Université Paris-Saclay

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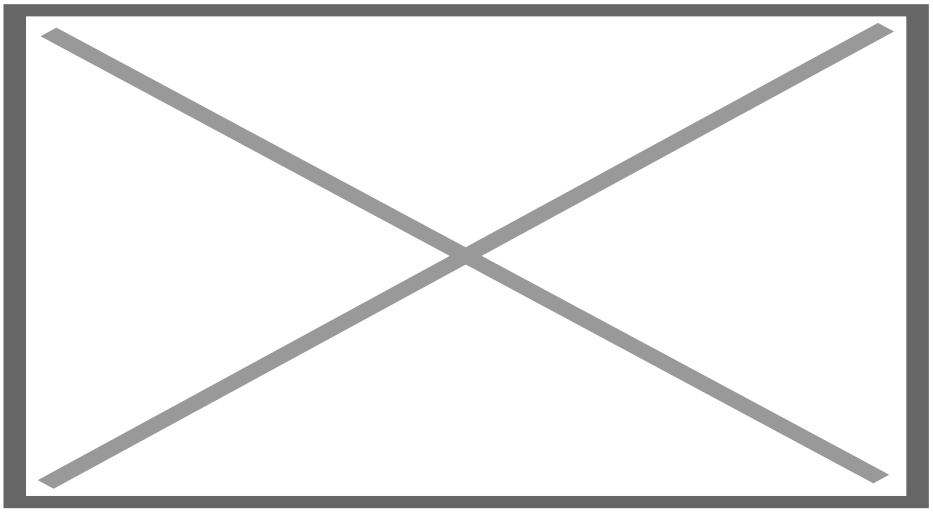
# M2 International Development and Registration of Medicine and Health Products

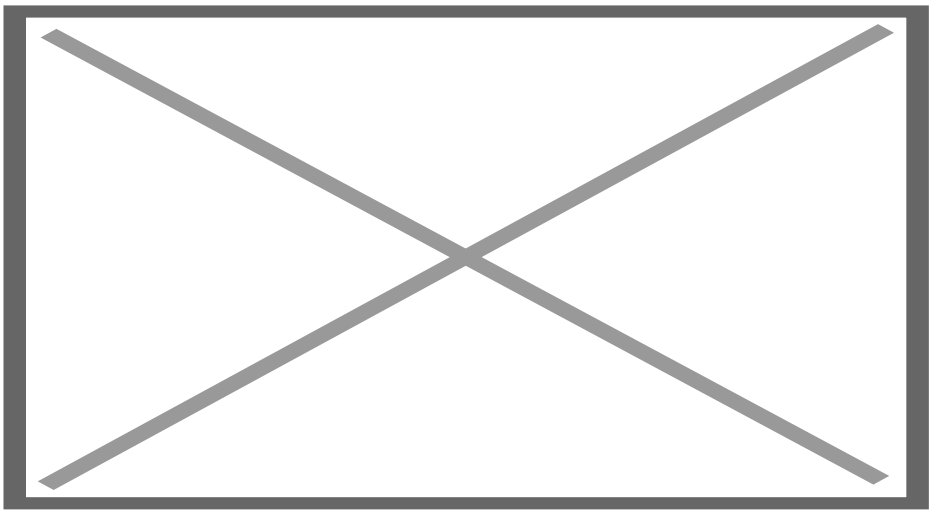
Master's degree
Specialisation Pharmaceutical Science
Enrolment type
Formation initiale
Formation en apprentissage
Formation continue
Language(s) of instruction
English
French

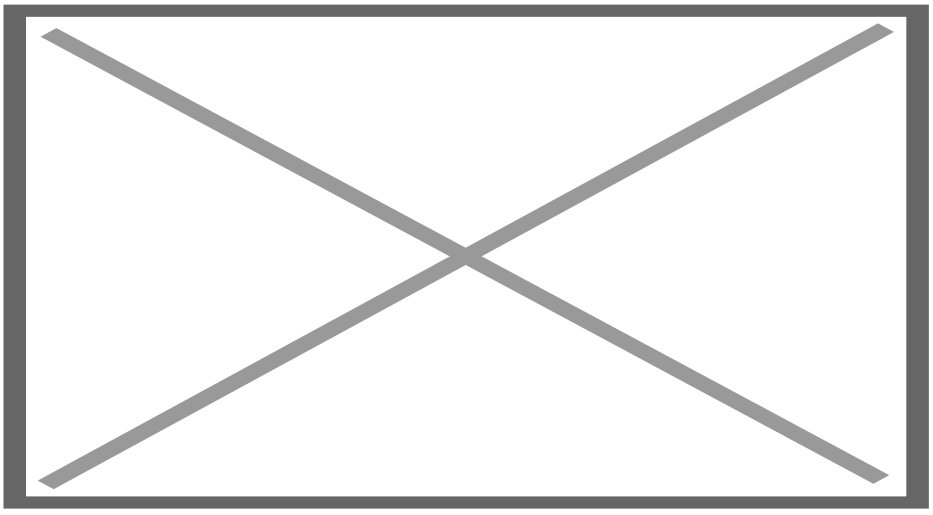
This curriculum prepares students for careers in regulatory affairs in a strategic international context, working within therapeutic innovation and being involved in the development and registration of healthcare products.

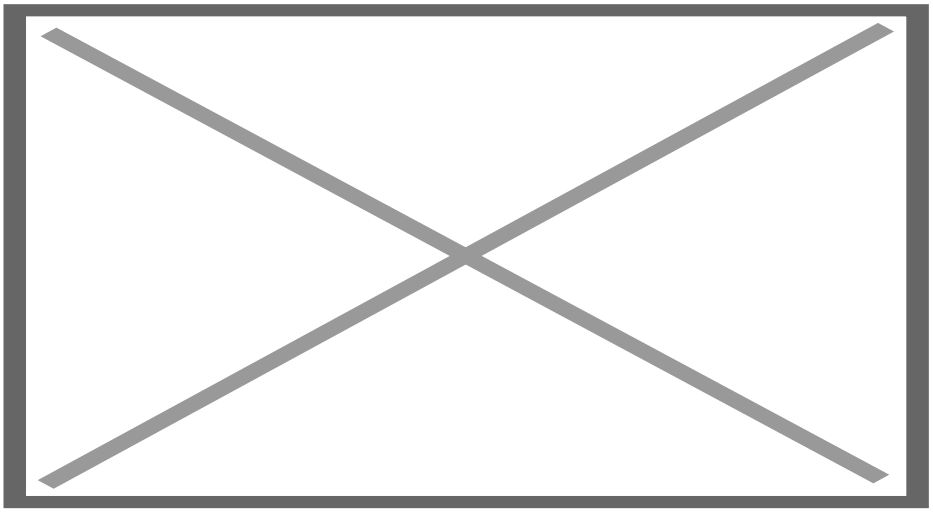
The DEIM curriculum will provide you with in-depth training in the scientific aspects of drug development and a global strategic understanding of international drug registration. The **international dimension** is covered by the course content, communication in English, and **mobility abroad** for training in companies.. The **approach to prepare students for the world of work** is permanentc, with 90% of courses taught by professionals working in the regulatory environment, support for students in acquiring soft skills adapted to the professional environment through various tutorials and independent projects, and a first professional experience in a global regulatory team, in France or abroad, as a work-study programme or internship for a period of 6 to 12 months. Offers are available from the Master's programme, thanks in particular to its extensive alumni network.

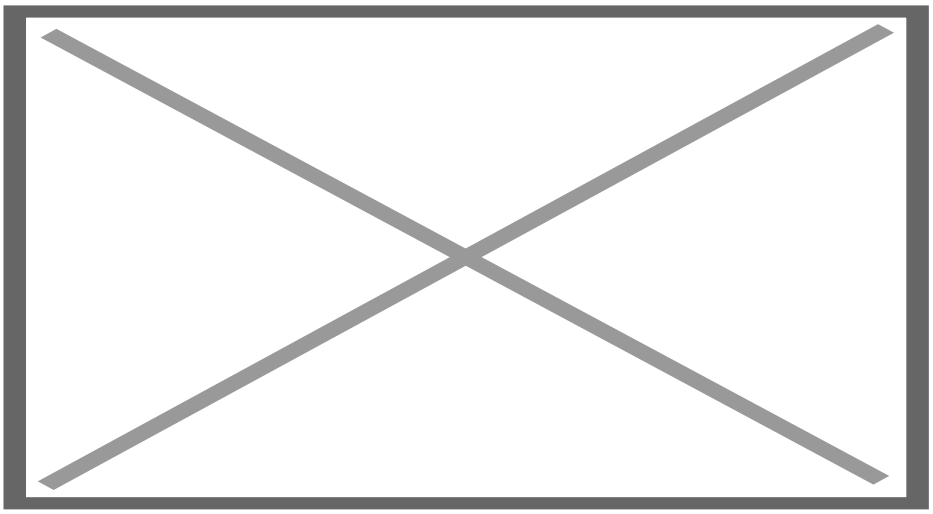
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# Information

- Overview
- Application requirements
- Schedule

Présentation

# Skills

- Help prepare and draft regulatory submissions within laboratories or service providers. -Monitor the regulatory environment (competitive watch, updates, guidelines, etc.), provide this information and advice on strategic regulatory issues to collaborators. -Be involved in interactions with regulatory authorities (answering questions, meetings, etc.). -Contribute to evaluation work and interactions with pharmaceutical companies for regulatory authorities (ANSM, EMA, etc.).

# Objectives

- Train medicines sector professionals in the scientific and regulatory aspects of drug development and registration. -Develop a strategic vision of international regulations (Europe and beyond).

# Débouchés

## Career prospects

### International regulatory affairs manager in the healthcare or consulting industries
### Legislative and regulatory watch officer
### Evaluator in national or international institutions

## Calendar

Start of programme (indicative date)
21/09/2025
Admission

## Capacity

### Available Places

18

## Target Audience and Entry Requirements

- students who have completed studies in healthcare (pharmacy, medicine, dentistry, veterinary medicine) in the European Union (and universities with an agreement), having validated the 5th year of study or equivalence with a 1st year Master's; * students who have validated a 1st year Master's in SMPS at a university offering a comparable level of teaching in France or in the European Union, after validation of specific knowledge prerequisites by the 2nd year Master's supervisor, in particular an in-depth knowledge of drugs; * be under 30 years of age to benefit from a work-study programme contract. * A good level of English is required.

## Période(s) de candidature

Inception Platform

From 01/03/2026 to 30/04/2026

# Supporting documents

## Compulsory supporting documents

Motivation letter.

All transcripts of the years / semesters validated since the high school diploma at the date of application.

Certificate of English level.

Curriculum Vitae.

## Additional supporting documents

Certificate of French (compulsory for non-French speakers).

VAP file (obligatory for all persons requesting a valuation of the assets to enter the diploma).

Recommendation letters.

Supporting documents :
- Residence permit stating the country of residence of the first country
- Or receipt of request stating the country of first asylum
- Or document from the UNHCR granting refugee status
- Or receipt of refugee status request delivered in France
- Or residence permit stating the refugee status delivered in France
- Or document stating subsidiary protection in France or abroad
- Or document stating temporary protection in France or abroad.

Details of the UEs taken for candidates outside the M1 Paris Saclay.

Programme

| Subjects | ECTS | Semester | Lecture | directed study | practical class | Lecture/directed study | Lecture/practical class | directed study/practical class | di le |
|---|---|---|---|---|---|---|---|---|---|
| Non-clinical and clinical drug development | 6 | Semester 1 | 65 | 20 | | | | | |

Charger le détail

| Subjects | ECTS | Semester | Lecture | directed study | practical class | Lecture/directed study | Lecture/practical class | directed study/practical class | di le |
|---|---|---|---|---|---|---|---|---|---|
| Strategy of registration of drugs produced by biotechnology and innovative therapies | 3 | Semester 1 | 35 | 5 | | | | | |
| Charger le détail | | | | | | | | | |
| Strategy of drug development and registration in European Union | 3 | Semester 1 | 35 | 5 | | | | | |
| Charger le détail | | | | | | | | | |
| Strategy of drug development and registration in non-European Union countries | 4 | Semester 1 | 40 | 10 | | | | | |
| Charger le détail | | | | | | | | | |
| Peri- and post-approval activities | 3 | Semester 1 | 30 | 10 | | | | | |
| Charger le détail | | | | | | | | | |

| Subjects | ECTS | Semester | Lecture | directed study | practical class | Lecture/directed study | Lecture/practical class | directed study/practical class |
|---|---|---|---|---|---|---|---|---|
| Strategy of drug development and registration | 6 | Semester 1 | 10 | 30 | | | | |
| Charger le détail | | | | | | | | |
| Approches professionnelles (Soft skills, veille règlementaire et congrès) | 3 | Semestre 1 | 6 | 3 | | | | |

| Subjects | ECTS | Semester | Lecture | directed study | practical class | Lecture/directed study | Lecture/practical class | directed study/practical class |
|---|---|---|---|---|---|---|---|---|

Charger le détail

| Subjects | ECTS | Semester | Lecture | directed study | practical class | Lecture/directed study | Lecture/practical class | directed study/practical class | dist lea co |
|---|---|---|---|---|---|---|---|---|---|
| Internship in regulatory affairs | 30 | Annualized | | | | | | | |

Charger le détail

| Subjects | ECTS | Semester | Lecture | directed study | practical class | Lecture/directed study | Lecture/practical class | directed study/practical class | dista learn cou |
|---|---|---|---|---|---|---|---|---|---|
| UE libre | 2 | Annualisé | | | | | | | |

Charger le détail

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|---|---|---|---|---|---|---|---|---|---|
| UE libre Catalogue S1 | 2.5 | Semestre 1 | | | | | | | |

Charger le détail

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|---|---|---|---|---|---|---|---|---|---|
| UE libre catalogue S1 et S2 | 2.5 | Semestre 2 | | | | | | | |

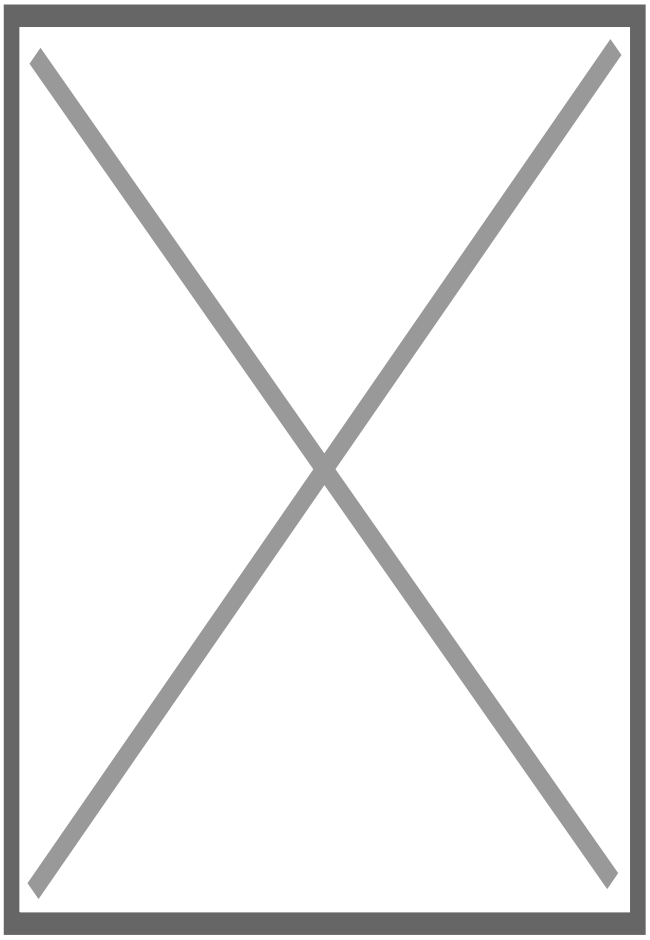
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# Teaching Location(s)

ORSAY

# Training campus

Javascript est requis pour visualiser cette carte.



### Saclay Moulon

Saclay / Gif-sur-Yvette / Orsay
Bus 4606 / 4609 / 4611 / 5154
RER B Le guichet
Voir
Student restaurant (CROUS)
Library
Sports facilities
Student residence

## Contact

- **Véronique LEBLAIS**

  PR

- **Véronique LEBLAIS**

  Responsable formation

http://www.universite-paris-saclay.fr/formation/master/sciences-du-medicament-et-des-produits-de-sante/m2-developpement-et-enregistrement-international-des-medicaments-et-autres-produits-de-sante