Syllabus for M.Pharm Clinical Research

Semester II

Clinical Research Methodology

Paper I – MPCR 201 T

Scope

After Completion of the course students should be able to understand various practical aspects of conduct a Clinical Trials. How to implement a clinical trial and its management.

Objective

After completion of the course students should be able to understand,

- What are the requirements for doing a good clinical project
- Documents required for a clinical trial project
- Inspection during the clinical trial
- Regulation of conducting clinical trial for biosimilars and medical devices.

THEORY 60 Hrs

1. **Clinical Trial Documents** 10 Hrs
    - Protocol designing
    - Investigator's brochure
    - Preparation & Amendments of ICF & CRF's
    - Importance of SOPs in clinical trial

2. **Clinical Trial Inspection and Audit** 10 Hrs
    - Types of audit
    - Preparation for audit
    - Regulatory requirements for audit
    - Clinical quality assurance audit

3. **Clinical Trial Outsourcing** 10 Hrs
    - Scope and role of CROs/SMO
    - Concept of outsourcing
    - Evaluation of time & cost for outsourcing

4. **Project Management in clinical Trials** 10 Hrs
    - Selection of clinical trial site
    - Investigator identification
    - Volunteers selection criteria & recruitment
    - Within-trial decisions e.g. code breaking, premature termination, monitoring & source documents verification

- Adverse event monitoring & expedited reporting of SAEs
- Data safety monitoring board
- Site monitoring visit
- Clinical trial report

5. Clinical Data Management 10Hrs

- History of Clinical Data Management
- Overview of Clinical Data Management
- Data Management plan
- Data capture & collection
- Case report form design
- Clinical database
- Database review and validation
- Discrepancy management and data closure

6. Essentials of Medical writing 10Hrs

- Fundamentals of good medical writing
- Types of Medical writing
- Types of Research publication
- Requirements for writing research articles

References:

1. Drug Discovery and Clinical Research by SK GUPTA, Jaypee Brothers Medical Publishers (p) ltd. Second Edition New Delhi
2. The Belmont Report Ethical Principles and Guidelines for the Protection of Human Subjects of research. Available at:http://www.nmmu.ac.za/documents/rcd/The%20Belmont%20report.pdf(1979).(accessed:November 2009)
3. Indian council of Medical research Ethical guidelines for biomedical research on Human Participants.2008, 27-9.
4. 45 US Department of health and Human Service. Protection of Human Subjects. Code of Federal Regulations Title 45,Part 46,Sub Part D

   Washington, DC: US Department of Health and Human Services, (revised Jan 2009)

Syllabus for M.Pharm Clinical Research

Semester II

Introduction to Pharmacoeconomics and Outcomes Research

Paper II – MPCR 202 T

Scope

After Completion of the course students should be able to understand the basic principles of Pharmacoeconomics i.e. to find out the best therapy at affordable cost, which should be based on patient reported outcomes.

Objective

After completion of the course students should be able to understand,

- Pharmacoeconomics
- Health Technology Assessment
- Systematic Review and Meta-Analysis in Evidence Based Medicines
- Patient Reported Outcomes Research

THEORY 60 Hrs

7. **Pharmacoeconomics** 10 Hrs
    - Principles of Pharmacoeconomics
    - Definitions, Perspectives & Costs
    - Methods & Applications of Pharmacoeconomics
    - Clinical pharmacy service evaluation
    - Strategies to incorporate pharmacoeconomics into pharmacotherapy
    - Conduct of pharmacoeconomics evaluation

8. **Health Technology Assessment** 10 Hrs
    - Introduction to HTA
    - Definitions & Importance of HTA
    - HTA process in different countries
    - Drug reimbursement policies in various countries
    - Health Economic evaluation: challenges and methodological issues for priority setting universal health coverage

9. **Systematic Review and Meta –Analysis in Evidence Based Medicines** 10 Hrs
    - Objectives of systematic review
    - Role and rationale for doing meta-analysis
    - Essential features of systematic review & meta-analysis
    - Significance of systematic review & meta-analysis
    - Methods to write a systematic review

- Merits and demerits of systematic review and meta-analysis

10 Hrs

10. **Patient Reported Outcomes Methods**
    - Introduction to Patient Reported Outcomes (PROs) Assessment-Development and validation
    - Patient preference methods
    - Establishing the content validity of PRO instruments
    - Patient preference methods used for QALYs

11. **Health Economics and Outcomes Research (HEOR)** 10 Hrs
    - Introduction to HEOR
    - Healthcare costs categories
    - Methods of HEOR Analysis
    - HEOR as a guide to policy makers

12. **Role of HEOR in Drug Development Process** 10 Hrs
    - Challenges & Opportunities for reimbursement and market access within biopharma research
    - Current and future uses of HEOR data in healthcare decision making in the US

References:

1. Moher *,Larissa Shamseer 1,Mike Clarke2,Davina Gheris3, Alessandro Liberati,Mark Petticrew4,Paul Shekelle5,Lesley A Stewart6 and PRISMA-P Group; Moher et al; Preferred reporting items for systematic review and meta-analysis protocols(PRISMA-P)2015 statement, Systematic Reviews2015 4:1
2. SUNY Downstate EBM Tutorial ;available at http://library downstate.edu/EBM2/research.htm
3. AK Akobeng;Understanding systematic reviews and meta-analysis Community child health, public health and epidemiology; Arch Dis Child 2005;90:845-848

Syllabus for M.Pharm Clinical Research

Semester II

Regulatory Affairs in Clinical Research

Paper III – MPCR 203 T

Scope

After Completion of the course students should be able to understand various regulations in India and other Countries to conduct a Clinical Trials. How to implement a clinical trial as per drugs and cosmetic act and in developing world.

Objective

After completion of the course students should be able to understand,

- Drug & Cosmetic Act
- Regulations for conducting Clinical trials
- Clinical Research Related Guidelines
- Practical Input of International Bodies
- Regulations for the Development and Clinical Trials of Biosimilars and Medical Devices

THEORY 60 Hrs

13. **Drug & Cosmetic Act** 10 Hrs

14. Regulations for Conducting Clinical trials 10 Hrs

- USA: Process of IND submission, NDA, Application for approval of a generic drug product (ANDA 505j), BLA
- UK: MHRA
- EU: Centralised procedure, Decentralized process, Mutual Recognition Procedure
- India: Schedule Y

10 Hrs

15. Clinical Research Related Guidelines

- Good clinical practice guideline (ICH GCPE6)
- Indian GCP guidelines
- ICMR Ethical guidelines for biomedical research

10 Hrs

16. **Practical Input of International Bodies**

- WMA
- CIOMS
- ICH

17. Regulations for the Development and Clinical Trials of Biosimilars 10Hrs

- Guidelines and Regulations
- Development and Quality aspects
- Safety and Efficacy, Clinical Development
- Principles for Development of Biosimilars
- Data requirements for Preclinical studies and Clinical trial application

18. Medical Devices: Regulations and Research 10Hrs

- Phases in the lifespan of a medical devices
- Conducting clinical trials on medical devices
- Medical devices regulations across the world

References:

5. Drug Discovery and Clinical Research by SK GUPTA, Jaypee Brothers Medical Publishers (p) ltd. Second Edition New Delhi
6. The Belmont Report Ethical Principles and Guidelines for the Protection of Human Subjects of research. Available at:http://www.nmmu.ac.za/documents/rcd/The%20Belmont%20report.pdf(1979).(accessed:November 2009)
7. Indian council of Medical research Ethical guidelines for biomedical research on Human Participants.2008, 27-9.
8. 45 US Department of health and Human Service. Protection of Human Subjects. Code of Federal Regulations Title 45,Part 46,Sub Part D

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Syllabus for M.Pharm Clinical Research

Semester II

Pharmacovigilance

Paper IV – MPCR 204 T

Scope

Overall objective is to familiarise the students with the objectives of Pharmacovigilance to ensure the safety of patients and their methods of analysing ADRs.

Objective

After completion of the course students should be able to understand,

- Benefit Risk Assessment in Pharmacovigilance
- Pharmacovigilance regulations in various countries
- Good Pharmacovigilance practice
- Pharmacovigilance of herbal drugs

THEORY 60 Hrs

19. **Benefit Risk Assessment in Pharmacovigilance** 10 Hrs
    - Definitions, Three Principles
    - Adverse health effect
    - Actual versus perceived benefits and risk
    - Turbo model, Factor effecting benefit risk balance
    - Stepwise approach to Benefit Risk Assessment

20. Pharmacovigilance Regulations in various countries 10 Hrs
    - UK
    - Europe
    - USA
    - India

21. Good Pharmacovigilance Practice (GPVP) 05 Hrs

22. **Setting up of a Pharmacovigilance Center** 05 Hrs

23. Pharmacovigilance of Herbal Drugs 10Hrs

24. Computer Based System Approach 10Hrs
    - Background
    - Methods of Safety data analysis
    - Informatics in Pharmacovigilance

- Computer bases tools for Pharmacovigilance

25. Vigilance Systems for Medical Devices 10 Hrs

- Medical device regulations and need of Harmonization
- Medical device regulations
- Medical device market: focusing BRICS

References:

1) Drug Discovery and Clinical Research (2nd Edition), SK Gupta, Jaypee Brothers Medical Publishers (P) Ltd.
2) Textbook of Pharmacovigilance (2nd Edition), SK Gupta, Jaypee Brothers Medical Publishers (P) Ltd.
3) Bigoniya P. Pharmacovigilance of Herbal Medicines: Current Status and Future Strategies. The Pharma review 2009; 7:39
4) 45 US Department of Health and Human Services. Protection of human subjects, Code of federal regulations. Title 45, Part 46, Subpart D.
5) Indian Council of Medical Research. Ethical Guidelines for Biomedical research on Human participants.2008, 27-9.