**MINISTRY OF HEALTH**

**NATIONAL INSTITUTE OF**

**POSTGRADUATE TRAINING OF DOCTORS**

**AND PHARMACISTS**

**CURRICULUM IN THE SPECIALTY TRAINING**

**CLINICAL PHARMACOLOGY**

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# CLINICAL PHARMACOLOGY

* 1. **DEFINITION:** Clinical pharmacology studies interactions between drugs and the human body, sick or healthy for evaluation, supervision and rational use of medicines in the prevention, diagnosis or treatment.
  2. **DURATION**

4 years

* 1. **STRUCTURE OF TRAINING**

1.3.1.The stage of employment, registration of social-administrative problems, presentation at the unit where he was assigned, choosing of tutor and fixing the work plan ( 2 weeks)

1.3.2. Basic pharmacology internship: 1 year

1.3.3. Legislation and organization internship: 1 year

1.3.4. Internal medicine internship: 3 luni

1.3.5. Intensive care and emergency medicine internship: 3 months

1.3.6. Clinical toxicology internship: 3 months

1.3.7. Internship at choice in a medical specialty other than the above: 3 months

1.3.8. Clinical pharmacology internship: 1 year

* 1. **CONTENT OF INTERNSHIPS**

**Basic pharmacology internship**

**1.4.1.1. Conference themes**

1. General pharmacodinamy
2. General pharmacokinetics
3. General pharmacotoxicology
4. Principles of pharmacologic therapy assessment bases
5. Pharmacological influencing of autonomic nerve transmission
6. Pharmacological influencing of cholinergic transmission
7. Pharmacological influencing of adrenergic transmission
8. Neuro-humoral transmission in the nervous system
9. General Anesthetics
10. Local Anesthetics
11. Hypnotics and sedatives
12. Mental ilness medication
13. Estrapyramidal disorders medication
14. Anticonvulsant medication
15. Opioid analgesics and their agonists
16. Drug abuse and addiction
17. Pharmacological influence on hormonal regulation
18. Pharmacological influence on the pituitary gland and its functions
19. Pharmacological influence on the thyroid gland and its functions
20. Pharmacological influence on the adrenal cortex and medulla and their functions

21. Insulin, oral hypoglycemics and pharmacological influence on the pancreas

22. Calcium, parathyroid hormone, calcitonin, vitamin D and other related substances

23. Pharmacological influence on tissue regulation

24. Histamine, bradykinin, serotonin and substances that act in their field

25. Prostaglandins, leukotrienes, platelet activating factor and substances that act in their field

26. Analgesics, anti-inflammatory, antipyretic, antirheumatic substances

27. Drugs used in the treatment of rheumatoid arthritis and gout

28. Antiasthmatics

29. The renin-angiotensin-aldosterone system and its pharmacological influence

30. Heart failure medication

31. Angina pain alleviating medication

32. Medication of arrhythmias

33. Antihypertensive medication

34. Medication of dyslipidemia

35. Antiulcerous medication

36. Pharmacological influence on the digestive motility and secretions

37. Pharmacological influence on the uterine motility

38. The chemotherapy of bacterial diseases

39. Chemotherapy of parasitic diseases

40. The chemotherapy of viral diseases

41. Anticancer chemotherapy

42. Pharmacological immunosuppression

43. Pharmacological influence on hematopoiesis

44. Pharmacological influence on hemostasis

45. Vitamins

**1.4.1.2. Practical activities grading**

1. The design, organization and performance of pharmacodynamic experiments: 3

2. The design, organization and performance of pharmacokinetic experiments: 1

3. The design, organization and performance of pharmacological experiments: 3

4. Data processing and statistical analysis 7

5. Writing and publishing scientific articles 2

6. Critical evaluation of pharmacology data in experimental literature 7

7. Final seminar

* + 1. **Legislation and organization internship**

**1.4.2.1. Conference themes**

1. Basis of Romanian and EU legislation in the field of medicines

2. Basis of Romanian and EU legislation in the field of biological products for human use

3. Basis of Romanian and EU legislation in the field of nutritional supplements and other related products

4. Basis of Romanian and EU legislation in the field of medical devices

5. Basis of Romanian and EU legislation in the field of cosmetics

6. Political aspects of medicinal products

7. Scientific and technical Issues related to authorization, supervision and control of medicinal products

8. Marketing authorization for medicinal products

9. Evaluation of Medicinal Products Preclinical Case pharmacology in order to authorize the marketing

10. Assessment of clinical efficacy of new medicinal products in order to authorize their marketing

11. Assessment of bioequivalence and interchangeability of medicinal products

12. Preclinical safety evaluation of medicinal products

13. Assessment of clinical safety of medicinal products

14. Quality evaluation of medicinal products

15. The rules of Good Clinical Practice

16. Assessment of clinical trial protocols for approvals to conduct clinical trials

17. GCP inspections

18. Rules of Good Laboratory Practice

19. GLP Inspection

20. The rules of Good Manufacturing Practice

21. GMP Inspection

22. Pharmacovigilance

23. Quality assurance of human medicinal products

24. Complaints regarding medicines

25. Adverse drug reactions

26. Non-conformities of drugs

27. Regulations regarding advertising of medicinal products

28. Withdrawal and destruction of drugs

29. Organizing the drug distribution network

30. Rules of practice for dispensing medicines and inspections on their compliance

31. Rules of practice for the storage of medicines and inspections on their compliance

32. Rules of practice of pharmacy and inspections on their compliance

33. The import and export of drugs

34. The pricing of medicines

35. The legislation on toxic substances and drugs and medicinal products containing them

36. Surveillance of toxic substances and drugs and medicinal products containing them

**1.4.2.2. Practical activities grading**

1. Assessment of administrative documents of a medicinal product submitted for authorization

Holder: 10

2. Evaluation of a preclinical pharmacology Case in order to authorize the placing on the market: 3

3. Evaluation of a preclinical toxicology Case in order to authorize the placing on the market: 3

4. Evaluation of the bioequivalence study for the authorization of placing on the market: 3

5. Evaluation of clinical documentation for the authorization of placing on the market: 3

6. Participation in the pharmaceutical case evaluation in order to authorize the placing on the market: 3

7. Evaluation of the clinical trial protocol for the approval of carrying out a clinical trial in Romania 4

8. Evaluation of advertising 5

9. Participation in GMP inspections 2

10. Participation in GCP inspections 4

11. Participation in inspections in the distribution network: 3

* + 1. **INTERNAL MEDICINE INTERNSHIP**

**1.4.3.1. Conference themes**

1. Chronic Obstructive Pulmonary Disease

2. Asthma

3. Lung Cancer

4. Pleurisy

5. Pulmonary Tuberculosis

6. Arrhythmias and Impulse Conduction Abnormalities

7. Angina and myocardial infarction

8. Heart failure, right hipertrophy, pulmonary edema

9. Hypertension

10. Vasculitis

11. Thrombotic vascular disease

12. Cardiopulmonary resuscitation

13. Collagen Diseases

14. Gastric and duodenal ulcers

15. gastric and colonic cancer

16. Malabsorption

17. Hepatitis, cirrhosis, liver cancer

18. Encephalopathy portal

19. Acute Pancreatitis

20. Diarrheal syndromes

21. Acute and chronic nephritis

22. Acute and chronic renal failure

23. Nephrotic syndrome

24. Diabetes

25. Disorders of acid-base and electrolyte balance.

**1.4.3.2. Practical activities grading**

1. Phlebotomy: 1

2. Thoracentesis 2

3. Paracentesis 2

4. Application a naso-gastric probe 2

5. EKG Interpretation: 50

6. Radiographs and CT scans: 50

7. The retrospective analysis of the cost / benefit of medication a patient 50 cases of observation charts

8. Report on adverse reactions encountered during the internship: 1 presented at the final seminar

9. Final seminar

* + 1. **Intensive care and emergency medicine internship**

**1.4.4.1. Conference themes**

1. General anesthesia

2. Spinal anesthesia

3. Local anesthesia

4. Hemodynamic rebalancing

5. Acute bleeding, gastrointestinal bleeding and thrombosis

6. Electrolyte and acid-base rebalancing

7. Fever and hyperthermia

8. Hypothermia

9. Pathophysiology and pain care

10. Chest discomfort and palpitations

11. Dyspnea and pulmonary edema

12. Syncope

13. Hypotensive collapse

14. Acute cardio-circulatory failure

15. Acute respiratory failure

16. Acute confusional states and coma

17. Abdominal pain

18. Jaundice

19. Acute intestinal obstruction

20. Acute toxic drug-induced hepatitis

21. Acute pancreatitis.

**1.4.4.2. Practical activities grading**

1. Spinal Tap 5

2. Placing a venous catheter 10

3. Placing an infusion: 30

4. Tracheal intubation: 20

5. Cardiac resuscitation electroshock 5

6. Retrospective analysis of cost / benefit of medication in patient: 50 cases of observation charts

7. Report on adverse reactions encountered during the internship: 1 presented at the final seminar

8. Final seminar

* + 1. **CLINICAL TOXICOLOGY INTERNSHIP**

**1.4.5.1. Conference themes**

1. Epidemiology of acute intoxications

2. Quantitative characteristics of acute toxicity

3. Classification of toxic substances

4. General toxicokinteics

5. General toxicodinamy

6. General data relating the medical conduct in acute intoxications

7. Decontamination of the poisoned patient

8. Evaluation of complete intoxication

9. Antidote in acute intoxication

10. Therapeutic methods to enhance the elimination of toxins from the body

11. Increased incidence of clinical acute poisoning

12. Acute drug poisoning

13. Acute poisoning with unknown substances

**1.4.5.2. Practical activities grading**

1. External decontamination of an intoxicated patient 5

2. Gastric lavage: 3

3. Assessment of acute poisoning 10

4. Completion of toxicologic information files 10

5. Implementation of algorithms for determination by laboratory analyses of an unknown toxic substance which produced a poisoning 5

6. Retrospective analysis of cost / benefit of a medication in a patient: 50 cases of observation charts

7. Report on adverse reactions encountered during the internship: 1 presented at the final seminar

8. Final seminar

* + 1. **CLINICAL PHARMACOLOGY INTERNSHIP**

**1.4.6.1. Conference themes**

1. Clinical evaluation and clinical experiment protocol

2. Election of the population for a clinical trial

3. Planning a clinical trial

4. Criteria tracking in a clinical trial

5. General criteria for calculating the required number of subjects in a clinical trial

6. The ethics of biomedical research on human subjects

7. Monitoring the clinical research

8. Best practices in clinical drug research

9. Standardization in clinical drug research

10. The audit of a clinical trial

11. Clinical observation chart - primary records

12. Quality control data. Quality indices calculated based on primary records

13. Validation of critical events

14. The analysis of a randomized trial strategy

15. Rules for stopping a clinical trial

16. Meta-analysis of therapeutic trials

17. Deviation from protocol

18. Information management and statistical analysis

19. Report of a clinical trial

20. Expert report on a clinical documentation

21. The functional organization of clinical pharmacology units

22. Clinical trials Phase I and II: objectives and methodological principles

23. Human pharmacokinetics

24. Phase III clinical study

25. Features of therapeutic trials in populations at risk

26. Assessment of clinical safety

27. Efficacy trials in phase IV

28. The high-tech products

29. The impact of therapeutic studies on medical practice.

**1.4.6.2. Practical activities grading**

1. Participation in pharmacokinetics and bioequivalence studies: 1

2. Participation in Phase II or III studies: 1

3. Conducting pharmacoeconomic studies: 1

4. Final seminar

**CLINICAL PHARMACOLOGY**

4 years

INTERNSHIPS AND COURSES – CONFERENCE

I.

* Basic pharmacology internship (I.1) 1 year
* Legislation and organization internship (I.2) 1 year

II.

* Internal medicine internship (II.1) 3 months
* Intensive care and emergency medicine internship (II.2) 3 months
* Clinical toxicology internship (II.3) 3 months

Internship at choice in a medical specialty other than the above (II.4) 3 months

* Clinical Pharmacology Internship (II.5) 1 year

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| --- | --- | --- | --- | --- | --- | --- | --- |
|  | 1st Year | 2nd Year | 3rd Year | | | | 4th Year |
| Internship | I.1 | I.1 | II.1 | II.2 | II.3 | II.4 | II.5 |