



UniSR

Università Vita-Salute
San Raffaele

Didactic Regulations

Master's Degree in Biotechnology and Medical Biology

Applicable for students who enrol in academic year 2022-2023

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Summary

Art. 1 Course of study admission	3
1.1 Knowledge required for admission	3
1.2 Admission procedure	3
Art. 2 Course Curriculum	3
2.1 Individual course curricula (where applicable)	3
2.2 International mobility and recognition of periods of study and learning spent abroad	3
Art. 3 Restrictions	4
Art. 4 Assessment	4
Art. 5 Final Exam	5
5.1 Definition of the roles associated with the Final Exam	5
5.2 Preparation of the Final thesis/dissertation	6
5.3 The Degree Examination	7
5.4 Calculation of Degree marks/GPA	7
5.5 Degree examination sessions calendar/ Time limits and obligations for candidates	7
5.6 Degree Exam Committee	8
5.7 Dissertation internship	8
Art. 6 University and course transfers	9
Art. 7 Admission to individual courses	10
Art. 8 Recognition of degrees awarded by foreign universities	10
Art. 9 Committees established within the Course Council	10
Art. 10 Protection of health and safety	11
Art. 11 Modifications	11
Attachments	11

Art. 1 Course of study admission

1.1 Knowledge required for admission

In order to be admitted to the Master's Degree in Biotechnology and Medical Biology, candidates must:

have a Bachelor's Degree in one of the following classes or be in possession of an equivalent academic qualification awarded abroad: pursuant to Ministerial Decree 270 Class L-2 Biotechnology, Class L-13 Biological Science; pursuant to Ministerial Decree 509/99: Class 1 Biotechnology, Class 12 Biological Science or a five-year degree in Biological Science and Biotechnology under older systems.

They must have an adequate level of linguistic competence, namely B2 in English according to the Common European Framework of Reference (CEFR) for language knowledge.

A certificate affirming **B2 level English** must be submitted within 18 month of matriculation.

In addition, **foreign students only** are required to submit a certificate affirming B2 level Italian by the time limit stated in the call for applications.

1.2 Admission procedure

For the assessment of their personal preparation, candidates will have to sit an admission test based on their ability to understand and analyse a scientific text in English. Candidates will have to answer multiple-choice and open-answer questions and be able to précis a text using a set number of characters.

Art. 2 Course Curriculum

The teaching activities are structured in accordance with the Course Curriculum specified in the appended Description of the training programme.

2.1 Individual course curricula (where applicable)

These Course Didactic Regulations do not provide for the submission of individual course curricula.

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

The University, on the basis of inter-institutional agreements or in the area of European and international programmes, supports, promotes and facilitates cycle one, two and three student exchanges with foreign universities, both within and outside Europe, providing support and guidance through its administrative and academic facilities.

The University is committed to respecting the regulations relating to the principles and procedures for recognition of periods of study spent abroad, in accordance with the main European references.

Students permitted to spend a period of study, internship or research abroad shall draw up a *Learning Agreement* with their academic supervisor using the format approved by the European Commission for mobility within the Erasmus+ programme, indicating the learning activities to be taken at the hosting university. The document will be signed by the Academic Supervisor. The recognition of credits awarded following the teaching activities performed must replace the credits provided for in the student's curriculum proportionally to the learning activities completed successfully abroad. Credits inserted as "additional" with respect to those provided for by the

student's curriculum for the purposes of obtaining the qualification shall not be counted for the purposes of the resources. There is maximum flexibility in choosing the learning activities to be inserted in the *Learning Agreement*, while pursuing full agreement with the educational objectives of the relative course.

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 will start, if applicable, at the end of the second year, if the student does not pass the exams in time for the graduation sessions scheduled during the academic year.

Pursuant to article 14 of the University Didactic Regulations, students with inactive, repeating student or course suspension status for more than four academic years forfeit their student status. Forfeiture does not apply to those who have passed all exams and only have a deficit relating to the final Degree exam.

Art. 4 Assessment

The types of exams and other forms of assessment are specified in the Single Annual Document appended to these Regulations and are defined in compliance with article 23 of the current version of the University Didactic Regulations and Didactic Regulations.

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 personal assessment, which may also take the form of an oral or written test.

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

Students are awarded the credits provided for with each learning activity when a passing grade is achieved on the relative exam.

The exams consist of oral and/or written tests, at the discretion of the lecturer, who provides information on the same at the beginning of the course. In the event of written exams, these will be archived by the Master's Degree course office. The possibility of progressive checks is also provided for in order to facilitate learning and effective student participation in the learning process.

The Exam Committees are appointed by the President of the Course Council at the beginning of each academic year, based on the suggestions of the Course Supervisor and the proven scientific expertise of its members. They must ensure examination sessions are attended by at least two members, of whom one must be the lecturer in charge of the course or activity.

For all other aspects relating to the formation of the exam committees, refer to the provisions of Article 24 of the University Didactic Regulations, general section.

The assessment of the students' progress is expressed as a mark out of thirty for exams and as a mark out of 110 for the final exam, with honours where applicable in both cases.

The passing score for the exam is 18/30. The examination committee may unanimously grant candidates the maximum score with honours.

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

If a course consists of multiple modules, the exam committee is usually presided over by the course coordinator.

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 dates of the award exams are communicated by the Head of the Course Council, subject to agreement with the lecturers and given the need for didactic scheduling. The six award exams provided for by the University Didactic Regulations, general section article 21 para. 10, are divided into winter, summer and autumn sessions in groups of two for each discipline. Students are informed of the dates of each group at least three months in advance. Only students who are up to date with their enrolment and course fees may be admitted to the exams and other assessments.

In the case of off-site written exams, students will be informed about any oral exam by the lecturer in charge of the learning activity.

Art. 5 Final Exam

The final assessment consists in the preparation and presentation of a dissertation, whose educational objective is for students to acquire the ability to carry out their own research and/or development work at scientific and technical/manufacturing organisations operating in the field of healthcare biotechnology.

More specifically, students will develop their experimental dissertations in advanced research laboratories, thereby allowing a continuous assessment of their research work with a critical discussion of the results obtained.

The purpose of the final assessment is therefore to verify the student's ability to analyse and discuss, in a clear manner and with full mastery, an original research subject to which the candidate has made a significant contribution with regard to both the conduct and the design of the research.

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

He/she is chosen by the student from amongst the permanent teaching staff of the 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 Educational Activities and Internships Office of any delays using the three-month assessment form.

He/she is a member of the Dissertation Committee.

Assistant supervisor

He/she is proposed by the Supervisor to the President of the Course 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 supervises the research activities of just one student a year during the dissertation 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, also informing the President of the Course and the Educational Activities and Internships Office 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 Examiner to inform them of the development of the dissertation project. He/she is invited to take part in the Degree Dissertation Committee.

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. The name of the examiner assigned to each candidate is stated in the dissertation session convocation.

He/she must receive the student's final dissertation at least two weeks before the degree examination.

He/she takes part in the degree examination as the main cross-examiner. He/she is a member of the Dissertation Committee.

5.2 Preparation of the Final thesis/dissertation

Dissertations have a scientific purpose that will be 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. Any

multimedia material may be presented during the exam and appended to the dissertation, but it may not replace it.

The choice of the content and the conduct of the dissertation activity take place under the guidance of the Supervisor and Assistant Supervisor.

The dissertation must be written in English.

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 defence of a written manuscript in which the experimental results obtained during the dissertation 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 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 Chair asks the Supervisor to suggest a score, having conferred with the Assistant Supervisor. The proposal is commented on initially by the 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 three terms.

The first is obtained from the average mark obtained in all exams, according to the formula: arithmetic mean $\times 110/30$. The mean is calculated by including the marks of the exams for the courses included in the course curriculum. For students who transferred from other institutions, those acknowledged by the dedicated committee will be included. Provision is made for honours by awarding an additional third of a point (30 with honours = 30.33).

The second term is the grade awarded in the Degree exam, and is in turn the average of the grades assigned by the individual committee members, on a scale of 0 to 10. It takes into consideration the overall quality of the dissertation and the level of the discussion.

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

Honourable Mentions may be awarded to candidates who, according to the criteria illustrated, achieve a theoretical mark at least six points higher than 110 and 4 or more honour marks.

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. Information on these aspects is available from the Student Center.

Specifically, candidates must submit 4 printed copies of their Dissertation, all of them signed at the end of the references section.

The copies of the Dissertation will be distributed one to the Supervisor, one to the Assistant Supervisor, one to the Examiner and one to the Student Center.

It must be given to the Examiner at least 15 calendar days before the date of the degree examination.

Two copies of the abstract in Italian and English, in addition to those bound into the dissertation, must be submitted to the Academic Office by the specified deadlines.

Candidates must take a copy of the dissertation with them on the day of the final exam for consultation by the members of the Oral Assessment Committee. This copy will be returned at the end of the degree examination.

At the end of the internship and of the project, at least 5 days before the examination session they intend to attend, students must hand in the internship assessment forms signed by the Student, Assistant Supervisor and Supervisor to the Educational Activities and Internships Office.

Students must check the information made available by the Student Center containing the most recent version of the rules for the submission of dissertation applications.

5.6 Degree Exam Committee

The Degree Exam Committees and their Chairs are appointed by the Course Council, which may delegate such appointments to the President of the Course Council. In the absence of the Course Council, these duties are assumed by the Faculty Council in compliance with the University Didactic Regulations. The Committee is appointed once candidates have handed in the required number of copies of the Final Dissertation to the Student Center.

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 and Examiner are members of the Committee. The Assistant Supervisor may also take part.

5.7 Dissertation 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 a Supervisor.

Once they have identified the field of research of interest and confirmed the possibility of conducting the dissertation internship in a laboratory, students must contact a member of the UniSR teaching staff to obtain an assessment of the scientific validity of the proposed dissertation subject-matter and confirmation of his/her willingness to act as the 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 with the corresponding procedures and timeline to the Educational Activities and Internships Office. 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 dissertation internship activities are already in place is available from the Educational Activities and Internships Office and via the Student Intranet.

Students may not officially commence their internship dissertation until they have received a positive opinion from the President of the Degree Course regarding the proposal with official notification from the Educational Activities and Internships Office.

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

Within the first 48 hours of activity, they must hand in to the Educational Activities and Internships Office an official start of internship form signed by the Supervisor, Assistant Supervisor and Student. 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 Universities

The acknowledgement of the ECTS credits acquired as a result of educational activities carried out at Foreign Host Universities will be proportionate to the educational activities completed successfully abroad, with the allocation of 1 ECTS credit for every 12 hours of educational activity.

Art. 6 University and course transfers

Requests for transfer to the University 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 Credit Commission:

- 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 deficit to be overcome;

In relation to the number of credits recognised, the duration of the course may be abbreviated by the Course Council. Any such shortening shall be decided on a case-by-case basis.

Enrolment in the first year of the course is conditional to the passing of the test, whereas transfers are only possible for years subsequent to the first.

After deciding on the recognition of a given number of credits, the BMB Course Council shall enrol the student into one of the years of the course, subject to compliance with the rules provided for

by these Regulations for enrolment in years subsequent to the first (article 7) and applicable legislation on the recognition of credits.

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 high-school diploma/secondary leaving certificate or other qualification issued abroad and considered acceptable, a university diploma, a bachelor's or master's degree, as well as holders of academic qualifications issued abroad, can enrol in the individual educational activities of courses, take the corresponding exams and receive the certification including indication of the credits, according to the conditions defined by the Faculty.
- 2) Whenever these activities are within limited-admission courses, enrolment must be approved in advance by the competent Course Council, on the basis of criteria previously identified by the same.

Applications must be made according to the conditions and deadlines published on an annual basis by the Student Center on the University website.

For all other aspects not covered herein, refer to the provisions of Article 32 of the University Didactic Regulations, general section.

Art. 8 Recognition of degrees awarded by foreign universities

Within the scope of its tasks, the BMB 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 shall be proposed by the Course Committee for the ratification of 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 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 certain 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 Degree Course Council and an opinion issued by the Lecturer-Student Joint Committee for those aspects for which it is responsible.

Attachments

Description of the training programme and learning methods

Description of the training programme and learning methods of the Master's Degree in Biotechnology and Medical Biology

The types of educational activity contemplated are:

1 COURSES

Courses are either core or elective; both types are educational 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 personal assessment, which may also take the form of an oral or written test.

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

Core courses

These are the mandatory courses provided for by the course curriculum. 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. The oral test may, however, be preceded by a preliminary written test, the outcome of which will determine eligibility for the oral test.

Elective courses

These are carried out within the educational activities chosen by students.

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 course curriculum. 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 BMB 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 BMB 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.

Teaching activities are split into semesters. Each class of the BMB Master's degree is assigned a Tutor who oversees and monitors the educational activities established by the BMB Course Council.

2 OTHER EDUCATIONAL ACTIVITIES SPECIFIED IN THE COURSE CURRICULUM

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:

Whole-class 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 Dissertation Internship of the 2nd year of the course.

Interactive teaching

These educational activities constitute a form of interactive or supplementary teaching typically involving a small group of students; this educational activity is led by a teaching assistant, tasked with facilitating the students assigned with acquiring the knowledge, ability and skills required to practice the profession. Learning occurs primarily through direct personal performance of practical and/or laboratory exercises, using stimuli deriving from analysing problems, through the deployment of the methodological skills required to solve them and make decisions.

Tutoring activities contribute to the achievement of the course's educational objectives. Each academic year, the Faculty Council appoints, by proposal of the BMB Course Council, the teaching assistants to be assigned to the activities scheduled for that period. These figures may be recruited from amongst the lecturers and researchers, but also from staff external to the Degree Course and Faculty, subject to annual checks.

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:

- 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 Joint Teaching Committee certifies the consistency between the credits assigned to the educational activities and the specific educational objectives.

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 course curriculum for the BMB 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 75% of the hours required for each core or elective course (80% in the case of Lab Courses) automatically acquire certification.

Course Curriculum

During the annual teaching planning phase, a different fraction of the total commitment may be assigned to individual study, which shall not, in any case, be less than 50% of the total hourly commitment. An exception is made for cases in which the educational activities have a high experimental or practical content.

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.