



UFFICIO MASTER E CORSI

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
A.Y. 2020/2021**

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; published on the University's online Register on 26.09.2016, published in the Official Bulletin B.U. no. 125 as amended;
- 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 and on the Official Bulletin B.U. no. 132, modified through Rectoral Decree. no. 8/2020 of 09.01.2020, published on the University's online register on 09.01.2020);
- 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 Official Bulletin BU 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 decision of the academic senate of the University of Siena on 7 April 2020 in which it was decided that, starting from the academic offering of academic year 2021-2022, the proposed characterization of a University Master as "Executive" be assessed by the Committee under ex art. 3, comma 3 of the University Regulations governing university Master's programmes, Advanced training courses, refresher courses, training courses and Summer and Winter schools. Furthermore, it has been decided to derogate from the scheduling of university Master's, programmes, Advanced training programmes, Training programmes, and summer and winter schools at the University of Siena;



- Having regard to the University's provisions concerning compliance with regard to self-employed work contracts, occasional or coordinated and continuous;
- 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 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;
- Considering that the Department Board proposed the institution of Advanced Scientific Training and Continuing Development Programme for academic year for AY 2020/2021, at the end of which students are awarded a second level university Master's degree;
- Having regard to report of 18 April 2020 of the Committee under art. 3, par. 3, of the Regulations governing University Masters at the University of Siena designated by the Academic Senate on 20 April 2017;
- Having regard to rectoral decree no. 752/2020 of 30.04.2020, subject to ratification by the Academic Senate and the Council, which besides postponing second instalment payment deadlines for Master's programmes in AY 2019/2020, orders that all university Master's programmes, Advanced training courses, refresher courses, training courses and Summer and Winter schools being activated for AY 2020/2021 have a minimum number of enrolled students to ensure cost sustainability and that there are no added expenses to the University;
- Given that the Committee under art. 3, par. 3, of the Regulations governing University Master's programmes at the University of Siena, in the 18 April 2020 report provided for some amendments for university Master's programmes;
- 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 on 23.03.2020 the Board of the Department of Medical Biotechnology of the University of Siena proposed the creation of an Advanced Scientific Training and Continuing Development Programme for academic year 2020/2021, 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 26.05.2020 approved the establishment of a second level university Master's programme in DRUG DEVELOPMENT AND CLINICAL APPLICATION for academic year 2020/2021;
- Given that the Council of the University of Siena on 29.05.2020 approved the creation of a second level university Master's programme in DRUG DEVELOPMENT AND CLINICAL APPLICATION for academic year 2020/2021

HEREBY DECREES

Subject of the notice

1.1 The University of Siena hereby establishes, for academic year 2020/2021, 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 biotechnological drugs. The programme is tailored for professionals with scientific or managerial backgrounds 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.

Modules 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.) are:

Alessandro Pini, Department of Medical Biotechnology, via Aldo Moro 2, 53100 Siena Tel: +390577232021 email: alessandro.pini@unisi.it

-Sandra Donnini, Tel: +390577234442 email: sandra.donnini@unisi.it

-Chiara Falciani, Tel: +390577232022 email: chiara.falciani@unisi.it

-Jean Denis Docquier, Tel: +390577233134 email: jddocquier@unisi.it

-Luisa Bracci, Tel: 0577232020 email: luisa.bracci@unisi.it

-Lucia Morbidelli, Tel: +390577235381 email: lucia.morbidelli@unisi.it

The Master's webpage is <http://www.ddca.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
 - Agricultural-industrial biotechnology
 - Pharmaceutical Biotechnology
 - Industrial Biotechnology
 - Medical Biotechnology
 - Veterinary Biotechnology
 - Chemistry
 - Pharmaceutical Chemistry and Technology
 - Industrial chemistry

- Pharmacy
- Biomedical 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 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)

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 reasoned provision, 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 Banchi 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: Toscana Life Sciences; Kedrion SpA; Philogen SpA; Zambon SpA; Vismederi Srl.; Fondazione Vita; GSK Vaccines; Setlance Srl.

Submission of applications

3.1 Applications must be submitted **no later than 12 February 2021** 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 OTHER QUALIFICATIONS: any qualification not already listed in the CV that the candidate wishes to submit for evaluation;
- declaration in lieu of certification indicating the presumed date of graduation (only those who apply/enrol conditionally).

The forms available at <http://www.unisi.it/didattica/corsi-post-laurea/master-universitari/modulistica-e-documentazione-master>, duly completed and signed, may be used for this purpose.

- 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 **22 February 2021**.

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.

Payment of stamp duty must be made from the personal area using the **PagoPA system**: students can pay directly or opt for deferred payment.

At the end of the online procedure, if it has been completed correctly, the student shall be able to print out the registration 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 6 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". 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. Payments must be made through the **PagoPA system** in accordance with instructions at <https://segreteriaonline.unisi.it>; further information is available at <https://www.pagopa.gov.it/>.

2) the second instalment, amounting to **1500 Euros** must be paid by **03 September 2021**. Students may access the page <https://segreteriaonline.unisi.it> using their Unisipass credentials. Payment must be made through the **Sistema PagoPA System**. No further communication will be provided regarding this deadline.

Proper enrolment in University of Siena programmes is subject to payment of the amounts due.

Payment of the first instalment secures enrolment.

The following applies if tuition fees are to be paid by a third party (Public Institution, Foundation, Company, etc.):

- o Payments by private agencies or companies must be made through the **PagoPA system** once the University sends them a notice for payment;
- o Payments by public agencies must be made through *Girofondo* to the account *Contabilità Speciale* n. 0038125 held by the University of Siena at Banca d'Italia. The procedure is in accordance with Law



27/2012, for Special Accounting.

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 In the event that the minimum number of students indicated under art. 2, par. 5 of this notice should not be 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 Academic Board from among the professors of the University of Siena;
- the Academic 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 Academic 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 2021 and end in March 2022.

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 take place at:

- *Polo scientifico San Miniato, Siena;*

8.5 Courses will be delivered in ENGLISH

The programme comprises the following academic areas:

IDENTIFICATION AND OPTIMIZATION OF LEAD COMPOUNDS

Credits= 2

Supervisors: PINI ALESSANDRO, FALCIANI CHIARA, BRACCI LUISA, DOCQUIER JEAN DENIS

Modules:

IDENTIFICATION AND OPTIMIZATION OF 'LEAD COMPOUNDS' Credits= 1

LIBRARIES IN DRUG DISCOVERY Credits= 1

PRECLINICAL DEVELOPMENT

Credits= 7

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

Modules:

EARLY BIOPHARMACEUTICAL DRUG DEVELOPMENT Credits= 1

SAFETY PHARMACOLOGY Credits= 2

CHEMICAL AND ANALYTICAL PROCESS DEVELOPMENT Credits= 1

ANIMAL MODELS Credits= 2



API FORMULATION Credits= 1

CLINICAL TRIALS

Credits= 6

Supervisors: PINI ALESSANDRO, MORBIDELLI LUCIA, MONTOMOLI EMANUELE, DONNINI SANDRA

Modules:

PHARMACOVIGILANCE Credits= 2

VACCINES Credits= 2

CLINICAL TRIALS PHASE I-III Credits=2

LEGISLATIVE ASPECTS

Credits= 5

Supervisors: PINI ALESSANDRO, BRUNETTI JLENIA, DONNINI SANDRA

Modules: INTERNATIONAL LEGISLATION Credits=2

DRUG APPROVAL PROCESS Credits= 2

ETHICAL COMMITTEES AND CENTRES FOR CLINICAL TRIALS Credits= 1

INTELLECTUAL PROPERTY

Credits= 5

Supervisors: PINI ALESSANDRO, FALCIANI CHIARA, DONNINI SANDRA, ZAZZI MAURIZIO

Modules:

GENERIC AND ORPHAN DRUGS Credits= 1

PATENT FILING AND MANAGEMENT Credits= 4

DATA INTEGRATION

Credits= 5

Supervisors: FURINI SIMONE, DONNINI SANDRA, BRUNETTI JLENIA, PINI ALESSANDRO

Modules:

SCIENTIFIC INSTRUMENTATIONS FOR PRECLINICAL AND CLINICAL TESTS Credits= 2

DATA SCIENCE, DATA BANKS AND BIG DATA Credits= 3

INTERNSHIP

Credits= 10

Internship supervisors: PINI ALESSANDRO, MORBIDELLI LUCIA, DONNINI SANDRA

Internship in a company or a public institute.

GSK, Kedrion, SetLance, Zambon, TLS, Fondazione Vita, Vismederi, Philogen

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

Final exam

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

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

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