



## Fourth (4<sup>th</sup>) year of Pharmacy study

**Second semester:** from January to May

**Exam period:** May / June

UE (Teaching unit)	ECTS
<b>UE 52</b> PUBLIC HEALTH - HEALTH POLICY	<b>6</b>
<b>UE 53 A</b> THERAPEUTIC EDUCATION 1 (specialty pharmacy)	<b>5</b>
<b>UE 70</b> RESEARCH AND DEVELOPMENT OF DRUGS / QUALITY APPROACH (specialty industry / research)	<b>15</b>
<b>UE 71</b> STATISTICS APPLIED TO INDUSTRIAL ISSUES (specialty industry / research)	<b>8</b>
<b>UE 72</b> FINANCIAL MANAGEMENT (specialty industry / research)	<b>5</b>
<b>UE 73</b> HUMAN RESOURCE MANAGEMENT (specialty industry / research)	<b>5</b>
<b>UE 74</b> INDUSTRY / RESEARCH FREE UE*	<b>4</b>
<b>UE 100</b> PHARMACY SPECIALIZED ACTIVITIES 1 (Herbal medicine, Aromatherapy, Homeopathy) : specialty pharmacy	<b>8</b>
<b>UE 101</b> PHARMACEUTICAL LEGISLATION AND SOCIAL LAW (specialty pharmacy)	<b>8</b>
<b>UE 103</b> PHARMACY FREE UE*	<b>4</b>

\*These free UEs can be chosen (subject to availability), but choice and registration to these “UEL” must be done imperatively on site.



## Quatrième (4<sup>ème</sup>) année des études de Pharmacie

**Second semestre :** de janvier à mai

**Période d'examens :** mai / juin

UE (Unité d'enseignement)	ECTS
<b>UE 52</b> SANTÉ PUBLIQUE - POLITIQUE DE SANTÉ	<b>6</b>
<b>UE 53 A</b> ÉDUCATION THÉRAPEUTIQUE 1 (Orientation OFFICINE)	<b>5</b>
<b>UE 70</b> RECHERCHE ET DÉVELOPPEMENT DU MÉDICAMENT / DÉMARCHE QUALITÉ (Orientation INDUSTRIE / RECHERCHE)	<b>15</b>
<b>UE 71</b> STATISTIQUES APPLIQUÉES AUX PROBLÉMATIQUES INDUSTRIELLES : (Orientation INDUSTRIE / RECHERCHE)	<b>8</b>
<b>UE 72</b> GESTION FINANCIÈRE (Orientation INDUSTRIE / RECHERCHE)	<b>5</b>
<b>UE 73</b> GESTION RESSOURCES HUMAINES (Orientation INDUSTRIE / RECHERCHE)	<b>5</b>
<b>UE 74</b> UE LIBRE INDUSTRIE / RECHERCHE*	<b>4</b>
<b>UE 100</b> ACTIVITÉS SPÉCIALISÉES OFFICINALES 1 (Phytothérapie, Aromathérapie, Homéopathie) : Orientation OFFICINE	<b>8</b>
<b>UE 101</b> LÉGISLATION PHARMACEUTIQUE ET DROIT SOCIAL (Orientation OFFICINE)	<b>8</b>
<b>UE 103</b> UE LIBRE OFFICINE*	<b>4</b>

\*Ces UE libres peuvent être accessibles (sous réserve de places disponibles), mais le choix et l'inscription à ces UEL doivent se faire impérativement sur place.

# UE 52 Public health - Health policy

6 ECTS

## Content

### Classes\*

- **Evaluation and management of risks and health crises**
  - Protagonists
  - Risk prevention policy
  - Actions for health education
  - Management process of health crises
  - Addiction prevention and treatment
- **Environment and public health**
  - Environment
  - Protagonists
  - Notion of contamination
  - Future of contaminants in compartments
  - Evaluation and management of health quality (air, water, soils)
  - Main axes of corporate social responsibility
  - Drug life cycle
- **Organization of a quality system and role of the pharmacist**
  - Clinical or therapeutic audit
  - Evaluation of professional practices

\* Classes (all students in amphitheater).

## Assessment

Final exam about classes.

## Contact

Yves Levi

# UE 53 B Therapeutic education 1

5 ECTS

## Content

### Classes\*

Definitions and fundamentals of patient's therapeutic education

Rational basis and perspectives of patient's therapeutic education

Information, advice, education: similarities and differences

Major pedagogical trends

Why and how to change a health behaviour?

Components of patient-caregiver communication: verbal and nonverbal communication, focus on the patient, representations, emotions...

### Tutorials\*

Introduction to pedagogy: learning to teach

\* **Classes** (all students in amphitheater), **Tutorials** (small groups of students).

## Assessment

Final exam about classes and tutorials.

## Contact

Christine Fernandez

# UE 70 Research and development of drugs / Quality approach

15 ECTS

## Content

### Classes\*

#### Module 1: Strategies and research projects in pharmaceutical industry

- **Design of molecules with a therapeutic potential**
  - Molecules from chemistry
  - Molecules from hemisynthesis or extraction
  - Biotechnologies
- **Experimental models used in pharmacology**
  - In vitro* studies
  - Ex vivo* studies
  - In vivo* studies: examples of animal models used in pharmacology
- **Identifying and optimizing molecules of therapeutic potential until defining « leads »**
- **Research careers**

#### Module 2: Pharmaceutical development: galenic and analytical development

- **Regulation: principle and importance of ICH guidelines in development: Q1 to Q10**
- **Analytical development and specifications**
  - Spreading of ICH guidelines in analytical development: Q1 to Q6
  - Analytical validation strategy
  - Research and assay of impurities
  - Spreading of specifications (monographs on control of raw materials, end products...)
  - Stability
- **Galenic development**
  - Place of pharmaceutical formulation/ pharmaceuticals in pharmaceutical development
  - New strategies: quality by design
  - Pre-formulation, early formulation, development of shapes/models for clinical trial, scaling up, defining the stages of qualification and validation
- **Careers in analytical development and pharmaceutical development**

#### Module 3: Non clinical development

- **SGL guidelines**
- **Toxicological drugs development**
  - Evaluation methods in toxicology
  - Choice of animal models and management of zootechnics
  - New methods applied to toxicology
- **Pharmacological drugs development**
  - Animal pharmacokinetics
  - Security pharmacokinetics
- **Statistics applied to a non clinical study**
- **Non clinical development careers**

#### Module 4: Clinical development

Regulation context: EGL

Exploratory phase of clinical development and implementation of goals and clinical trial protocols

First administration to human: goals and constraints, maximum tolerated dose

Phase 2 clinical trials: effective dose

Phase 3: analysis of actual effectiveness

Statistics applied to clinical development

Security pharmacology

Pharmacovigilance (Drug safety) and clinical trials

Support process: rules concerning management of flow of therapeutic units and rules related to distribution channels

Clinical development careers

### **Module 5: Drug registration file**

Completing the registration file

Registration plan

Registration procedures and regulatory stages

CTD file (Common Technical Document) and different modules

### **Module 6: R&D project management**

Different stages of a project

Project management tools applied to R&D

### **Module 7: Quality approach applied to the different stages of R&D**

Quality system applied to R&D

Risk management

Dealing with non-conformities/conformances, change control, applied to R&D

Examples of quality tools applied to R&D and associated documents

R&D quality indicators and instrument panels

### **Module 8: Traceability and information systems applied to the different stages of R&D**

R&D pharmaceutical, medical and biological databases and traceability

R&D major operating softwares

\* **Classes** (all students in amphitheater)

### **Assessment**

Final exam about classes.

### **Contact**

Armelle Biola-Vidamment

# UE 71 Statistics applied to industrial issues

7 ECTS

## Content

### Classes\*

- **R&D statistical tools**
  - Sampling plans
  - Analysis of variance (ANOVA)
  - Experimental designs
  - Multivariate statistics (ACP, MLR, PLS)
- **Production: Development and process control (QBD, PAT)**
- **Preclinical and clinical studies**

### Practical works\*

R&D statistical tools

\* **Classes** (all students in amphitheater), **Practical works** (smaller groups of students in order to study in adapted practical rooms/laboratories).

## Assessment

Final exam about classes.

Continuous assessment for the practical works with report writings, oral presentations and/or lectures. Attendance to practical works needs to be approved.

## Contacts

Pierre Chaminade  
Jérémie Botton

# UE 72 Financial management

5 ECTS

## Content

### Classes\*

Rules and principles of accounting and associated vocabulary

Analytical results, ratios and financial analysis

Operating accounts and balance sheets

Different aspects of contracts (technical and scientific aspects of specifications, legal aspects and definition of responsibilities, financial aspects...)

\* **Classes** (all students in amphitheater)

## Assessment

Final exam about classes.

## Contact

Catherine Dubernet

# UE 73 Human resource management

5 ECTS

## Content

### Classes\*

- Challenges and issues of human resources management
- Rules concerning labour law and staff management
- Different stages of a recruiting process
- Daily and team management
- Organizing and conducting meetings
- Position qualification, rules and safety standards applied to staff
- Training (rules about training, accreditations, training courses)

### Tutorials\*

- Daily and team management
- Organizing and conducting meetings

\* **Classes** (all students in amphitheater), **Tutorials** (small groups of students)

## Assessment

Final exam about classes and tutorials.

## Contact

Eric Henriët



# UE 100 Pharmacy specialized activities 1 (Herbal medicine, Aromatherapy, Homeopathy)

8 ECTS

## Content

### Classes\*

- **Homeopathy**
  - Homeopathic medicine
  - Principles of homeopathy
  - Major homeopathic remedies
- **Herbal medicine and aromatherapy**
  - General notions, herbal medicine product regulation
  - Aromatherapy
  - Herbal medicine according to pathology
  - Herbal medicine: product reference listing / comments on formulas
  - Herbal medicine: advice at pharmacy

### Tutorials\*

- Herbal medicine: product reference listing / comments on formulas
- Herbal medicine: advice at pharmacy

\* **Classes** (all students in amphitheater), **Tutorials** (small groups of students)

## Assessment

Final exam about classes and tutorials.

## Contacts

Pierre Champy  
Christophe Fourneau

# UE 101 Pharmaceutical legislation and social law

8 ECTS

## Content

### Classes\*

#### Module 1: Pharmaceutical legislation

- **The pharmacy owner and his/her staff**
  - Pharmacists' terms of professional practice
  - Owner's obligations of personal practice
  - Other general obligations
  - The staff: assistant pharmacists, pharmacy technicians, pharmacy students, and non-qualified staff
  - Owner's and staff's responsibilities
- **Operating the pharmacy**
  - Premises and layout
  - Supply channels
  - Business scope of the pharmacist
  - Sale to the public (sale of prescription drugs, over-the-counter sale)
  - Observance of professional secrecy, of the code of ethics
  - Legal and illegal business practices
  - Obligations related to pharmacy operating
- **Demographic and geographic distribution of pharmacies**
  - Rules for opening a pharmacy: creations, transfers, and combinations
  - Obtaining, using, and losing the license
- **Different operating structures of a pharmacy**
  - Pharmacy property
  - Operating on one's own name
  - Unincorporated association or joint ownership
  - Operating company (SNC, SARL, EURL, SELARL, and SELAS)
- **Pharmacy and matrimonial regimes**
  - Matrimonial regime general scheme
  - Pharmacy regime during marriage
  - Liquidation of the matrimonial regime and future of the pharmacy
- **Delivery of health products subject to special regulations**
  - Drugs on list I and II
  - Narcotics and similar products
  - Medicine subject to restricted prescription
  - Other products subject to a specific regime
- **Pharmacovigilance reminders**

#### Module 2: Social law

- **Sources of labour law**
  - International sources
  - National sources
  - Conventional sources
  - Conventions
  - The hierarchy of norms
- **Administrative and regulatory framework**
  - Administrative framework: labour inspection
  - Labour law judges: le conseil des Prud'hommes (the Labour Court)
- **Recruitment**

- **Conclusion of an employment contract**
- **The employment contract**
  - Definition
  - Optional clauses
  - Different types
- **Execution of the employment contract**
  - The employer's obligations (remuneration, working hours, holidays, gardes, and emergencies)
  - The employee's obligations
- **Modification of the employment contract**
  - Modification of the working conditions
  - Modification in the legal situation of the employer
- **Termination of the employment contract**
  - Force majeure
  - Termination by non-attendance
  - The transaction
  - Contractual termination
  - Resignation
  - Dismissal for personal reasons
  - Redundancy
- **The powers of the entrepreneur**
  - The normative power: the rules
  - The employer's disciplinary power
  - Harassment
- **The exercise of the right to organize in the pharmacy**
- **The right to training**

### **Module 3: Practical case of pharmaceutical legislation / social law**

\* **Classes** (all students in amphitheater).

#### **Assessment**

Final exam about classes.

#### **Contacts**

Hélène van den Brink  
Caroline Mascret