



# Certificate Regulations

including the Certificate trainee's  
code of rights and obligations

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# 1. General provisions & definitions

## 1.1. Introduction

These Regulations are reviewed annually by the Eu2P Executive Board and should be approved by each Eu2P Academic Partner. The Regulations should be read in conjunction with the guidelines and regulations published by each of the Eu2P Academic Partners specifically those relating to local study, assessment, academic appeals and complaints, as well as with the Eu2P Standard Operating Procedures and the Eu2P Terms of Sales. All Eu2P Certificate Trainees and trainers are provided with a copy of the Eu2P Certificate Regulations via their on-line account and each Trainee is required to endorse on-line such a document before starting the Certificate training. Trainees are subject to these Regulations, which also detail their rights and obligations once registered on a Certificate programme.

## 1.2. Purpose of the certificate programme and of the certificate regulations

The purpose of the Eu2P Certificate programme is to provide Trainees with the necessary academic and/or professional background the knowledge, skills and methods required in a particular field of Pharmacovigilance and Pharmacoepidemiology to enable them to conduct scientific work, to critically assess and integrate scientific findings and knowledge, and to act responsibly. In order to achieve the overall intent of the programme, the Eu2P Certificate Programme benefited from a very close collaboration between academic, regulatory and professional experts to link research and instruction through a network of six universities of high repute (Bordeaux, Barcelona, Rotterdam, Utrecht, Hertfordshire, and Napoli), two regulatory agencies and pharmaceutical companies throughout Europe. The purpose of this document is to provide a clear framework of regulation for Eu2P Certificate Trainees throughout their study at Eu2P. It also enables Trainees to understand how the programme is managed and administered. Regulations make clear minimum requirements and standards for students and staff.

## 1.3. Definitions

**For the purpose of good understanding, the following terms shall have the meaning ascribed to them herein:**

- “Academic Misconduct” means any action or attempted action by a Trainee that may result in the creation of an unfair academic advantage or an advantage or disadvantage to another member of the academic community.
- “Cheating” means any attempt by a Trainee to gain an unfair, improper or dishonest advantage in the assessment process.
- “Collusion” means any situation where there is evidence of the representation by a Trainee individual of work which he or she has undertaken jointly with another person as having been undertaken independently of that person.
- “Course Coordinator” means the institution in charge of the consistency of the topics content and responsible:
  - ☑ **For organising training formats (choice of lecturers, tutors, content update, ...)**
  - ☑ **For coaching the Trainee’s work**
  - ☑ **For implementing assessment sessions.**

When the Course Coordinator is an Academic Partner, the Course Coordinator equals the Module Coordinator.

When the Course Coordinator is a Course Provider Partner, the course delivery and respective assessment activities will be undergone under the pedagogical responsibility of the Academic Partner to which such course is related to.

- “Course Provider Partner” means an individual or a public or private body, which is a Party to this agreement and which participates in the training and tutoring activities under the pedagogical responsibility of one or several Eu2P Academic Partner(s).
- “Domain” means a set of Modules that are educationally gathered in terms of education field or expertise related to Pharmacovigilance and Pharmacoepidemiology.
- “Domain director” means the representative of an Academic Partner, who is in charge of the consistency of the Modules and the research project general organization within a domain.
- “Domain co-director” means the representative of an Academic Partner or of an Associated Member, supporting the Domain Director in the Modules general organization within a domain.
- “Eu2P General Conditions of Use” means the terms and conditions that bind all users of the Eu2P website.
- “Eu2P Privacy Policy” means the terms and conditions applying to all Eu2P users as regards their rights and obligations towards privacy issues.
- “Eu2P e-learning platform General Conditions of Use” means the terms and conditions that bind all Trainees and trainers when using the Eu2P e-learning platform.
- “Live Teaching Sessions” means the training sessions relating to the theoretical content of the curriculum that are either face-to-face or synchronous sessions on the e-learning platform.
- “Module” means a unit of study, which develops a set of one or several learning outcomes through “Training areas”.
- “Module coordinator” means a representative of an Academic Partner designated by the related Domain Director. S/he is responsible for the day-to-day management of a module including all aspects of teaching, learning and assessment.
- “Other Academic Misconduct/Assessment Offences” relates to Evidence that a student failed to comply with an Academic Partner ‘s assessment and examination regulations, other than those offences falling under the categories of cheating, collusion and plagiarism.
- “Plagiarism” means the misappropriation or use of others ideas, intellectual property or work (written or otherwise) without acknowledgement or permission.
- “Student” means a Trainee enrolled in a Eu2P Certificate programme, who has been enrolled in an academic programme no later than in the last two years preceding her/his application to Eu2P and who is not engaged in a full-time professional occupation.
- “Training area” means a set of one or more “learning paths” that may be composed of teaching, learning and assessment sessions.
- “Trainee” means the student or professional enrolled into a Eu2P Certificate programme.

## 2. Certificate trainee's registration & curriculum

### 2.1. Admission and registration

All the rules and procedures concerning selection and admission to the Eu2P Certificate programme are defined under “the Eu2P Terms of Sales” and have been acknowledged by the applicant when validating the on-line application.

They are part of the present Certificate Regulations and are binding upon the parties in case of any conflict arising because of the selection and / or admission process.

Once selected by the relevant Domain Board and payment of the Certificate fees is secured the Trainee is registered by the Eu2P central office. In case of payment by several instalments over the duration of the course, the Trainee is registered by the Eu2P Central Office upon payment of the 1st instalment before the course starting date.

The Eu2P central office forwards all necessary information for registration to take place in each Eu2P Academic Partner.

Registration as a Eu2P Certificate Trainee entitles students to participate in Modules (either face-to-face or by e-learning), sit examinations within the chosen study programme and to use the different Eu2P universities' facilities.

If the Trainee is withdrawn or quits the Eu2P Certificate programme during the course of the academic year, such Trainee will not receive any refund of tuition fees.

### 2.2. Standard period of study

The standard period of study for one Certificate will be set up in advance by the Module-related coordinator and according to the Eu2P Calendar defined each year by the Executive Board. Trainees will be informed of such period of study on applying for that Certificate.

**As a general rule:**

- A standard Certificate training corresponds to 3 ECTS credits i.e. Runs over 9 weeks and corresponds to a trainee workload of one day a week followed by an assessment session.
- An extended Certificate training corresponds to 6 ECTS credits i.e. Runs over 18 weeks and corresponds to a trainee workload of one day a week followed by an assessment session.

Such standard period of study may be extended by the relevant Module coordinator taking into account exceptional circumstances duly evidenced by the Trainee (e.g., long illness).

Eu2P reserves the right to alter the agenda of any training due to circumstances beyond its control without being obliged to refund Trainees. All trainees will be consulted about any material change at the earliest opportunity.

In exceptional circumstances, training can be cancelled or postponed by the trainers. In these circumstances Eu2P will use reasonable endeavours to notify Trainees of the cancellation or postponement of training.

However, Eu2P cannot guarantee that Trainees will be informed of such cancellation before the date of the training.

## **2.3. ECTS credits value**

ECTS credits means European Credit Transfer and Accumulation System (ECTS) credits. It is a European academic standard for comparing the study attainment and performance of Trainees of higher education across the European Union. For successfully completed trainings, ECTS credits are validated with the view of obtaining a qualification. In the Eu2P Consortium, one ECTS represents 25 hours of Trainee's workload.

## **2.4. Training attendance**

For all Trainees, attendance of at least eighty per cent of the Eu2P Live Teaching sessions is required for graduation. Such attendance requirement may be fulfilled using recorded teaching sessions facilities.

Upon request, a dispensation from the attendance requirement may be granted at the discretion of the Domain Director for up to 20% of the live teaching sessions. Any absence beyond 20% should be a matter of discussion for the Programme Examination Board. The Trainee shall present her/ his request by a formal letter explaining the reasons under which s/he claims for dispensation: the letter shall need to be addressed to the Domain Director involved by the dispensation request.

In the event that the Trainee does not meet the attendance requirement for the programme and no serious adverse circumstances exists, the Programme Examination Board may at their discretion withdraw the Trainee from her/his programme of study.

## **2.5. Web-based training**

Eu2P provides its theoretical training content through a web-based learning management system called the Eu2P e-learning platform.

All theoretical training material will be made available to the Trainee through that platform. However, due to the specificity of the e-learning format, the Trainee does not have any guarantee on the training (live sessions) availability in areas with time zone different from the GMT one.

Each Trainee is identified and is granted rights to access the Eu2P e-learning platform tools and resources.

Trainees are reminded that minimal IT skills and equipment are required for use of the Eu2P e-learning platform. Non-complying with any of the criteria relating to broadband access, IT equipment and to an efficient web browser could lead to user experience problem that would not be under Eu2P responsibility.

**Trainee's services within the platform include:**

- Access to training resources (course content, documents, tests, work assignments, revising resources such as recorded video lessons);
- Training sessions attendance (web meeting, chat or voice over IP conference);
- Training contents sharing with trainers (work assignments) and other Trainees (group work);

- Interaction with trainers and other Trainees (forum, chat, conference meeting);
- Monitoring of personal progression and test scores;
- Information about course events (platform announcements, agenda, email alerts);
- Feedback about courses (course survey);
- User support from the e-learning platform team.

**Trainee's coaching within the platform is provided through:**

- Trainer teams ;
- Lecturers who provide online courses and can daily interact with their Trainees and evaluate their learning competencies on-line;
- Facilitators who coach Trainees throughout the e-learning part of their training programme;
- Administrative staff who communicates with trainers and Trainees to inform them about course programme events and course schedule via email or an internal agenda;
- Technical & support staff who trains and helps platform users in their activities within the e-learning platform.

### 3. Certificate trainee's assessment

The Certificate assessment process leads to the award of a Eu2P Certificate in the chosen Domain of Pharmacovigilance and Pharmacoepidemiology.

The aim is to determine whether the Trainee has a fundamental understanding and mastering of her/his field of study.

The Eu2P Certificate assessment rules are described in the following sections. In case of change in the Eu2P Certificate assessment policy, the Regulations will be accordingly updated for the following academic year.

#### 3.1. General rules

The Eu2P Certificate assessment process encompasses grade-based and pass/fail assessment in the corresponding Module.

All Module-specific assessments are conducted in English.

The Module assessment format is determined in advance by the Module coordinator: it can be written or oral through computer-based procedures.

The grade for each Module assessment is determined by the respective Module coordinator, based on her/his local grading system.

**Local grades are then:**

- Converted into the Eu2P ECTS grading system according to the following table approved each year by the Eu2P Programme Examination Board.
- Only the first decimal place after the decimal is used when calculating the grades; all further decimal places are dropped without rounding off.

**For the 2025-2026 academic year the Eu2P grading table is as follows:**

Eu2P Grades translation		Université de Bordeaux	University of Hertfordshire	Universiteit Utrecht	Erasmus MC Rotterdam	Universitat Autònoma de Barcelona	Università Luigi Vanvitelli
A+	EXCELLENT	16,0 - 20	80 - 100	8,5 - 10	8,5 - 10	9,0 - 10	29 - 30 LODE
A	VERY GOOD	14,0 - 15,9	70 - 79	7,5 - 8,4	7,5 - 8,4		27 - 28
B	GOOD	12,0 - 13,9	60 - 69	7,0 - 7,4	7,0 - 7,4	7,0 - 8,9	23 - 26
C	PASS	10,0 - 11,9	50 - 59	5,5 - 6,9	5,5 - 6,9	5,0 - 6,9	18 - 22
F	FAIL	0 - 9,9	0 - 49	0 - 5,4	0 - 5,4	0 - 4,9	0 - 17

The Programme Examination Board regularly reviews the assessment process and at least once a year within the deadline fixed by the annual Eu2P calendar.

The Trainee is informed by the Eu2P central office of the grades earned in individual Modules.

The Trainees may repeat Eu2P specific Modules assessments s/he failed, according to the respective Module Coordinator University rules as described in the section “Failure in the Certificate assessment process”.

## **3.2. Failure in the Eu2P certificate assessment process**

### **Eu2P referral and re-enrolment opportunity policy**

Referral is defined as a reassessment opportunity for Trainees who have been unsuccessful at their first attempt (that is, trainees who have received an F grade) in so far as the relevant Module Coordinator University rules allow for such reassessment.

Such re-assessment possibilities must however take place within the relevant Module Coordinator University calendar and the common calendar deadline set up in the annual Eu2P calendar.

- Trainees who are successful in referred assessment(s) will be awarded a capped module grade of 50%, a C Pass Grade.
- Trainees who are unsuccessful in a referred assessment (that is, at second attempt) will not be given further opportunity to submit for assessment. If they are unsuccessful in a referred assessment they will be given the opportunity to re-enrol on that module.

Re-enrolment is defined as the opportunity for a Trainee to repeat a module that was previously failed at first and second attempt.

In offering re-enrolment, the Eu2P Programme Board considers that the Trainee requires substantial further study in the module and that it is normal for that Trainee to repeat all assessment elements, irrespective of his or her overall performance.

In cases where the Eu2P Programme Examination Board decides that it is not a requirement to repeat all assessment elements, it will, in consultation with the relevant Module Coordinator identify the elements to be repeated.

The trainee may also wish to drop this failed Module and enrol into a different Module, only if available on the validated Masters programme of study and at the discretion of the Programme Examination Board. Further re-enrolment on the replacement module is not allowed.

In case of re-enrolment (whether in the same Module or a replacement one), the Trainee will have to pay fees for this new Module enrolment at the student rate.

Following re-enrolment on any Module, attendance will be required and the numeric grade(s) awarded will be those actually achieved in the assessment.

## **3.3. Extenuating circumstances**

Extenuating Circumstances are significant circumstances beyond a Trainee's control that could affect his or her ability to perform to his or her full potential in assessment.

If a Trainee has problems or difficulties significantly affecting performance on his or her module, he or she should discuss this with the appropriate member of staff in the University responsible for the module. The Module Coordinator or Domain Director may take appropriate action, such as extending the deadline for submission of a piece of work. Where it is believed that there are significant Extenuating Circumstances adversely affecting performance, which should be drawn formally to the attention of the Programme Examination Board when it meets to consider the translation of grades or confirm progression or award.

## 4. Academic misconduct

*(Based on previous Eu2P Regulations, the Education and Examination Regulations of the Pharmaceutical Sciences Department of Utrecht University, the University of Hertfordshire Assessment and Examinations rules).*

### 4.1. Definitions

As a common rule among the Academic Partners, Academic Misconduct is defined as any action or attempted action by a Trainee that may result in the creation of an unfair academic advantage or an advantage or disadvantage to another member of the academic community.

**More particularly and for the purpose of these Eu2P Regulations, the following definitions will apply:**

#### **Cheating**

This is an attempt to gain an unfair, improper or dishonest advantage in the assessment process where on the balance of probability it could reasonably be construed that a Trainee intended to gain an unfair, improper or dishonest advantage.

#### **Cheating includes:**

- Impersonation - either where a Trainee allows any other person to take an assessment on their behalf or to present themselves as being that student or where a current Trainee takes an assessment on behalf of another Trainee;
- Obtaining or attempting to obtain unauthorised access to examination papers;
- The copying of, or attempting to copy, the work of another candidate in the examination or other in class assessment, whether by getting access to what he or she has written or is writing or by asking him or her for information in whatever form;
- The use of aids including internet search, papers, books, notes, personal notes or revision notes in any form, or other devices of any kind other than those permitted in the instructions of the examination paper, with the intention of using such item or, in fact, using such item. This includes, for example, unauthorised information stored in the memory of a pocket calculator, mobile telephone, computer, personal organiser or any other device;
- Requesting a temporary absence from an examination room (or any other room in which a formal assessment is taking place) with the intention of gaining, or attempting to gain, access to information that may be relevant to a formal assessment;
- False statements made in order to receive special considerations by the Eu2P Programme Examination Board or to obtain extensions to deadlines or exemption from work;
- Assisting or attempting to assist another Trainee to gain or attempt to gain an unfair, improper, or dishonest advantage in the assessment process;
- The purchase or theft of material submitted for assessment.

## **Collusion**

**This covers the following situations:**

- Where there is evidence of the representation by a Trainee individual of work, which he or she has undertaken jointly with another person as having been undertaken independently of that person.

## **Other academic misconduct and offences**

**This covers the following situations:**

- Where there is evidence that a Trainee failed to comply with one Eu2P Academic Partner assessment and examination regulations, other than those offences falling under the sections relating to cheating, collusion, plagiarism and includes:
  - ✔ **The falsification of data including the creation of false written materials or statistical data or its alteration, for example, by the invention of the statistics presented or the invention of quotations or references;**
  - ✔ **The duplication of assessed work – the submission of broadly similar work completed by the Trainee for academic credit as part of the same programme without express acknowledgement of the previous submission;**
  - ✔ **The removal of an examination script or examination stationery or other materials from the examination room (or any other room in which a formal assessment is taking place);**
  - ✔ **Failure to comply with the instructions of an invigilator;**
  - ✔ **The introduction into the examination room of any personal notes or revision notes in any form or stationery;**
  - ✔ **Permitting or assisting another to present work that has been copied or paraphrased from Trainee's own work without attribution or as if it were the work of the other;**
  - ✔ **Breach of professional confidentiality;**
  - ✔ **Failure to obtain ethics approval prior to undertaking work involving human participants;**
  - ✔ **Failure to comply with the terms and conditions of an ethics approval granted for work involving human participants.**

## Plagiarism

**This is the representation by an individual of another person's work (including another student) as their own or use of another person's work without acknowledgement including:**

- The importing of phrases from another person's work without using quotation marks and identifying the source;
- Making a copy of all or part of another person's work and presenting it as the Trainee's own work by failure to disclose the source;
- Without acknowledgement of the source, making extensive use of another person's work, either by summarising or paraphrasing the work merely by changing a few words or by altering the order in which the material is presented; paraphrasing must be marked as such (by explicitly linking the text with the original author, either in text or a footnote), whereby the impression is not created that the ideas expressed are those of the Trainee;
- The use of the ideas of another person without acknowledgement of the source or the presentation of work which substantially comprises the ideas of another person and which represents these as being the ideas of the candidate;
- Resubmission of the Trainee's own earlier work without source references, and allowing this to pass for work originally produced for the purpose of the course, unless this is expressly permitted in the course or by the lecturer;
- Submitting papers obtained from a commercial institution (such as an internet site offering excerpts or papers) or having such written by someone else in return for payment.

## 4.2. Consequences of academic misconduct

Allegations of cheating, plagiarism, collusion and other academic misconduct as defined in the Eu2P Certificate Regulations should be made, in writing, by the respective examiner or Module coordinator to the appropriate person in the partner organisation where the module is delivered.

An investigation will be carried out in accordance with local partner regulations using the Eu2P Report Template for the Reporting of Assessment Offences –. The Eu2P Programme Examination will on completion submit the Report with recommended action to the Chair of the Eu2P Programme Examination Board for consideration.

**The Board at their absolute discretion will impose one of the academic penalties identified as follows from minor to major penalty:**

1. No penalty – Grade awarded remains
2. Written Warning
3. Award of an F Grade - Fail allowing a referral opportunity
4. Award of an F Grade - Fail but no referral opportunity. The student has to repeat the Module(s)
5. Withdraw from Programme

In all assessment offence cases, the following indicators of seriousness should be taken into account by the Board when deciding on an appropriate academic penalty.

**In the cases of plagiarism whether:**

- There is a similarity index of 10% or more, excluding citations and bibliography
- The plagiarism is verbatim copying or highly derivative\*;
- The assessment is highly derivative\* without any referencing or whether it is highly derivative but mainly footnoted or acknowledged in the bibliography;
- The plagiarised parts are dispersed throughout the assessment or are in one section;
- Analytical content/academic opinion has been plagiarised or is whether the plagiarised section(s) purely descriptive;
- The conclusion has been plagiarised;
- The Trainee admits or denies the offence;
- There has been any previous offences

**In the cases of collusion, consideration should be given to:**

- The instructions given to the Trainees – did the assessment involve any initial element of group/ collaborative work;
- Whether there appears to be collusion in relation to more than 10% of the assessment material;
- Similarity of wording;
- Whether the structure of the answer is the same/similar;
- Whether the development of the argument/ critical content is very similar;
- Whether the conclusion is very similar;
- Whether the student admits or denies the offence;
- The number of previous offences.

Plagiarism / collusion will be deemed to amount to cheating where the Trainee has bought or stolen an answer, including buying or stealing an answer from a fellow or former student.

**In the cases of cheating consideration should be given to:**

- The seriousness of the offence;
- The number of previous offences;
- The extent of the advantage gained;
- Whether the student admits or denies the case.

In the event that cheating is found proven the minimum penalty would be a fail grade in the particular assessment.

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\* In relation to plagiarism, the term highly derivative assumes the source(s) are used verbatim or closely paraphrased.

## 5. Extension of an assessment period

### 5.1. CASE 1: Request of extension

- The Trainee sends by e-mail his/ her request of extension to the trainers through the Eu2P Central office (no later than the initial date of submission) using a dedicated form that is available on the e-learning platform (Trainees' center), accompanied with evidence.
- Extension can be granted by the Eu2P Central office for a maximum of 10 working days (in any case: no later than date of exam/ end of module period) upon justified explanations.
- No penalty is applied within this extension period.

### 5.2. CASE 2: No request of extension or submission later than the extended date or unsuccessful request of extension

- The grade will be reduced by 10% for each day after the submission date (or after the extended submission date).
- In case of delivery later than 5 days following the submission date or following the extended submission date: the Trainee will fail the assignment and may have to retake the piece of work (depending on the Module assessment rules).

### 5.3. CASE 3: Group assignments

Preamble: This only applies when individual group members (1 or more) are too late. When the complete group is late no specific rules apply and this can be treated as case 1 or 2.

- Group members will inform the trainers.
- The Trainee who is late will have to work individually on the assignment and will have to accept consequences as stated above, i.e., delivery after the deadline will be seen as a retake and graded with maximum pass grade. If late submission is then graded with less than pass mark, the Trainee will fail the module.

In addition, the affected group members will receive an extension according to the rules stated above, i.e., extension can be granted for a maximum of 10 working days, and no penalty will be applied within this extension period.

## **6. Certificate diploma award**

### **6.1. Granting of ECTS credits**

The granting of the credits corresponds to the various components of the related Module programme and is conditional on success in the related assessment.

### **6.2. Award of the joint certificate**

The Trainee admitted into the Eu2P Certificate programme and having successfully completed the Certificate assessment requirements, i.e. Obtained at least an overall pass assessment shall be awarded a joint Certificate from the Eu2P Academic Partners.

The Trainee who does not meet these requirements will receive a certificate of attendance.

The Eu2P Consortium aim is to deliver a unique joint Certificate.

Such a single joint Certificate is recognised in each of the issuing Eu2P Academic Partners, following completion of all recognition processes in each of the Eu2P Academic Partners involved. The Eu2P joint Certificate award is made under the individual legal responsibility of the signing Eu2P Academic Partners.

The joint Certificate is printed and issued by the Université de Bordeaux.

It is signed by the chairperson of the Programme Examination Board, and includes the logos of all Eu2P Academic Partners.

The title of the Certificate is the following: "Certificate in (Domain Name) + (Module name) + number of ECTS credits validated".

### **6.3. Revocation of the certificate**

Should it be confirmed by a Partner after the publication of results that a Trainee has committed an assessment offence on an examination, the Programme Examination Board will need to review in the light of the evidence submitted the original decision made.

Prior to taking its decision, the Programme Examination Board shall give the particular Trainee an opportunity to present in writing her/his case to the chair of the Board.

If the case is found proven, the Programme Examination Board reserves the right to withdraw an award from any of its graduates. The grounds for such action might include, but are not necessarily limited to the following: an assessment offence; a Trainee's behaviour that would devalue the nature of the award or otherwise discredit the whole Eu2P programme.

# 7. Certificate trainee's obligations

## 7.1. General points

The Eu2P Trainee has certain obligations in addition to those derived from her/his registration at the different universities' partners of the Eu2P Certificate Consortium.

### Registration will impose the following obligations:

- The Trainee must actively participate in the courses, timely submit any assigned homework and fulfil at their best ability the examination requests, respecting academic honesty and integrity.
- In particular, and concerning academic integrity and honesty standards, the Trainee must not cheat nor indulge in cheating, collusion, and /or plagiarism (i.e. Submitting an assignment that contains work that is not the Trainee's one, without indicating the correct sources of such parts).
- The Trainee must comply with the general standards and rules of decency and respect when interacting with fellow Trainees or members of Eu2P Certificate Consortium, or when using any of the Eu2P universities' facilities. Unacceptable behaviour includes, but is not limited to, sexual harassment and intimidation, aggression and violence, discrimination.
- The Trainee must follow instructions and rules of her/his trainers. In particular, Eu2P reserves the right to refuse admission or to require a Trainee to leave a face-to-face training or a live training session on the e-learning platform if her/his behaviour is considered disruptive, likely to cause damage, nuisance, offence or injury, or is otherwise unacceptable. Eu2P may on occasion have to conduct security searches to ensure the safety of Trainees and the venue. The unauthorised use of photographic and recording equipment is prohibited. Mobile phones must be switched off during a face-to-face or during a live training.
- Face-to-face trainings may be filmed by Eu2P. Trainees attending a face-to-face training consent to filming and sound recording as members of the audience. These recordings may be distributed to the public via on-demand video archives on the Eu2P website.
- If on site of one of the Eu2P Academic Partners, the Trainee must follow the rules of such university, in particular those relating to the management and care of university facilities and buildings.
- When the Trainee is convened for a face-to-face examination by a given Module coordinator, such Trainee must follow the examination rules set out by the Academic Partner to which the Module coordinator belongs (in particular rules on ID proof, conduct during examination session, use of documentation, cheating).
- When the Trainee is convened for an on-line examination by a given Module coordinator, such Trainee must follow the examination rules set out by the Module coordinator.
- The Trainee must follow regulations displayed on the Eu2P e-learning platform concerning the responsible use of IT resources, and also strive to prevent nuisance from undesired use of these facilities. In particular, the Trainee must comply with the Eu2P e-learning platform General Conditions of Use and the Eu2P Privacy Policy.
- In addition, study programme-specific codes of conduct may apply, for example in relation to dealing with patient data. The related module coordinator will inform the Trainee of this.

## **7.2. Trainee' s personal expenses**

### **Training material expenses**

Eu2P training programme extensively uses online-based tools and communication technologies. Therefore, each Trainee must be equipped with computer equipment and Internet access.

### **Living expenses**

During the Eu2P training, the Trainee must ensure that s/he has adequate funds to cover her/his living expenses.

**The Trainee needs to budget for the academic year the following potential expenses:**

- Accommodation;
- Utility bills (Gas, electricity and water, telephone, internet and mobile);
- Food;
- General living costs (clothes, books, insurance, networking, socialising, ground transportation, etc.).

Eu2P Module examination may require additional travel expenses that must be borne by each Trainee.

## **7.3. Social security & health insurance obligations**

Concerning social security & health insurance, the Trainee enrolled in the Eu2P Certificate programme shall be informed by the Eu2P central office that s/he is required to subscribe to a personal insurance covering any consequences of health problems, accident or civil liability.

Each Eu2P Academic Partner undertakes to provide appropriate information to the Trainee for her/his registration in the national health system or for the provision of other kinds of health insurance that may be required.

## 8. Certificate trainee's rights

### 8.1. General points

The Eu2P Trainee has certain rights in addition to those derived from her/his registration at the different universities' members of the Eu2P Certificate Consortium.

**Registration will confer the following rights:**

- The Trainee has a right to:
  - ☑ **Participate in courses within the chosen study programme;**
  - ☑ **Support and assistance from Eu2P training teams;**
  - ☑ **Academic freedom and autonomy in her/his intellectual pursuits and development;**
  - ☑ **Be treated with courtesy and respect.**
- The Trainee has a right to reasonable notice of the general content of the course; however, due to the specificity of the e-learning format, the Trainee does not have any warranty on the training (live sessions) availability in any area with time zone different from the GMT one.
- The Trainee has a right to reasonable notice of what will be required of her/him, and the criteria upon which her/his performance will be evaluated. The Trainee has a right to have her/his performance evaluated promptly, conscientiously, and without prejudice or favouritism.
- The Trainee has a right to perform a student course evaluation by way of an online survey.
- The Trainee has right to submit a complaint Partner if they feel they are not treated reasonably and in accordance with the local Academic Partner's by a member of Eu2P faculty or if disagreeing with a decision.
- The Trainee has a right to be free from illegal discrimination and sexual harassment.
- The Trainee has a right to benefit from reasonable disability-related arrangements as specified in an agreed study needs agreement and support related to a potential disability situation both during the admission process and his/her period of study within Eu2P.
- The Trainee has a right to examine and communicate ideas by any lawful means.
- The Trainee has a right to privacy and confidentiality subject to the Eu2P privacy Policy and to each Eu2P University rules and regulations.
- The Trainee has a right to protection against unauthorized disclosures of confidential information contained in her/his educational records. The Trainee has a right to examine and challenge information contained in her/his educational records.
- The Trainee has a right to use of student facilities offered within any of the Eu2P Academic Partners.

### 8.2. Services

Each Eu2P Academic Partner agrees to provide all reasonable assistance to the Trainee helping her/him with incoming procedures such as finding housing, having access to language courses, libraries, canteens, study rooms and computer facilities or providing help to in-coming Trainees with formalities such as permits of stay. The main contact points shall be the respective Eu2P Academic Partners International Offices.

The Eu2P Academic Partners undertake to cover each Trainee admitted to the Eu2P Certificate programme with public liability insurance coverage for any accidents incurred within the university buildings and third party liability for damage that they may involuntarily cause to a person or their properties.

## 9. Certificate trainee's complaints and appeals

### 9.1. Complaints

#### Informal process

When a Trainee has a complaint, s/he is advised to raise the matter directly with those concerned in the first instance. The procedure of the Academic Partner concerned should be followed. Each Academic Partner will consider such complaints fairly and do their best to resolve any difficulties. If a Trainee is dissatisfied with the response to an informal complaint or request, then a formal written complaint should be made in accordance with the procedures laid down by the Academic Partner concerned.

#### Formal complaints

##### *Complaints involving one particular Academic Partner*

The Trainee wishing to complain about a specific training, service or facility provided by a given Eu2P Academic Partner shall invoke the complaint procedure of that institution.

Detailed information about the corresponding complaints process at each institution will be obtained from the Modules Coordinators where necessary.

The Trainee may obtain assistance in preparing complaints from the appropriate advisory body at each institution.

##### *Complaints involving the whole Eu2P Consortium*

The Trainee wishing to complain about the overall organisation of the Certificate programme shall address her/his complaint to the Executive Board, which will deal with it during its review meetings under the following process:

The Trainee who feels that s/he has been wrongly affected by a particular aspect of the Certificate organisation, may ask to have her/his prejudice taken into account and remedial action be taken, by sending within ten calendar days of the date of the particular event or notification of such particular aspect affecting her/his personal situation, a request for action, at the following address: [eu2p.office@eu2p.org](mailto:eu2p.office@eu2p.org)

The Executive Board will consider the complaint and notify the Trainee of its decision within 30 calendar days of receipt of the Trainee's complaining e-mail.

In the event that a trainee has had his or her request dismissed by the Executive Board then a trainee may, in limited circumstances, make representations to the vice-Chancellor or nominee at the Université de Bordeaux.

Representations which have to be submitted via the Eu2P central office can be made only on the grounds that exceptional circumstances apply.

The grounds on which trainees are permitted to lodge an appeal against a recommendation or decision made by the Executive Board in the context of a student complaint are limited.

**The Complainant may request a review by the Vice-Chancellor or nominee where he or she (the Complainant):**

- Wishes information not already brought forward at an earlier stage or new information which may be relevant to the case, to be considered,
- Believes that there has been procedural irregularity or bias.
- The Executive Board will advise the Trainee of the legal remedies available to her/him pursue her/his complaint before a judicial or arbitral instance. Such remedies include the ability of the Trainee to access the UK Office of the Independent Adjudicator in limited circumstances.

## **9.2. Academic appeals**

The Trainee wishing to appeal against a decision relating to the assessment process within the remit of a specific module shall invoke the appeals procedure of the given Eu2P Academic Partner institution.

Detailed information about the corresponding appeals process at each institution will be obtained from the Modules Coordinators where necessary.

The Trainee may obtain assistance in preparing an appeal from the appropriate advisory body at each institution.

In the event that the Trainee wishes to make an appeal relating to a decision made by the Eu2P Programme Examination Board, the trainee should submit the request in writing to the Chair of the Executive Board within 10 working days of the published decision.

**The grounds on which trainees are permitted to lodge an appeal against a recommendation or decision made by the Programme Examination Board are limited to the following:**

- That the Eu2P Programme Examination Board had been advised beforehand of medical or other serious adverse circumstances and failed to appreciate their significance when arriving at their decision or recommendation.
- That there was a material administrative error or procedural irregularity associated with the conduct of the board and/or proceedings were not conducted in accordance with the approved Certificate Regulations.
- That there was inconsistency on the part of the Eu2P Programme Examination Board.

**The written submission should include:**

- A summary of the case and grounds for requesting the review;
- The date on which the decision/recommendation was taken by the Eu2P Programme Examination Board;
- Any relevant documentary evidence.

In the event that a Trainee has had his or her request dismissed by the Executive Board then a Trainee may, in limited circumstances, make representations to the vice-Chancellor or nominee at the Université de Bordeaux.

Representations that have to be submitted via the Eu2P central office can be made only on the grounds that exceptional circumstances apply.

**The grounds on which Trainees are permitted to lodge an appeal against a recommendation or decision made by the Executive Board are limited to the following:**

- That the correct procedure has not been followed and/or that all the relevant circumstances have not been considered and/or there is new evidence not previously considered by the Eu2P Executive Board.
- That the Trainee believes that there has been procedural irregularity or bias.
- In limited circumstances a Trainee may have access to the UK Office of Independent Adjudicator.

# **10. Certificate trainee's records**

## **10.1. General - Confidential character of the trainee's records**

The privacy and confidentiality of the Trainees' records shall be preserved as outlined in the Eu2P privacy and security policy and in the privacy policies applicable in each Eu2P University according to the General Data Protection Regulation (GDPR) (EU 2016/679) as well as to all relevant local laws.

The official Trainee's records shall be maintained only by members of the Eu2P central office and Eu2P Universities staff employed for that purpose. In particular, members of this administration and instructional staff will have access to the Trainees' records for legitimate purposes such as Trainee advising, administrative planning and statistical reporting.

## **10.2. Academic performance**

The Eu2P central office gathers in one individual file all marks obtained by a Trainee in her/his Module examination session.

Copy of her/his file is addressed to the different Eu2P universities academic offices for transcript in each local Trainee's file system.

## **10.3. Access to records**

Access to the Trainee's official records and files is guaranteed to every Trainee subject to the limitations provided by each relevant local law of any Module coordinator.

Upon completion of the Certificate assessment process, the Trainee may request feedback commensurate with the regulations of the Academic Partner(s) with responsibility for the assessment concerned.

The Trainee may apply to the chairman of the Programme Examination Board within one month of each assessment session for access to her/his files. The chairman of the Programme Examination Board shall determine the place and time of such access.

Trainee records will not contain information regarding the Trainee's race, religion, disability, political opinions, social opinions, or membership in any organizations other than honorary and professional organizations directly related to the educational process.

Records of behavioural or academic misconduct and subsequent sanctions that may have been imposed will be maintained in the relevant Eu2P Academic Partner and in the Eu2P central office.

# 11. Quality of the certificate programme

The Eu2P training programme aims at achieving high academic standards.

**This is ensured by:**

- A strong expertise within Eu2P;
- Domains responsibility relies on selected academics, experts in their fields, major and highly skilled professionals belonging to pharmaceutical companies and regulatory agencies;
- All Eu2P Academic Partners have Master degree awarding powers;
- All Eu2P Academic Partners are located in European countries that have signed up to the Bologna Agreement;
- A robust quality assurance system;
- Eu2P Academic Partners have overall responsibility for the academic standards and quality of the programme; this responsibility is exercised and overseen through the Executive Board.;
- Eu2P Partners develop quality guidelines and standard operating procedures that cover the main quality items described in the ENQA report on “Standards and Guidelines for Quality Assurance in the European Higher Education Area”;
- Eu2P Academic Partners recognise the equivalence of each Academic Partner’s quality assurance procedures. When the Trainee studies under the responsibility of a Module coordinator, the relevant institutional quality assurance protocols of this Module coordinator apply;
- Eu2P Partners implement a monitoring tool of post-graduation career and graduate rate.

## 11.1. Eu2P training content & delivery quality

Eu2P implements a cross-quality review of the Modules training material under the final approval by the Executive Board.

Trainees’ feedback is secured on each Domain training material & delivery through a report form to be completed on conclusion of each course and before the final assessment. Participants are asked to evaluate the work of the lecturers or tutors by means of an anonymous questionnaire. Former participants and their organizations are also regularly contacted in order to gather suggestions and appraisals relating to the Certificate programme implementation.

## 11.2. Eu2P assessment quality

Eu2P pays a particular attention to the fairness and quality of its assessment process.

**This is insured by two complementary processes:**

- The Eu2P Programme External Examiner: an independent Eu2P Programme External Examiner is appointed by the University of Hertfordshire to have oversight of the whole programme assessment and to ensure its equity.
- A cross-partner assessment review. This is undertaken by the Eu2P Programme External Examiner to confirm the academic standards of all modules across all partners are consistent with master’s level study and that there is appropriate and consistent assessment of trainees. This review is conducted according to a specifically developed “Standard Operating Procedure: The External Review of Assessment Policy”.

# 12. Eu2P certificates consortium governance

## 12.1. The Eu2P executive board

As regards the Eu2P Certificates programme, the Executive Board shall be responsible for its organisation and the collaboration within the Eu2P Certificates Consortium.

**It is composed of:**

- One member from each of the Eu2P Academic Partner
- One member from each of the Eu2P Associated Partner

As long as those institutions have signed one the Eu2P Diplomas Agreements.

Additional experts or qualified persons may be invited by any member of the Executive Board to attend its meetings with a role of non-voting advisor.

**Its main activities are:**

- To define and to update the general course prerequisites, optional and mandatory course contents, course levels, and to identify learning pathways according to level and course type;
- To define the Eu2P Certificates registration features e.g. Tuition fees;
- To deal with all financial aspects of the Eu2P Certificates programme, including financial relationships between the Eu2P partners;
- To overall define the course planning and lecturer mobility;
- To annually define the Eu2P calendar (application, selection, training, and assessment sessions);
- To involve additional lecturers and facilitators;
- To define and update the Eu2P Certificates quality policy;
- To treat any Eu2P complaint by a Eu2P Trainee relating to the Trainees' selection or to the overall organisation of the Eu2P Programme;
- To treat any appeal by a Eu2P Trainee relating to a decision made by the Eu2P Programme Examination Board.

## 12.2. The Eu2P domain boards

One Eu2P Domain Board is set up for Certificates relating to each of the Eu2P Domains.

**This board is composed of:**

- The Domain Director and co-director
- The related Modules coordinators

**Each Domain Board main activities are:**

- To review all applications to the Eu2P Certificates depending of that Domain and to select Trainees to be enrolled in the corresponding Certificate programme.
- According to the general educational outline defined by the Education Board, to organise the consistency of the Modules general organization within such Domain.

## 12.3. The Eu2P programme examination board

The Eu2P Programme Examination Board manages the Certificate awards.

**This board is composed of:**

- Representatives of each Eu2P Academic Partner
- The Eu2P Programme External Examiner

The Eu2P Programme Examination Board ensures that the assessment process is conducted in accordance with Eu2P Programme regulations and with each University Module Coordinator local rules.

**The Programme Examination Board tasks include:**

- To define and update the study regulations;
- To define and update the assessment regulations including the modalities to be fulfilled by Trainees for completing the Eu2P Certificates Programme;
- To receive the Modules assessment results from the relevant Domain Directors;
- To consider the assessment results achieved by Trainees within a said Domain, and to confirm the award of a Certificate;
- To define and update the Eu2P External Examiner policy;
- To consider the Eu2P Programme External Examiner's annual report;
- To produce and publish at the start of each academic year a schedule of dates for exams, retakes and Programme Examination Board meeting(s).

## 12.4. The Eu2P Central office

The Eu2P central office is in charge of the management and coordination of the overall Eu2P programme organisation and the preparation of all necessary reports under the control of the Eu2P Executive Board.

This central office is based in the Université Bordeaux premises with dedicated personnel for internal and external administration, management, collaborative agreement, student complaint, communication, IT, multimedia and e-learning platform related tasks.

**The Trainee can contact the Eu2P central office:**

- By e-mail at [eu2p.office@eu2p.org](mailto:eu2p.office@eu2p.org)
- By postal mail at the following address:

**Eu2P Central office**  
Université de Bordeaux  
146 rue Léo Saignat - Case 36  
33076 Bordeaux cedex  
FRANCE

**The Eu2P central office is responsible for all operational activities and provides information and support for:**

- Course catalogue & calendar database;

- Trainee application, Certificate trainees' selection & overall database;
- Trainer services;
- Trainee services;
- Examinations organisation and results collection;
- Diploma delivery;
- Fees (collection, redistribution);
- Quality procedures;
- Communication activities.

**Qualification procedures:**

- Alumni follow-up.