**
Exercises on Spontaneous reports,		
Module X	**Practical session on Causality assessment and MedDRA**	**5hrs**
Assessment of Causality based on Naranjo scale for the given cases, MedDRA Coding Demo		

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.

RBVRR Women's Co¥ege of Pharmacy

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Barkatpura, Hyderabad —500 027.

CERTIFICATE COURSE ON

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RBVRR Women's College of Pharmacy

(Approved by AICTE & PCI, Affiliated to Osoiania **University)**
Barkntpura, Hyderabad —**500 027.**

CERTIPICATE COURSE ON

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Group no - 11

RBVRR Women's College of Pharmacy

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Barkatpura, Hyderabad —500 027.

CERTIFICATE COURSE ON

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4. How was the d b t es k r

Very good

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6. Controlled clinical trials are essential for assessing?

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d. Ensuring the detailed information.

RBVRR Women's College of Pharmacy

(Approved bé **AICTE & PCI, Affiliatetl** lo Ftsninnia 1 **n'*•rvit)'}**
Barkatpura, Hyderabad —**500** 027.

CERTIFICATE COURSE ON

FEEl3B.tCK FORM fOn Del'-i fSesaion-41

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2. Nanieofihe institute: RBVRR women's college of Pharm
3 Einail addtess: aqsafo085@gmail.com
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Excellent.
☐ Very good.
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6 Controlled clinical irials are essential for assessing?

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c. Safety and dosage.
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   6-7 yrs

10. . Inforiucd content form witl not givc informalion about....

a. To d‹:cide whether lo enroll in Clinical trials
b. T› c. plain possible benefits and risks.
c. To !e8ve the cIinicBI ria)s anytime.
d. Ensuring the detaï1eü infòrmation.

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CERTIFICATE COURSE ON

hEEUD.4CX FURkl rOR D.4\'-J fSession-1)

1. Name of'the participant : Nishath Fatima
   Name ofthc insiitmc: RBVRF Womens college of Pharmacy
3. Emai aJdrms: wgshathfatima.mio1@gmail.com.
J. Ho› u as rite content deliv red by ihe speaker?
   Very good
   0 Good
   0 Excellent
5. Ho» do you rage the session?
   N Excellent.
   0 Vcr'y good.
   0 Good.

6. Coniroll0d clinical trials are essential for assessing?
   a. Compound screening
      The efficacy:and safety of ness treatment.
   c. Safety and dosage.
   d. New drug Approval.

„„/'/. New' treatments thai have been tested in a laboratory have

n. bio ri3l‹s u hntsocvcr w'hcn used ii i cliiiicul ii info.
b. Risk when used in clinical trials.
c. ki licacy and elléctiveness
   Efficacy and safety as ›vel 1.

Which is not the principle of GCP as per ICH?

a. It shouid be initiated only if anlicipated benefits justify the risk.
b. It should br scienlifically sound and described in a clear and deiail protocol.
c. Its protocol must have received pi'ior approval from the ethics committed
d. the confidentiality' of the subjects shnuld not be protected all the time.

. Timeline to complete all three phases of clinical vials before ihe llceniing stage after Covid-l9?

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

Al 0. lnfiorn1cd «onsent form x'ill not give information about....

To decide whether to enroll in Clinical lrials
b. To explain possible benefits and rfsks.
c. To leave the clinical trials anytime.
d. Ensuring the detailed information.

pharm D- 1st yr - 12

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CERTIFICATE COURSE ON

FEEDB.4C/X FOR.If FOR D.4'\ -I fSesslon-IT

1. Name ot'the parricipaol Maseera Shaku
2. Name of the institute: RBVRR Womens College of Pharmacy
3. Email address: maseerashaku108@gmail.com
4. How' was the content delivered bj' t11e speaker?
   - Z Very good
   - God
   - Excellent

.5. Hon do x'ou rate the session?
   - cellent.
   - Very yood.
   - Z Good,

6. Controlled clinical trials are essential for assessing?
   - a. Compound screening
   - A. The **efficacy** and safety of new treatment.
   - c. Safety and dosage.
   - d. Nev' drug Approval.

Ness trmtments that have been tested in a laboratm have

- a. No risks whatsoever when used in clinical trials.
- b. Risk is hen used in clinical trials.
- c. Efficacy and effectiveness
- @ Efficacy and safety as well.

N8. Which is noi the principle of'C¡CP as per ICH*
- a. It should be initiated only if anticipated benefits justify lhe risk.
- b. It should be scientifically sound and described in a clear and detail protocol.
- c. lis protocol must have received prior approval *from* the ethics comminee.
- JT he conhdenliality of the subjects should not be protected a!1 the time.

H. Tiiiieline to complete all three phases of clinical trials before the licerising stage after Covid-197

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

10. Informed consent form will not give informalion about. ...

- To decide whether to enroll in Clinical trials
- b. To explain possible benefits and risks.
- c. To leave the clinical trials anytime.
- d. Ensuring the detailed information.

30/10/23

”””T:w- o

°*’ Group

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CERTIFICATE COURSE ON

tF,FiHB tCK **FOILS**I FOR D **t1'-1 fSsssion-ï**]

1. Name of the participant : Asma Fatima
?.. Naine of the institute: RBVRR women's college of pharmacy
3. Fmail address: Asmafatima65 2001@gmail.com
4. Ho \’ \›'ns the content d iverc b} h speak r
   - O Very good
   - Good
   - Exceilent

ú. Ho\\ dn s'ou rate the scssion?
   - Excellenf.
   - G Ver}’ good.
   - O Good.

6. Controlled clinical trials are essentia] for assessing?
   - b: Compound screening
   - The efficacy and safetj of nes treatment.
   - s•r«y and dosage.
   - , del› drug Approval.

7. N«› H utiit«iil» thztf hóvc been tested in a Ia6oraloig’ Ilavc
   - a. No risks Lvl\atsocvci who u cJ i i li ii ai h ials.
     It isk ›‹’hen used in clinical irials.
   - o. EtJiuac¿ and ef ccti\’encss
   - d. Et"ficac;’ and satety as well.

8. \\’Iiich is not the principie ot“GCP as per TCH?
   - a. It should be ii itiat<J u il i(aiilíciPated befiufits justig’ the risc:.
   - b. It should be scientifically erm d and drsrrihed in s rlear and detail protocol,
   - c. 11s protoco! must have received prior approvai from the ethics committee.
     The confidentiality of the subjects should noi be protected all the time.

‘1. Ï’i JlcTinc to compleic all \hree phases or clinical irials befÒre the licensing stage afrer Covid-19?
   - a. 12-14 yrs
   - b' 9-10 \’rs
   - c. 6-7 yrs
   - ?-3Ym

(). IntòmJed consent fonn will not give information about....
   - a. To decide *w'hetlier* to enroll in Clinical trials
   - b. To explain possible benefits and risks.
   - To leave the clinical trials anytime.
   - d. Ensuring the detailed information.

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CERTIFICATE COURSE ON

FEEDBACK FOR8I FOR D.tY-I fSession-4)

1. Name of the participant : Syeda Zuaina Parveen Pharm-D IV year
2. Name ofihe insiitute: RBVRR Women's College of Pharmacy
3. Email address: pzuaina@gmail.com

1. How was the co tent deliver: the speaker?
   - Very good
   - G Good
   - Excellent

s. Her do you rate the session?
   - 0 Excellent.
   - Vapgpod.
   - 0 Gocd.

6. Conlrolled clinical trials are essential for assessing?
   a. Compound screening
   The efficacy and safeiy of new treatment.
   c. Safety and dosage.
   d. New drug Appi oval.

7. best treatments that have been tested in a laboratory have
   a. No risks whatsoever when used in clinical trials.
   b. Risk when used in clinical trials.
   c. EtTicacy and effectiveness
   Efficacy and safety as well.

8. Which is not the principle of GCP as per HH?
   a. It should be initiated only if anticipated benefits justify the risk.
   b. lt should be.scientifically sound and described in a clear and detail protocol.
   c. Its protocol must have received prior approvalfrom the ethics committee.
   The contideniiality of the subjects should not be protected all the time.

. Timelinc \o complete all \hrw phase of clinical trials before the licensing stago after Covid-t9?

I I2-14 yrs
   b. 9-10 yr
   c. 6-7 yrs
   d. 2-3 yrs

10. ItlForme4 content form will not give infonnation about....
   To decide «'hether to enro(I in Clinical trials
   b. To explain possible benefits and risks.
   c. To leave ihe clinical triais:anytime.
   d. Ensuring the detailed information.

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CERTIFICATE COURSE ON

FEEDBACK FOR4f FOR I3.41"-I (Session-1)

1, frame of the participant : Velpula Anusha
2. Name of the institute: RBVRR Women's College of Pharmacy
3. Email address: anushavelpula9833@gmail.com
4. How was the content delivered spya he
   - Q Very good
   - @ Good
   - O Excellent
5. How' do you rate the session?
   - U Excellent.
   - O Very good.
   - €I Good.

. Controlled clinical trials are essential for assessing?
   a. Compound screening
   N The efficacy and safety of new treatment.
   c. Safety and dosage.
   d. New drug Approval.

7'7. New treatments that have been tested in a laboratory have

a. No risks whatsoever when used in clinical trials.
b. Risk when used in clinical trials.
. Efficac} and eftbctiveness
1. Efficac}' and saféty as \ve]I.

g. which is nor the principle of GCP as per ICH?
   a. It should be initiated only if anticipated @nefits justify the risk.
   b. It should be scientifically sound and described in a clear and detail protocol.
   C. Its prOtOCDl lTltiSt have received prior approVal from the ethics committee.
   The confidentiality of the subjects should not be protected all the time.

9. Timeline to complete all three phases *at* clinical trials before the licensing stage after Covid-19?

a. I2-14 yrs
b. 9–10ym
. fi-7 yrs
d.- 2-3 yrs

0. lnfonned consent form wi!l not give information about....

a. To decide u'helher to enroll in Clinical jri8ls
b. To explain possible benefits and risks.
To leave the clinicBl trials anvtiine.
d. Ensuring the detailed information.

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CERTIFICATE COURSE ON

FEEDB‹c"c r'oR›‹ **FOR OBl"-i fSession-1)**

I. Name o£the participant : G» Eshitha Pharm-D 5th year Group-IV
ż. Name ofthe Jnstitute: R.B.V.R.R Women's College of Pharmacy
3. Email address: Mshitha1104@gmail.com
4. How › 'as the content delivered by the speaker2
   - Ver; good
   - Good
   - ☐ Excellent

. FIo du you rate the sesgion?
   - ☐ Excellent.
   - Very good.
   - Z Good.

6. Controlled clinical trials are essential for assessing7
   a. Compound screening
   b. the efficacy and safety of view treatment.
   Safety and dosage.
   d. New drug Approval.

. New trcatnaents that have been tested in a *lal›oratoy'* have

a No risks whatsoever when used in clinical trials
b. Risk when used in clinical trials.
c, E.fficąc¿ and e&eEtiveness
d. Efficacy and sBfety as ›vetł.

g z hich is not the principle of GCP as per ICH?
a 11should be initiated only if anticipated benefits justify the risk.
b. It should be scientifically sound and described in a ctear and detail prmocol.
c. 11s protocol inust have ieceived prior approval frnm the ethics cornminee.
The confidentiality of the subjects should not be protected all tłu time.

J9. Timeline to complete all three phase3 Of clinical trials before the licensing stage after Covid-19*

"I2-14 'rs
b. 9-10 yrs

d. *-3 yrs

1. Infarrned cousent torm will nas give information about....

To decide whether to enroll in Clinical trials
b. To e.xpiain possible benefits and risks.
c. Fo leax'e the clinical trials anytime.
d. Ensuring the deiailed information.

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CERTIFICATE COURSE ON PHARMACOVIGILANCE

3

FEEDBACK FORM FOR DAY-3

1. Name of the participant : AQSA FATIMA
2. Name *of* the institute: RBVRR women's college of Pharmacy
3. Email'address: aqsa fa0093@gmail.com
4. How was ihe ct t d [iver b the Mr?(Ms.Uma Priya)
   - Very good
   - ☐ Good
   - ☐ Excellent
5. How do you rate the session?
   - ☑ Excellent.
   - I Very good.
   - O GB
6. Solicited reports among the Zollowing
   - c l i n i c a l trails. ,
   - b. Literature reports.
   - c. Spontaneous reports.
7. \ f IW\ g - t tonn is accepted standard fcr expedited AF reporting
8. SAE ieporis will be recieved from
   - s o l i c i t e d source
   - b. Unsolicited source
   - c. Contractual Agreements
   - d. All the above.
9. is responsible for regulatory reponing.

lfi. An tinto and occurrence for which there is adequate evidence of an associatinn with ltte m.ediciiial product of interest is cB[ied

- Identifiable risk
- b. Possible risk
- c. lmportant risk
- d. Potential risk

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B

CERTIFICATE COURSE ON PHARMACOVIGILANCE

tEt. EiB 1t'K FORMI FOR DA¥'-3

1. Name of the participant : ROOFI
'. Panic ufihe institute: RBVRR WOMEN'S COLCEGE OF PHARMACY.
3. 1?tnaI address: roofirahman3@gmail.com
4. How was the content delivered by the speaker?(Ms.Uma Priya)
   - ☐ Very good
   - ☐ Good
   - ☑ Excellent

ñ. Ho\\' do you rate the session?
   - W Excellent.
   - ☐ Very good.
   - Good.

G. St›licit J rcports among the follo\\"ing
   - a. Clinical trails.
   - b. Literature reports.
   - c. Spontaneous repo›rts.
   - d. Internet reports.

7. @ ,/ I'onn is accpied stan‹1ard for expedited AE reporting

8. S.IE reports \\iII be recie 'ed from
   - Solicited source
   - b. Unsolicited source
   - c. Contractual Agreements
   - d. All the above.

^J. is responsible for regulator' reporting.

0. An unto\Yard occurrence for hich there is adequate evidence of an association with the medicinal product of interest is called
   - a. Identifiable risk
   - b. Possible risii
   - d. Po+entia risk

K

Group -

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R»r stniirn. Hxdembad –6hb027.

CERTiricxTr cOUeSE oN rIix covicwaNCE

FEEDBACK FORM FOR DAY-3

I. Name of the panicipanl - HANIYA JABEEN

*. Name ufthe institute: XLBRRWCP

3. Email address: jabeenhaniya882@gmail.com

4. How was the content delivered by the spe$ker?(Ms.Uma Priya)

- ☐ Very good
- N o a
- ☐ Excellent

3. How do you rate the session?

- ☐ Excellent.
- C Vety good.
- Good.

6. Solicited reports among the following

- Clinical mails.
- b. Literature reports.
- c. Spontaneous reports.
- d. Intemet raporis.

7. liirm is accepted standard for expedited AE reporting

8. SAE reports mill be relieved from

- Solicited source
- h. Unsolicited source
- u. Contractual Agreements
- d. All the above.

9. IQ _ is responsible for regulatory reporting

10. An **untoward** occurrence for which there is adequate evidence of an association with the medicinal product of interest is called

- identifiable risk
- b. Possible risk
- c. Iɔuportant risk
- d. Potential risk

Group : f#

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CERTIFICATE COURSE ON PHARMACOVIGILANCE

1. Name ofltlJe pnrticipani : M.G. Yogeshwari
2. Natnc ot"tIle institute: RBVRR WOMEN'S COLLEGE OF PHARMACY
3. Email address:
4. How n!as the come e e ed b3 pe er?(Ms.Uma Priya)
   Ver}' yood
   Gocd
   Excellent
5. He› Ju ;'ou rate the scs ion '2
   0 Excellent.
   Very good.
   Z Good.
6. Soliciied reports anion$ th oivin$
   Clinical trails.
   b. Literature reports.
   c. Spontaneous reports.
7. €1 fffT)-€ I form is accept rd for expedited AE reporting
8. SAE reports will be recieved from
   a. Solicited source
   b. Unsolicited source
   c. Contractual Agreements
   .DII the abov e.
9. s responsible for regulatory reporting.
10. An untoward occurrence for ivhich there is adequate evidence of Rfl ilSSOCiation with the medicinal product of' interest is called
    . identifiable risk.
    b. Possible risk
    c. linponant risk
    d. Potential risk

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CERTIPICATE COURSE ON PHARMACOVIGILANCE Group -17

FEEDBACK FORM FOR DAY-3

1. Ne' er ‹he participan : M.Harshini Sri, PHARM-D VI th YEAR, Rollno. 11
2. Name of the instituée: RBVRR Women's College of Pharmacy
3. Email address: harshini@gmail.com
4. How Tas the content delivered by the spoa er?(Ms.Uma Priya)
   - Vert good
   - ☐ Good
   - ☐ Excellent
5. How do you rate the session?
   - Excellent.
   - U Ver}g oo d.
   - O Good.
6. Solicited reports among the following a)
   - Clinical trails.
   - b. Literature repom.
   - c. Spontaneous reports.
   - d. Interuei repnns.
7. Ç 10 lY) 1 form is accepted stand pedited AE reporting
8. SAE reports +il1 he recieved from H)
   - a. SOïiCitgü SOUFCC
   - b. Unsolicited source
   - c. Contractuai Agreements
   - All the above.
9. HCPs | Sponsor | Investigator | EC is responsible for regulatory reporting.
10. An untoward occurrence for which there is ade ate evidence of an association with the e is adequate medicinal produci of interest is cal!ed (a)
    - Identifiable risk
    - b. Possible tisk
    - c. Important risk
    - d. Potential risk

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CERTIFICATE COURSE ON PHARMACOVIGILANCE

FERDBaCK FOR¥l FOR DAY-3

I. Name oftfie participam : Sabahat Casim
2. Name of lhe iristitute: MRM college of pharmacy
3. Einail address: sabahatcasim@gmail.com
4. How was the content delivered by the spe er?(s.Uma Priya)
   - Veq good
   - Good
   - ☑ Excellent

ń. HɔJ • du }'ou r the session'*
   - Excellent.
   - E Very gooci.
   - ☐ Good.

ó. Sulicited reports among ihe £allo\ving
   a. Clinical trails.
   L teratiire reports.
   c. Spontaneous reports.
   d. inicrnct rcports.

7. _____(J_____ form is a- epted standard tor expedited AE reporting

8. SAE reports will be nieved from
   a. Solicited sotirce
   b. Unsoiicited source
   c. Coritrąctual Agreenze nts
   he above.

9. _____ responsible for regulatory reponing.

10. An utitoward occurrence for which there is adequate evidence of an association with the mcdicinal product of interest is called
   a. ldenlifiable risk
   b. Possible risk
   c. lmportant risl
   d. Potential risk

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3

CERTIFICATE CODRSE ON PHARMACOVIGILANCE

FEEDB.4CI¢ FOR.II FOR D.II'-I

1. Name of the participant : PIU M
2. Name of the institute: WWW college of Pharmacy
3. Email address: Sona Wb«nsv.m [illegible] gmail.com
4. How' was the content delivered by the speaker?(s.Uma Priya)
   - c< Very good
   - Good
   - Excellent
5. How' do you rate the session?
   - Excelleni.
   - 0 Very good.
   - a Good.
6. Solicited reports among the following
   - a. Clinical trails.
   - Literature reports.
   - «. Spontaneous reports.
   - d, Intemel reports.
7. CIQ M2 form is accepted stnndard for c.xpcditcd AE reporting
8. SAE reports will be recieved from
   - . a. Solicited scurce
   - b. Unsolicited source
   - c. Contractual Agreements
   - DII the abuve.
9. is responsible for regulatory reporting.
10. An untoward occurrence for which there is adequate evidence of an association with the medicinal product of interest is called
    - identifiable risk
    - b. Possible risk
    - c. Important risk
    - d. Potential risk

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S

CERTIFICATE COURSE ON PHARMACOVIGILANCE

FEEDB.tCK FORSf FOR D.4h'-3

I. Ntime of the participani : Bompally Lahari.
2, Name of the institute: RBVRR womens college of pharmacy
3. Email address: laharibompally@gmail.com
4. How was the content delivered y the pe er?(Ms.Uma Priya)

Rd Very good
M Good
O Excellent

3. Hon do you rate the session*

O Excellent.
Very good.
E GOUd.

d. Solicited reports among the follov'ing

. Clinical trails.

b. Literature reports.

c. Spontaneous re orfs.

d. Internet reports.

7. _____// ____@_____ form is accepted standard for expedited AE reporting

8. SAE i'eports vill be recieved trom

Solicited source

b. Unsolicited source

c. Contractual **Am cements**

d. All the above.

9. s responsible for reyulatoy' reporting.

10. .In untoward occurrence for which there is adequate evidence of an association with the medicinal product of **interest** is called

Identifiable risk.

b. Possible risk

c Important risk

1. Potential risk

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CERTIFICATE COURSE ON PHARMACOVIGILANCE

FEt:LiB.xCK FOUNT FOR pA¥"-3

1. Name of the participant : Syeda Zuaina Parveen Pharm D 5th year
2. Name of the institute: RBVRR Women's College of Pharmacy
S. Email address: _____
4. How way. the content d:elivéred by the speaker?(Ms.Uma Priya)
   - Very good
   - Good
   - Excellent

. Hot do you rate the session'*
   - BE.xcellent.
   - Very good.
   - O Good.

6. Solicited reports among the following
   - ICI inical trails.
   - Literature reports.
   - c. Spontaneous reporrs.
   - d. lntemei reports.

/. CIOMS torm is accepted standard tor expedited Ali reporting

8. SAE reports »'iil be recieved front
   - a. Solicited source
   - b. Unsolicited source
   - c. Contractual Agree nts Agreements

   LAH the abo ve.

9, is esponsible for regulatory reporting.

10. An untoward occurrence for which there is adequate evidence of an association with the medicinal product of interest ir called
    - identifiable risk.
    - b. Possible risk
    - c. Important risk
    - d. Potential risk

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(4)

CERTIFICATE COURSE ON PIIARMACOVIGILANCE

FEEDBACK FORM FOR DAY-3

1. Name of the participant : Kulsoom Fatima
2. Name of the institute: RBVRR Women's college of pharmacy
3. Email address: kulsoomf41@gmail.com
4. How was the content delivered by the sp ller?(Ms.Uma Priya)
   - ☐ Ver good
   - ☐ GO0d
   - Excclleiil
5. How do you rate the session?
   - ☐ lxce!lent.
   - ☑ Very good.
   - O Good
6. Solicited reports among the following

   Clinical trails.

   l i t e r a t u r e repons.

   c. Spontaneous reports.

   d. Internet reports.

7. 5 rm pted standard for expedited AE reporting

8. SAE reports will be recieved from

   a. Solicited source

   b. Unsolicited source

   c. Contractual Agreements

   LAH the above.

t h i s r e s p o n s i b l e for regulatory reporting.

10. An tlntoixard occurrence for which there is adequate evidence of an associalion with the medicinal product of interest is called

    Identifiable risL

    b. Possible risk

    c. Important risk

    d. Potential risk

Pharmacovigilance - It's the activities of identification/ termination, assessment, management and prevention of adverse drug reactions / adverse events.

(2) The valid criteria for ICSR are 4:
i) valid Patient details - patient demographics like age, sex etc
ii) valid Reporter details - who is reporting such as HCP/non HCP.
iii) valid Drug details - that caused the reaction
iv) valid ADR details - such as when it began and nature & severity

(3) MedDRA - Medical dictionary for regulatory activities.
It's validated international medical terminology dictionary used for standardization, uniformatily globally and ease for regulatory authorities.
It includes signs & symptoms, diseases, surgeries, surgical procedures etc

(4) Objectives of narrative writing:
The primary objective of narative writing is to make a comprehensive report of the case reported in a consice manner to help regulatory authorities review the cases in proper time period.
It provides the important details such as 1. Report types, 2. Reporter, 3. Pt demographics, 4. Medical & drug history, 5. suspected drug details, 6. ADR details & Medical evaluation.

(6) PTO.
(6) The different countries have diff. ADR forms. These ADR
(5) forms are used to report ADR's to their regulatory authorities
& In UK - united kingdom we use Yellow card system.
In India we use CDSCO's forms [CDSCO - Clinical inter...]

organisation for medical sciences) etc as they report to regulatory authorities such as India - CDSCO, USFDA, PTO.

(6) In Australia we use Blue card as the ADR reporting form.

(7) Different sources of SAE are 4 types

i) Solicited sources providing structured cases

ii) Unsolicited sources providing unstructured cases

iii) Regulatory authorities

iv) Contractual agreements

They provide the sources for serious adverse events which can then be reviewed by higher authorities / regulatory bodies

(8) Challenge, de-challenge and Re-challenge are all done in cases of ADR - adverse drug reaction.

- Challenge - when we suspect a drug that's being given to cause ADR and assess it's temporal relationship with the adverse event i.e drug given causes ADR

de-challenge - when the drug causing Adverse event is withdrawn / discontinued.

R challenge suspected drug previously discontinued / withdrawn is administered again to the patient

e challenge can be tve / -ve → tve dechallenge - ADR stopped after drug stopped.
→ -ve dechallenge - Drug stopped ADR not stopped.

Rechallenge can be tve / -ve

'e*' *'*"è - °a7 9"'^"*° »e•'

unstructured report by a Healthcare professional or non-HCP e patient / public to the higher authorities such as ethics Committee or regulatory authorities about drug and the adverse event / ADR that occured.

Modules — Module 1 - Regional Admin. Information
Module 2 → Quality overall summary.

(10) Triage is the second step in the clinical reporting cycle. It means prioritisation of the cases received, which can be of different types such as solicited / unsolicited case reports and cases can be classified according to their seriousness also.
The solicited case reports are structured and reported by HCPs / RA / EC whereas the unsolicited / unstructured cases can be reported by patients / general public.

(11) The adverse events can be reported by any Healthcare professional or any patient / their relative of patient who has experienced the adverse event. There are various forms available in diff countries to report the ADRs such as UK - Yellow card, Australia - Blue card, India - CIOMS form.
These are then reviewed by the regulatory authorities.
The adverse event reported follow this cycle below:

- Case report receipt → Triage → Data entry → QC review → Medical review → case submission

- The type of reporter is also important as HCP know the proper information and the way to report due to their knowledge

of drugs and hence provide structured cases, whereas general public / patients due to their lack of knowledge of drugs by ADRs provide unstructured cases.

The properly reported cases should include:

Valid details of patient, reporter, drug and ADR

The type of report received is then decoded by medical writing and medical coding and with the help of Narrative writing we provide the report in a comprehensive form for the review by regulatory authorities.

∴ The reports by HCPs are more trustable & need less time

(12) Causality - It is development of relationship between the suspected drug and the adverse drug reaction.

~~The factors involved in~~ Causality can be assessed by 2 main scales / algorithms

i) WHO - UMC scale

Certain
Probable
possible
unclassified
unclassifiable

ii) Naranjo's Scale.

↓

Definite ≥ 9
Probable 5-8
possible 2-4
doubtful <2

These are used to classify the ADR based on the questions provided and then marks given based on these marks they are categorized.

They are answered based on the clinician's judgement or experience.

factors based on which ~~AOR~~ by developed is.

i) Temporal relationship drug and

)

iii) Dechallenge & re-challenge

Causal relationship can be developed / assessed.

28/40

RBVRR Women's College of Pharmacy

(Approved by AICTE & PCI, Affiliated to Osmania University)
Barkatpura, Hyderabad - 500 027.

ASSESSMENT TEST

Time: 1 hi . **Max Marks: 40M**

Name of the Purti«iyant: _____

Nu me of the Institutc: RBVRRWCP

Email address: farúhanaaaz22@gmail com.

Answer all the following questions. **10x1M= 10** M

1. In clinical research proof of concept includes.....
   a. A sment of drug/therapy.
   c o m p a r i s o n of new drug to placebo or standard therapy.
   c. Biostatislical analysis.
d. Testing of beneficial effects and undesirable effect.

i c a l trial process doesn't involve.....

a. Random allocation and assignment.
b. Allocation sequence.
. Actual administration of intervention to the general population.
. The active yroup.

Risk/benefit balance of medications include.....

a. Medicines are safe.
   No medicine is without **risk.**
c. No medicine is safe.
d. Approve medicines nre safe.

. Pharmacovigilance is needed in every country except.....

a. Dit”ference in drug.
b. Difference in distribution and use.
C. Difference in pharmaceutical quality and composition.

d. Medication error.

5. Which of the Iol1O\vil1g is the correct chronological order o£ADE reports journey*

Reponer Q£IV RA Dataznwy.

b. Data Clttry —+ QPPV Iteporter - kA.

C. QPPV DBta cntry Reporter RA.

d. Datn entry •—+ Reporter —•• QPPV —•- RA.

6. ICH harmonised TRlPAttTlTE guitlelincs include all except,..

a. Details uF knn wi advcrsc eflect,

b. Reporting time frames.

. Informing investigators and ethics committee about new safety of drugs.

d. Managing blinded therapy cases.

7. Naranjo scale is the method to access

a. Clinical event and drug

Adverse drug reaction

c. Conditional causality

d. None of the above.

8. Timeline to complete all three phases of clinical trials before the licensing Stage al1«r Cnt id-l9?

a. I2-14 yrs

b. 9-10 yrs

-7 yrs

d. 2-3 yrs

9. SUSAR SShculd be reported within

da}'s

b. 15 days

c. 30 days

d. 10 days

ro. Chamcleristics ol‘casc narrative include oll except

u. Medical 1-history.

b. Alopsy findings.

c. Use of abbrex iations and Acronyms.

olo°rnoiJon should be presented in chronological order.

Etich ‹tuustiun carries 2 h'Iurks I0x2M= 20 M

\. \\'\JO"s definition of PV?

?. +’alid criteria's for a« ICSR?

*. \\’hat is 'tledDRA?

4. tt'hat are Objectives of Narrative writing?

S. \\'rite about Countr'v specific ADR forms.

b. \Vrite about modules of CTD Cycle

7. Dift”erent sources of SAE reports

8. \I'riie about Challenge, de challenge and Re-challenge.

9. U"hat is spontaneous reporting?

10. \t'hat includes in a triage

Each question carrie» 5 Marks 2x5M= 10 M

1I . \Vho can rcyort the adverse cvents and significance of the reporter in life cycle saléty of me4icinLs and ensuring public health

12. Uctinz Causality and what arc tlic factors/parameters involved in assessment of the Causality.

Pharmacovigilance:- The science and activities relating to the detection, assessment, understanding and prevention; reporting of an ADR

Group (1)

Patients, report in the ADR reporting center. done by HCP's, nurses, General Public; science/medical students.

3) MedDRA:- Medical Dictionary for Regulatory activities. It is a clinically validate international medical terminology used by regulatory authorities and regulatory biopharmaceutical industries

---

↳ Internati
↳ MMSO and updated by company subscribers
↳ structure facilities; case analysis; reporting; electronic communication
↳ typically used for coding adverse events

Ans 2.) Valid criteria for ICSR:- Individual Case study Report. It is documented about ADR; compliant about defecti

(1) Identification of P
(2) Identifiable reporter.
(3) Suspect product
(4) Adverse event or fatal outcome.

~~Ans 3) Country specific ADR forms:-~~

Ans 4.) Objectives of narrative writing:- Narrative writing is an integral part of ADR of medical writing service. objective is to communicate all key info. in comprehensive way reviewer to make them to understand the consequence it may lead to the occurrence of ADR event and its related management

Ans

Spontaneous Reporting:

Causa

MHRA. It is
and the ADR noted.

ues illness or injury.

6) Triage:-

5 levels of triage:-

level 1:- Resuscitation
level 2:- Emergency
level 3:- urgent level
level 4:- semi urgent
level 5:- nonurgent

components of:
↳ Assign/
↳ Visual
↳ Vital signs

Ans 8) challenge:-

⇓

Exposing the suspected drug to the Patient / subject to observe the effect.

Dechallenge:-

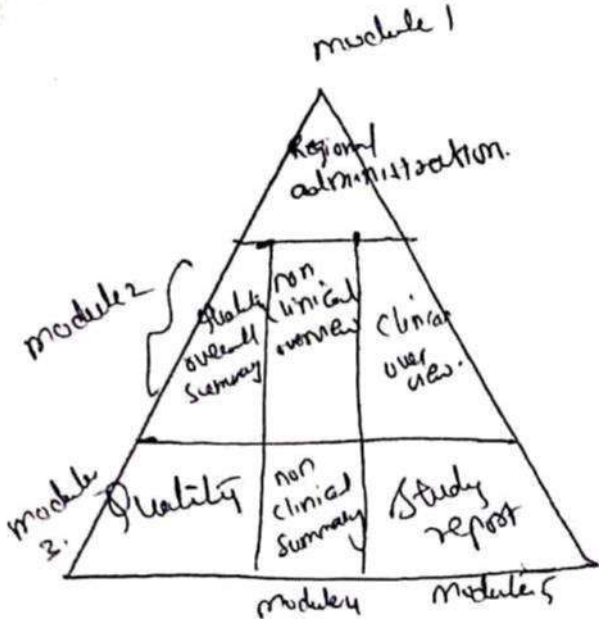
⇓

drug and removing it from therapy as after challenge the serious ADR was observed. check whether the ADR. symptoms reduced

ieved from the

Serious
(1) unsolicited source ; solicited (2) source ; contractual agreement (3) and
regulatory authorities (4)
sources

causality:-



(2)

Ans 1) Causality:- It is the process of assessment and reporting of an ADR done by HCPs, clinical pharmacist; nurse; medical students.

It includes:- Algorithms
Expertise advice.

(2½)

WHO recommended uppsala monitoring scale:- Certain
Probable/likely.
Possible
Unlikely
Unclassified/Conditional
unassessable/
unclassifiable

Naranjo's scale:- Definite (>9)
probable (5-8)
Possible (1-4)
)

Ans 5) Ans:) Country specific ADR:-

WHO - FDA
European

(1/2)

29/12

RBVRR Women's College of Pharmacy

yyrv›!eâ b3 AICTE & PCI, Affiliated to OsmanÎa University')
Barkatpura, Hyd0fiabad —o00 027.
ASSESSMENT TEST

Time: lhr. **Max Marks: 40M**

lnme uf th0 Particip2nl: Syeda Zuaina Parveen
hame ul the Institute: RBVRR Women's Pharmacy College of Pharmacy
Emuil address: pzuaina@gmail.com

Ariège er all the follois ing questions. 10r1.81= 10 hI

1. In clinical research proof of concept includes…….
   a. Assessment of drug/therapy.
   Comparison ofnetv drug to placebo or standard therapj .
   c. Biostatistical anal}'sis.
   d. Testing of beneficial effects and undesirable efTect.
2. Clinical trial process doesn't involve……..
   a. Random allocation and assignment.
   b. Allocation sequence.
   Actual administration of intervention to the general population.
   d. The active group.
3. Risk/benefit balance of medications include.....
   a. Medicines are safe.
   o medicine is without risk.
   c. No medicine is safe.
   prove medicines are sale.

harmacovigilance is needed in ever›' county' except.....

a. DitTerence in drug.
b. DifTerence in distribution and use.
C. Di!T Fgfjc · iFl pharmaceutical q«•lit}'and composition.

NJedicaiion error.

3. Which ctf the fol)o ving is the correct chrnnnIogic‹tI g{Jcr ul”ADE rcp +SJ•* *• *

M. Reporter QPPV RA inta cull'.

b. Data ents’ QPPV - Reporter RA.

c QPPV Datzunry —•Ruporttr Rd.

d. f3ote cnfry Repnncr QPPV hA.

6. ICII harmonised TRIPS\RT(TE ,uid••lincs include :‹Il uxccpt...

a. Details of kno»s ad ’erse cfTcct.

b. Reporting time frames.

c. lnformin3 investigators and ethics committee about new safety of drugs.

d. Managing blinded therapy cases.

7 amjo scale is the method to access

a. Clinical e ’ent and drug

Id 'erse drug reaction

c. Conditional causality

d. 'done of the above.

8. Timeline to complete all three phases of clinical trials before the licensing stage after Co›’id-

b. 9-10 yrs

c. 6-7 yrs

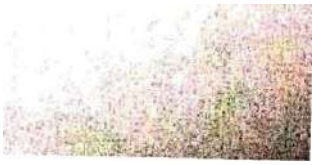
FUS R”s should tic reporird wiihin

a 7 days

. G I S days

c. 30 days

d. 10 days



10. Chara"!** *! I case narrative include all Lxcept

a. M

b. Atupsy Fiodinys.

Use *ot'* abbreviations and acronyms.

d. ln£crni»tion should be presented in chronological order.

Each question carries 2 Mnrks 10.x2M= 20 iYl

I›' WHO's definition of PV?

2.' Valid criteria's for an lCSR?

3• \\'hat is MedDRA?

4." 4'hat are Objectives of Narrative n rising?

S. Write about Country specific ADR /orms.

6: \Vrite about modules of CTD Cycle

7. • Different sources of SAE reports

8. \Vrite about Challenge, de challenge and Re-challenge.

9. « V'liat is spontaneous reporting?

10. What includes in a triage

Each question carries 5 Marks 2i5A€=10M

11. Who can report the adverse events anJ significance of lhe reporter in life cycle sa(eiy of' medicines and ensuring public health

12. Delinc Causality and what sre the factors/parameters involved in assessmentof the Causality.

PV:

Answer all (2M)

1A Pharmacovigilance: According to the science of activities that is related to identification, assessment, understanding and prevention of adverse drug reaction and drug-related problems.

3A MedDRA: MedDRA is the Medical dictionary of the terms of Regulatory Activities.

→ terminology by regulated authorities & bio-pharmaceutical agency.

→ It contains the medical terminologies that are standardized and globally accepted by most of the regulatory authorities

→ the terminologies are used in regulatory process, pre-clinical trials, & post marketing surveillance, data entry, data retrieval, evaluation & prescription

4A Narrative Writing: It is a drug safety document.
It explains briefly about the Adverse events. It summarizes the data accumulated.
The adverse events are the one's experienced by the patient during the clinical trials & post marketing studies.
Objectives: → To communicate all key information in a comprehensive way to the reviewers. to make them understand the circumstances that have led to the occurrence of the adverse & subsequent management

7A Sources of SAE reports:

There are mainly 4 sources.

1) Solicited Report
2) Unsolicited Report
3) Contractual Agreement
4) Regulatory Authorities.

2A Valid Criteria for an ICSR

→ Identifiable patient details
→ Identifiable reporter details
→ Identifiable suspect drug
→ Identifiable Adverse Reaction

8A Challenge: To challenge in an ADR is to check association of the drug to the adverse reaction by withdrawing & readministering the ~~drug~~ suspected drug in the patient.

Dechallenge: Here the drug is withdrawn from the patient and monitor if the reaction persist or stops.

Rechallenge: After the removal of the suspected drug, the drug is again readministered to see if the reaction occurs again. If patient shows the reaction, rechallenge is +ve

9A Spontaneous Reporting: It is a type of unsolicited reports or communication. The reporting can be done by HCP or a consumer, competant authority, marketing authorization holder or other organization that describes that one or more suspected ADR in a patient who is a given the medical product

→ It is not an organized or structured data.

6A The different modules of CTD cycle are:

Module 1: Regional Administration Information
Module-2: Clinical overview or Summary
Module-3: Quality.
Module-4: Non-clinical study Reporting
Module-5: Clinical study Reporting.

2

5A ADR forms of different countries:

i) United kingdom: Yellow Card
ii) ustralia:
iii) India: ADR reporting form.

2

iv) "

→ CIFO for reporting SAE

10A

Triage includes:

→ Duplicate search
→ Seriousness
→ Case number
→ Causality
→ Expedited.

1/2

Answer Each (5M).

12M Causality Assessment: It is a method of assessing the relationship between the drug and the adverse reaction.

Important factors:

→ Identifiable patient
→ Identifiable reporter
→ Identifiable drug (suspected)
→ Identifiable adverse reaction.

Scales for Causality Assessment:

→ The most widely used scale is WHO scale; it includes or measures the ADR in following aspect → Certain
→ Probable
→ Possible
→ Unlikely
→ Unclassified
→ Unaccessible.

→ Other algorithms are: → Naranjo's Scale
→ Karch & Lasagna.

→ There are 3 main methods:

a) Expert opinion
b) Algorithms
c) Bayesian Method.

→ The above methods helps detection & conformation of ~~of~~ association.

→ Naranjo's Scale – ~~Greater than~~ 9 – Definite
5-8 – Probable.
1-4 – Possible
less 1 – Doubtful.

1) Adverse events can be reported by both the HCPs as well as the non-HCPs.

→ Reporting of ADR can prevent any future adverse reaction occurence

→ Treatment expenses for ADR can be reduced

→ Effective use of drug.

→ Awareness among the HCPs and the general public for careful / negligent use of medication

→ Early reporting can be helpful to prevent untoward serious medical events

29½/40

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(Approved by AICTE & PCI, Affiliated to Oxmania University)
Barkatpura, Hyderabad - 500 027.
ASSESSM NT TEST

Time: t hr. й4ax Starks: 40M

hsnte of tht Pnrticiynnt: HAReA A3t3RlTHA

Nume oftlie institute: RgveR uot«tEr‹se coLL6ДE Dr PHRI2/'Дд+\

Eniail address:

*\nsiver all the following questions. l0xlM= 10 M

nical reseatch proof of concept includes.....

a. Assessment of drug/therapy.
b. Comparison of new drug to placebo or standard therapy.
c. Biostatistical analysis.

Testing of beneficial effects and undesirable effects

2. Clinical trial process doesn't involve.....

a. Random allocation and assignment.
h. Allocation sequence.

Actutil administration of intervention to the general populationv

d. The active grou

3. Risk/benefit balance of medications include.....

a. Medicines are safe.

No medicine is without risk

c. No medicine is safe.'
d. Approvemedicincs are safe.

4. Pharmacovigilance is needcd in ever›' «•tiПtry cxccpt.....

a. Difference in drug.
ь. DiFerenceinШstdbutionandse.
a DiSirehccinphanлaceuticalqualit Дndc0mposidon.

d. / Icdicatini› error.

hich of the following is the correct chronological order of ADE reports journey?

a. Rcporiet QPPV → RA → Data entry.

b. Daxa «i e' QPPV—• Rep rtcr RA.

c. QPPV → Data entry → Reporter → RA.

d. Data cms —+ Reporter QPPV → RA.

6. harmonised TRIPARTITE guidelines include all except...

Derails of known adverse effect.

b. Reporting time frames.

c. Informing investigators and ethics committee about new safety of drugs.

d. Managing blinded therapy cases.

7. Narnjo scale is the method to access

a. Clinical event and drug

b. Adverse drug reaction

e. Conditional causality

d. None of the above.

8. Timeline to complete all three phases of clinical trials before the licensing stage after Covid-

b, 9-10 j rs

II-7 yrs

d. 2 " yrs

SU s should be reponed i'ithin

7 days

b. 15 days

c. 30 daysy

d. 10 days "

haracterisiiCs of case narrative include all except

8

b. Atopsy Findings.
c. Use of abbreviations and acronyms.S
d. Information should be presented in chronological orders

E.ich question carries 2 Marks I0x2M- 20 M

1. WHO's definition of PV?
2. Valid criteria's for an ICSR?
   What is MedDRA?
   What are Objectives of Narrative writing?
5. \Vrite about Country specific ADR forms.
b. M'rite about modules of CTD Cycle
7. Different sources of SAE reports
8 'Write about Challenge, de challenge and Re-challenge.
9. \Vliat is spontaneous reporting?
10. What includes in a triage

Each question carries S Marks 2x5M= 10 M

11. Who can report the adverse events and significance of the reporter in life cycle safety of medicines and ensuring public health

12, Define Causa)ity and what are ihe factors/parameters involved in assessment of the Causality.

p'o"""'"""'"t "

&<e+Å»*$ As <8o: FLxo=m»=^+Q « dJ'°'*@J '*

process $ dentification , assessment , understanding , prevention of an adverse reaction is called pharmacovigilance.

★ This is an important field giving importance to safety & efficacy of patients.

aæ. r»r an Individual Case vStudy Reports ;

The valid criteria contains 4'

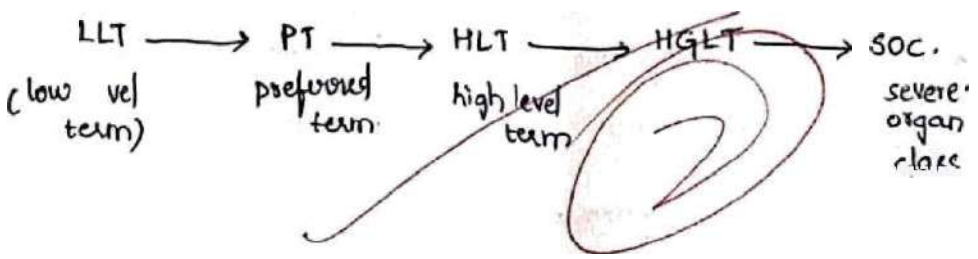
i. Identifiable patient
ii. Identifiable Reporter
iii. vSuspect drug
iv. An adverse event / adverse drug reaction.

4 •t 'æ thus H oül»śÁ«n» •A : ^ ^'"*' thought be valid and further processed.

4ïr+s, f°I*d DRA ‹ Medical Dictionary of Regulatory Activities

_____

_____ medical language



7.

Ans:- The different sources of SAE reports are divided into 3:

1. Solicited : data is collected from a structured / organised sources like pharmaceutical company ; patient support programmes. physicians

2. Unsolicited :- from unorganised sources ; → literature, social media, patients & their family members. internet.

3. Contractual agreements → company, third party etc..

Sources < HCP [physician, nurse, pharmacist..] / non-HCP [lawyers, patients, literature] family members

8.

Ans:- Challenge :- It is to focus & know whether a drug is causing event with some risks. ⟶ helps in causality assessment

It is of 2 types

Rechallenge → re-administration of drug.

- +ve: drug ⟶ ADR ⟶ stop drug → no ADR → re-administration → ADR persists
- -ve: drug → ADR → stop drug → no ADR → re-administration → no ADR.

Dechallenge → withdrawal or decrease in dose of drug.

- +ve: drug → ADR → stop drug → no ADR
- -ve: drug ⟶ ADR → stop drug → ADR persists

★ +ve Re & Dechallenge confirms the causal relation.

rative writing :- It is the process of writing a case report in a comprehensive, summarized / concised way intellectually such that it is easy to read & understand.

Objectives :-

1. to understand how to write a personal narrative.
2. to classify the elements of writing process.
3. to know the procedure of writing a final draft of a professional narrative :
4. to make a concised summary.

5.

Ans:- Alternative dispute Resolution (ADR)

→ refers to the different ways people behave to resolve a dispute without trials.

6.

Ans:- CTD

↓

It involves 5 modules. c are arranged in the form of a triangle.

① → It includes regional administration of information.
It doesn't come in CTD.

② → complete review | clinical overview, clinical summary | non-clinical overview, non-clinical summary.

③ → Quality

④ → clinical reports

⑤ → non-clinical reports.

9.

Ans:- Spontaneous reporting :- It is the type of reporting in which the reporting has to be done immediately.

Eg: SUSAR (suspected, unexpected severe Adverse Reaction)

10

Ans

10.
Ans:- Triage → It is 2nd step of Case processing.
It includes :- relatedness.
expited reporting.

III [5M]

12.
Ans:- Causality : It is the relationship established between suspected drug & the adverse reaction.

---

1. Time duration → Interval between development RDF CEM
drug administration.
2. challenge, Rechallenge & Dechallenge.
3. other factors [disease]
4. overdose | toxicity.
5. previous history < Genetic / past history

→ ry Auth ty.
→ Patient / his/her caregiver → HCP [physician, pharmacist, nurse]
→ QPPV. → Sponser
→ pharmaceutical company.
→ Investigator.

Significance of report:

The information is said to be true
↓
requires less time for processing.

→

report on time] side can be
prevented & patient is been saved.

28/40

RBVRR Women's College of Pharmacy

(Approved by AICTE & PCI, liated to Osmania University)
Barkatpura, Hyderabad - 500 027.

ASSESSMENT TEST

3"ime: 1 hr. Max Marks: 40M

Name of the Participant: yJ2p

N*m• or the i»siii•e: pc yrf›P

Email address: tahuhrdous17@gmail.com.

Answer all the following questions. 10x1M= 10 M

In clinical research proof of concept includes.....

a. Assessment of drug/therapy.
b. Comparison of new drug to placebo or standard therapy.
iostatistical analysis.
d u s t i n g of beneficial el'fects and undesirable effect.

inical trial piocess docsn"t involve.....

n. Random allocation mid assignment.
b. Allocation sequence.
Actual administration of intervention to the general population.
d. The active group.

b 1 le on clud

edi ine e dicati s ine

No medicine is without risk.
c. No medicine is safe.
d. Approve medicines are safe.

3. Pharmacos'igilance is needed in every country except.....

a. Difference in drug.
fference in distribution and use.
c. Differencein pharmaceutical quality and composition.

Medication error.

5. Which of the following is the correct chronological order of ADE wpo«ˢJ-••••-

a. Reporter QPPV RA Oata entry'.

b. Data entry QPPV Reporier RA.

c. QPPV ••• Data entry Reporter RA.

d. Data entry Reporter - QPPV RA.

6. ICH harmonised TRIPARTITE guidelines include all excepi...

a. Details of known adverse elTect.

b. Reporting time frames.

c. lnforminginvestigstorsmndethicscommittoe2boutnts'safet)ofdrugs.

d. Manugingblindedtheapycvs.

7. Namjoscaeislhz mzthodto access

a. CWnca|eventaud dog

Adverse drug reaction

e. Conditional causality

d. None of tho above.

8. Tinem 'yyleline tO Co{y}plete all thrCe phQsQS of clinical trials c/o£c th* lic2nsin/ stutt* Qttfi£ /*U*'›/ 19?

a. 12-14 yrs

b. 9-10 yrs

6-7 yrs

d. 2-3 yrs

9. SUSAR s should be reported is'ithin

a. 7 days

15 days

c. 30 days

d. 10 days

0. Characte

a. Med

6

b. ltopsy Field› IS,S•

QU se of' nbbreviations hud ocFOfi1'rnS-

d. lnti›r+•iio»sliouldbe presentedin chronological order.

l0x2M= 20 M

Each que.ation carries 2 Mnrks

„r. \VHO"s detinition of PV?

J. I*alid criteria's tor an ICSk?

. fi'hai is RledDRA?

„4. chat are Objectivesof Narrative whiting?

5. V'rite about Country specific ADR fOJTfl5

h'rite about modules ot"CTD Cycle

Different s0urces of SAE reports

ñ'rite about Challenge, de challenge and Re-challenge.

What is spontaneousreporting?

i0. What includes in a triage

2x5M= 10 M

Each question cnrries S M8*

t t. Who can report the adverseevents and significance ofthe reporter in life cyc1e safety où medicines and ensuring public health

t2. Define Causality and Whitl ilF[2] thc:. fâclorS/p°'•"'° te,S involved in ossessmant orthe Causality.

Tahura Fardous

Each question carries 2 marks. 10x2m = 20m.

1Ans) It is a science of activity related to the identification, & assessment, & understanding, & prevention of the Adverse drug rxn & Adverse event.

2Ans) MedDRA - Medical Dictionary of Regulatory Activities.

It is a clinical validated international medical terminology by ~~reg~~ Regulatory authorities & regulated bio-pharmaceutical agencies. The terminology is used through entire regulatory process, pre-clinical trials & post marketing for data entry, retrieval, evaluation & prescription.

4Ans) It is a drug safety document which explains briefly about adverse event experienced by patients during ~~clini~~ course of clinical trial studies & post market studies.

Aim of narrative is to communicate all key information in comprehensive way to reviewers to make them understand circumstances that may have led to the occurance of adverse events & subsequent management.

3Ans) Valid for an ICSR are:-

(1) Patient details.
(2) Reporter details.
(3) Identifiable suspect drug.
(4) Identifiable adverse suspected reaction.

7Ans) SAE are serious adverse events & various sources of SAE are:-

(1) Solicitated Reports.
(2) Unsolicitated reports.
(3) Contractual contracted Agreements.
(4) Regulatory Authorities.

Challenge - It is the association of ADR drug to the ADR & withdrawal or re-administration of the suspected drug.

De-challenge - ~~Drug~~ The drug is withdrawn or stopped & suspected rxn is monitored to assess whether it inued or stopped.

Re-challenge - The administered drug is withdrawn or stopped & after the ~~suspected~~ rxn is stopped the drug is re-administered.

A spontaneous report is unsolicited communication by the HCP or consumer complaint authority, marketing authorization holder or other organization that describes one or more suspected ADR in pqii/,si ›śihp was given one or more medicinal products & the ~~the~~ dose not derive from a śtcdy •

module -1 :- Regional Administration Information.
module - 2 :- clinical overview / summary.
module - 3 :- Quality.
module - 4 :- Non clinical study Reporting
module - 5 :- Clinical study Reporting.

Triage include :-
- Duplicate search
- seriousness.
- case number.
- causuality.

The following ADR forms are used in following countries :-
① India - Ad. ADR reporting form. ④ UK - yellow card.

Question carries - 5 marks:

&xs torn.

Ans) ⓐ causality - It is method used for the assessment of ADR or AOE with the suspected drug.

Factors / parameters involved in assessment of causality are:-

NHO

Ø Ñ3ænj0 *z‹gle* •

yera ¢ć•je AoeKm°°+— ”“ taking into account in clinical pharmacological aspects of the case history of the observation.

ø— doo='•u•t'<<^

ⓑ Naranjo - scale -

>9 - DEFINITE.

1-8 - Probable.

»«:*ã

The

fi nr#ouæ ar eP•f rr.

non-HCP. HCP & Pharmacists can be also reported by professionals includes- Doctors, Nurses.

Help in identifying the prominent cause of the

Enables to monitor the adverse drug reaction &

maintain

identify & assess

29/40

RBVRR Women's College of Pharmacy

(Approved by AICTE & PCI, Affiliated to Osmania University)
Barkatpura, Hyderabad - 500 027,
ASSESSMENT TEST

Tiiiie: 1 hr. **Max Marks: 40M**

Numc of the Participant: V. Tejaswini
h:tn›e ɒf the Institute: RRVRR ka ¢P
Email u4dress: -

wer oil the folio» ing questions. **10x1M= 10 M**

l clinical research proof of concept includes.,.....
a. Assessment of drug/therapy.
. Comparison of new drtig to placebo or slandard therapy.
c. Biostatistical analysis.
d. Testing of beneficial effects and undesirable effect.

2. Clinical trial process doesn't involve……..
a. Random allocation and assignment.
b. Allocation sequence.
Actual administration of intervention to the general population.
d. e active group.

k/bencfit balance of medications iNclfide.....
a. Medicines are safe.
No medicine is avid out risk.
c. No riiedicine is safe.
d, Approve medicines ares8fu.

4. harniacovigilance is needed in every country except.....
o. Difference in drug.
Q. Difference in distribution and use.
Difference in phai mncetitical quitlity and composition.

d. Mcc!ication error.

5. Wlticl› ofthc (ollowing is the COrrcct chronoloyiCâl order où ADE repons journcj'J

a. I\epurtcr QPPV —• RA Data entr}.

h, Data cntry —•+ QPPV Reporter RA.

c. QPI^V —• Data entry îteporter — RA.

d. Dntzt entry —•+ Rcportcr QPPV - - RA.

6. ICH liarmonised TltlPAXTlTE guidclines include all cxceyt...

a. -.Dctails er knowx advcrsc clTcct.

b. IcportilJg time trames.

I tfcrming iizvqstigntrirs and ctliics cnmi zitfcc ahortt nc \ salut} ‹ t"air i¿ï.

d. Managing blindcd ti crapy cas'cs.

7. Narii)0 sctiIc is lIJc mcthnd to access

a. C\inicul cvcyl and druy

h. Aclvci'sc Jrtib rc«ction

c." ConJitic›nnl caiisxlity

rl. Nnnc ol"the ahovc.

8. T'ţtjjg|mC ttJ cc\ţrtţjlttte pll thr« pţJascS cl"cIiniCztl £ricl5 the liccilsillg state :\tÎtr L"ciî id-

l12-14 yrs

b. 9-10 jrs

d. 2-3 yrs

9. SUSAR s should be rcportcd within

a Y days

c 30dgs

d. |0ô«y«

10. Characteristics ofctls0 linrrhtive iiic]tide illl ext:cpt

a. Medical History.

Use of abbreviations and acronyms.

d. Information should be presented in chronological order.

5

E:›ch questioit «arriex 2 t4lcrks 10x2M= 20 M

1. \\"HO's definition of PV? .
2. I'nlid criteria's for an ICSR? •
3. \\'hat is ‹XledDRA? .
4. l'hat are Objectives orNarrative writing? •
5. \l'rite aboui Country specific ADR forms.
6. \\'rite about modules of CTD Cycle •
7. Oift"erent sources of SAE reports .
8. \Vrite about Challenge, de challenge and Re-challenge.
9. \\'hai is spontaneous reporting? .
10. H"hat includes in a triage

Each question carries 5 Marks 2x5M= 10 M

11. \\'hu céf} FC]3Urt thc adverse eventsand siynlficnnce of the reporter in life cycle safety of medicines anJ ensuring public hcdltl\
12. Uclinc C:iusality onJ U'bgf ijFe the tttcfurs/p:ii'ametcrsinvolved in assessment oaths CauSnlity.

1

According to the WHO, Pharmacovigilance is defined as science & activities related to assessment, understanding & prevention of Adverse events or any other Drug Related P...

Goals:

- Ensuring rational & safe therapy
- Assessment of Benefit-Risk analysis of medications
- Educating & creating awareness.

2. Valid Report Criteria for Individual Case Safety Report

① Identifiable
② Identifiable Patient
③ Suspect Product (Drug/Device)
④ The Adverse Event.

3. *\•*Rh —s u ţ‹ q jy\‹g;/oj ğ;,ş„ y for Regulatory

batum ae universally

So that there is streamlined flow of information processing

MedRA Hierarchy [to establish the increasing level of inclusivity]

Eg:

SOC System Organ Class
HLGT High level Groupterm
High Level term
LLT Low level term
PT éitJuitd lu‹t,

GI symptoms
Nausea, Vomiting
~~Vomiting~~
Feeling of Vomiting
Feeling Queasy

Since, a large number of modifications (Addition, D, happen, MedRA is updated twice a year.

" \\u*na \jyg,yc č &yt•*Ï*ù•

↳ Should be clear & concise

Should be described in chronological order of event

↳ Should medical & clinical information

↳ You-Id not reveal any signs of Pt identity (maintain confidentiality).

The objective of narrative is to provide comprehensive report(s) of event at a glance. This is made in order for the Viewer/Reader(RA) to grasp the complete inform by a time.

5. Country Spec ADR Forms

Country

India - CDSCO - ADRRF (Advcise Drug Reporting Form)

USA - FDA - Me

UK - MHRA - Yellow Card

Australia - TGA - Blue Card

Module 1: Regulatory

Module 2:

Module 3:

Module 4: Quality Review

Module 5:

SAE Reports

The SAE reports can be reported by HCP's & Non HCP's

Solicited Reports are those be derived from Organised Class System Data.

Patient Safety Reports

those that are not derived from Organised Class System Data

Eg: Spontaneous Reports, Literature, Internet

& t oMcng‹ ù »^t ø •‹**"'^*'*=*

bx "|jci \1o + -oJ«n4\ Regimen

Dechallenge: When an AE is experienced by using a drug, the act of withdrawal of the suspect drug is x\Jed 9ec^b4t ,

When the wi & ADR resolves, it

is !* T\vŁ "bEŁr\hLLENüt

vrx«' » \nu i‹ ,\t y „ **Im t••>L ,

re-introducing the
to try to

a causal relationship.

+ve Rechallenge → ADR appears after re-introd drug

-ve Rechallenge → ADR does not appear " " "

9) Spontaneous report is an unsolicited communicati of an ADR from a HCP / public to the RA' manufacturer.

If one Physician reports the one ADR observed it assessed; reports

Spontaneous report are unsolicited reports i.e they are not derived from any study / organised Class Data system..

It is also a part of Post Marketing Surveillance

^ *° first «a, $ case rxon

b Rena'•< ê«°<tæi, q,p «<anu>r

for:

suspect ... the ...

...verse Events are defined as any untoward medical occurance in a Pt / clinical ... subjected, administered ē tx, c̄ may or may not be related to the treatment

↳ Pharmacist
↳ Patient
↳ General

3½

Significance of Reporter.

Drug Discov — Preclinical → Clinical Trial → PMS

... ases of a drug, there can be AE / ADRs observed.

As each stage of CT is limited to certain no's, the assessment of ADR is mostly by the PMS (Phase IV)

The general public has to be aware of any kind of side effects (Layman term) can be reported.

Only if we report we know, we can regulate.

The case of spontaneous reporting lacks in the ... through many reson it is not reporting like bias.

... significantly impact the drug safety

relationship b/w the drug & Event.

There 2 scales used to assess causality.
→ They algorithms can deduce a causal relation
① Uppsala Monitoring Scale

1) Definite

2 1/2

Naranjo Scale
A set of 10 Questions ⇒ Yes, NO, Dont kno

Doubtful
Possible -

(>

PV Certificate Course Summary

Title: Certificate Course in Pharmacovigilance

Organizer: RBVRR Women's College of Pharmacy in association with ClinoSol Research Private Limited .

No. of registered participants: 65

Day 1

Speaker: Mr. CS Mujeeb, CEO, ClinoSol Research Pvt Ltd.

Clinical research and pharmacovigilance are integral in ensuring the safety and effectiveness of medical interventions. The historical context highlights the evolution of these fields, and current practices emphasize collaboration, early detection, and effective risk communication. Adverse drug reactions are diverse, and their detection and reporting involve various methods, including sophisticated IT systems. The collection, validation, and timely reporting of adverse events are essential components of a robust pharmacovigilance system.

Day 2

Speaker: Ms. Uma Priya, Director, ClinoSol Research Pvt Ltd.

Signal detection is a critical component of pharmacovigilance, involving the systematic identification and evaluation of potential safety concerns. The process includes qualitative and quantitative methods, utilizing diverse data sources such as spontaneous reports, clinical trials, literature, electronic health records, social media, and databases. The signal management process flow ensures a systematic approach to validating, confirming, and addressing signals, with an emphasis on risk assessment, communication, and documentation. Effective signal detection and management contribute to maintaining the safety profile of pharmaceutical products throughout their lifecycle.

Day 3

Speaker: Ms. Uma Priya, Director, ClinoSol Research Pvt Ltd.

The Pharmacovigilance lifecycle involves rigorous processes from pre-marketing safety assessments to post-marketing surveillance. Emphasis on signal detection, risk management, and regulatory reporting ensures the continuous monitoring of drug safety. The integration of comprehensive safety assessments, robust risk management plans, and collaborative efforts with healthcare professionals and regulatory agencies contribute to maintaining a favorable benefit-risk profile throughout the entire lifecycle. Continuous improvement and global harmonization further enhance the effectiveness of pharmacovigilance in safeguarding public health.

Day 4

Speaker: Dr. Rathan Kumar Moka,Sr Medical writer, IQVIA.

Medical writing involves the creation of various scientific and regulatory documents. The collection of reports in pharmacovigilance encompasses diverse types of reports, validated for accuracy and completeness within specific time frames. A narrative is a brief summary of the adverse events experienced by the patients during a clinical trial of a drug. It is submitted along with the clinical study report to establish any causal relationship between the events experienced by the patient and the drug under investigation. This also helps in establishing the drug safety profile. Narrative writing is a crucial aspect where detailed clinical stories, adhering to standardized language and regulatory guidelines, are developed to provide a comprehensive account of adverse events. These narratives, subject to medical review, contribute to safety reports submitted for regulatory compliance.

Day 5

Speaker: Mr. CS Mujeeb, Founder, Clinosol Pvt Ltd.

Causality assessment is a systematic and structured process used in pharmacovigilance to evaluate the likelihood and strength of the relationship between a drug and an adverse event. Various methods and tools, each with its strengths and limitations, are employed to systematically evaluate the evidence supporting or refuting a causal association. The process requires careful consideration of temporal relationships, biological plausibility, and the exclusion of alternative explanations. Despite challenges, causality assessments contribute valuable information to the overall understanding of drug safety profiles and inform regulatory decisions and risk management strategies.

Day 6

Morning Session

Speaker: Dr. Mohammed Sibgatullah,Director Medical affairs , ORCIMED Life sciences

Pharmacovigilance operates at both national and international levels, with each country establishing its system for monitoring drug safety, reporting adverse reactions, and enforcing regulations through regulatory authorities. National efforts involve collaboration between healthcare providers, regulators, and the pharmaceutical industry, emphasizing risk communication and guideline development. Internationally, organizations like the World Health Organization (WHO) and the International Council for Harmonisation (ICH) play key roles in standardizing practices and facilitating global collaboration. The exchange of safety information, standardized terminologies, and harmonized guidelines contribute to a cohesive approach in ensuring drug safety on a global scale.

Afternoon session (Day 8)

Speaker: Hemanth Kumar, Safety system Configuration Manager, GSK

Pharmacovigilance software plays a crucial role in managing and analyzing safety data efficiently. Various software solutions are available, and some popular pharmacovigilance software includes Oracle Argus Safety, Aris Global's Life Sphere, and Veeva Vault Safety.

These platforms offer functionalities for case management, signal detection, regulatory reporting, and overall safety surveillance. They help streamline pharmacovigilance workflows, ensuring compliance with regulatory requirements and facilitating the timely detection of safety signals. These software solutions contribute to the effective and systematic management of safety information throughout the product lifecycle. Oracle Argus Safety system, the case processing workflow involves data import, case assessment, safety data management, and signal detection. Automated workflows streamline routine tasks, and the system facilitates expedited and periodic regulatory reporting.

Day 7

Speaker: Mr. CS Mujeeb, Founder, Clinosol Pvt Ltd.

Narrative writing within the context of pharmacovigilance education involves the strategic utilization of case studies and simulations to bridge the gap between theoretical knowledge and practical application. In designing a program aimed at enhancing participants' understanding of drug safety monitoring, an effective approach was adopted, offering an engaging learning experience. By immersing participants in real-world scenarios through case studies and simulations, the program facilitated the application of theoretical concepts to practical challenges, thereby fostering a comprehensive and actionable understanding of drug safety monitoring principles.

Day 9

Speaker: Mr. CS Mujeeb, Founder, Clinosol Pvt Ltd.

Expedited reporting is an immediate reporting of serious and unexpected adverse reactions to regulatory authorities. It is a cornerstone of pharmacovigilance, facilitating the early detection and management of potential safety issues, thereby safeguarding patient health and contributing to the ongoing evaluation of a drug's benefit-risk profile. Understanding the diverse sources of cases, reporting time frames, and standards for expedited reports is crucial in maintaining an effective pharmacovigilance system. Timely and accurate reporting from healthcare

professionals, patients, clinical trials, and post-marketing studies, along with adherence to regulatory standards, ensures the continuous monitoring and evaluation of drug safety throughout its lifecycle.

The mock interview session enhanced interview skills and performance, boosted confidence, and increased the chances of success in real job interviews.

Day 10

Speaker 1 : Mitesh Reddy, Consultant , Training strategies at Clinosol Reserach Pvt Ltd.

Medical coding in pharmacovigilance enhances the efficiency and reliability of safety data analysis, contributing to the overall understanding of drug safety profiles and supporting regulatory compliance throughout a product's lifecycle. Medical Dictionary for Regulatory Activities (MedDRA) is a standardized medical terminology used internationally for classifying and coding adverse event information associated with medical products, including pharmaceuticals. It provides a common language for the accurate and consistent exchange of regulatory information. Standardised MedDRA Queries (SMQs) are predefined sets of MedDRA terms grouped together based on specific medical conditions or areas of interest. SMQs facilitate standardized and systematic analysis of safety data, enabling efficient identification and assessment of potential safety concerns during pharmacovigilance activities.

Speaker 2: Dr. Sridhar Y, , Associate Vice President of CDMA Hetero

A career in pharmacovigilance involves ensuring the safety of pharmaceutical products throughout their lifecycle, from development and clinical trials to post-marketing surveillance. Pharmacovigilance specialists collaborate with regulatory authorities, healthcare professionals, and pharmaceutical companies to ensure compliance with safety regulations and contribute to the continuous improvement of drug safety profiles. This field offers diverse career paths, including roles in drug safety monitoring, regulatory affairs, and quality assurance within pharmaceutical companies, contract research organizations (CROs), and regulatory agencies. A strong

background in life sciences, pharmacy, or related fields, along with attention to detail and analytical skills, is essential for a successful career in pharmacovigilance.

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

BOGHI Engineering

GREEN CHEMISTRY IN DRUG DISCOVERY

19th -24th DECEMBER 2022

TARGET AUDIENCE

- Under Graduates
- Post Graduates
- Research Scholars
- Science Enthusiasts

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

Registration Fee: 1000/-

Last Date for Registration:
16th Dec 2022

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.

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 offering the following courses:

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

VISION

To be a National Women Pharmacy Professional leader in transforming lives through innovative, vigorous and compassionate approach to Pharma education.

MISSION

RBVRRWCP preparing and empowering girl students by providing continuous awareness programmes to succeed in changing world apart from regular curriculum

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.**

CERTIFICATE COURSE ON GREEN CHEMISTRY IN DRUG DISCOVERY

Value added course		
Course: Green Chemistry in Drug Discovery		
Code: GCDCC005	Credits: 4	Total No. of Hours: 36hrs

The aim of conducting this certificate course is to raise awareness on the role of green chemistry in drug design and development. The Course is focusing on basic principles of green chemistry, designing, alternate energy sources, catalysis in green synthesis and current updates in Green chemistry.

UNIT I: PRINCIPLES AND CONCEPTS OF GREEN CHEMISTRY — 5 HOURS

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 — 8 HOURS

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 — 8 HOURS

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

UNIT IV: RENEWABLE RESOURCES AND GREENHOUSE EFFECT — 8 HOURS

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. — 7 HOURS

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.

PROGRAMME SCHEDULE

DATE	MORNING SESSION 10.30AM-1.00PM	AFTERNOON SESSION 2.00PM-4.30PM
19/12/22	**10.00-10.30AM: Inaugural Session** **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
20/12/22	**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
21/12/22	**Dr. GunaSekar G.H.** Scientist & Assistant Professor AcSIR, Department Of Catalysis & Fine Chemicals. CSIR-IICT Hyderabad	**Dr. T. Saravanan** Assistant Professor School of Chemistry University of Hyderabad Hyderabad
22/12/22	Hands on Training on **Microwave Synthesizer**	Hands on Training on **Microwave Synthesizer**
23/12/22	**Prof. B.M. Reddy** FNAE, FNASc, FRSC, FTASc, FAPASc Senior Professor Emeritus Department of Chemistry BITS Pilani, Hyderabad Campus Hyderabad	**Dr. Jeevana Jyothi** HOD, Associate Professor RBVRR Women's College Department of Chemistry & Forensic Science Barkatpura
24/12/22	**Prof. M Thirumala Chary** Professor of Emeritus, Chemistry JNTUH University College of Engineering , Science & Technology Hyderabad	**Prof. M. Sumakanth** Principal, RBVRR Women's College of Pharmacy Valedictory Session

SUBJECT EXPERTS

MR. DR. SRINIVAS NANDURI

Professor, Department of Chemical Sciences, NIPER Hyderabad

DR. BHOOMI REDDY RAMA DEVI

Professor & Head of the Department, JNTUH

DR.G.H.GUNASEKAR

Scientist & Assistant Professor AcSIR, Department Of Catalysis & Fine Chemicals. CSIR-IICT.

PROF. B.M. REDDY

Senior Professor Emeritus
Department of Chemistry
BITS Pilani, Hyderabad Campus

DR. T. SARAVANAN

Assistant Professor
School of Chemistry
University of Hyderabad

DR. V. NAVEEN REDDY

Assistant Professor,
Department of Chemistry,
Nizam College.

DR. K. PREMALATHA

Assistant Professor
Department of Chemistry
University College for Women
Osmania University

PROF. M THIRUMALA CHARY

Professor of Emeritus Chemistry
JNTU Hyderabad JNTUH University College of Engineering , Science & Technology Hyderabad

DR. JEEVANA JYOTHI

Associate Professor
RBVRR Women's College, Barkathpura.

PROF. M. SUMAKANTH

Principal
RBVRR Women's College of Pharmacy

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Program Coordinator

Dr. M.Vijaya Bhargavi

Associate Professor & Head
Department of Pharmaceutical Chemistry
RBVRR Women's College of Pharmacy.
98480 54391

For Queries Contact

Mrs. V. Padmaja: 9849583030
Mrs. P. Archana : 8660723852
Mrs. Sajida Afreen : 7702236567

College Code: 1706

RBVRR WOMEN'S COLLEGE OF PHARMACY

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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

RBVRR Womens college of pharmacy - SEMINAR HALL

Date: 07/04/2023 to 12/04/2023

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

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

Patron
Prof. K. Muthyam Reddy
Hon. Secretary cum correspondent
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 C002	**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	**7 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	**7 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

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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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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
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Certificate course on quality by design in formulation development

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
□ 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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FEEDBACK FORM DAY 3

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- ☑ 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 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

□ 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 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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Certificate course on quality by design in formulation development

FEEDBACK FORM DAY 5

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

□ excellent

□ very good

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□ excellent

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Certificate course on quality by design in formulation development

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 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
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4.How was the content delivered by the speaker..
□ excellent
☑ very good
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College Code: 1706

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CERTIFICATE COURSE ON
DESIGN OF EXPERIMENTS IN PHARMACEUTICAL DEVELOPMENT

Date:
1st May,2023 – 6th May,2023

Venue:
Seminar Hall
RBVRR Women's College of Pharmacy

INAUGURAL SESSION:
Dr. K.V. Ratnamala,
Associate Professor,
Dept. 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. K.V. Ratnamala Associate Professor, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy	Session-1: 1st May 2023 at 11:00 am Session-2: 1st May 2023 at 2.00 pm Session-1: 2nd May 2023 at 11:00 am Session-2: 2nd May 2023 at 2.00 pm
2. Dr. G. Uma Rani Associate Professor, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy	Session-1: 3rd May 2023 at 11:00 am Session-2: 3rd May 2023 at 2.00 pm Session-1: 4th May 2023 at 11:00 am Session-2: 4th May 2023 at 2.00 pm
3. Dr. A. Krishna Sailaja Professor & Head, Dept. of Pharmaceutics, RBVRR Women's College of Pharmacy	Session-1: 5th May 2023 at 11:00 am Session-2: 5th May 2023 at 2.00 pm Session-1: 6th May 2023 at 11:00 am Session-2: 6th May 2023 at 2.00 pm

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Value Added Course		
Course: Certificate course on design of experiment in pharmaceutical development		
Code: DOE F004	**Credits:** 2	**Total No. of Hours :**36

A certificate course in Design of Experiments (DOE) for pharmaceutical development provides participants with a comprehensive understanding of experimental design principles tailored to the industry's specific needs. Through this program, individuals learn to optimize processes, reduce variability, and elevate product quality by implementing efficient experimental designs. The course fosters informed decision-making, facilitates cost reduction through streamlined experimentation, and accelerates time to market for new pharmaceutical products. Moreover, it cultivates a culture of continuous improvement within organizations, promoting competitiveness and adherence to regulatory standards. Graduates of this program are positioned for professional advancement and contribute to driving innovation and excellence in pharmaceutical development.

Objectives: The objectives of a certificate course in Design of Experiments (DOE) for pharmaceutical product development are to optimize processes, enhance product quality, improve efficiency, reduce costs, ensure regulatory compliance, facilitate data-driven decision-making, foster innovation, and support professional development

SYLLABUS:

UNIT 1	**INTRODUCTION**	**6 HRS**
Introduction basic need and Strategy of Experimentation, Typical applications of Experimental design, Basic Principles, Guidelines for Designing Experiments.		

Unit II	Basic Statistical Concepts	7 HRS
Basic statistical concepts covers Overview and applications of statistical methods which includes Measures of central tendency and variability.Probability Distributions: Normal, binomial, and Poisson,Confidence intervals, hypothesis testing.Correlation and Regression: Relationship between variables.Experimental Design: Basics and applications.Statistical Process Control (SPC): Monitoring manufacturing processes.Quality by Design (QbD): Principles and statistical tools.Software Applications: Hands-on experience with statistical software.		

UNIT III	Experimental Design	7 HRS
Experimental design covers Basics and objectives of experimental design,Hypothesis testing, ANOVA, regression,Full, fractional, and mixed factorial designsResponse Surface Methodology in Optimizing processes and formulations.Robust Parameter Design in Optimizing performance under uncertainty,Hands-on training with statistical software.Case Studies: Real-world applications in various fields.		

Unit IV	Analysis And Interpretation Methods	8 HRS
Introduction to Analytical Techniques,Data Interpretation Skills,Quality Control and Assurance,Regulatory CompliancesProblem-Solving Abilities,Risk Assessment and Mitigation,Communication Skills,Continuous Improvement		

Unit V	**Quality By Experimental Design**	8HRS

"Quality by Experimental Design" in pharmaceutical transdermal drug delivery system (TDDS) development:

1. Introduction to Quality by Design (QbD)
    - Overview of QbD principles and their importance in pharmaceutical development.
    - Application of QbD concepts to transdermal drug delivery systems.
2. Basics of Experimental Design
    - Understanding experimental design principles.
    - Types of experimental designs: full factorial, fractional factorial, and screening designs.
3. Factorial Designs for TDDS
    - Designing experiments to study the effects of multiple factors on TDDS performance.
    - Analysis of factorial experiments using statistical techniques.
4. Optimization Techniques
    - Response surface methodology (RSM) for optimizing TDDS formulations.
    - Desirability functions for multi-criteria optimization.
5. Risk Assessment and Mitigation
    - Identifying critical quality attributes (CQAs) and critical process parameters (CPPs) for TDDS.
    - Application of risk assessment tools in QbD for TDDS development.
6. Statistical Process Control (SPC) in TDDS Manufacturing
    - Monitoring and controlling TDDS manufacturing processes using SPC tools.
    - Control chart analysis for ensuring TDDS quality and consistency.
7. Case Studies and Applications
    - Analysis of real-world case studies demonstrating the application of QbD and experimental design principles in TDDS development.
    - Hands-on exercises and projects involving experimental design and optimization of TDDS formulations.
8. Regulatory Considerations
    - Understanding regulatory requirements and guidelines relevant to QbD implementation in TDDS development.
    - Documentation and reporting of QbD studies for regulatory submissions.

Design of experiments Course Outcomes:

After completion of this course

1.Students gain a solid understanding of fundamental statistical concepts such as hypothesis testing, analysis of variance (ANOVA), regression analysis, and statistical process control (SPC). This knowledge forms the foundation for applying statistical methods effectively in pharmaceutical development.

2.Students learn how to design and analyze experiments to optimize pharmaceutical formulations. By systematically varying factors like excipient concentrations or processing parameters, students can identify the optimal conditions for achieving desired product characteristics such as stability, bioavailability, and drug release profile.

3.Process Optimization Skills: Through DOE, students learn how to systematically optimize manufacturing processes to ensure product quality and consistency. They gain skills in identifying critical process parameters (CPPs) and understanding their impact on product quality attributes.

4.By applying statistical tools to real-world pharmaceutical problems, students develop problem-solving skills. They learn how to identify sources of variability, troubleshoot process issues, and implement data-driven solutions to improve product quality and process efficiency.
5.Preparation for Regulatory Requirements: Students understand the importance of statistical methods in meeting regulatory requirements for pharmaceutical development. By learning how to design experiments and analyze data rigorously, students are better prepared to support regulatory submissions and comply with guidelines such as those outlined by the International Council for Harmonisation (ICH).
6.Analysis and Interpretation Methods in Pharmaceutical Product Development is to equip students with the skills to effectively analyze and interpret data throughout the product development lifecycle. This includes understanding analytical techniques, applying statistical methods for quality control, ensuring regulatory compliance, enhancing problem-solving abilities, and improving communication
7. Students will gain a deep understanding of QbD principles, methodologies, and tools relevant to pharmaceutical and biopharmaceutical product development.

- Problem-Solving Skills: They will develop the ability to apply QbD concepts to solve complex problems in product formulation, process optimization, and quality control.
- Critical Thinking: Students will learn to critically evaluate processes and identify critical quality attributes (CQAs) and critical process parameters (CPPs) that impact product quality.
- Communication Skills: They will enhance their ability to communicate effectively with cross-functional teams, regulators, and stakeholders regarding QbD strategies, risk assessments, and quality control measures.
- Application in Real-world Scenarios: Students will be able to apply QbD principles to real-world scenarios, such as developing robust manufacturing processes, addressing regulatory requirements, and troubleshooting production issues.

- Regulatory Compliance: They will understand regulatory guidelines and expectations related to QbD implementation, ensuring compliance throughout the product lifecycle.
- Collaborative Work: Students will develop skills for collaboration and teamwork, working across disciplines to achieve common quality goals.
- Continuous Learning and Improvement: They will cultivate a mindset of continuous learning and improvement, adapting QbD strategies to evolving industry standards and technological advancements.

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Certificate course on by design of experiment in pharmaceutical development

FEEDBACK FORM DAY 1(session -1)

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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 experimentation in scientific research?

a) To prove a hypothesis b) To gather data and test hypotheses c) To support preconceived notions d) To confirm existing beliefs

7Which of the following is NOT a basic need of experimentation? a) Reproducibility b) Control c) Randomness d) Bias

8.Why is control important in an experiment?

a) To ensure that only one variable is changed at a time b) To make the experiment more complicated c) To confuse the participants d) To introduce bias

9.Randomization in experimentation helps to:

a) Ensure that all participants are identical b) Minimize the effects of confounding variables c) Increase bias in the results d) Simplify the experimental design

10.Which strategy is used to eliminate the influence of extraneous variables in an experiment?

a) Randomization b) Control c) Manipulation d) Replication

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Certificate course on by design of experiment in pharmaceutical development

FEEDBACK FORM DAY 1(session -1)

1.Name of the participant: Chenchavam Tulasi

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3.Email address: chenchavamtulasi@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 experimentation in scientific research?

a) To prove a hypothesis b) To gather data and test hypotheses c) To support preconceived notions d) To confirm existing beliefs

7Which of the following is NOT a basic need of experimentation? a) Reproducibility b) Control c) Randomness d) Bias

8.Why is control important in an experiment?

a) To ensure that only one variable is changed at a time b) To make the experiment more complicated c) To confuse the participants d) To introduce bias

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FEEDBACK FORM DAY 1(session -1)

1.Name of the participant: Keerthana G

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3.Email address: keerthanag@gmail.com

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

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✓ very good

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FEEDBACK FORM DAY 1(session 2)

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3.Email address: nida.mirza.baig1a@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 term for the phenomenon where participants' expectations or beliefs about an experiment affect their behavior?

a) Confirmation bias b) Placebo effect c) Hawthorne effect d) Observer bias

7.Which of the following is NOT a common type of experimental design?

a) Cross-sectional b) Longitudinal c) Correlational d) Experimental

8.What is the purpose of blinding in experimentation?

a) To prevent the researcher from knowing which participants are in the control group b) To prevent participants from knowing which treatment they are receiving c) To prevent the data from being analyzed d) To ensure that the experiment is conducted in a biased manner

9.Which statistical method is commonly used to determine whether the results of an experiment are statistically significant?

a) T-test b) ANOVA c) Chi-square test d) Regression analysis

10Which of the following is NOT a potential ethical concern in experimentation?

a) Informed consent b) Deception of participants c) Fabrication of data d) Harm to participants or society

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Certificate course on by design of experiment in pharmaceutical development
FEEDBACK FORM DAY 1(session 2)

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2.Name of the institute:.....Rbvrmwcp.....
3.Email address:.....archetha@gmail.com
4.How was the content delivered by the speaker..
☑ excellent
□ very good
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Certificate course on by design of experiment in pharmaceutical development

FEEDBACK FORM DAY 2(session_1)

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3.Email address: chavandivya16@gmail.com

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

- ☑ excellent
- ☐ very good
- ☐ Good

5. How do you rate the session

- ☐ excellent
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A) To ensure that all treatment groups are exactly the same B) To reduce the effects of confounding variables C) To increase the sample size D) To guarantee that the experiment will yield statistically significant results

7.Which of the following is NOT a common type of experimental design? A) Completely Randomized Design B) Matched Pairs Design C) Latin Square Design D) Sequential Design

8.What is a factorial experiment?

A) An experiment that involves only two levels of the independent variable B) An experiment that manipulates more than one independent variable C) An experiment conducted in a laboratory setting D) An experiment that uses a factorial analysis to analyze the data

9.What is the purpose of blocking in experimental design?

A) To ensure that each treatment group has the same number of participants B) To group similar experimental units together to reduce variability C) To randomize the assignment of treatments to participants D) To control for extraneous variables that cannot be controlled experimentally

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FEEDBACK FORM DAY 2(session_1)

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

- ☑ excellent
- ☐ very good
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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
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6.What is the main advantage of a randomized complete block design (RCBD) over a completely randomized design (CRD)?

A) RCBD allows for the comparison of more than two treatments. B) RCBD reduces the variability within treatment groups. C) RCBD accounts for the variability between blocks. D) RCBD requires a smaller sample size.

7.In pharmaceutical product development, what is the primary purpose of a Phase III clinical trial?

A) To assess the safety and efficacy of the drug in a large population B) To determine the optimal dosage of the drug C) To investigate potential drug interactions D) To obtain regulatory approval for marketing the drug

8.Which statistical method is commonly used to determine the sample size for clinical trials in pharmaceutical product development?

A) Analysis of variance (ANOVA) B) Power analysis C) Chi-square test D) Student's t-test

9.What is the purpose of randomization in a clinical trial?

A) To ensure that participants are evenly distributed across treatment groups B) To prevent participants from dropping out of the study C) To control for confounding variables D) To increase the likelihood of obtaining statistically significant results

10Which of the following statistical techniques is commonly used for analyzing pharmacokinetic data?

A) Regression analysis B) Survival analysis C) Non-parametric tests D) Area under the curve (AUC) analysis

What is the purpose of the placebo in a clinical trial?

A) To serve as a standard against which the efficacy of the drug is compared B) To ensure that participants remain blinded to the treatment they are receiving C) To enhance the effectiveness of the active drug D) To minimize the risk of adverse effects in participants

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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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FEEDBACK FORM DAY 3(session_1)

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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 is the primary goal of Quality by Design (QbD) in pharmaceutical manufacturing?

A) To minimize production costs B) To comply with regulatory requirements C) To ensure consistent product quality and performance D) To maximize production output

7.Which of the following is NOT a key principle of Quality by Design (QbD)?

A) Designing quality into the product B) Understanding and controlling the manufacturing process C) Continuously monitoring product quality during production D) Performing quality testing only at the final stage of production

8.What is the purpose of a Design of Experiments (DOE) in Quality by Design (QbD)? A) To optimize the manufacturing process parameters B) To identify critical quality attributes (CQAs) of the product C) To validate the manufacturing process D) To conduct stability testing on the finished product

9.Which statistical tool is commonly used to analyze the results of a Design of Experiments (DOE)?

A) Analysis of Variance (ANOVA) B) Regression analysis C) Chi-square test D) Student's t-test

10What is the purpose of a risk assessment in Quality by Design (QbD)?

A) To identify potential failures in the manufacturing process B) To determine the acceptable quality limits for critical process parameters C) To evaluate the impact of process variability on product quality D) To ensure compliance with regulatory guidelines

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

□ excellent

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

□ excellent

☑ very good

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5. How do you rate the session

□ excellent

☑ very good

□good

6.Which regulatory agency emphasizes Quality by Design (QbD) principles in its guidelines for pharmaceutical development?

A) International Conference on Harmonization (ICH) B) Food and Drug Administration (FDA) C) European Medicines Agency (EMA) D) World Health Organization (WHO)

7.What is the primary benefit of implementing Quality by Design (QbD) in pharmaceutical manufacturing?

A) Reduced production costs B) Improved product quality and consistency C) Faster time to market D) Increased manufacturing capacity

8.Which phase of Quality by Design (QbD) focuses on identifying and understanding the critical quality attributes (CQAs) of the drug product? A) Quality Risk Management B) Design Space C) Control Strategy D) Target Product Profile

9.What is the purpose of a Control Strategy in Quality by Design (QbD)?

A) To establish specifications for raw materials and finished products B) To continuously monitor and control critical process parameters C) To identify and mitigate potential risks in the manufacturing process D) To define the range of acceptable quality attributes for the product

10Which of the following is NOT a component of the Quality by Design (QbD) framework?

A) Risk Assessment B) Design Space C) Quality Control D) Continuous Improvement

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FEEDBACK FORM DAY 3(session_2)

1.Name of the participant: Tailors Keerthana

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

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FEEDBACK FORM DAY 4(session_1)

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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

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6.What is the purpose of a crossover design in pharmaceutical research?

A) To compare the efficacy of two or more treatments simultaneously B) To eliminate carryover effects from previous treatments C) To randomize participants into different treatment groups D) To increase the power of the statistical analysis

7.Which type of experimental design involves randomizing participants into different treatment groups and measuring the outcome of interest at a single time point?

A) Crossover design B) Factorial design C) Parallel-group design D) Latin square design

8.What is the primary advantage of a factorial design in pharmaceutical research?

A) It allows for the comparison of more than two treatments simultaneously. B) It eliminates carryover effects from previous treatments. C) It ensures that participants are evenly distributed across treatment groups. D) It reduces the variability within treatment groups.

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FEEDBACK FORM DAY 4(session_1)

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

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FEEDBACK FORM DAY 4(session_2)

1.Name of the participant: Gr. Harshitha

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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 phase of pharmaceutical development is most closely associated with the implementation of experimental design?

A) Pre-clinical development B) Clinical development C) Formulation development D) Manufacturing process development

7.What is the purpose of blocking in experimental design?

A) To ensure that each treatment group has the same number of participants B) To group similar experimental units together to reduce variability C) To randomize the assignment of treatments to participants D) To control for extraneous variables that cannot be controlled experimentally

8.Which type of experimental design involves each participant receiving all treatment conditions in a random order?

A) Crossover design B) Parallel-group design C) Factorial design D) Latin square design

9.What is the purpose of blinding in experimental design?

A) To prevent participants from dropping out of the study B) To ensure that the experiment is conducted in a double-blind manner C) To reduce the influence of biases on the outcome of the study D) To increase the likelihood of obtaining statistically significant results

10Which of the following is a potential disadvantage of a crossover design?

A) It requires a larger sample size compared to parallel-group design. B) It may not be suitable for treatments with long-lasting effects. C) It is more susceptible to carryover effects. D) It cannot accommodate more than two treatment conditions.

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FEEDBACK FORM DAY 4(session_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 phase of pharmaceutical development is most closely associated with the implementation of experimental design?

A) Pre-clinical development B) Clinical development C) Formulation development D) Manufacturing process development

7.What is the purpose of blocking in experimental design?

A) To ensure that each treatment group has the same number of participants B) To group similar experimental units together to reduce variability C) To randomize the assignment of treatments to participants D) To control for extraneous variables that cannot be controlled experimentally

8.Which type of experimental design involves each participant receiving all treatment conditions in a random order?

A) Crossover design B) Parallel-group design C) Factorial design D) Latin square design

9.What is the purpose of blinding in experimental design?

A) To prevent participants from dropping out of the study B) To ensure that the experiment is conducted in a double-blind manner C) To reduce the influence of biases on the outcome of the study D) To increase the likelihood of obtaining statistically significant results

10Which of the following is a potential disadvantage of a crossover design?

A) It requires a larger sample size compared to parallel-group design. B) It may not be suitable for treatments with long-lasting effects. C) It is more susceptible to carryover effects. D) It cannot accommodate more than two treatment conditions.

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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.Which statistical method is commonly used to analyze pharmacokinetic data in pharmaceutical development?

✓ A) Analysis of Variance (ANOVA) B) Survival analysis C) Non-parametric tests D) Area under the curve (AUC) analysis

7.What is the purpose of performing a power analysis in pharmaceutical research?

A) To determine the optimal dosage of the drug B) To identify potential side effects of the drug C) To estimate the sample size needed to detect a significant treatment effect D) To analyze the variability in response to the drug among different individuals

8.Which of the following statistical tests is commonly used to compare means between two independent groups in pharmaceutical studies?

✓ A) Student's t-test B) Chi-square test C) Analysis of Variance (ANOVA) D) Wilcoxon signed-rank test

9.What does the term "pharmacodynamics" refer to in pharmaceutical development?

A) The study of the absorption, distribution, metabolism, and excretion of drugs B) The study of drug interactions with biological systems and their effects C) The study of the biochemical mechanisms of drug action ✓ D) The study of adverse reactions to drugs

10Which statistical method is commonly used to analyze categorical data in pharmaceutical research?

✓ A) Analysis of Variance (ANOVA) B) Chi-square test C) Regression analysis D) Student's t-test

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

- □ excellent
- □ very good
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- □ excellent
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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 purpose of conducting a post-hoc analysis in pharmaceutical research?

A) To determine whether the results are statistically significant B) To compare multiple treatment groups after detecting a significant omnibus test result C) To assess the validity of the experimental design D) To control for Type I errors in hypothesis testing

7.Which statistical measure is commonly used to express the association between two variables in pharmaceutical studies?

A) Odds ratio B) Hazard ratio C) Pearson correlation coefficient D) Relative risk

8.What is the primary purpose of conducting a sensitivity analysis in pharmaceutical research?
A) To assess the variability in response to the drug among different individuals B) To identify potential side effects of the drug C) To examine the robustness of study results to changes in assumptions or parameters D) To determine the optimal dosage of the drug

9.Which statistical technique is commonly used to analyze time-to-event data, such as survival or recurrence times, in pharmaceutical studies?

A) Analysis of Variance (ANOVA) B) Cox proportional hazards model C) Wilcoxon signed-rank test D) Friedman test

10.What is the purpose of conducting subgroup analyses in pharmaceutical research?

A) To assess the validity of the experimental design B) To identify potential side effects of the drug C) To explore differences in treatment effects among different subpopulations D) To determine the optimal dosage of the drug

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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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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 goal of employing Quality by Experimental Design in transdermal drug delivery system (TDDS) development?

✓ A) To increase the production capacity of the TDDS B) To ensure compliance with regulatory requirements C) To optimize the formulation and manufacturing process D) To reduce the cost of production

7.Which statistical method is commonly used to optimize the formulation parameters in TDDS development?

A) Analysis of Variance (ANOVA) B) Regression analysis C) Chi-square test D) Student's t-test

8.What is the purpose of conducting a factorial design in TDDS development? A) To investigate potential drug interactions B) ✓ To compare the efficacy of different drug delivery systems C) To optimize multiple factors simultaneously D) To analyze the pharmacokinetics of the drug

9.Which of the following is NOT a key principle of Quality by Experimental Design in TDDS development?

✓ A) Designing quality into the product B) Understanding and controlling the manufacturing process C) Conducting stability testing at different temperatures D) Employing statistical techniques to optimize parameters

10 What is the primary advantage of employing Quality by Experimental Design in TDDS development?

A) It ensures regulatory compliance B) It reduces the time and cost of development C) It eliminates the need for clinical trials ✓ D) It guarantees a high success rate in product launch

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

□ excellent

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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 phase of TDDS development is most closely associated with the implementation of Quality by Experimental Design?

A) Pre-formulation studies B) Formulation development C) Preclinical studies D) Clinical trials

7.What is the purpose of establishing a Design Space in Quality by Experimental Design for TDDS?

A) To define the range of acceptable quality attributes for the product B) To identify critical process parameters that need to be controlled C) To specify the operating conditions under which the manufacturing process will consistently produce a quality product D) To conduct stability testing on the finished product

8.Which statistical method is commonly used to analyze the results of a factorial design in TDDS development?

A) Analysis of Variance (ANOVA) B) Chi-square test C) Regression analysis D) Student's t-test

9.What is the primary purpose of employing a crossover design in TDDS development?

A) To investigate the effects of different formulation parameters B) To eliminate carryover effects from previous treatments C) To assess the stability of the drug in different conditions D) To compare the efficacy of different drug delivery systems

10.What is the role of Multivariate Data Analysis (MVDA) in Quality by Experimental Design for TDDS development?

A) To optimize the manufacturing process parameters B) To analyze complex relationships between formulation variables and product quality C) To identify critical process parameters that need to be controlled D) To determine the optimal dosage of the drug

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

□ excellent
□ very good
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