



SUBJECTS FOR THE COMPETITION TO OCCUPY THE VACANT POSITION OF PROFESSOR, POSITION 37

Position 37, Professor : Médicaments biologiques (FFR, III); Pharmacovigilance (FFR, III); Biological drugs (F, III); Pharmacovigilance (F, III); Pharmacovigilance (F, V); Pharmacovigilance (FFR, V)

1. Biological drugs – definition, characteristics, particularities, classification, effective European regulations regarding biological medicines
2. Obtaining methods for biological drugs – genetic engineering
3. Hemotherapy – labile products obtained from blood
4. Hemotherapy – stable products obtained from blood
5. Active immunoprophylaxis – vaccines – definition, mechanism of action, classification, side effects, national vaccination schedule, examples
6. Passive immunoprophylaxis – serums – mechanism of action, adverse reactions, examples
7. Monoclonal antibodies - mechanism of action, side effects, applicability in therapy, examples
8. Biological drugs isolated from the pancreas, thyroid, pituitary gland, and thymus used as hormone therapy
9. Biological drugs recommended in digestive system and hepatic pathologies
10. Newly approved biological drugs
11. Pharmacovigilance - definition, history and objectives; pharmacovigilance activity in Romania; the role of the National Agency for Medicines and Medical Devices (ANMDM) in pharmacovigilance activity
12. The pharmacist's role in pharmacovigilance activity
13. Adverse drug reactions – classification, mechanism of action, drug interactions
14. Adverse event. Reporting an adverse reaction. Systems for spontaneous reporting of an adverse reaction
15. Dermatological adverse drug reactions
16. Gastrointestinal adverse drug reactions
17. Hepatic adverse drug reactions
18. Cardiovascular adverse drug reactions
19. Hematological adverse drug reactions
20. Renal adverse drug reactions
21. Aspects of pharmacovigilance in pregnancy and nursing
22. Aspects of pharmacovigilance in pediatrics
23. Aspects of pharmacovigilance in geriatrics

References:

1. Biological drugs course – electronic support available on: <https://moodle.umft.ro/>
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13. Pharmacovigilance course – electronic support available on: <https://moodle.umft.ro/>
14. European Medicines Agency. Pharmacovigilance training materials. <https://www.ema.europa.eu/en/human-regulatory/overview/pharmacovigilance/pharmacovigilance-training-materials#collection-of-adverse-drug-reactions-section>
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