



MASTER'S AND COURSES OFFICE
Rectoral decree
Classification: III/5
No. of annexes: 0

**CALL FOR APPLICATIONS FOR
THE SECOND LEVEL UNIVERSITY MASTER'S PROGRAMME IN
DRUG DEVELOPMENT AND CLINICAL APPLICATION
Academic Year 2019/2020**

THE RECTOR

- Having regard to Ministerial Decree no. 270 of 22 October 2004 (Amendments to the regulations on the educational autonomy of universities, approved by decree no. 509 of the Ministry of Universities, Scientific Research and Technology on 3 November 1999) and art.3, par. 9 in particular;
- Having regard to the Inter-ministerial Decree issued by the Ministry of Education, Universities and Research (MIUR) and the Ministry for Public Administration, and the change implemented on 9 July 2009 regarding the equivalence of the university degrees of the classes referred to in the ministerial decrees of 4 August 2000 and 2 April 2001 and the university degrees of the classes referred to in the ministerial decrees of 16 March 2007 and 19 February 2009;
- Having regard to the MIUR Inter-ministerial Decree and the Ministry of Public Administration and Innovation of 9 July 2009 concerning the equivalence of degree diplomas under the regulations not yet reformulated pursuant to Ministerial Decree 509/99, granted by state and non-state universities authorized to issue legally valid qualifications, and the second cycle degrees (*laurea specialistica*) of the classes referred to in the ministerial decrees of 28 November 2000, 2 April 2001 and 12 April 2001, and the second cycle degrees (*laurea magistrale*) of the classes referred to in the ministerial decrees of 16 March 2007 and 8 January 2009;
- Having regard to Italian Law no. 240 of 30 December 2010 concerning the organisation of universities, academic staff and recruitment, and the Government's mandate to improve the quality and efficiency of the university system;
- Having regard to the Inter-ministerial Decree issued by the Ministry of Education, Universities and Research (MIUR) and the Ministry for Public Administration, and the change implemented on 11 November 2011 concerning the equivalence of the diplomas issued by the three-year specialization programmes, instituted pursuant to Italian Presidential Decree no. 162/1982, and of university degrees under Law no. 341/1990 of the same duration, to degrees falling under former Ministerial Decrees 509/1999 and 270/2004, for the purpose of participating in public competitions;
- Having regard to the Statute of the University of Siena issued by Rectoral Decree no. 164/2012 of 7 February 2012, published in the Official Gazette No. 49 of 28 February 2012, as amended by Rectoral Decree no. 93/2015 of 28 January 2015, published in the Official Gazette No. 37 of 14 February 2015, and in the Official Siena University Bulletin - Supplemented under no. 114 - in force since 14 February 2015;
- Having regard to the Electoral Regulations and regulations for the constitution of University of Siena bodies issued by Rectoral Decree no. 813/2018 of 08.06.2018, published on the University's online Register on 09.11.2018, as amended by Rectoral Decree no. 1805/2018 of 08.11.2018, published in the

University's on-line Register on 09.11.2018, as amended by Rectoral Decree no. 6/2019 of 07.01.2019 and published on the University's online Register on 07.01.2019;

- Having regard to the University Regulations issued by Rectoral Decree no. 1332 dated 26.09.2016;
- Having regard to the Decision of the Council dated 21 December 2018 regarding the determination and allocation of deductions withheld from funding for teaching activities, non-commercial research activity and other external funding;
- Having regard to the Regulations concerning university Master's programmes, Advanced training courses, refresher courses, training courses and the Summer and Winter schools of the University of Siena, issued by Rectoral Decree no. 1564/2017 dated 13.12.2017 and published on the University's online Register on 14.12.2017;
- Having regard to the Regulations governing the assignment of teaching duties issued by Rectoral Decree no. 1529 dated 17 October 2012, posted on the University's online register on 18.10.2012 and published in University Bulletin no. 101, as amended, as well the guidelines for the educational offering;
- Having regard to the Decision of Siena University's Academic Senate on 6 November 2012 which sets out that Master's, specialization, refresher and training programmes, as well as summer schools, pertain to the proposing Department;
- Having regard to the resolution of the Academic Senate of 17 December 2012, which establishes the requirements for holding any online meetings among the collegial bodies of the postgraduate schools, Doctoral and First or Second level Master's programmes and Advanced training courses;
- Having regard to the resolution of the Academic Senate of the University of Siena dated 4 February 2014, which approved the criteria for self-evaluation of university master's degree programmes;
- Having regard to the resolution of the Council of the University of Siena dated 26 March 2014, which set the maximum remuneration for the Head of a University Master's programme and for the lecturers, pursuant to art. 8 of the Regulations on University Master's programmes at the University of Siena;
- Having regard to the Resolution of the Academic Senate of 2 December 2014 which approved the new scheduling of the First and Second level university Master's programmes, Advanced training courses, Training courses, Refresher courses and Summer Schools on offer starting in academic year 2015/2016;
- Having regard to the resolution of the University of Siena's Academic Senate of 16 January 2018, which established the standard agreement schemes for First and Second level university Master's programmes, Advanced training programmes, Training programmes, Refresher courses and Summer Schools;
- Having regard to the decision of the Council on 19 January 2018 which made it possible for University of Siena technical and administrative staff with open-ended or fixed-term contracts and with at least six months of completed service, to take single Courses of the Master's Programmes or the entire university Master's Programme, where these are relevant to the service;
- Having regard to the University's provisions concerning compliance with regard to self-employed work contracts, occasional or coordinated and continuous;
- Having regard to art. 3, par. 1 of the University of Siena Regulations governing university Master's programmes, Advanced training courses, refresher courses, training courses and Summer and Winter schools, which establishes that proposals for instituting university Master's programmes must be approved by the Departments;
- Having regard to the agreement between the University of Siena and Siena University Hospital (*Azienda Ospedaliera Universitaria Senese*, AOUS) regarding the enrolment over and above the prescribed number of AOUS employees on university Master's programmes and Courses organized by the

University of Siena;

- Having regard to the 2 April 2019 report by the Committee, set up pursuant to art. 3, par. 3 of the Regulations on University Masters of the University of Siena and designated by the Academic Senate at the meeting of 20 April 2017;
- Given that the Committee, established pursuant to art. 3, par. 3 of the Regulations on University Masters of the University of Siena, in the report of 2 April, 2019 considered it necessary that some university masters and courses include the grounds for derogating from the minimum number of 10 participants, and in certain cases, indicate an appropriate maximum number of candidates, new grounds were adopted and then approved by the respective Departments;
- Having regard to the decision of the Academic Senate on 7 October 2014 which established that the University of Siena would take part in the AlmaLaurea study on University Masters;
- Having verified that the Board of the Department of Medical Biotechnology of the University of Siena on 12 March 2019 proposed the creation of an Advanced Scientific Training and Continuing Development Programme for academic year 2019/2020, at the end of which students are awarded a second level university Master's degree in DRUG DEVELOPMENT AND CLINICAL APPLICATION;
- Given that the Academic Senate of the University of Siena on 7 May 2019 approved the establishment of a second level university Master's programme in DRUG DEVELOPMENT AND CLINICAL APPLICATION for academic year 2019/2020;
- Given that the Council of the University of Siena on 24 May 2019 approved the creation of a second level university Master's programme in DRUG DEVELOPMENT AND CLINICAL APPLICATION for academic year 2019/2020;

HEREBY DECREES

Subject of the notice

1.1 The University of Siena hereby establishes, for academic year 2019/2020, the Advanced Scientific Training and Continuing Development Programme of the Department of Medical Biotechnology, at the end of which a Second level Master's degree in "DRUG DEVELOPMENT AND CLINICAL APPLICATION" (hereinafter the university Master's programme) will be awarded.

1.2 The Master aims to train professionals in the area of preclinical and clinical drug development, focusing on biotechnology drugs. The Master is tailored for professionals with scientific or managerial background who operate in small- to medium-sized businesses (PMI) or large companies involved in drug development, in reference oncology departments (CROs) involved in pharmaceutical trials, or for doctors, biologists, biotechnologists or pharmacists who, within healthcare structures, are administratively or clinically responsible for testing new drugs on humans.

Courses will address the following:

- Notions of 'lead compound' identification and optimization and preclinical development. GLP and GMP production, assessment of bioanalytical methods, mandatory animal testing, formulation of active pharmaceutical principles, the role of CROs in preclinical analysis, dossier presentation for clinical trials;
- Legislative aspects. Drug legislation, procedures for presenting an 'Investigational New Drug', organization of clinical trials, drug registration, ethics committees and clinical testing centres;
- Clinical testing. Phase I, phase II, phase III clinical trials, with real examples of drug and vaccine trials in humans, post-approval clinical evaluation, pharmacovigilance, pharmacoconomics;
- Data Science and Integration. Database use to organize trials, 'big data' analysis, statistical analysis,

scientific instrumentation to support preclinical and clinical trials;

- Intellectual property. Filing, managing and maintaining patents, patents on use and patent families, use licenses, secrecy and privacy, orphan, original and generic drugs.

The programme also entails an internship in a public or private institution involved in drug development.

1.3 The contact persons for the Master's programme organization and teaching activities (lectures, calendars, lecture rooms, etc.) is:

Sandra Donnini, Department of Life Sciences, Tel: 0577234442 email: sandra.donnini@unisi.it

Luisa Bracci, Department of Medical Biotechnology, Tel: 0577232020 email: luisa.bracci@unisi.it

Alessandro Pini, Department of Medical Biotechnology, Via A. Moro 2, 53100, Siena, Tel:0577232021 email: alessandro.pini@unisi.it

Chiara Falciani, Department of Medical Biotechnology, Tel: 0577232022 email: chiara.falciani@unisi.it.

Admission requirements

2.1 For admission to the University Master's programme, applicants must hold one of the following qualifications:

- DEGREES AWARDED IN ACCORDANCE WITH THE REGULATIONS IN FORCE PRIOR TO MINISTERIAL DECREE 509/99:
 - Pharmaceutical Biotechnology
 - Industrial Biotechnology
 - Medical Biotechnology
 - Veterinary Biotechnology
 - Chemistry
 - Pharmaceutical Chemistry and Technology
 - Pharmacy
 - Biomedical engineering
 - Chemical engineering
 - Engineering management
 - Medical engineering
 - Medicine and surgery
 - Veterinary medicine
 - Dentistry and dental prosthetics
 - Biology
 - Healthcare planning
 - Natural sciences
- SECOND CYCLE DEGREES PURSUANT TO MINISTERIAL DECREE 509/99 (*LAUREE SPECIALISTICHE*) AND TO MINISTERIAL DECREE 270/2004 (*LAUREE MAGISTRALI*):
 - Class LS6- Biology
 - Class LS8- Industrial biotechnology
 - Class LS9- Medical, Veterinary and Pharmaceutical Biotechnology
 - Class LS14- Pharmaceutical science and Industrial pharmaceutical science
 - Class LS26- Biomedical engineering
 - Class LS27- Chemical engineering
 - Class LS34- Engineering management
 - Class LS46- Medicine and surgery

- Class LS47- Veterinary medicine
- Class LS52- Dentistry and dental prosthetics
- Class LS62- Chemistry
- Class LS68- Natural sciences
- Class LS92- Statistics in Experimental research
- Class LM-41-MEDICINE AND SURGERY (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-13-PHARMACY AND INDUSTRIAL PHARMACEUTICAL SCIENCE (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-42-VETERINARY MEDICINE (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-46-DENTISTRY AND ORTHODONTICS (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-6-BIOLOGY (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-8-B-INDUSTRIAL BIOTECHNOLOGY (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-9- MEDICAL, VETERINARY AND PHARMACEUTICAL BIOTECHNOLOGY (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-21-BIOMEDICAL ENGINEERING (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-22- CHEMICAL ENGINEERING (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-31-ENGINEERING MANAGEMENT (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-54- CHEMISTRY (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-60- NATURAL SCIENCES (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-71- SCIENCE AND TECHNOLOGY IN INDUSTRIAL CHEMISTRY (new regulations pursuant to Ministerial Decree 270/04)
- Class LM-86- ZOOTECHNICS AND ANIMAL TECHNOLOGY (new regulations pursuant to Ministerial Decree 270/04)

The committee reserves the right to assess the applications of candidates whose CV reports further training and/or specific activity in the programme's field of interest.

Applicants must in any case hold the following academic qualifications:

- a university degree (*diploma di laurea*)
- or a first cycle, three year degree
- or a three year vocational school diploma
- or any other qualification pursuant to art. 5 of Law 251/2000 in the health professions, as long as the applicant also holds a five-year upper secondary school diploma,

2.2 The following persons may also apply for admission:

- applicants holding an academic qualification equivalent, pursuant to the laws in force, to one of the qualifications for admission listed in art. 2, par. 1.
- for enrolment purposes only, applicants with foreign academic qualifications that can be considered equivalent by virtue of level, nature, content and academic rights (access to other programmes) to the Italian qualification required for admission to the selected programme.

2.3 The applicant must meet the aforementioned requirements by the Master's programme application deadline.



If the student has not obtained the qualification required for admission by the application deadline indicated under art. 3, paragraph 1, he/she may enrol in the selected university master's programme on a conditional basis prior to that deadline, indicating the presumed date of graduation on their declaration in lieu of certification, which must be submitted via the online admission procedure.

The candidates must notify the Master's and Courses Office (master-corsi@unisi.it) that the qualification has been obtained by the date of the test/curriculum evaluation indicated under art. 5, paragraph 2. This notice must be accompanied by a copy of a valid identity document.

Failure to meet the indicated requirements may lead, at any moment and with provision of appropriate justification, to the student being excluded from admission to the Master's programme by the Master's and Courses Office.

2.4 Enrolment in the university Master's Programme cannot be completed in the case of simultaneous enrolment on a TFA (Active Training Internship), a PAS (Special Qualification Path), a Specialization Course for teaching assistance for students with disabilities or with Study Programmes at other Universities, where allowed under their regulations.

2.5 The number of places available on the Master's Programme has been set at a minimum of 10 and a maximum of 15.

2.6 Students with disability percentages greater than or equal to 66% who declare an ISEE (Equivalent Economic Situation Indicator) value no greater than € 22,000.00 shall be admitted over and above the prescribed number provided that they meet the requirements for admission to the programme and have passed any required selection procedures.

Students to whom this paragraph refers are entirely exempted from payment of the registration fees, and are not taken into consideration for the purpose of calculating the minimum number of programme places to be filled. The latter may not constitute more than 10% of the total number of students, unless the relevant body makes a motivated decision to allow otherwise; whatever the case, this number may not be less than 1.

In the event that the number of students satisfying both requirements should exceed the limit specified above, the benefit will be awarded in accordance with the admission ranking.

In the event that the number of applications for admission should not exceed the number of places indicated in the selection notice, the programme's decision-making body will determine the objective criteria for granting the aforementioned benefits.

In order to apply for this benefit, the interested students must fill out the appropriate fields during the online procedure, and attach a photocopy of their disability certificate and an ISEE (Equivalent Economic Situation Indicator) self-certification showing that their family unit does not have an income value greater than € 22,000.00.

Applicants with disabilities pursuant to Law no. 104 of 5 February 1992, and the subjects referred to by laws 68/1999 and 170/2010, must contact the *Ufficio accoglienza disabili e servizi DSA* (Disability Services) – Via Bancchi di Sotto no. 55 – Siena, Italy – Tel. 0577-235415

2.7 The university Master's programme lasts 12 months, and calls for the completion of 60 university credits.

2.8 The Programme is supported by: Zambon Kedrion Spa, Philogen Spa, Fondazione vita Toscana Life Sciences, GSK vaccines srl, and SetLance srl.

Submission of applications

3.1 Applications must be submitted **no later than 10 January 2020** exclusively online through the University of Siena website <https://segreteriaonline.unisi.it>. Applications submitted after the deadline will be refused.

3.2 Instructions for completing the application

a) before completing the application, students must login to the system:

- I. click on "Registration" (only if you do not have an active or previously existing account with the University). Once the registration procedure has been completed, you will be issued a **username** and **password** that can be used to login to the system in order to access the services offered and modify the data entered. Your login credentials, shown on the screen, can be printed from the registration confirmation page, and will be sent by email to the private e-mail address indicated during the procedure.

or, if you already have an active or previously existing account with the University

- II. click on "Recover UNISIPASS credentials" (if you have forgotten your username and/or password)
- b) after having logged in with your credentials (if you have another student record, select it to continue), click on the "Registrar" menu and choose "Admission Test";
- c) choose the programme type;
- d) choose the programme in which you wish to pre-enrol;
- e) fill in the application.

Once the procedure has been completed, the system issues a receipt of "application for admission to the selection procedure".

3.3 During the online procedure, applicants **must** upload the following documents in the section "**Gestione titoli e documenti per la valutazione**" ("Management of qualifications and documents submitted for assessment"):

- CURRICULUM VITAE (CV)
- ANY PUBLICATIONS
- ANY OTHER QUALIFICATIONS: any qualification not already listed in the CV, which the candidate wishes to submit for evaluation;
- for students with disability percentages greater than or equal to 66% only: a self-certification indicating an ISEE (Equivalent Economic Situation Indicator) income value no greater than € 22,000.00 for their family unit.
- For those holding qualifications awarded abroad:
 - **for non-European Union citizens resident abroad**, a copy of the qualifications obtained abroad indicating the legal duration of the programmes;
 - **EU and equivalent applicants**, a copy of the qualifications translated into Italian, authenticated, legalised and provided with the declarations of value required.

As of 1 January 2012, with the entry into force of Article 15 of Italian Law 183/2011, administrations can no longer accept certifications issued by other Public Administrations or by public service operators concerning conditions, personal qualities or facts. The certificates are always replaced by self-certifications or affidavits.

Please note that documentation NOT EXPRESSLY REQUESTED by this notice and attached through the online registration procedure will not be taken into consideration for evaluation by the relevant selection committee.

3.4 Applicants holding foreign citizenship and EU citizens with an academic qualification obtained



abroad must, during the online procedure, attach the qualifications indicated in art. 4 hereunder. Non-EU citizens residing in Italy must also provide a copy of their residence permit.

Those who are unable to complete the online procedure can contact the International Place – (Mon-Fri 9.30 am - 1 pm, Tue and Thu also 3 pm - 5 pm) by calling the freephone number 800-221-644 (from an Italian landline only) or telephone + 39-0577-232111, or by sending an e-mail to internationalplace@unisi.it.

The International Place also offers assistance to international students (accommodation, permits, healthcare assistance, and language support).

3.5 Applicants cannot generally refer to documents and qualifications submitted to this Administration as attachments to applications for admission to other programmes.

3.6 The Administration shall bear no responsibility for any lack of communication resulting from incorrect contact information provided by the applicant or from the applicant's failure or delay in notifying a change of e-mail or mailing address, nor for any problems attributable to third parties, unforeseeable circumstances, or force majeure.

3.7 Applications submitted with incomplete or incorrect documentation will be refused.

3.8 Based on their individual needs, applicants with disabilities pursuant to Law no. 104 of 5 February 1992, and the subjects referred to in laws 68/1999 and 170/2010, must make specific requests regarding any assistance required and the potential need for additional time in order to take any admission tests. For this purpose, they must contact the *Ufficio accoglienza disabili e servizi DSA* (Disability Services) in Via Banchi di Sotto no. 55 – Siena – Tel. 0577-235415.

Rules for applicants with foreign citizenship and for EU citizens with an academic qualification awarded abroad

4.1 Applicants with an academic qualification awarded abroad that is equivalent, for enrolment purposes and by virtue of its level, nature, content and academic rights (access to further programmes), to the Italian qualification required for admission to the chosen programme, may request enrolment. Enrolment, however, remains subject to verification of the study documentation's compliance, for the sole purpose of enrolment, by the First and Second level Programmes Division, and to passing the respective admission tests/evaluation of qualifications, where required.

4.2 **EU and equivalent applicants** holding foreign qualifications must attach these to the admission application, duly completed by the Italian diplomatic offices in the country regulating the institution that awarded the qualification. These qualifications must be translated into Italian, authenticated, legalised and provided with the declarations of value required.

Non-EU citizens resident abroad must submit a copy of the admission application along with copies of the qualifications obtained abroad that indicate the legal duration of the programme. The University of Siena reserves the right to request a translation from the applicant.

For programmes where enrolment in a professional register/order is also required, the relative certificate in original or certified copy must be presented together with its Italian translation.

4.3 Upon enrolment, **the original qualification awarded** (translated, authenticated, legalised and provided with the required value declarations), perfected by the appropriate Italian diplomatic offices, must be attached, without which enrolment will not be completed.

Non-EU citizens must also present a copy of the receipt of the application for a residence permit or a copy of a valid residence permit.

Non-EU citizens resident abroad must also present a copy of the passport with a specific entry visa for non-

tourist reasons.

4.4. The provisions for access to the programme by applicants of foreign and EU citizenship with an academic qualification obtained abroad can be found on the website of the Ministry of Education, Universities and Research <http://www.studiare-in-italia.it/studentistranieri/> .

Evaluation and exams

5.1 Admission to the university programme will be in accordance with a merit-based ranking drawn up on the basis of the submitted CV's. Qualifications falling under any one of the following categories will be taken into consideration:

- Academic qualification 18/30
- Specialization diplomas or certificates and professional qualifications 6/30
- Other qualifications 6/30

CV assessment will take place on 21/01/2020.

Suitable applicants are those who obtain a score of at least 18/30.

5.2 The criteria for the evaluation of these qualifications will be established beforehand by the appropriate body during the first meeting

5.3 The committee shall prepare a summary sheet for each applicant containing a detailed list of his/her qualifications divided into the various categories and the corresponding scores.

5.4. Admission will be granted to applicants positioned suitably in the ranking.

5.5 In the case of equal merit, preference will be accorded to the younger applicant.

5.6 Should an applicant decline the offer of admission, the next person in the ranking shall be admitted. Replacements will be made in this manner up until the start of the programme.

Enrolment procedure

6.1 The *Ufficio Master e Corsi* (Master's and Courses Office) will send, via the private email address indicated during the online registration procedure, specific notice to each applicant admitted to the Master's Programme regarding the deadline for enrolment through the "Segreteria online" service

Alternatively, notification may be sent by regular mail, telegram or fax.

Once the procedure has been completed, the system generates the payment form for the first/single instalment of tuition fees, in the amount established under par. 2 of this article.

The excess students indicated under art. 2 par. 6 are exempt from payment of tuition fees, but will nevertheless be required to pay the € 16.00 virtual stamp duty using the MAV bank form.

The MAV form in question is a payment slip that can be printed out and used at any bank in Italy.

Students can also pay tuition fees online using a credit card.

Esse3 (the computer system that manages student records) normally receives payment confirmation within 48 hours.

Once students have completed the online procedure correctly, they can print out their enrolment receipt.

Enrolment only becomes effective once the tuition fee has been paid. Those who have not paid the fee by the start of the programme will be considered withdrawn and will lose their student status.

Applicants of foreign and EU citizenship with an academic qualification obtained abroad must, on pain of exclusion from the programme, deliver or post the following documents to the Master's and Courses Office by the deadline indicated in the notification:

- a) original qualifications indicated in art. 4 above for applicants of foreign and EU citizenship with an

academic qualification obtained abroad;

- b) copy of the residence permit for non-EU citizens as per art. 4, par. 1;
- c) non-EU citizens resident abroad must also present a copy of the passport with a specific entry visa for non-tourist reasons.

The original documents referred to in point "a" must be delivered or posted to the Master's and Courses Office, no later than six months from the start of the programme, under penalty of forfeiture. Until then, foreign students or students with a qualification obtained abroad will be considered "provisionally enrolled".

Enrolment is considered complete only once it has been verified that the applicant has met the admission requirements. Up until that time, enrolment is to be understood as provisional.

The Administration shall bear no responsibility for any lack of communication resulting from incorrect contact information provided by the applicant or the applicant's failure to notify or delay in notifying any changes in e-mail or mailing address, nor for any problems attributable to third parties, unforeseeable circumstances, or force majeure.

Pursuant to art. 75 of Italian Presidential Decree no. 445 of 28/12/2000, and without prejudice to the provisions of art. 76 in criminal matters, in the event that verification of self-certifications should reveal any false statements, the applicant in question shall forfeit any benefits resulting from the false statement itself.

6.2 The tuition fee amounts to **3000 Euros**, net of any duties and bank fees. This sum must be paid in two instalments:

- 1) the first **1500 Euro instalment**, to which the amount of € 16.00 must be added for virtual stamp duty, must be paid at the time of enrolment using the form specially downloaded during the online procedure.
- 2) the second instalment, amounting to **1500 Euros**, must be paid by **03 September 2020**. Students may download and print out the MAV form by accessing the web page <https://segreteriaonline.unisi.it> using their Unisipass. No further communication will be provided regarding this deadline.

To complete the procedure quickly without any error, applicants are advised to send a copy of the MAV payment receipt to the Master's and Courses Office by e-mail (master-corsi@unisi.it) or fax. Proper enrolment in University of Siena programmes is subject to payment of the amounts due; payment of the first instalment secures enrolment.

If tuition fees are to be paid by a third party (Public Institution, Foundation, Company, etc.), contact the *Ufficio Master e corsi* (email master-corsi@unisi.it) before the deadline to receive the necessary instructions for payment.

Payment of tuition fees by a third party must be declared in a formal letter of commitment submitted by the deadline for enrolment.

6.3 As the programme falls within the scope of the University's institutional activities, and not its commercial activities, the fees are not subject to V.A.T. and no invoice can therefore be issued.

6.4 If the minimum number of students indicated under art. 2, par. 5 of this notice is not reached, the programme will be cancelled and the Administration will arrange for the reimbursement of the enrolment fee, excluding the amount of €16.00 paid for virtual stamp duty.

University Master's administrative bodies

7.1 The administrative bodies of the University Master's programme are:

- the Director, elected by the Teaching Board from among the professors of the University of Siena;
- the Teaching Board, composed of the heads of the academic areas of the University Master's Programme and chaired by the Director;



- Board of Directors elected by the Teaching Board from its members and chaired by the Director.

Programme of study

8.1 Attendance is mandatory. Justified absences are permitted up to a maximum of 20% of the planned internships, traineeships and lectures.

8.2 The university Master's programme will begin in March 2020 and end in March 2021.

The Master's degree must be completed no later than 3 months after the conclusion of programme courses: the studies will otherwise lapse.

8.3 The calendar will be communicated by the Master's programme Management.

8.4 Teaching activities will be held at the following location:

-*Polo scientifico San Miniato* (San Minato Science complex) in Siena;

8.5 Courses will be held in: ENGLISH.

Adequate knowledge of the language is required.

The programme covers the following academic topics:

IDENTIFICATION AND OPTIMIZATION OF 'LEAD COMPOUNDS'

credits= 2

Supervisors: PINI ALESSANDRO, FALCIANI CHIARA

Modules:

IDENTIFICATION AND OPTIMIZATION OF 'LEAD COMPOUNDS'

credits= 1

LIBRARIES IN DRUG DISCOVERY

credits= 1

PRECLINICAL DEVELOPMENT

credits= 7

Supervisors: FALCIANI CHIARA, PINI ALESSANDRO, FUSI FABIO, DONNINI SANDRA

Modules:

EARLY BIOPHARMACEUTICAL DRUG DEVELOPMENT credits= 1

ANIMAL MODELS credits= 2

CHEMICAL AND ANALYTICAL PROCESS DEVELOPMENT credits= 1

API FORMULATION credits= 1

SAFETY PHARMACOLOGY credits= 2

CLINICAL TRIALS

credits= 6

Supervisors: PINI ALESSANDRO, FALCIANI CHIARA, DONNINI SANDRA

Modules:

CLINICAL TRIALS, PHASES I-III credits= 2

VACCINES credits= 2

PHARMACOVIGILANCE credits= 2

LEGISLATIVE ASPECTS

credits= 5

Supervisors: PAOLINI ANDREA, PINI ALESSANDRO, FALCIANI CHIARA, FROSINI ANDREA,

Modules:

INTERNATIONAL LEGISLATION credits= 2

DRUG APPROVAL PROCESS credits= 2

ETHICS COMMITTEES AND CENTRES FOR CLINICAL TRIALS credits= 1

INTELLECTUAL PROPERTY

credits= 5

Supervisors: FROSINI ANDREA , PINI ALESSANDRO, FALCIANI CHIARA

Modules:

PATENT FILING AND MANAGEMENT credits= 4

GENERIC AND ORPHAN DRUGS credits= 1

DATA INTEGRATION

credits= 5

Supervisors: FALCIANI CHIARA, SALVINI LAURA, PAOLINI ANDREA, PINI ALESSANDRO

Course:

DATA SCIENCE, DATABASES AND BIG DATA credits= 3

SCIENTIFIC INSTRUMENTATION FOR PRECLINICAL AND CLINICAL TESTS credits= 2

INTERNSHIP

credits= 10

Internship Supervisors: PINI ALESSANDRO, FALCIANI CHIARA, DONNINI SANDRA

Internship in a company or public institution:

GSK, Zambon, Philogen, Kedrion, TLSSet, Lance, Fondazione Vita

Internship activities will be defined by a special programme drafted by the Teaching Board.

Final exam

9.1 The final exam, which confers 20 credits, will consist of:

- AN INTERVIEW TO ASSESS KNOWLEDGE ACQUIRED
- A FINAL THESIS OR REPORT

9.2 The final exam will be marked as points out of one hundred and ten.

9.3 In order to sit the final exam, students must login to their "*Segreteria online*" ("*Online Registrar*") profile, click in the left-hand column on "*Conseguimento titolo*" - "*bacheca conseguimento titolo*" ("*Graduation*" - "*Graduation Noticeboard*") and follow the procedure by selecting the present session.

During the online procedure for applying for graduation, the student must make the € 16.00 payment for the virtual revenue stamp.

Those enrolled on a university Master's programme must complete the Almalaurea Questionnaire.

Awarding of the qualification

10.1 Pursuant to art. 6 of the Regulations governing University of Siena Master's programmes, the university Master's degree is awarded, following certification of the conclusion of the programmes, signed by the Managing Director and the Rector of the University of Siena.

Conferment of the Master's degree and relative credits are conditional on:

- a) payment of the full enrolment fee;
- b) fulfilment of attendance requirements;

- c) passing the intermediate tests;
- d) passing the final exam;
- e) completing the AlmaLaurea questionnaire.

10.2 To receive the final certification, students who have completed the activities and fulfilled obligations must submit a special request using the form available at the Master's and Courses Office. Upon conclusion of the Master's Programme, a diploma will be prepared; while completing the procedure indicated in the previous article, payment of an additional € 16.00 for virtual stamp duty is required.

Withdrawal from the Master's programme

- 11.1 Students may withdraw from studies provided that they are up to date with the payment of fees owed up to the day they submit the specific withdrawal form available at http://www.unisi.it/sites/default/files/allegati/modulo_rinuncia_corsi_master_4.pdf.
- 11.2 Failure to pay fees does not constitute tacit withdrawal from studies: students who do not pay the instalments due cannot continue their studies in any way but have not terminated their relationship with the University of Siena and cannot carry out any other enrolment.
- 11.3 Withdrawal does not entitle students to receive any reimbursement of fees paid.

Changes to the notice

- 12.1 Any changes to this notice will be posted on the University's online register (www.unisi.it) and on the University's specific programme web pages.
- 12.2 It is incumbent on the Management of the university master's programme to notify the entitled parties of any changes to this notice.

Insurance coverage

- 13.1 As the administrative headquarter of the Master's programme, the University of Siena will guarantee that enrolled students are covered by civil liability and accident insurance. The University of Siena guarantees students the same insurance coverage for the compulsory internship of the University Master's Programme carried out at facilities other than those of the university, as indicated in this notice or subsequently identified after formal agreement between the parties. Risks not covered by the university policy will be incumbent on the host structures, or else on the student.

Processing of personal data

- 14.1 The processing of applicants' personal data is carried out by the University of Siena exclusively for institutional purposes and for managing this competition notice. Information on the processing of students' personal data is available in the Privacy section of the University Portal <https://www.unisi.it/ateneo/adempimenti/privacy>.
- 14.2 The University undertakes to respect the confidential nature of the data and information provided by the applicant, which will be processed in accordance with EU Regulation 679/2016 on the protection of personal data and Legislative Decree no. 196/2013 Privacy Code, for provisions that are not incompatible with the Regulations. The Data Controller is the University of Siena, legally represented by the Rector pro-tempore, Prof. Francesco Frati. The Applicant may assert his/her rights (articles 15 and subsequent of the EU Regulations) by contacting the Data Controller; send a message to the certified email address rettore@pec.unisipec.it, or the e-mail address segreteria.rettore@unisi.it;



14.3 The provision of data is required to manage the relationship between the Student and the University (e.g. selection, admission, enrolment, managing student records, etc.). Refusal to allow said processing will lead to exclusion from the competition.

Procedure manager

15.1 Pursuant to articles 4, 5 and 6 of Law no. 241/1990, as amended, the Procedure Manager is hereby identified as Dott. Paolo Genovese, Head of the Master's and Courses Office at the University of Siena.

Final provisions

16.1 For all matters not covered by this notice, please refer to the Regulations governing University Master's Programmes and the internal rules and regulations of the University of Siena, as well as the applicable national legislation.

Siena, date of the digital signature

The Rector
Francesco Frati

Approved by
The Procedure Manager
Paolo Genovese

Approved by
The Deputy Managing Director
Giovanni Colucci