

## DENOMINAZIONE MASTER

### UNIVERSITY II LEVEL MASTER'S DEGREE IN DRUG DEVELOPMENT - INDUSTRIAL AND CLINICAL APPLICATION AY 2021/2022

#### OBJECT OF THE CALL (ART. 1 COMMA 2)

1.2 The Master's degree aims to train professionals in the field of activities related to the preclinical and clinical development of drugs, with particular regard to biotechnological drugs. The ideal beneficiary of this master's degree is a professional with scientific or management training who works in SMEs or large companies that develop drugs, or in CROs that deal with pharmaceutical experimentation, as well as doctors, biologists, biotechnologists or pharmacists who, within institutions, have organizational or clinical responsibilities for human experimentation of new drugs. The courses will cover the following disciplines:

- Outline of identification and optimization of 'lead compounds'
- Preclinical development. GLP and GMP manufacturing, evaluations of bioanalytical methods, mandatory animal tests, the formulation of the active pharmaceutical ingredient, the role of CROs in preclinical analyzes and presentation of the dossier for clinical trials
- Regulatory issues pharmaceutical legislation, practices for the presentation of 'Investigational New Drug', the organization of clinical trials, drug registration, ethics committees and clinical trial centers.
- Clinical trial Phase I, phase II and phase III clinical trials, with real examples of drug and vaccine testing in humans, post-approval clinical evaluations of the drug, pharmacovigilance, pharmacoeconomics.
- Data Science and Integration. Use of databases for the organization of trials, 'big data' analysis, statistical analysis, and scientific instrumentation in support of preclinical and clinical experimentation.
- Intellectual property - Patent filing, management, and maintenance. Patents of use and patent families, licenses of use, secrecy and privacy, orphan drugs, original and generic. The candidates' training will be completed with internships in companies operating in the drugs development sector.

#### ACCESS DEGREES (ART. 2 COMMA 1)

##### Requirements

2.1 In order to enroll in the university master's degree one of the following requirements must be satisfied:

- DEGREES OBTAINED IN ACCORDANCE WITH THE REGULATIONS IN FORCE UNDER Ministerial Decree 509/99 - Access allowed:
  - Pharmaceutical Biotechnologies
  - Industrial Biotechnologies
  - Medical Biotechnologies
  - Veterinary Biotechnologies
  - Chemistry
  - Pharmaceutical Chemistry and Technology
  - Industrial Chemistry
  - Pharmacy
  - Biomedical Engineering
  - Chemical Engineering
  - Medical Engineering
  - Medicine and Surgery
  - Veterinary Medicine
  - Dentistry and Dental Prosthetics
  - Biological Sciences
  - Health programming sciences
  - Natural Sciences
- SPECIALIZED DEGREES PURSUANT TO DM 509/99 AND MASTER'S DEGREES PURSUANT TO DM 270/2004:

- Class LS8-Industrial Biotechnologies
- Class LS9-Medical, Veterinary and Pharmaceutical Biotechnologies
- Class LS14-Pharmacy and Industrial Pharmacy
- Class LS26-Biomedical Engineering
- Class LS27 - Chemical Engineering
- Classe LS46-Medicine and Surgery
- Class LS47-Veterinary Medicine
- Class LS52-Dentistry and Dental Prosthetics
- Class LS62-Chemical Sciences
- Class LS92-Statistics for Experimental Research
- - Class LM-41-MEDICINE AND SURGERY (new system pursuant to DM 270/04)
- Class LM-13-PHARMACY AND INDUSTRIAL PHARMACY (new system pursuant to DM 270/04)
- - Class LM-42-VETERINARY MEDICINE (new system pursuant to DM 270/04)
- Class LM-46-DENTISTRY AND DENTAL PROSTHESIS (new regulation pursuant to DM 270/04)
- Class LM-6-BIOLOGY (new system pursuant to DM 270/04)
- Class LM-8-INDUSTRIAL BIOTECHNOLOGIES (new system pursuant to DM 270/04)
- Class LM-9-MEDICAL, VETERINARY AND PHARMACEUTICAL BIOTECHNOLOGIES (new system pursuant to DM 270/04)
- Class LM-21-BIOMEDICAL ENGINEERING (new system pursuant to DM 270/04)
- Class LM-22-CHEMICAL ENGINEERING (new system pursuant to DM 270/04)
- Class LM-54-CHEMICAL SCIENCES (new system pursuant to DM 270/04)
- Class LM-60-NATURE SCIENCES (new system pursuant to DM 270/04)
- Class LM-71-SCIENCES AND TECHNOLOGIES OF INDUSTRIAL CHEMISTRY (new system pursuant to DM 270/04)

#### **NUMBER OF PLACES (ART. 2 PARAGRAPH 5)**

2.5 The number of places for admission to this master's degree is set at a minimum of 8 and a maximum of 15.

**Enrollment is possible until the maximum number of available places has been filled.**

#### **MASTER'S DEGREE DURATION IN MONTHS (ART. 2 PARAGRAPH 7)**

2.7 To be awarded the master's degree, with a duration of 12 months, students must obtain 60 university training credits.

#### **APPLICATION DEADLINE (ART. 3 PARAGRAPH 1)**

##### **Applications submission**

3.1 The application for enrollment must be submitted **no later than 15 March 2022**, exclusively online, through the website <https://segreteriaonline.unisi.it> of the University of Siena. Enrollments in the course received after the aforementioned date will not be accepted.

#### **DOCUMENTS TO BE ATTACHED (ART. 3 PARAGRAPH 3)**

3.3 During the online procedure, applicants must, attach **as a mandatory requirement**, the following documents, in the section "Allegati domanda di Immatricolazione" (attachments to the enrollment application):

- Only for foreign students or students with a degree obtained abroad:
  - a. Original degrees copies as provided for in article 4 above for foreign citizens and EU citizens in possession of an academic degree obtained abroad.
  - b. Copy of the residence permit for non-EU citizens referred to in art. 4 paragraph 1.

- c. Copy of the passport with a specific entry visa for study purposes for non-EU citizens residing abroad.

The original documents referred to in point "a" must be submitted to the Ufficio Master e Corsi, no later than 6 months before the beginning of the course, under penalty of waiver. Until then, foreign students or students with a degree obtained abroad will be "enrolled subject to conditions".

#### RULES FOR FOREIGN APPLICANTS (ART. 4)

##### ***Rules for applicants of foreign citizenship and for EU citizens in possession of an academic degree obtained abroad***

4.1 Applicants in possession of a foreign academic degree equivalent, in terms of level, nature, content and academic rights (access to further courses) to the Italian academic qualification requested to have access to their chosen course, may apply for enrollment. Enrollment, however, remains subject to verification of the regularity of the study documentation, for the sole purpose of enrollment, carried out by the First and Second level Courses Division as well as the passing of the respective admission tests/qualifications evaluation, where required.

4.2 **EU applicants and equivalent** in possession of degrees obtained abroad must submit the latter attachments to the admission application duly completed by the Italian Representatives competent for the territory of the country of the institution that issued the qualifications. These qualifications must be translated into Italian, authenticated, legalized, and submitted with the required dichiarazioni di valore (value declarations).

**Non-EU applicants residing abroad** must submit the application for admission together with a copy of the qualifications obtained abroad showing the legal duration of the courses. The University of Siena reserves the right to ask the candidate for a translation.

For courses where enrollment in a professional register is a requirement, the applicants must present the corresponding certificate in an original or certified copy together with the translation into Italian.

*The pre-enrollment for applicants (international students) who need an entry visa for study purposes, must be sent through the UNIVERSITALY portal (<https://www.universitaly.it>).*

4.3 At the time of enrollment **the originals of the academic degrees** (translated, authenticated, legalized and with the required dichiarazioni di valore- declarations of value), completed by the competent Italian Representatives for the territory, must be attached under penalty of non-completion of the enrollment.

**For non-EU citizens** it is also compulsory to present a copy of the receipt of the application for a residence permit or a copy of the valid residence permit.

**Non-EU citizens residing abroad** must also present a copy of their passport with a specific entry visa for study purposes.

4.4. Provisions for access to the course for applicants of foreign citizenship and for EU citizens in possession of academic degrees obtained abroad can be found at the website of the Ministero dell'Università e della Ricerca <http://www.studiare-in-italia.it/studentistranieri/>.

#### ENROLLMENT FEES (ART. 5 PARAGRAPH 1)

5.1 The enrollment fee amounts to **2000 euros**, net of any charges and bank commissions. This sum must be paid in two installments:

- 1) The first installment amounting to **1000 euros**, to which the sum of 16.00 euros will be added for the payment of the electronic stamp duty, to be paid at the time of enrollment. Payment must be made through the **PagoPA system** according to the instructions on the site <https://segreteriaonline.unisi.it>. For further information visit: <https://www.pagopa.gov.it/>.
- 2) The second installment, amounting to **1000 euros**, no later than **01/09/2022**, accessing the web page <https://segreteriaonline.unisi.it> with your own Unisipass. Payment must be made through **Pago PA System**. No further communication will be issued regarding this deadline.

In the event that registration fees should be borne by third parties (public bodies, foundations, companies, etc.) the following is necessary:

- o Payments by private bodies or companies, must be made through the **PagoPA system**, upon reception of a payment notice sent by the University of Siena
- o Payments by a public body, must be effected through a *Girofondo (bank transfer)* on the account of Contabilità Speciale no. 0038125 in the name of Università degli Studi di Siena at the Banca d'Italia. The

procedure refers to Law 27/2012, for Special Accounting.

The payment of the contribution by a third party is considered formalized with a letter of commitment no later than the enrollment deadline date.

#### **BEGINNING AND END OF THE MASTER'S DEGREE (ART. 7. PARAGRAPH 2)**

7.2 The university master's degree course will start in April 2022 and end in April 2023.

The University Master's degree course must be obtained, in any case, no later than 3 months from the conclusion of the courses, under penalty of decline of studies.

**SEGRETERIA ONLINE (online secretariat) ( <https://segreteriaonline.unisi.it/Home.do> ) to apply for admission / registration**

**FURTHER INFORMATION IS AVAILABLE IN THE CALL FOR APPLICATIONS IN ITALIAN**