SYLLABUS
R & D
SUMÁRIO

TECHNOLOGY OF BIOPROCESSES IN THE PRODUCTION OF PHARMACEUTICAL INGREDIENTS

MICROBIOLOGICAL CONTROL

APPLICATION OF ORGANIC SYNTHESIS IN THE PRODUCTION AND DEVELOPMENT OF DRUGS

PHARMACOLOGY APPLIED TO THE PHARMACEUTICAL INDUSTRY

CONTROL OF PHYSICAL-CHEMICAL QUALITY IN THE PRODUCTION AND DEVELOPMENT OF DRUGS

SCIENTIFIC RESEARCH METHODOLOGY

RESEARCH AND DEVELOPMENT IN PHARMACEUTICAL TECHNOLOGY

RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY

RESEARCH AND TECHNOLOGY OF MEDICINE PLANTS

ADVANCED SEMINARS - MONITORING
## SYLLABUS

TECHNOLOGY OF BIOPROCESSES IN THE PRODUCTION OF PHARMACEUTICAL INGREDIENTS

## PROFESSOR

Prof. Dr. Aline Ramos

## INTRODUCTION AND OBJECTIVES

To present fermentation and biotransformation processes used in the production of drugs, intermediates and additives. Discuss relevant factors in the research and development of bioprocesses. Review relevant legislation.

## TARGET AUDIENCE

<table>
<thead>
<tr>
<th>Students of the Professional Master's Degree in Management, Research and Development in Industry.</th>
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### COURSE LOAD

30 hours

### TOTAL CREDITS

02

## COURSE MENU

- Introduction to bioprocesses, brief history and general concepts.
- Microbial metabolism.
- Fermentation processes for the production of pharmaceutical inputs.
- Biotransformation / bioconversions for the production of drugs and intermediates.
- Genetically modified organisms.
- Optimization of bioprocesses.
- Specific legislation
METHODOLOGY

Oral presentation, reading and analysis of scientific articles, seminars.

INSTRUCTIONAL RESOURCES

- Scientific journal search databases
- Computer
- Data Show

PERFORMANCE EVALUATION

Participation in class activities. Seminar. Exam.

BIBLIOGRAPHY


- Leis 11.105/05 e 13.123/15.
SYLLABUS
MICROBIOLOGICAL CONTROL

PROFESSOR
Prof. Dr. Joseli Rocha Nogueira

INTRODUCTION AND OBJECTIVES
Provide the student the critical knowledge to evaluate microbiological methods to control the microbiological quality of drugs, medicines and cosmetics.

TARGET AUDIENCE | COURSE LOAD | TOTAL CREDITS
--- | --- | ---
Students of the Professional Master's Degree in Management, Research and Development in Industry. | 15 hours | 01

COURSE MENU
- Methods of microbiological analysis for the evaluation of drugs, medicines and cosmetics.
- Introduction to microbiological control
- Microbial contamination in pharmaceuticals, correlates and cosmetics
- Water microbiology in the process and as a product
- Analysis of the microbial quality of non-sterile products
- Methods for enumeration and identification of microorganisms
- Control of sterile products
- Sterility test
- Preservative effectiveness
- Microbiological control of manufactured products: non-sterile drugs and cosmetics
- Environmental control
- Control of microbial contamination during manufacturing
- Risks associated with microbial contamination.
- Validation of analytical methods: accuracy, accuracy, reproducibility

**METHODOLOGY**

Oral presentation, reading and analysis of scientific articles, seminars.

**INSTRUCTIONAL RESOURCES**

- Data Show.
- Digital handouts with presentations.
- Computer.
- Laboratory equipment and accessories.

**PERFORMANCE EVALUATION**

Participation in class activities. Seminar. Exam.

**BIBLIOGRAPHY**

SYLLABUS

APPLICATION OF ORGANIC SYNTHESIS IN THE PRODUCTION AND DEVELOPMENT OF DRUGS

PROFESSOR

Prof. Dr. Claudia Brandão / Prof. Dr. Marcus Nora / Prof. Dr. Erika Carvalho

INTRODUCTION AND OBJECTIVES

• Discuss key approaches to drug synthesis comparing laboratory and industrial scale synthesis.
• To familiarize students with the main reactions and concepts used in organic synthesis for the synthesis of drugs

TARGET AUDIENCE | COURSE LOAD | TOTAL CREDITS
Professionals of the pharmaceutical industry related to the areas of Evaluation and Prospecting. | 30 hours | 02

COURSE MENU

• History of discovery and development of new drugs
• History of the development of organic synthesis
• Synthetic approaches
• Types of retrosynthesis (Sinton, retron, "chiron")
• Chiral drugs and approaches in asymmetric synthesis
• Techniques that increase the efficiency of a synthesis
Drug design
Evaluation of synthetic routes of drugs (comparison between bench synthesis and industrial synthesis)

**METHODOLOGY**

Oral exposure Classroom activities Exercises

**INSTRUCTIONAL RESOURCES**

- Data Show.
- Books.
- Computer.

**PERFORMANCE EVALUATION**

Seminars and / or exam and participation in classes. The choice of assessment is at the discretion of the teacher.

**BIBLIOGRAPHY**

SYLLABUS

PHARMACOLOGY APPLIED IN THE PHARMACEUTICAL INDUSTRY

PROFESSOR

Prof. Dr. Mariana Souza and Prof. Dr. Elaine Rosas

INTRODUCTION AND OBJECTIVES

Address topics in the Pharmacology chair in drug for R & D, as well as the production and post-production of drugs.

<table>
<thead>
<tr>
<th>TARGET AUDIENCE</th>
<th>COURSE LOAD</th>
<th>TOTAL CREDITS</th>
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<tbody>
<tr>
<td>Students of the Professional Master's Degree in Management, Research and Development in Industry.</td>
<td>45 hours</td>
<td>03</td>
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</table>

COURSE MENU

- Cellular and molecular biology
- Pharmacokinetics
- Pharmacodynamics
- Pharmacological tests for the discovery of new drugs
- Pharmacology of Natural Products
- Clinical Pharmacology
- Pharmacovigilance
## METHODOLOGY
Oral presentation, reading and analysis of scientific articles, seminars.

## INSTRUCTIONAL RESOURCES

- Data Show.
- Digital handouts with presentations.
- Computer.
- Laboratory equipment and accessories.

## PERFORMANCE EVALUATION
Participation in class activities. Seminar. Exam.

## BIBLIOGRAPHY

- Bases Farmacológicas Da Terapêutica De Goodman E Gilman, Mc Graw Hill; Edição: 12ª.
- Specific journals in the area
SYLLABUS

CONTROL OF PHYSICAL-CHEMICAL QUALITY IN THE PRODUCTION AND DEVELOPMENT OF DRUGS

PROFESSOR

Prof. Dr. Erika Carvalho / Prof. Dr. Karen Medeiros

INTRODUCTION AND OBJECTIVES

Discuss the main techniques used for the quality control of Drugs in development and production.

TARGET AUDIENCE | COURSE LOAD | TOTAL CREDITS
---|---|---
Students of the Professional Master's Degree in Management, Research and Development in Industry. | 60 hours | 04

COURSE MENU

- Analytical methods for the evaluation of drugs, medicines and cosmetics.
- Pharmaceutical compendia and regulation
- Pharmaceutical forms and control protocols
- Control of pharmaceutical and phytotherapeutic specialties
- Main techniques in the routine control of active inputs and medicines: volumetric, spectrophotometry and chromatography
- Development of methods and validation
- Tools for evaluation of quality deviations and characterization of imperfections and impurities: advanced techniques
- Analytical tools in drug and drug research and development
- Spectroscopic techniques in drug quality control (atomic absorption, I.V., U.V-vis, RAMAN, NMR, Masses)
- Thermogravimetric techniques (DSC, TGA)

**METHODOLOGY**

Oral presentation, reading and analysis of scientific articles, seminars.

**INSTRUCTIONAL RESOURCES**

- Data Show.
- Digital handouts with presentations.
- Computer.

**PERFORMANCE EVALUATION**

Participation in class activities. Seminar. Exam.

**BIBLIOGRAPHY**

- GIL, ERIC S. Controle Físico-Químico de Qualidade de Medicamentos, 3ª Ed.
- Farmacopéias (Brasileira, Norte Americana, Britânica, etc.), sempre as edições mais atualizadas e em vigor.
SYLLABUS

SCIENTIFIC RESEARCH METHODOLOGY

PROFESSOR

Prof. Dr. Tatiana Aragão

INTRODUCTION AND OBJECTIVES

Present methods and types of research so that the student is able to develop his dissertation with autonomy and security.

TARGET AUDIENCE | COURSE LOAD | TOTAL CREDITS
--- | --- | ---
Pharmaceutical professionals linked to all areas of the course | 30 hours | 02

COURSE MENU

- Introduction to academic thinking
- Presentation of research types
- Bibliographic survey
- Research methods for research and development studies
- Research methods for management studies

METHODOLOGY

Oral Exposure; Activities in class Exercises; Practical activity.
## INSTRUCTIONAL RESOURCES

- Data Show.
- Computador.

## PERFORMANCE EVALUATION

Work delivery 6 months after the end of the course

## BIBLIOGRAPHY

- Data bases
- Papers and books related to scientific methodologies
**SYLLABUS**

**RESEARCH AND DEVELOPMENT IN PHARMACEUTICAL TECHNOLOGY**

**PROFESSOR**

Prof. Dr. Helvécio Rocha

**INTRODUCTION AND OBJECTIVES**

- Present the basic principles of pharmaceutical technology, the main concepts and their situation in the drug development scenario in Brazil and in the world.
- Present the main concepts, techniques and methodologies in the characterization of pharmaceutical inputs (active principles and excipients).
- Present the main techniques of manufacturing pharmaceutical forms, their routes of administration, mechanisms of evaluation, stability and scheduling.
- Introduce the basic concepts of packaging for pharmaceutical use.
- Present advances in the area of drug delivery systems, with market perspectives, advanced pharmaceutical forms and evaluation mechanisms.

**TARGET AUDIENCE**

Students of the Professional Master's Degree in Management, Research and Development in Industry.

**COURSE LOAD**

60 hours

**TOTAL CREDITS**

04

**COURSE MENU**

- Lecture 1 - Presentation lecture
- Course presentation
• Introduction to pharmaceutical technology
• Contextualization of the national and international scenario
• Introduction to the basic concepts of sector legislation

• Lectures 2, 3 and 4 - Introduction to the crystallization and characterization of pharmaceutical inputs - M.Sc. Livia Prado (Farmanguinhos)
• Introduction to drug crystallinity
• Crystallization of drugs and impact on the quality of pharmaceutical production
• Introduction to the study of crystallography
• Characterization techniques
• Case studies

• Lecture 5 - Pharmaceutical inputs: characterization of processability and other characterization techniques
• Evaluation of fluidity methods
• Introduction to the concepts of compressibility of pharmaceutical solids
• Excipient Functionality
• Dissolution techniques applied to the characterization of inputs

• Lessons 6 and 7 - Biopharmacotechnics
• Introduction to Biopharmacotechnics
• Definitions and applications of the biopharmaceutical classification system
• Understanding bio-awareness
• National and international legislation on the pharmaceutical classification system

• Lessons 8 and 9 - Development and production of solid dosage forms
• Classification of forms
• Manufacturing Methods
• Detailing of the steps of granulation, mixing, compression and coating
• Flowcharts of manufacturing processes
• Principles of Stability of Solid Forms
• Manufacturing Scheduling
• Evaluation methods
• Case Study

• Lecture 10 - Topical pharmaceutical forms - focus on transdermal systems - Prof. Dr. Katty Gyselle de Holanda e Silva (UFRJ)
• Topical formulations
• Basic methods of manufacturing and control
- Use as drug delivery systems

**METHODOLOGY**

Oral presentation, work activities and case of study.

**INSTRUCTIONAL RESOURCES**

- Data Show.
- Digital handouts with presentations.
- Computer.
- Laboratorial equipments

**PERFORMANCE EVALUATION**

Participation in class activities. Seminar. Exam.

**BIBLIOGRAPHY**


- Others Scientific papers
**SYLLABUS**

**RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY**

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**PROFESSOR**

Prof. Dr. Claudia Regina Brandão Gomes / Prof. Dr. Karen Medeiros

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**INTRODUCTION AND OBJECTIVES**

Familiarize students with the key steps that involve the process of drug development within a Pharmaceutical industry.

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<tbody>
<tr>
<td>Pharmaceutical professionals</td>
<td>30 hours</td>
<td>02</td>
</tr>
</tbody>
</table>

**COURSE MENU**

- National and international scenario of the pharmaceutical and pharmacochemical industry
- Development of new drugs
- Preclinical and clinical research
- Drug development
- Knowledge management
- Genomics and proteomics in the pharmaceutical industry
- Herbal medicines

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**METHODOLOGY**

Oral Exposure; Class activities; Exercises.
### INSTRUCTIONAL RESOURCES

- Data Show.
- Books.
- Computer.

### PERFORMANCE EVALUATION

Seminars and / or proof and participation in classes. The choice of assessment is at the discretion of the teacher.

### BIBLIOGRAPHY

- Specific periodicals in the area.
- Papers or other sources suggested by invited speakers
SYLLABUS

RESEARCH AND TECHNOLOGY OF MEDICINE PLANTS

PROFESSOR

Prof. Dr. Ana Claudia Amaral / Prof. Dr. Maria Raquel Figueiredo

INTRODUCTION AND OBJECTIVES

• To show the basic principles of herbal technology and the development situation of herbal medicines in Brazil and in the world.
• Present the main techniques, quality control, legislation and methodologies of medicinal plants and their products.
• Present the steps of obtaining the technological product from medicinal plants
• Describe the main approaches of medicinal plants for drug development

TARGET AUDIENCE

Students of the Professional Master's Degree in Management, Research and Development in Industry.

COURSE LOAD

45 hours

TOTAL CREDITS

03

COURSE MENU

• Introduction of medicinal plants as a therapeutic resource
• Medicinal plants as sources of raw materials for the pharmaceutical industry
• Medicinal plants and phytotherapeutic production
• Active plant principles: pharmaceuticals and phytotherapics
• Transformation of vegetal material into technological product
• Evaluation of the quality of plant material
- Technological development of herbal medicines
- Production and quality control of herbal medicines
- Pharmaceutical forms (objectives and planning considerations)
- Stages of biological trials of the medicinal plant
- Brazilian legislation for the area of herbal medicines

**METHODOLOGY**

Oral presentation, work activities and case of study.

**INSTRUCTIONAL RESOURCES**

- Data Show.
- Digital handouts with presentations.
- Computer.
- Laboratorial equipaments

**PERFORMANCE EVALUATION**

Seminars and / or exam. The evaluation is at the discretion of the teacher; Participation in class

**BIBLIOGRAPHY**

- Others papers.
SYLLABUS

ADVANCED SEMINARS - MONITORING

PROFESSOR

Master Coordination

INTRODUCTION AND OBJECTIVES

Advice and show standards to the student throughout the Course until his final dissertation. Thereby providing the scientific and technological training. Hope that student be able subsidies to pursue academic studies. It will deal with the norms for the elaboration of scientific works, according to ABNT (Brazilian Association of Technical Standards), creating and offering contributions to the other disciplines in the application of standards for knowledge management. In this management, it is important to emphasize 5 elements for reflection, namely philosophical knowledge, logical discourse is the basis of work; artistic knowledge, intuition is the basis of work; religious knowledge, dogma is the basis of work; scientific knowledge, laboratory experience (evidence of fact) is the basis of work. It is in this scientific framework that discipline focuses.

Goals:
• Provide basic knowledge on knowledge management in scientific methodology aiming at the successful defense of the master's dissertation;
• Reflect on the construction of technology through scientific academic foundations;
• To propose the exchange of ideas and knowledge of related themes among students;
• Identify gaps in the construction of the dissertation and raise questions that may subsidize the student to discuss and propose improvements.

TARGET AUDIENCE | COURSE LOAD | TOTAL CREDITS
--- | --- | ---
Students of the Professional master is in management, | 15 hours | 01
Research and Development in the Pharmaceutical Industry.

**COURSE MENU**

- Scientific methodology
- Harmonization of procedures in the light of the Internal Regulation of the
- Lectures and / or lectures with teachers or executives of high performance in the area of the Course

**METHODOLOGY**

Lectures, analysis, discussion of academic norms and scientific articles of methodology and harmonization of procedures for the elaboration of the dissertation in the light of the Internal Regulation and Guidance guides of the Course.

**INSTRUCTIONAL RESOURCES**

- Multimedia
- Computer
- Movies
- Scientific articles and books

**PERFORMANCE EVALUATION**

The evaluation will have an individual and group participation in the classroom, through the discussion and interpretation of the course norms and scientific methodologies for the final presentation of the Master Dissertation. In this sense, the student's ability to adapt his work theme to the academic norms, as well as his scientific maturity throughout the Course. All tasks include note.

**BIBLIOGRAPHY**

- Regulamento Interno do Curso de Mestrado em Gestão, Pesquisa e Desenvolvimento na Indústria Farmacêutica.
- Guias emitidos pelo Colegiado de Pós-graduação do Curso de Mestrado em Gestão, Pesquisa e Desenvolvimento na Indústria Farmacêutica.
- Norma de escrita científica da Associação Brasileira de Normas Técnicas (ABNT).

Some useful links:
- http://ava.unit.br/dokeos/conteudo/pdf/mc_u01_t01.pdf