

Accreditation Report

International Programme Accreditation of
International University of Health, Exercise & Sports (LUNEX) & COGNOS International GmbH

Luxembourg, Germany

“Good Manufacturing Practice (GMP) training”

BioNTech Prep Classes, BioNTech Bootcamp

I Procedure

Date of contract: 18 September 2023

Date of the submission of self-assessment report: 1 October 2023

Date of site visit: 19 October 2023

Attendance by ACQUIN office: Mrs. Giorina Maratsi

Accreditation decision: 4 December 2023

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The **Assessment Report** of the peer-review experts is **based on** the self-assessment report of the Higher Education Institution (HEI) and extensive discussions with the HEI management, deans and/or heads of the departments, heads of study programme(s), lecturers, staff representatives, students, and alumni.

The basis of the **Assessment Criteria** is part 1 of the “Standards and Guidelines for Quality Assurance in the European Higher Education Area” (ESG) in the current official version. At the same time the national context, particularly the national regulations regarding the establishment of study programmes, are taken into account.

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II Introduction

The experts would like to thank the representatives of the HEI, as well as students that have taken part in the discussions and willingly shared information and their views during the site visit. The discussions are valuable not only for the assessment of the institution, but also for a better understanding of the legal and sociocultural context of the local higher education system.

Evaluation basis for the peer-review experts is the self-assessment report of the HEI as well as intensive discussions during the (online) site visit with the HEI management, deans and/or heads of the departments, head(s) of the study programme(s), study programme(s) coordinators, teachers, lecturers, administrative staff, and students.

Main objective of the accreditation procedure is to assess the quality of the study programmes and compliance with the "Standards and Guidelines for Quality Assurance in the European Higher Education Area" (ESG). The ESG standards are applied as main assessment criteria in the international accreditation procedure. In addition, the respective country-specific criteria and standards are taken into account.

A group of experts was set up, which ensured that all areas relevant to the accreditation procedure (e.g. legal, structural, social etc. aspects) as well as the ESG, and national criteria were considered. The peer-review experts include professors, representatives of the professional practice and the student representative. A certificate with the ACQUIN seal is awarded upon accreditation of the study programme.

1 The Higher Education System in Luxembourg & Germany

The study programme is being offered by a cooperation between LUNEX University (Luxembourg) and Cognos International GmbH (Germany).

According to Eurydice (2023) data of European Commission, the Ministry of Higher Education and Research in Luxembourg is responsible for the higher education. Luxembourg's education system is influenced by country's wide cultural and linguistic diversity, despite being one of the smallest EU member states. Higher education system in Luxembourg allows a variety of bachelor, master and doctoral studies offered by the University of Luxembourg and other institutions providing higher education, some of which collaborate with foreign education providers.

In Germany the responsibility for the education system is divided between the Federation and the Länder. The tertiary sector hosts institutions of higher education of different types (universities, Fachhochschulen, colleges of art and music) and other establishments that offer study courses.

Both Luxembourg and Germany have aligned their national qualifications systems to the European Qualifications Framework (EQF).

2 Short profile of HEI

LUNEX University is a higher education institution situated in the Grand Duchy of Luxembourg. The university focuses on sports and health-related education and currently provides regular academic programmes as defined under article 28 bis, paragraph 3 of the law on the organization of higher education. The university received its accreditation as a higher education institution by means of the Ministerial Decree of the Ministry of Higher Education and Research of 2 June 2015.

The university offers five Bachelor programmes: Bachelor in Physiotherapy, Bachelor in Sport and Exercise Science, Bachelor in International Sport Management, Bachelor in Nutrition, Fitness and Health, and Bachelor in Corporate Health Management and Well-being, as well as three Master study programmes: Master in Physiotherapy, Master in Sport and Exercise Science, and Master in Sport Management and Digitalisation, all accredited by means of the Ministerial Decree of the Ministry of Higher Education and Research.

Since the inception of LUNEX University, there has been a steady growth in student numbers, demonstrating that the university is providing relevant and sought-after programmes. Currently, more than 1.000 students are enrolled at LUNEX University. It bases its activity on publicly available guidelines and strategic objectives, making constant efforts to provide current and potential students with clear, accurate and updated information about its activities, including its academic programmes, admission requirements, learning outcomes and qualifications achieved at the end of these programmes.

Special emphasis is laid on the Pre-Bachelor Foundation Programme, that prepares students with missing scientific and language skills for the accredited study programmes leading to bachelor's and master's degrees. The scientific training for BioNTech "Good Manufacturing Practice (GMP) training" has been developed by the faculty of this Pre-Bachelor Foundation Programme that is used to teach non-native students in English and Science.

LUNEX University incorporates the results of its own research into the teaching curriculum it delivers. Academic staff are active in their research fields and their expertise fits the teaching

curriculum and modules taught. Bachelor and Master students develop their own research projects during their dissertation or Master thesis under the supervision of academic staff.

LUNEX University has adequate financial resources to support existing and new programmes. The university has grown steadily since 2017; it reached a positive EBIT in 2019 and generated enough cash flow to allow further investments. Detailed information about the amount of the tuition fees of LUNEX's Bachelor and Master programmes and the payment plan for the study programmes is published on the website. During the academic year the financial results of the university are regularly presented to its stakeholders and discussed in regular meetings.

COGNOS International GmbH is part of COGNOS International Group and a sister company of LUNEX University. It provides professional education and educational projects to companies and institutions worldwide. A special focus lies in Africa and educational projects as part of developmental programmes. COGNOS International and LUNEX are both serving BioNTech in the education of its staff. The tuition of the BioNTech GMP Trainings is covered by BioNTech. The fees were negotiated in a bilateral contract and are not disclosed. There are no additional fees for students or participants.

3 General information on the study programme: “Good Manufacturing Practice (GMP) training”

Location	LUNEX University, Luxembourg and COGNOS International GmbH, Hamburg
Date of introduction	September 2023
Standard period of study	Prep Classes: 6 Weeks (3x2), Bootcamp: 4 weeks, Quality Control 2 weeks
Number of ECTS credits	Preparatory Classes: 6 ECTS, Bootcamp: 4 ECTS, Quality Control 2 ECTS
Number of study places	N/A
Number of students currently enrolled	28
Average number of graduates per year	N/A
Form of study	Extra-occupational and distance learning online (80-90%), 10-20% synchronous ses- sions, optionally in presence on-site
Tuition fee	Not disclosed – covered by client or funding or- ganizations

III Implementation and assessment of the criteria

1 ESG Standard 1.1: Policy for quality assurance

Institutions should have a policy for quality assurance that is made public and forms part of their strategic management. Internal stakeholders should develop and implement this policy through appropriate structures and processes, while involving external stakeholders.

1.1 Implementation

LUNEX University has established a comprehensive quality assurance and governance programme. The quality management department contributes to maintaining a high standard of research and teaching, as well as the successful completion of studies. The management principles and tools (governance) ensure that the standards and guidelines for quality assurance in the European higher education area (ESG) are implemented effectively.

The primary focus areas of LUNEX policy for quality assurance include the continuous improvement processes, feedback culture, transparency through information, dedicated administration and control by academic councils (Teaching and Learning Council and Research Council). These bodies participate in the quality assurance cycle by analysing feedback and implementing improvements to academic processes, research, and teaching. Elected student representatives participate in the Teaching and Learning Council.

1.2 Assessment

The self-assessment report provided extensive information about LUNEX University's quality assurance policy and its main aspects were also discussed with the expert team during the online meeting. More specifically, the points "Continuous improvement", "Feedback culture", "Transparency through information", "Dedicated administration" and "Control by academic councils" form the framework for assuring high quality. On the homepage further information about these guidelines and a specific email address to request more information about LUNEX University's QMS is provided. Practically, monitoring of the policy is mainly addressed via an internal audit by the Quality Management of the COGNOS AG Group, the major shareholder of the university. In addition, an external company performs external audits, including check of compliance with the group's internal QMS. The main feedback tools are student surveys for each individual module in a study programme, followed by an analysis and identification of potential critical points. Along with other information sources provided by programme leader

discussions with cohort representatives or feedback given by guest lecturers, module monitoring reports and programme reviews are written every year. The programme reviews are considered and approved by the members of the Teaching and Learning Council. More specifically, the self-assessment report mentions about the possibility for students to discuss quality issues with responsible persons and provides information about key figures, which inform the management about student movement, student success or publications and results of funding applications.

The criterion is fulfilled, because LUNEX University has a publicly available policy for quality assurance and appropriate structures with internal and external stakeholders to implement, monitor and revise processes according to this policy.

1.3 Conclusion

The criterion is **fulfilled**.

2 ESG Standard 1.2: Design and approval of programmes

Institutions should have processes for the design and approval of their programmes. The programmes should be designed so that they meet the objectives set for them, including the intended learning outcomes. The qualification resulting from a programme should be clearly specified and communicated, and refer to the correct level of the national qualifications framework for higher education and, consequently, to the Framework for Qualifications of the European Higher Education Area.

2.1 Implementation

The BioNTech Good Manufacturing Practice (GMP) Bootcamp are certificate programmes that are specifically designed to prepare newly hired employees for a job as an operator in a mRNA vaccine production facility, especially the BioNTainer. The trainings have been developed together with BioNTech to prepare hires without prior scientific education to understand the scientific basics of (mRNA) vaccine production (GMP Prep Classes) and to teach the essential basics of (mRNA) vaccine production and the behavioral principles in a lab or GMP production environment (GMP Bootcamp).

The training curriculum has been chosen in a joint team approach (COGNOS International; LUNEX; BioNTech) with regard to relevance and applicability on the job. All training modules have been created by LUNEX faculty according to LUNEX University standards and have been checked and approved by BioNTech for correctness, relevance, and applicability on the job. The trainings are also aiming for BioNTech employees (e.g. in controlling, HR) that did not

have a prior scientific training but still want or need to understand the core processes and products of BioNTech.

All modules of the trainings can be adapted so employees can take them self-paced next to their work and earn a certificate. Training content and approach has been tested for relevance and applicability in test training using BioNTech employees – both operators, staff, and management. Participants have been international from multiple locations. In addition, volunteering students have been used to test the training. Feedback has been collected and integrated to improve the training.

In terms of modules' structure, BnT modules include Fundamentals of Chemistry, Fundamentals of Biology & Biochemistry, as well as Microbiological Aspects & Hygiene. The Bootcamp module includes Introduction to mRNA vaccines, GMP & regulatory framework, Data Integrity & Data management, Drug Substance, Drug Product and Quality Control. The last module is about Quality Control for mRNA.

The daily working load is defined to be 240 min, with the option to stretch the learning time in a self-paced manner to fit into an occupational schedule, if necessary. This allows employees to attend this training as extra occupational activity. The ECTS of each module is calculated with 2 to 4 ECTS, depending on the volume of topics. Each unit in a module contains practice quizzes to train for exams, since the questions used in these practice quizzes are taken from the same question banks as the ones of the exams. At the end of each unit, there is an exam – called knowledge check. The module ends with a final exam (covering all the units) to verify and document the learning outcomes. For security reasons tests can be made using a common proctoring software. Test results are stored and basis for issuing of the certificate.

2.2 Assessment

The study programme appears to be oriented towards the needs of training of employees of BioNTech. The programme is fully integrated within LUNEX University, some existing courses support the programme ("Pre-Bachelor Foundation Programme"). In this way, the study programme fully supports the four purposes of higher education as defined by the Council of Europe. This includes a familiarisation with technical issues related to science of modern drug and vaccine development of also non-scientific staff, which is appreciated. The learning outcomes are clearly defined and appear suitable for students to attain the learning objectives. They also correspond to the correct level of national qualifications framework and EQF.

The workload is clearly presented and deemed adequate. The curriculum applies advanced teaching methods and an impressive learning platform that allows student interaction, progression, and support.

Stakeholders are regularly involved into the design of the learning process through "training the teachers" (by BioNTech employees) and feedback from the students is taken into consideration.

Lastly, the study programme is submitted to ongoing monitoring and review by dedicated staff and experts, ensuring that it is up-to-date, relevant, and aligned with the needs of the students and industry.

2.3 Conclusion

The criterion is **fulfilled**.

3 ESG Standard 1.3: Student-centred learning, teaching, and assessment

Institutions should ensure that the programmes are delivered in a way that encourages students to take an active role in creating the learning process, and that the assessment of students reflects this approach

3.1 Implementation

The “Good Manufacturing Practice (GMP) training” has been developed in a student-centered flipped classroom approach. LUNEX has coupled this proven pedagogical method with problem-based learning to foster and nurture critical thinking skills, problem-solving abilities, and communication skills.

The teaching process starts by providing students with a problem/situation to investigate before the lesson, which allows the students to discover and analyse a set of concepts - individually or in groups. In class, students are expected to discuss their interpretations and/or the acquired knowledge. During lesson time, the teacher guides the students to draw conclusions, clarifies their questions, builds connections between the concepts, and makes a summary at the end of the lesson. The self-paced learning modules always start with an exercise where students need to research a scientific task and write a short essay on it, which is published for all peer participants. As this is set up like a blog, it works across different time zones therefore participants do not need to log in simultaneously. This exercise fosters discussion among peers and encourages participants to look for their own answers and draw their own conclusions.

The actual training material can be accessed after completion of the “Research and discuss” exercise and consists of texts, interactive graphics, simulations, and video material that has been produced to explain the content and understand the learning outcomes. To consolidate the knowledge acquired, students are expected to work through the material and deepen the acquired knowledge with a set of exercises, quizzes, and flashcards to train new vocabulary. For each topic of the programme, resources are provided to students to support the acquisition of theoretical knowledge. These resources include 5–10-minute videos explaining the main

concepts and learning outcomes, written documents, and schematic summaries. The videos, interactive graphics and problem-based case studies are designed to offer practical knowledge and consolidate the theoretical learning outcomes in a safe and effective manner.

The diverse and multinational group attending the GMP Prep Classes and the GMP Bootcamp calls for an inclusive and integrating teaching concept that reflects individual preferences and cultures. LUNEX University implemented in 2019 the LUNEX University Equality and Diversity Policy, which sets out the rights and obligations applicable to all LUNEX University employees and students.

3.2 Assessment

The programme coordinators developed an outstanding flipped classroom concept employing a diverse array of asynchronous online learning resources coupled with synchronous video sessions to clarify questions and consolidate the learning outcomes. This allows for self-paced learning and is suitable for employed students with a varying scientific background.

Even though not explicitly apparent in the self-assessment report, the integration of ethics and scientific literacy is evident. The interviews during the online meeting indicated that it is a fundamental aspect of the teaching staff's self-conception and, consequently an integral part of the lectures.

By requiring students to independently research and discuss new topics before accessing course materials, the study programme fosters autonomy and confronts the students with the responsibilities of scientists and reasoning behind regulations (i.e. being asked to look for an enantiomer will likely lead to the students reading about thalidomide).

The interaction among participants and ability to create a peer-feeling among them distinguishes this from many other online programmes, even though this may be partially attributed to participants working for the same company. The assessments are fully transparent and sufficient for verifying the defined learning outcomes. The teachers are easily accessible, open to discussion, and promptly incorporate student feedback into the course.

3.3 Conclusion

The criterion is **fulfilled**.

4 ESG Standard 1.4: Student admission, progression, recognition, and certification

Institutions should consistently apply pre-defined and published regulations covering all phases of the student "life cycle", e.g. student admission, progression, recognition and certification.

4.1 Implementation

The “Good Manufacturing Practice (GMP) training” is exclusively designed with and for BioNTech’s employees as well as for new hires. Thus, admission to these trainings is following BioNTech’s recruitment guidelines. LUNEX University offers a test to assess the individual needs of each candidate to take the GMP training – especially if they should be advised to attend Prep Classes before attending the Bootcamp. This is very advisable for BioNTech employees without prior scientific training in order to introduce the scientific basics for the essential GMP Bootcamp. With the approval of BioNTech, the non-exclusive parts of these trainings might be offered to external students as well as part of a developmental or a university programme.

Participants will pass multiple tests during the training. These tests are all online and can be performed with proctoring software that checks for irregularities and cheating. First, there are practice quizzes in each unit that can be repeated and have no time limit. Practice quizzes serve to self-test the learning progress without grading. It gives the student feedback on his performance without being graded. At the end of each unit, there is a graded online test called “Knowledge Check”. Knowledge Checks are mandatory and time limited. People can train with practice quizzes for the knowledge checks. The knowledge check needs to be completed within 24 hours of completing a unit – with only one attempt. Failing a Knowledge Check does not prevent the student from moving on – he/she receives feedback on his/her mistakes and recommendations for further study.

After each module, there is a final exam that needs to be completed to move to the next module. The final exams are also mandatory, time-limited and have a threshold of at least 50% correct answers to pass. The threshold can be adjusted according to client needs but will not go below 50% for passing. The final exam can be taken twice. The sum of knowledge checks contributes to 40% of the final grade, whereas the final exam counts 60%.

4.2 Assessment

The admission process and requisites for applicants are clear. The admission to trainings is based on BioNTech’s recruitment guidelines and is supported by LUNEX University test systems that assesses the individual needs of each candidate. Therefore, it can be concluded that the process is highly transparent. The process according to which non-exclusive parts of trainings might be offered to external students as part of a developmental or a university programme is not yet reported.

The programme includes several steps to monitor the learning progression of students, which include reliable and strict on-line tests. Student progression is assessable by the mandatory

and time limited graded online test “Knowledge Check”, which does not prevent to move forward with the learning programme, the time-limited 50% correct answer threshold exam at the end of each module, which must be passed to move to the next module. This double integrated evaluation process will result in the final grade.

LUNEX university adopts the procedures reported in Lisbon Recognition Convention also by exploiting the Pre-Bachelor Foundation Programme dedicated to students with missing scientific and language skills. In this specific case, the programme involves BioNTech as partner. However, the compliance with Lisbon protocol should be better clarified.

Regarding the completeness of students’ information received, the certificate of completion reports properly the qualification obtained at the end of the training, as well as the achieved skills.

In overall, the programme is well organized and has developed well-defined procedures in terms of student admission, progression, evaluation, recognition and certification. These procedures satisfy the requirement of transparency and can promote social and scientific integration among people with different background. In the future, the recruitment process should guarantee a certain percentage of enrolments open to non-BioNTech related students.

4.3 Conclusion

The criterion is **fulfilled**.

5 ESG Standard 1.5: Teaching staff

Institutions should assure themselves of the competence of their teachers. They should apply fair and transparent processes for the recruitment and development of the staff

5.1 Implementation

Design, preparation and teaching of GMP modules are done by LUNEX faculty, supported by BioNTech experts. The main responsible faculty of these programmes are three professorial staff of the university. Apart from LUNEX staff, two BioNTech experts are taking part in the modules. Both are appointed lecturers at LUNEX University.

The recruitment of new employees is designed to support the long-term strategy of LUNEX University and is carried out in accordance with Personnel Planning, as defined within the context of Business Planning. The recruitment process is defined in the LUNEX University Personnel Recruitment Policy, and the workflow below illustrates the uniform, target-oriented procedure for the job advertisement, selection and hiring of new employees. The basis is forward-looking personnel planning in order to be able to react sufficiently to the needs of the

university as well as to changing framework conditions. The positions can be advertised both internally and externally. Professional qualifications have priority over filling vacancies quickly. The appointment criteria are prepared during the selection process by an appointment committee. The appointment committee is composed of several representatives of the academic area in which the professorship is required. When there is a large number of applicants, a pre-selection is made on the basis of documents submitted by the applicants. Criteria such as academic education, scientific publications record, teaching and practical experience, research funding, academic achievements, and evaluation results of other universities are evaluated. The weighting of these criteria is determined by the tasks that the applicant will perform in their designated role. The appointment committee then conducts personal interviews with the pre-selected candidates who are then required to give presentations on subject-specific topics or their area of research/ expertise. After the decision by the appointment committee, and endorsement of the university senate, the ordinary appointment of the chosen candidate to the position of professor at the university takes place.

5.2 Assessment

Among the strengths of the study programme is the high commitment and enthusiasm of teaching staff, all of which are sufficiently trained and qualified to carry out the learning process. In addition, they receive support from various experts in the field from BioNTech employees if needed, while at the same time retaining their academic freedom in terms of subjects taught. In addition to their teaching responsibilities, teaching staff is also actively involved in research and other scholarly activities. They are encouraged to engage in research and to publish their findings in leading academic journals, which helps to enhance the institution's reputation and to provide students with access to the latest research and knowledge in their respective fields.

The application and implementation of advanced teaching methods, fully supported by LUNEX University is highly appreciated and appears to be fit for purpose for the training of students.

The addition of training in soft skills such as cultural management is recommended, as the subject of the study programme touches on vaccine equity and distribution in low/medium income countries.

5.3 Conclusion

The criterion is **fulfilled**.

6 ESG Standard 1.6: Learning resources and student support

Institutions should have appropriate funding for learning and teaching activities and ensure that adequate and readily accessible learning resources and student support are provided.

6.1 Implementation

All module content that needs to be learned is integrated into the Learn Management System (LMS) used for the GMP training. The LMS in use can differ from training to training, depending on the local IT backbone of the client (usually CANVAS or Success Factors as LMS). No additional material is required to study the programme. Presentations that are covered in the learning videos can be downloaded or printed by the student to allow individual studying.

Faculty is approachable to every student during scheduled contact time and for questions or clarifications via messages in LMS, email or even telephone. In the first trainings the reaction time has been proven to be very short.

In addition, learning progress is reviewed continuously and students that show slow learning progress are actively contacted. This allows the early identification of learning issues to offer individual support.

6.2 Assessment

The online resources offered by LUNEX University encompass all the necessary elements to attain the specified learning outcomes. While numerous external resources are currently integrated into the lectures, the university plans to gradually replace them with video lessons produced in their dedicated studio.

To enhance the offline availability of the courses, it is recommended to expand the range of downloadable resources, particularly given occasional reports from students about infrequent technical issues.

6.3 Conclusion

The criterion is **fulfilled**.

7 ESG Standard 1.7: Information management

Institutions should ensure that they collect, analyse and use relevant information for the effective management of their programmes and other activities.

7.1 Implementation

LUNEX University uses several methods to obtain the widest picture possible and make informed decision about areas in which teaching content or the general learning conditions can be improved.

Key Figures form a part of Quality Assurance at LUNEX University. Student Recruitment, the Exam Office, and Study Services provide the management with statistics on student movement and student success within their respective areas on a weekly or monthly basis. In the area of research, key figures such as the number of publications, success of funding applications, funding amounts, and impact factors are provided to the management on a regular basis.

Human Resources department produces key figures for the management on staff movement, staff academic achievement, ratios of staff of a certain rank or title to staff overall or to students.

7.2 Assessment

LUNEX University adopts various appropriate procedures to collect and analyse information on the study programmes and related activities that include surveys, face-to-face meetings with programme committee, stakeholders, management, the cohort representatives, assignment, exam results, feedback from BioNTech about the skills achieved by students on the overall programme, teaching (module evaluation) and internships. The data and information are centralised and analysed accordingly to ensure an effective management and continuous improvement of the programme. Importantly, collected information includes appropriateness to learning outcomes, placement quality and quantity, quality of guest lecturers, defining an action plan, identification of good practice. This pool of information can be multimodally analysed to get required information on the programme outcomes.

The involvement of all actors participating at different levels to the data and information collection, evaluation and analysis involving management, program committee, stakeholders, students, teachers, institutional representatives, and partners together with qualifications awarded, summary of year (various subtopics), teaching and learning feedback, summary of review of all modules guarantee wide, continuous, and complete view of the programme quality compliance. This process allows for identifying major critical points that will be addressed to make the programme more effective, to redirect actions and discuss measures that are implemented into the teaching and administration.

The students play a major role in the surveys and providing for indirect feedback with exam results. Therefore, students are main players in the process and programme organization. Although the involvement of students is reported in several points of the programme, it is suggested to provide more concrete information how students involvement on information and

data analysis is implemented. The programme has continuous, complete, effective and multipoint view of monitoring the programme that can measure the efficacy, the teaching/learning outcomes.

7.3 Conclusion

The criterion is **fulfilled**.

8 ESG Standard 1.8: Public information

Institutions should publish information about their activities, including programmes, which is clear, accurate, objective, up-to date and readily accessible.

8.1 Implementation

The hierarchy and structure at LUNEX University are clearly defined and published on the LUNEX University website. LUNEX University has a highly professional web presence with up-to-date information about all activities, programmes and many other subjects of importance for students and other stakeholders. A specific site allows to request tailored information material.

8.2 Assessment

Regarding the “Good Manufacturing Practice” programme, all information is so far only available to current BioNTech employees and newly hired staff. The public has currently no chance to get information about the course, but the management of LUNEX University assured the expert team about publication of at least some information after graduation of the first group of participants.

The criterion is already fulfilled in a specific context, as those people for which the programme was set up, have access to all information. As in a broader context, the public should be also able to access information about the programme, the criterion will be probably completely fulfilled after public availability of information.

8.3 Conclusion

The criterion is **fulfilled** on the specific context of this programme.

9 ESG Standard 1.9: On-going monitoring and periodic review of programmes

Institutions should monitor and periodically review their programmes to ensure that they achieve the objectives set for them and respond to the needs of students and society. These reviews should lead to continuous improvement of the programme. Any action planned or taken as a result should be communicated to all those concerned.

9.1 Implementation

LUNEX University has an integrated system of feedback around academic teaching quality, starting with surveying students on the teaching they received in each module (module evaluation). Internships are also surveyed from both the students' and Institute's views. Students are sent a short summary of the feedback for each individual module identifying major points that will be addressed before the next time the module is taught. In addition, programme leaders hold face-to-face meetings with the cohort representatives twice a year, which gives students an opportunity to discuss their thoughts and concerns in person. Each iteration of a module within an accreditation cycle is subject to review and amendment. Part of the programme review at the end of each period addresses relevant new information coming out of recent research, internal or external, or the way a certain concept is taught, and updates and/or changes are integrated into the new semester module.

Module monitoring reports are produced from the module evaluation surveys, program committee meetings and additional students' and stakeholders' (e.g., guest lecturers) feedback noting common themes and useful feedback to continuously improve the module quality. Information in the module monitoring reports thus includes distribution of grades, failure and dropout rates, a summary of actions taken since last report, module evaluation comments, analysis of assessment results, other comments. The information of these data from the module surveys and module monitoring reports, topics noted in face-to-face meetings as well as student support requests within one program are collated into a program review report by the relevant program leader for each academic programme. It is then used as input into the annual programme reviews where measures are suggested and discussed, and then implemented into the teaching (or administration) for the next period.

Each programme review is considered and approved at the Teaching & Learning Council (TLC) level by the members of the Council. Changes supporting programme improvement are reviewed at TLC level. Moreover, student representatives have regular meetings with the Academic Director and the Head of Administration.

9.2 Assessment

As the programme was set up for BioNTech, the company has a strong level of interest to keep the course content up to date. Furthermore, BioNTech has highly qualified experts for the more specific fields of the course, which reviewed the learning content during the implementation of the programme and checked needs of adaptation. During the online meeting, the expert team got the impression that improvement of programmes is of high priority for LUNEX University in general. The intensive discussion with current participants clearly showed that the feedback

from students is welcome. As the programme is currently only available to employees of BioN-Tech, the needs of society, which are one objective in this standard, are not relevant currently.

The criterion is fulfilled, because monitoring and reviewing of the programme to enable continuous improvement is ensured.

9.3 Conclusion

The criterion is **fulfilled**.

10 ESG Standard 1.10: Cyclical external quality assurance

Institutions should undergo external quality assurance in line with the ESG on a cyclical basis

10.1 Implementation

To ensure the relevance of its programmes in Luxembourg and within the greater context of Europe, and the employability of its graduates, LUNEX University operates in compliance with the Bologna Process. The selection process of which programme to develop is data-driven and taking into consideration the interests of the various stakeholders. The need for practical careers and professions within the local area (Luxembourg) and Europe is prioritised, and programmes are developed in alignment with international education systems and professional requirements.

As part of the preparation for a new accreditation, over and above the programme reviews, the content of the programme is reviewed against further criteria, such as industry needs and changes, employability, changes in professional definitions or certification so that it remains as current and relevant as possible.

10.2 Assessment

LUNEX University has developed and established robust procedures of quality assurance as part of its strategic planning. It embraces the concept of Cyclical External Quality Assurance as a process of periodic external evaluation of the quality of higher education institutions, as well as of academic and training programmes.

A successful accreditation by a recognized, independent accreditation agency enhances the credibility of an institution, therefore LUNEX University decided to undergo an external accreditation procedure for its GMP programme as an opportunity for continuous enhancement that ensures the high quality of the offered programme at European and international level.

10.3 Conclusion

The criterion is **fulfilled**.

IV Recommendation to the Accreditation Commission of ACQUIN

1 **Assessment of compliance the Standards and Guidelines in the Higher European Area (ESG) in the actual official version**

The study programme „Good Manufacturing Practice (GMP) training“ was assessed on the basis of the "Standards and Guidelines for Quality Assurance in the European Higher Education Area" (ESG), and the national or other relevant regulations.

The expert group concludes that the **ESG standards** 1.1 (Policy for quality assurance), 1.2 (Design and approval of programmes), 1.3 (Student-centred learning, teaching and assessment), 1.4 (Student admission, progression, recognition and certification), 1.5 (Teaching staff), 1.6 (Learning resources and student support), 1.7 (Information management), 1.8 (Public information), 1.9 (On-going monitoring and periodic review of programmes) and 1.10 (Cyclical external quality assurance) are fulfilled.

The assessment criteria are as follows:

Standard 1.1 Policy for quality assurance: Universities have a publicly accessible quality assurance strategy, which is part of their strategic management. This strategy is developed and implemented by internal stakeholder representatives through appropriate structures and processes, involving external stakeholders.

The criterion is **fulfilled**.

Standard 1.2 Design and approval of programmes: Universities have procedures for the design and approval of their courses. The courses are designed in such a way that their objectives, including the desired learning outcomes, can be achieved. The qualification obtained during a degree program is clearly defined and communicated; it refers to the corresponding level of the national qualifications framework for higher education and, consequently, the qualifications framework for the European Higher Education Area.

The criterion is **fulfilled**.

Standard 1.3 Student-centred learning, teaching and assessment: Universities ensure that the courses offered are carried out in such a way as to encourage students to play an active role in the design of the learning process and that this approach is also taken into account when assessing students / examinations.

The criterion is **fulfilled**.

Standard 1.4 Student admission, progression, recognition and certification: Universities ensure that the courses offered are carried out in such a way as to encourage students to play an active role in the design of the learning process and that this approach is also taken into account when assessing students / examinations.

The criterion is **fulfilled**.

Standard 1.5 Teaching staff: Universities ensure the competence of their teachers. They use fair and transparent procedures for the recruitment and further training of their employees.

The criterion is **fulfilled**.

Standard 1.6 Learning resources and student support: The university has adequate funding to finance study and teaching and ensure that there is always a sufficient and readily available range of learning and support available for their studies.

The criterion is **fulfilled**.

Standard 1.7 Information management: Universities ensure that they collect, analyse and use the relevant data relevant to the successful conduct of studies and other activities.

The criterion is **fulfilled**.

Standard 1.8 Public information: Universities publish easily understandable, correct, objective, up-to-date and well-accessible information about their activities and courses of study.

The criterion is **fulfilled** on the specific context of this programme.

Standard 1.9 On-going monitoring and periodic review of programmes: Universities are constantly monitoring their courses and regularly reviewing them to ensure that they achieve the goals set and meet the needs of students and society. The tests lead to a continuous improvement of the courses. All affected parties will be informed about any measures planned or resulting from this.

The criterion is **fulfilled**.

Standard 1.10 Cyclical external quality assurance: Universities regularly undergo external quality assurance procedures in accordance with the ESG.

The criterion is **fulfilled**.

2 Accreditation Recommendation

The peer-review experts recommend an **unconditional accreditation** of the „Good Manufacturing Practice (GMP) training“.

The peer-review experts recommend the following **recommendations**:

(General) recommendations

1. In the future, the recruitment process should guarantee a certain percentage of enrolments open to non-BioNTech related students.
2. The addition of training in soft skills such as cultural management is recommended, as the subject of the study programme touches on vaccine equity and distribution in low/medium income countries.
3. To enhance the offline availability of the courses, it is recommended to expand the range of downloadable resources, particularly given occasional reports from students about infrequent technical issues.

V Decisions of the Accreditation Commission of ACQUIN

Based on the evaluation report of the expert group and the statement of the Higher Education Institution, the Accreditation Commission of ACQUIN has made its decision on 04 December 2023.

The training concept “Good Manufacturing Practice (GMP) training” (BioNTech Prep Classes, BioNTech Bootcamp) at the International University of Health, Exercise & Sports (LUNEX) and the COGNOS International GmbH is accredited without any conditions.

The accreditation is valid until 30. September 2030.

The following recommendations are given for the further development:

- In the future, the recruitment process should guarantee a certain percentage of enrolments open to non-BioNTech related students.
- The addition of training in soft skills such as cultural management is recommended, as the subject of the study programme touches on vaccine equity and distribution in low/medium income countries.
- To enhance the offline availability of the courses, it is recommended to expand the range of downloadable resources, particularly given occasional reports from students about infrequent technical issues.