



UniSR

Università Vita-Salute
San Raffaele

Didactic Regulations

Master's Degree in Biotechnology for Innovative Therapeutics

Applicable for students who enrol in academic year 2025-2026

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Where these Regulations use the masculine form in an over-extended manner, it is intended to refer inclusively to all persons, irrespective of their gender.

Article 1 – Course Admission

1.1 Knowledge required for admission

To be admitted to the Master's Degree in Biotechnology for Innovative Therapeutics, candidates must have obtained a Bachelor's degree belonging to class L-2 (Biotechnologies, pursuant to Italian Ministerial Decree 270), class 1 (Biotechnologies, pursuant to Italian Ministerial Decree 509), L-13 (Biological Sciences, pursuant to Italian Ministerial Decree 270) or class 12 (Biology, pursuant to Italian Ministerial Decree 509), or an equivalent qualification in Biological Sciences or Biotechnologies obtained under a previously-applicable five-year system, or an equivalent qualification obtained abroad and considered compliant.

Proficiency in the English language equal to level B2 of the Common European Framework of Reference (CEFR) is also required. Candidates are required to submit level B2 certification to demonstrate this proficiency.

1.2 Admission procedure

Candidates' academic background will be assessed by means of an admission test that will be entirely in English. This test consists of the comprehension and analysis of a scientific article, with multiple-choice questions and open-answer questions on chemistry, mathematics and biological sciences. Candidates will also be required to produce a précis of the article using a limited number of characters and suggest a title for it.

Greater details are contained in the call for applications, which also defines the number of places available at local level each year.

Art. 2 – Study Plan

The teaching activity is structured according to the Study Plan specified in the attached Description of the training programme.

2.1 Individual Study Plans

Pursuant to Article 11(4-bis) of Italian Ministerial Decree no. 270/2004 (individual study plan), it is possible to obtain the degree in accordance with an individual study plan that also includes training activities other than those provided for by the Didactic Regulations, on the condition that they are consistent with the Didactic System of the course for the academic year of enrolment.

To this end, students must present the Course Council with a request for approval of their individual study plan by the start of the current year. The individual study plan proposed by the student will be assessed by a special committee appointed by the President of the Course Council and, once it has been approved by the Course Council, it will be forwarded to the competent

offices of the University, which will take care of its storage and monitor the student's compliance with it throughout the duration of the course.

Individual study plans may be modified during the course of the studies, subject to approval by the Course Council, in accordance with the timeframes provided for by the University Didactic Regulations.

2.2 International mobility and recognition of periods of study and learning spent abroad

The Master's degree course, on the basis of inter-institutional agreements or within the context of European and international programmes, provides for the possibility of carrying out part of one's studies at foreign universities, by granting support and guidance through its administrative and academic functions, as provided for in Article 20 of the University Didactic Regulations.

Art. 3 – Restrictions

With reference to the provisions of Articles 14 and 15 of the University Didactic Regulations, General Section, the Course Council has not identified mandatory exams required on an annual basis, or courses for which an annual certificate of attendance is necessary, or a minimum number of credits which students must acquire, as a requirement for passing to the next year of the course.

'Repeating student' status is given to students who, at the end of the second year of the course, have not passed all the examinations specified in the study plan by the dates set out in the academic year calendar for graduation sessions.

Art. 4 – Assessment

Assessments may take the form of examinations or any other form of assessment, such as an aptitude test, the nature of which will be defined once a year by the Course Supervisor/Coordinator in accordance with the Didactic System and the Dublin Descriptors it contains.

The Course Supervisor/Coordinator is under obligation to provide students with detailed information on the assessment processes when lessons start. These processes will also be published in the course teaching activity syllabuses.

Students will acquire the corresponding ECTS credits when they pass an assessment.

The Exam Committees are set up in accordance with Article 24 of the University Didactic Regulations.

Assessment of the individual learning activities of the student's choice is not expressed as a numerical grade, but as pass/fail awarded as the result of an examination.

Credits relating to language skills may be recognised, on the basis of certifications issued by bodies internal or external to the University for each of the languages subject to confirmation of suitability by the competent academic body.

The exam dates are communicated by the President of the Course Council, subject to agreement with the lecturers and given the need for didactic scheduling. The six examination rounds provided for by the University Didactic Regulations, general section Article 21(10), are divided into winter, summer and autumn sessions. The Degree Course President, by annual resolution, schedules the dates of the above-mentioned exam rounds at suitable intervals.

Art. 5 – Final Exam

The final exam of the educational programme consists in drafting and subsequently discussing a dissertation, as a key and highly qualifying aspect of the learning process. The main purpose of this activity is to develop the advanced and specialised skills required to carry out scientific research and/or technological development activities in the field of biotechnologies applied to health in a fully independent manner.

During this process, candidates are required to demonstrate that they possess sound theoretical and methodological knowledge, as well as the ability to critically address and resolve complex issues, by combining the principles of scientific research with the practical requirements of the technical and productive setting. Dissertations are a unique opportunity for acquiring an in-depth interdisciplinary perspective on biotechnologies for health, and promote an innovative and disciplined approach for addressing the challenges of this sector.

More specifically, students will be involved in the completion of an experimental dissertation conducted in the advanced research laboratories on campus or in universities, research institutes or biotech companies in Italy or abroad. This experience will allow students to measure themselves against an ongoing assessment of their work, favouring a critical discussion of the results obtained and the improvement of their analytical and methodological skills.

During the discussion, candidates will be required to demonstrate a high level of self-sufficiency, a critical spirit and advanced scientific skills. They will also be expected to present the results of their work with precision, a disciplined methodological approach and an adequate command of technical and scientific language.

5.1 Definition of the Roles associated with the Final Exam

In order to give the dissertation research internship the greatest didactic importance, students will be assisted by the following roles, who are responsible for guiding and assessing the research activity carried out.

Supervisor

The supervisor is chosen by the student from amongst the permanent professors and researchers, including those on a fixed-term contract, of Vita-Salute San Raffaele University (UniSR) Faculty of Medicine and Surgery. The lecturer suggested by the student is entitled to decide whether to accept the role of Supervisor. The reasons for any refusal must be clearly explained to the student.

The Supervisor is assigned responsibility for the dissertation student. He/she acts as guarantor of the appropriateness and originality of the dissertation project, the scientific competence of the Assistant Supervisor and the proper conduct of dissertation activities.

Together with the student and Assistant Supervisor, he/she assesses the progress of the research project and any corrections to the overall dissertation set-up, including the deadline.

If he/she observed a significant delay in the development of the dissertation programme, he/she is under obligation to promptly inform the second-year Tutors, who will jointly implement appropriate support actions. Students must inform the President of the Course and the Practical Activities Service of any delays using the three-month assessment form.

Assistant supervisor

He/she is proposed by the Supervisor to the President of the Course Council on the basis of his/her expertise and reputation in his/her scientific discipline.

He/she may be a lecturer or a researcher (post-PhD or equivalent) of UniSR or belong to an organisation affiliated with UniSR.

He/she is responsible for the research activities of just one student a year during the thesis internship, assessing the scientific and methodological ability-learning process and the development and structuring of the research project.

If the Assistant Supervisor observes a significant delay in the development of the dissertation programme, he/she is under obligation to promptly notify the Supervisor, as well as the President of the Course and the Practical Activities Service of the delay.

He/she supervises students during the drafting of the dissertation manuscript.

He/she must be available to meet with the Supervisor and Co-examiner to inform them of the development of the dissertation project.

Co-examiner

He/she is chosen by the Tutors of the second year of the Master's Degree course on the basis of his/her scientific expertise in the field forming the focus of the dissertation and acts as the main cross-examiner during the degree examination.

5.2 Dissertation drafting

Dissertations have a scientific purpose that is judged with regard to their content and formal aspects and they also constitute one of the administrative documents required for the award of the qualification.

The purpose of the Master's Degree dissertation is to affirm the candidate's contribution to an experimental research project in terms of its conduct, trial design and data analysis. Multimedia material may be presented during the examination. This material must be appended to the dissertation, but it may not replace it.

Students will choose the subject matter of their dissertation from among the projects presented by the researchers affiliated with the relevant site to the President of the Course Council through the Academic Secretariat by the end of January. Any dissertation projects presented after this deadline will have to be approved by the Course Council.

Students may make their choice following the presentation of the aforesaid projects, which will take place during the first few weeks of the second semester.

Dissertations must be written in English and under the guidance of the Supervisor and Assistant Supervisor.

Each manuscript must include an abstract in Italian and in English, providing a summary of the work.

5.3 The Degree Examination

The Degree Examination consists in the dissertation and the discussion of a written manuscript in which the experimental results obtained during the thesis internship are discussed and interpreted, confirming or refuting the initial hypothesis. The Dissertation is presented (in

multimedial electronic form) and discussed before the Committee meeting in a public Degree Examination. Following the candidate's oral presentation, the members of the Committee, particularly the Co-examiner, may ask the candidate questions and make comments and judgements on the contents of the Dissertation and its presentation. At the end of the discussion, in a meeting restricted to the Committee members, the Committee President asks the Supervisor to suggest a score, having conferred with the Assistant Supervisor. The proposal is commented on initially by the Co-examiner and subsequently by the Committee. The Committee establishes the degree mark on the basis of the candidate's academic curriculum and the assessment of the final examination.

A passing mark is equivalent to 66/110.

5.4 Calculation of Degree marks/GPA

The Degree mark, expressed out of one hundred and ten, is the result of the sum of the following terms.

The first is obtained from the average mark obtained in all exams, according to the formula: weighted mean $\times 110/30$. The mean is calculated by including the marks of the exams for the courses included in the study plan. Provision is made for honours by awarding an additional third of a point (30 *cum laude* = 30.33).

The second term, which accounts for a maximum of ten points, takes into account the verbal presentation of the dissertation project, its discussion and the assessment of the written dissertation, and is calculated by the Committee as follows:

- a maximum of four points for the exposition of the dissertation project (up to two points for the presentation of the dissertation and up to two points for its discussion as proposed by the entire Committee);
- a maximum of four points for the assessment of the written dissertation as proposed by the Co-examiner for the discussion before the Committee.

In exceptional cases, if the candidate demonstrates an extraordinary conceptual contribution and experimental commitment, a further two points can be allocated with the unanimous decision of the Committee.

Honours may be awarded to candidates who, on the basis of the above criteria, achieve a theoretical mark at least four points higher than 110. Honours may only be awarded with the unanimous agreement of the Committee.

A mention of honour may be awarded to candidates who, according to the criteria illustrated, achieve a theoretical mark at least seven points higher than 110 and 2 or more honour marks. Mentions of honour may only be awarded with the unanimous agreement of the Committee.

5.5 Degree examination sessions calendar / Time limits and obligations for candidates

In each academic year there are three degree examination sessions, according to a calendar defined at the beginning of the academic year and posted on the Student Intranet and Student Noticeboards.

Candidates are under obligation to check and comply with deadlines and the administrative obligations imposed.

5.6 Degree Exam Committee

Degree Exam Committees are appointed by the Course Council or the President of the Course Council.

The Committee consists of a minimum of 7 members, of whom at least 5 must be members of the permanent teaching staff and/or researchers on a fixed-term contract. The Supervisor, Co-examiner and Assistant Supervisor are members of the Committee.

5.7 Thesis internship

The choice of the content of the dissertation and its preparation, which must involve experimental work in a research lab for a total of at least 12 months, will take place under the guidance and responsibility of the Supervisor.

Once the student has identified the scientific topic of interest and verified the possibility of performing a thesis internship at a laboratory, he/she contacts a member of the UniSR teaching body to obtain an opinion on the scientific validity of the proposed dissertation subject and confirmation of the member of staff's willingness to act as Supervisor. In the case of difficulties identifying a Supervisor, students may seek the assistance of the second-year Tutors, who will refer them to a member of the UniSR teaching staff with expertise in a scientific field related to that of interest to the student.

The Supervisor acts as guarantor with regard to the appropriateness of the proposed research. Students hand in the internship proposal to the Practical Activities Service in accordance with the applicable terms and conditions. The proposal must be lodged at least two weeks prior to the date on which the student intends to commence the dissertation activity to allow time for the completion of the administrative processes. For dissertations carried out in countries outside Europe, students must also personally arrange the documentation required to carry out the necessary research activities. The list of organisations with which framework agreements for thesis internship activities are already in place is available from the Practical Activities Service and via the Student Intranet.

Students may not officially commence their thesis internship until they have received a positive opinion from the President of the Degree Course regarding the proposal with official notification from the Practical Activities Service.

This notification is provided subject to a career check and students may not have an educational debt amounting to more than 20 first-year ECTS credits.

Students must notify the Practical Activities Service of the start of the activity within the first 48 hours. From this date, a total of at least 12 months must elapse before they may present their dissertation in the degree examination.

Acknowledgement of the curriculum ECTS credits awarded at Foreign Host Organisations

The acknowledgement of the ECTS credits acquired, following educational activities carried out at host universities, research institutes or biotechnology companies under agreements, will take place by allocating 1 ECTS credit for every 10 hours of educational activities completed with a successful assessment through lectures and seminars certified by the host organisation, equivalent to the learning activities of the student's choice carried out at the home site.

Art. 6 – University and course transfers

Incoming transfer requests from students enrolled at other universities in Italy and abroad, military academies or other similar institutes and requests for Master's Degree course transfers are subject to approval by the Course Council, which, having consulted the Transfer Committee:

- a) assesses the possibility of partially or fully recognising the student's academic career up to that point in time, approving some or all the exams taken and any credits awarded.
- b) recognises the credits acquired up to the number of credits of the same scientific disciplinary sector (or group of the same) provided for by the didactic regulations of the course. In all cases of student transfers between Master's Degree Courses belonging to the same class, the number of credits for the same scientific disciplinary sector directly awarded to the student may not be below the limit provided for by applicable legislation.
- c) recognises the credits by evaluating the actual case on the basis of the didactic and cultural similarities.
- d) indicates the year of the course in which the student shall be enrolled;
- e) establishes any educational debt to be overcome.

Enrolment in the first year of the Course is conditional to the passing of the test.

Art. 7 – Admission to individual courses

The possibility to sign up to individual courses is governed as indicated below.

- 1) Students in possession of a five-year secondary leaving certificate or other qualification obtained abroad and recognised as being suitable, may apply to enrol in individual educational activities and sit the relative examinations and obtain certification including the indication of the ECTS credits and mark obtained, on the basis of the procedures defined by the Faculty, within the scope of the criteria established by the Academic Senate.
- 2) Applications must be submitted according to the conditions and deadlines published on an annual basis by the Student Center on the University website.
- 3) Enrolment in individual Courses must be approved by the Course Council.

For all other aspects not covered herein, the provisions of Article 31 of the general section of the University Didactic Regulations shall apply.

Art. 8 – Recognition of degrees awarded by foreign universities

Within the scope of its tasks, the Course Council may deliberate on the equivalence of academic qualifications achieved abroad on the basis of cultural agreements and recognition of academic qualifications achieved abroad, as well as recognition of studies carried out abroad; this task may be exercised in compliance with the legislation in force, without prejudice to the powers and any authorisations of Authorities foreseen by the regulations in force.

Art. 9 – Committees established within the Course Council

The President may suggest to the Course Council the establishment of advisory committees. The type, composition and appointment and operative procedures of such committees will be proposed by the Course Council and approved by the Faculty Council.

The Teaching Committee is an advisory body of the Course Council President whose composition is established by the Course Council President every year. Teaching Committee members may include lecturers that do not belong to the Course Council but are involved in activities associated with previous courses (e.g. Bachelor's Degree) or subsequent courses (e.g. PhD). The President may invite student representatives to take part in Teaching Committee meetings. Teaching Committee meetings, which are held about one week before Course Councils, usually have a monthly frequency; however, their convocation is at the discretion of the President. The purpose of these meetings is the preliminary discussion and formalisation of matters that will subsequently be subjected to the official approval of the Course Council.

Art. 10 – Protection of health and safety

When carrying out internship or practical activities, with regard to health and safety regulations, students are considered equivalent to workers. Consequently, they are subject to the same protective measures and responsibilities and are therefore required to comply with the relevant legal requirements, with the restrictions and prohibitions enforced by occupational health and safety, radioprotection and accident prevention laws, and with any other regulations enforced by the Host Organisation with the same purposes.

The University has formalised and centralised a series of activities strictly related to the risk exposure profile of the individual study programme, with a view to implementing the applicable legal provisions.

In short, depending on the specific indications for each Course of study, students are under obligation to:

- participate in the initial information and educational initiatives and those included in the teaching activities calendar organised to ensure compliance with the provisions set forth in Articles 36 and 37 of Legislative Decree 81/08 "Information and training of workers and their representatives" and in Legislative Decree no. 101/2020 on radioprotection;
- take part in the initial and periodic health monitoring activities for issuance of the compliance certification required before starting practical activities involving exposure to risks;
- use the collective and individual protective equipment provided in compliance with the instructions and training imparted;
- comply with the general safety measures and the safety specifications drawn up and made available from time to time.

Curricular and extracurricular activities involving exposure to a specific risk may therefore not be authorised to commence until the preliminary activities required to safeguard the health and safety of each student have been implemented.

Repeated failure to comply with the above obligations shall result in the suspension of the activities involving exposure to a specific risk until such time as the legal obligations have been fulfilled.

Art. 11 – Modifications

Modifications to these Didactic Regulations are decided on by the Faculty Council, subject to a proposal from the Course Council and an opinion issued by the Lecturer-Student Joint Committee for those aspects for which it is responsible.

Annexes

Description of the training programme and learning methods

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The types of educational activity contemplated are:

1 COURSES

Courses are either core or elective; both types are learning activities to be recorded in the teaching register.

The assessment of the individual activities carried out by students may be evaluative, i.e. expressed as a numerical mark, or certifying, with the simple acknowledgement of the corresponding credits (pass), certified by the Course Supervisor on the basis of his/her assessment in the form of an oral or written test or both.

Assessment of the single activities is individual and has the purpose of confirming the acquisition of the knowledge and skills characterising the activity included in the curriculum.

Core courses

These are the compulsory courses provided for by the study plan. They can be formed by combining different courses, even those from different scientific disciplinary sectors, in order to reach a specific common educational objective. They can also include tutoring to complement the academic lessons. The achievement of the educational objectives can be verified by means of evaluation tests during the course itself, whose negative result does not have any repercussions on admission to the final exam: Exams must be formally certified by an exam committee presided over by the Course Supervisor and consist in an oral or written assessment of learning. Oral tests may, however, be preceded by a preliminary written test, the outcome of which will determine eligibility for the oral test.

Learning activities of the student's choice

Every year, the Faculty Council, upon the proposal of the Course Council, defines the optional teaching activities offered, which may consist of lectures, seminars, interactive courses in small groups, and placement activities, from which the students choose until they have reached the total number of ECTS credits required by the study plan. Students may also choose elective courses within the educational activities offered by other degree Courses at the University, subject to approval by the respective Course Councils, and provided they are compatible with attendance obligations. The exam consists in a certifying assessment of learning.

If multiple lecturers are involved in the educational activities of a course, the Faculty Council, by proposal of the Course Council, appoints a Supervisor responsible for ensuring the proper conduct of all the educational activities required to achieve the objectives set for the course. This person is tasked with:

- providing students with a reference figure for the course;
- advising the Biotechnology for Innovative Therapeutics (BIT) Course Council on how teaching duties may be assigned to lecturers and tutors on the basis of their stated availability, in line with the specific educational objectives of the course;
- advising the BIT Course Council on how to distribute teaching times as agreed by the lecturers of the course;
- coordinating the preparation of the exams;
- presiding over the exam committee of the course he/she coordinates and suggesting its composition in compliance with the University Didactic Regulations.

At the start of the academic year, the Degree Course Council will establish the minimum threshold of registered students required to activate elective courses.

In the event of special organisational requirements, elective courses may define a maximum number of students who can register.

Teaching activities are split into semesters. Each class of the Master's Degree in Biotechnology for Innovative Therapeutics is assigned a Tutor who oversees and monitors the educational activities established by the BIT Course Council.

Courses and other educational activities may be organised as described in greater detail in this annex.

Each ECTS credit corresponds to 25 hours of student work regarding the following activities:

TEACHING METHODS

The degree course is provided as a blended learning programme, and the method by which each learning activity is delivered is stated in the relevant syllabuses.

Classroom lessons

Lessons which cover a specific topic identified by a title and which is part of the course curriculum. They are held by a lecturer, according to a predefined timetable, and provided to students enrolled in a given course year:

"Seminars" are educational activities held by one or more speakers invited by the Course Supervisor on the basis of their specific expertise. Seminars have the same characteristics as lectures and are therefore recorded in the lesson register. Seminar activities may also be inter-university and given in the form of a videoconference.

The programme also includes a considerable amount of non-classroom teaching activities that allow students to foster a modern approach to biotechnology, also by learning how to critically evaluate research projects and scientific studies.

Laboratory research activities

These take place during the Thesis Internship of the second year of the course as defined in Article 5.7.

Individual study activities

For each course, the portion of the total hourly commitment reserved for personal study and other learning activities of an individual type will vary depending on the type of the course itself.

These activities account for the time dedicated to personal study or other individual learning activities, including tutoring, and they comprise at least 50% of the total hourly commitment.

The hours reserved for this type of learning are devoted to:

- to personal study in preparation for exams.
- independent or tutor-led individual assessment of the achievement of the educational objectives;
- independent or tutor-led use of the teaching aids made available by the Degree Course for self-learning and self-assessment;
- voluntary work in affiliated national and international research facilities.

The credits corresponding to each course are awarded to students when they pass the

corresponding exam or, where provided for, by certification by the lecturer.

The above forms of teaching can be delivered using the following methods:

- Delivered teaching: may consist in the delivery of educational content by means of video lessons recorded by the lecturer in charge of the course. This method is similar to conventional lectures and focuses on the presentation of content by the lecturer.
- Interactive teaching: consists in online teaching activities that actively involve students through e-tivities and collaborative activities, such as interactive video conferences, assignments, work groups and educational assessments. The aim is to encourage interaction and cooperation between students and lecturers.

Coordinating lecturers provide further details in the relevant syllabuses.

Preparatory courses

When specific preparatory courses are required for each teaching activity, they are indicated in the list of teaching activities appended to these Regulations.

Attendance

Students must attend formal, informal and professional learning activities as stated in the study plan for the BIT Master's Degree Course.

Attendance is recorded by automated means using badges. The data are made available to both Course Supervisors and Students (through the Intranet). Students require the attendance certificate issued by the Course Supervisor to the Student Center in order to sit the corresponding exam. Students who have attended at least 50% of the hours required for each core or elective course (80% in the case of Lab Courses) automatically acquire certification.

The Italian version of this Regulations is the only legal means of communication of the relative contents and in case of dispute, the Italian version shall prevail.