



**Cyprus Agency of Quality Assurance and Accreditation in  
Higher Education**

**Republic of Cyprus**

**External Evaluation Report  
Program of Study**

**Institution: University of Nicosia**

**Program of Study: MSc in Drug Regulatory Affairs.**

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## **INSTRUCTIONS:**

The present document has been prepared within the framework of the authority and competencies of the Cyprus Agency of Quality Assurance and Accreditation in Higher Education, according to the provisions of the “Quality Assurance and Accreditation of Higher Education and the Establishment and Operation of an Agency on Related Matters Laws of 2015 to 2016” [N. 136 (I)/2015].

**The document is duly completed by the External Evaluation Committee for each program of study. The ANNEX (Doc. Number 300.1) constitutes an integral part of the external evaluation report for the external evaluation accreditation of a program of study.**

**EXTERNAL EVALUATION COMMITTEE:**

<b>NAME</b>	<b>TITLE</b>	<b>UNIVERSITY / INSTITUTION</b>
Marie Louise De Bruin	Professor	University of Copenhagen
Angelique Dimitracopoulou	Professor	University of the Aegean
Dimitrios Lamprou	Professor	Queen's University Belfast
Dionysios (Dennis) Douroumis	Professor	University of Greenwich
Ioanna Zacharia	Student Representative	University of Cyprus

## INTRODUCTION:

### I. The External Evaluation procedure

The EEC panel was briefed by Dr Eleni Deliyianni Education Officer of the Agency of Quality Assurance and Accreditation in Higher Education, who accompanied the panel to the University of Nicosia.

The panel received presentations from the Rector, the vice Rector of Academic Affairs, Head of the Life and Health Sciences Department, and Dean of Distance Learning Unit. These presentations covered the following topics:

- structure, the history and the academic programs of the university
- departmental structure and mission
- organization and structure of the distance learning unit.

This was followed by a presentation by the Director of the proposed MSc in Drug Regulatory Affairs that covered:

- program profile, including aims and objectives
- administrative structure
- feasibility study
- learning outcomes and structure of program of study
- student admission criteria
- faculty and teaching staff

Furthermore, a demonstration was given of two of the courses that were already in distance learning format on Moodle.

The panel were able to ask questions throughout these presentations and there was an interesting and informative dialogue. In total, 10/18 members of the teaching personnel were present at the meeting (5/6 Full-time staff members; 0/2 Visiting professors; 5/10 Special Scientists).

The panel was able to have a private meeting with the teaching staff, 3 students (2 distance learning MSc students over the phone and face to face with 1 regular MPharm student) and the program director. The on-site visit was completed with a very informative guided tour of the Distance Learning Unit, labs and library facilities.

The panel was able to scrutinize the following documentation before the visit:

- Master of Science in DRA 100.1.5 (GR)
- 200.1 Application for Evaluation – Accreditation for Program of Study (GR and EN)
- MSc in Drug Regulatory Affairs study guide v2018 (dated 2017)
- MSc DRA 500.3..xlsx (GR)
- MSc DRA Degree Sample

At the meeting, the panel was given the following paper documents:

- Distance Learning Faculty Handbook (March 2018, EN)
- PowerPoint slides presentation program Coordinator (EN)

After the meeting, the panel was sent:

- Student evaluation reports for five randomly selected courses (GR)

## II. The Internal Evaluation procedure

The panel was provided with the internal evaluation documentation, which was comprehensive and positive. The report provided a good summary of general guidelines and procedures that are available at the University, which supplemented the details provided about the program in the first part if doc number 200.1.

## **FINDINGS:**

### **1. EFFECTIVENESS OF TEACHING WORK – AVAILABLE RESOURCES**

#### **- Organization of Teaching Work**

The Teaching Work is considered sufficient by the panel. The structure of the distant learning program in Drug Regulatory Affairs is defined in Study Guide and relevant material are accessible on the e-Learning Platform (Moodle). The program consists of 15 courses in total (7.5 ECTS) with 3 elective courses including, postgraduate assignment and a range of formative and summative assessments. It is an 18 months program consisting of 3 semesters with 4 courses per semester delivered in 13 weeks. The panel found the structure appropriate for the successful delivery of the program.

#### **- Teaching**

The teaching team involved in the program consist of 18 members staff of which 6 are full time employees and 12 are part – time. The numbers appear sufficient for the delivery of the program and teaching responsibilities were allocated equally. The courses are not fully placed on the e-Learning platform but the panel feels that there is enough time to complete the courses before the start date of the program. The program coordinator has established an Independent External Advisors committee which will play a key role in the evaluation of the learning outcomes, preparation of courses, overview of exam questions/reports and student feedback. The facilities and the equipment for the delivery of the DL courses are of high standards while there is on site support for any technical issues. The academic staff receives continuous training on the usage of equipment and materials for the course delivery.

There was a minor concern from the panel about the clarity of the assessment criteria in some assignments and the teaching team should address it in due time.

#### **- Teaching personnel**

The academics involved in the teaching activities and the delivery of the course have a strong background in drug discovery and development, pre-clinical and clinical evaluation, and regulatory affairs. Most of them have industrial background with long experience in Regulatory Affairs.

The panel is satisfied with the existing experience of the teaching team in the design of teaching courses as they are also actively involved in the delivery of the MPharm program.

## 2. PROGRAM OF STUDY AND HIGHER EDUCATION QUALIFICATIONS

### - **Purpose and Objectives and learning outcomes of the Program of Study**

The course objectives, and student learning outcomes are clear and are appropriate for the curriculum of the proposed course. There is a detailed description of what students are expected to cover for the successful completion of the course.

### - **Structure and Content of the Program of studies**

The structure of the program is appropriate for its objectives and ambitions and for the mode of delivery by distance learning. The curriculum consists of 10 compulsory courses, covering the all the subsections of the EU registration dossier, regulatory requirements outside the EU and several broader topics, such as regulatory strategy and ethics. The elective courses offer the opportunity to specialize in one of the following directions: herbal medicines, medical devices or Health Technology Assessment.

### - **Quality Assurance of the Program of studies**

The University has a clear structure for the quality assurance and the University procedures will be followed for the particular course. Moreover, the Distance Learning Unit will collect all the appropriate feedback for this course, and the academic staff will make sure that the program will regularly evaluated in order to ensure, and further enhance, the overall quality of the learning experience for all students.

### - **Management of the Program of Study**

All the staff members that have been allocated for the program have experience in Regulatory Affairs and the relative subjects but only one member of staff is experienced in DL. Nevertheless, the DL Unit has experience to support the staff who already have complete the appropriate training. The panel has concerns about the workload of Dr Petrou and an immediate response from the University will be needed if this course is accredited. There will be a significant workload in the organization and management of the program for Dr Petrou. Therefore, the panel recommends teaching relief for Dr Petrou as he is already heavily involved in the management of another program.

### - **International Dimension of the Program of Study**

The proposed program in Drug Regulatory Affairs is highly specialized and novel. Currently, there is an increased demand for the delivery of courses in Regulatory Affairs while there is a very limited number of similar programs in EU and Middle East institutions.

### - **Connection with the labor market and the society**

The Program Coordinator provided evidence in the form of support letters from pharmaceutical industry and the Cyprus Association of Pharmaceutical Companies. Industry demands for skillful and trained employees with excellent understanding in Regulatory Affairs have not met yet. In addition, the landscape of Regulatory Affairs is continuously changes and evolves. The panel is convinced that the program will enhance the employability of the graduates.

### 3. RESEARCH WORK AND SYNERGIES WITH TEACHING

#### - Research Teaching Synergies

Permanent staff members are involved in research relevant to the content of individual courses. This will inform the teaching, particularly in the courses on drug discovery and development, pre-clinical and clinical studies, pharmacovigilance and herbal medicines.

Drug regulatory affairs is an applied discipline. However, regulatory science, particular the subtype where tools and standards are developed that can facilitate regulatory decision-making, offers the opportunity to do research. The panel encourages the program faculty to explore the possibilities to identify topics where their current (basic) research activities align with regulatory procedures for drug approval and regulatory decision-making.

With respect to the Post Graduate Assignment (PHAR-614), The panel noticed that the research project credits are rather low (7,5 out of the total ECTS for the whole program). The panel was informed that for most programs at the University of Nicosia, the size of the research project is equivalent to 2 times the size of an average course. For the program of Drug Regulatory Affairs this would translate to 15 ECTS. The panel recommends increasing the credits of the Post Graduate Assignment (PHAR-614) to 15 ECTS and align with other programs at the University of Nicosia.

The panel suggests also that the Program Coordinator and teaching team should work closely in order to provide adequate support and prepare students for the Post Graduate Assignment.

#### **4. ADMINISTRATION SERVICES, STUDENT WELFARE AND SUPPORT OF TEACHING WORK**

##### **- Administrative Mechanisms**

Based on the PowerPoint presentation during our visit and on the interactions with the administrative staff (e.g. during the onsite visit to DL Unit and Library), the panel were satisfied that administrative mechanisms are sufficient for the delivery of this programme. It was clear that the University has established strategies and have mechanisms in place to support DL, technologies to be used by the academics and support DL students.

##### **- Infrastructures / Support**

From the visit to the DL Unit and Library, the presentation and demonstrations (e.g. use of the online system, searching for books, and telephone support), it is clear that there is a highly professional and well-trained personnel, and well-developed infrastructure at the University for the support (academics and students) of DL courses. The Distance Learning Unit is well-organised and responsible to support and administrate the DL, which an important element for the successful delivery of this course. This Unit has excellent infrastructure which is equal to other high ranking academic institution across Europe.

##### **- Financial Resources**

The panel is not aware of any issues and haven't seen a business plan

## 5. DISTANCE LEARNING PROGRAMS

With regards to the DL approach, the EEC is referred to the “Quality Standards and Indicators” mentioned in the current template as well as to the additional ‘Criteria for the Distance Learning Programmes of Study’ of DIPAE.

The committee acknowledges the University of Nicosia has experience, gained over a number of years of delivering DL programmes. Here in after EEC acknowledges the dimensions where the University of the Nicosia and/or the specific program has excellent or satisfactory approaches, while presents comments and suggestions regarding other dimensions that need improvements.

### (A) Regarding the General Distance Learning Institution Structure and Infrastructure:

The University of Nicosia, regarding the Distance Learning Programs, among others, disposes:

- (I) A defined General Model of Distance Education via on line technologies, involving completely by distance courses and services and face to face final exams that take place in exams centers around the world.
- (II) An elaborated Organizational Administrative Structure, involving an appropriate number of administrative staff devoted to the support of distance learning students.
- (III) An appropriate Infrastructure especially in terms of building (a specially dedicated building), technological infrastructure (teleconferencing rooms, PC laboratories rooms, servers, etc.) and qualified IT personnel.
- (IV) Electronic Libraries rich and appropriate for the specific Program
- (V) Policies related to the needs of Distance Learning via Technologies. In particular, EEC would like to mention the following:
  - (1) They have defined General Guidelines for the Development and Delivery of Distance Learning Programs via online technologies.
  - (2) They have defined an E-learning Code of Practice
  - (3) They have produced a new, more concrete and elaborated Distance Learning Faculty Handbook, with Guidelines for the Development and Delivery of Distance Learning Courses (March 2018)
- (VI) The “Pedagogical Planning Unit for Distance Education”: University of Nicosia has not yet established this kind of Unit. However, according to the Rector, UNIC has finished the procedures so as to recruit the head of this Unit.  
It is recommended the functioning of this Pedagogical Planning Unit as soon as possible that will allow to: (a) Prepare appropriate teaching training methods and material for advanced learning methods, according to the DIPAE criteria, especially on the domain of adults’ education, distance learning collaborative methods etc. (b) Support teachers to

produce appropriate learning material, learning activities, and various assessment methods appropriate for high level learning objectives, and collaborative learning (c) Support Lecturers in the learning approaches problems resolution.

## B) REGARDING THE PROGRAM STUDY GUIDE

The Study Guide of the Program under evaluation can be considered as completely developed. According to the corresponding DIPAE, the Study Guide for each Course, includes in a weekly base (and for the 13 weeks) at least the following:

- Clearly Defined Objectives and expected learning outcomes;
- Presentation of the main educational material of the week
- Outline of the set of activities (e.g. self-assessment activities), and eventual assignments
- Planning of the online lectures, the online discussions (via Webex), the discussions on forums etc.
- Bibliographic References and suggestions for further study.

The Courses Study Guides contain also in the beginning an introduction regarding to the content and the general approach of the course, as well as a table presenting an overview of the course method, including the number of the interactive sessions (e.g. 4 teleconferences /Webex sessions), the number of assignments, the mode of the final grade calculation (e.g. 40% Continuous assessment, + 60% final exam).

However, it is to be noted that:

- Regarding the DIPAE criteria 7.4: There are missing the self-correction guides for self-assessment activities/exercises.
- Regarding the DIPAE criteria 2: The study guides have predicted interaction with the teacher and among the students, mostly via on-line discussion, or forum asynchronous discussions. It is suggested to conceive and add some collaborative learning activities that are important for the specific program content (e.g. appropriate for case studies and conflict resolution between pharmaceutical companies and drug regulation policies).

## C) Regarding “LEARNING ANALYTICS” approaches to support educational or administrative approaches

The committee is glad that University of Nicosia has been started to use Learning Analytics Indicators so as to further support the educational process and the learners via some Learning Analytics Indicators produced by the Moodle Platform. However, EEC has the feedback from a student of another DL Master Degree Program, that these indicators are not well calibrated and do not really help students to be aware of their participation and self-regulate their activity.

It is strongly recommended to proceed as soon as possible to further improve the use of these Indicators by:

- ⇒ Thoughtful and concrete decisions of the University of the Nicosia Senate related to the application of Learning Analytics on Distance Learning Programs.

In fact, the DL programs can exploit the functionalities of the adopted Distance Learning Platform (Moodle/ i.e. see: [https://docs.moodle.org/33/en/Learning\\_analytics](https://docs.moodle.org/33/en/Learning_analytics) ). However, the use of Learning Analytics, according to the best practices of Universities, must be used in an institutionalized way, under the Senate study, approval, and decisions on how and which specific Learning Analytics approaches and methods to use for: (a) the support of learners (e.g. awareness and self-regulation), (b) the support of lecturers (monitoring students, awareness on the teaching methods effectiveness), (c) administrative support, (d) institution support on decisions' taken. All the indicators must be tested and evaluated by all the involved human agents (students, teachers, administrative personnel, academic administration).

It is to be highlighted that Learning Analytics it is not a matter of technical persons or administrative persons. Thus, it is recommended that University of Nicosia, establish a high level "Committee on Learning Analytics Ethics" (with the participation of Senate members), with the scope to assure that the University Learning Analytics applied processes respect the related laws of the country (Data protection and Privacy related laws), as well as the EU laws, regarding the students as well as the institution staff (teachers, lecturers, administration). Inform the students on what data are stored and analyzed and why, Define the "Consent form for Students", as well as the "Data Protection Compliance" forms for all the involved personnel (e.g. ICT personnel, teachers, administration).

In addition to the above recommendations the University has to take into account the new European Regulation on Data Protection.

#### **D) Recommendation regarding the GDPR (General Data Protection Regulation) of the European Community, 25 May 2018.**

All the Universities have to assure their compliance with the GDPR European Regulation that was decided 18 months ago, and it is actually effectively applied, from 25 May 2018.

The Rector of University of Nicosia has assured the EEC that has started to explore the issue. However, it is to be noted that the compliance of all the processes of the UNIC needs time, effort and personnel as well as an important number of changes in the internal and external University procedures.

Taking into account that maybe other Universities present also delay on their preparation regarding GDPR regulation compliance, EEC would like to suggest to DIPAE to communicate with the Office of Commissioner for Personal Data Protection in Cyprus in order to supervise the current situation.



## 6. DOCTORAL PROGRAMS OF STUDY

N/A

## CONCLUSIONS AND SUGGESTIONS OF THE EXTERNAL EVALUATION COMMITTEE<sup>1</sup>

The panel believes that the University of Nicosia developed an interesting program for a new curriculum in Drug Regulatory Affairs, which is unique in its setup, as a distance learning program and the first to be offered in Southern Europe.

The program will be rolled out by an enthusiastic team of young teachers currently working at the University of Nicosia, supplemented by a number of newly appointed Special Scientists, providing the additional expertise from regulatory practice (both from Pharmaceutical companies and regulatory authorities).

The program will address the expressed need for skilled Regulatory Affairs specialists. Before the program can start, however, the panel recommends that the following weaknesses (including specific comments in Sections 1-5) will be addressed:

- The teaching team needs to ensure timely feedback to students on the top of the self-assessment.
- The teaching team needs to provide consistent criteria for marking (e.g. penalties when word limits are exceeded)
- The panel encourages to appoint one of the full-time teaching staff members per semester to oversee the quality and support the special scientists in the academic teaching.
- The panel noticed that the research project credits are not adequate to standard MSc programs. We recommend increasing the credit to 15 ECTS and align with other programs.
- There is a lack of sufficient training mechanisms. The Rector should initiate the process for the appointment of the appropriate personnel to establish the pedagogical planning unit for DL programs.
- To assure EU GDPR compliance for all UNIC processes as well as for the specific program.

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<sup>1</sup> It is highlighted, at this point, that the External Evaluation Committee is expected to justify its findings and its suggestions on the basis of the Document num.: 300.1. The External Evaluation Committee is not expected to submit a suggestion for the approval or the rejection of the program of study under evaluation. This decision falls under the competencies of the Council of the Agency of Quality Assurance and Accreditation of higher education.

Doc. Number: 300.1

## Quality Standards and Indicators

### External Evaluation of a Program of Study

Institution: University of Nicosia
Program of Study: MSc in Drug Regulatory Affairs
Duration of the Program of Study: 18 months
Evaluation Date: 24th May 2018

The present document has been prepared within the framework of the authority and competencies of the Cyprus Agency of Quality Assurance and Accreditation in Higher Education, according to the provisions of the “Quality Assurance and Accreditation of Higher Education and the Establishment and Operation of an Agency on Related Matters Laws of 2015 to 2016”.

The document describes the quality standards and indicators, which will be applied for the external evaluation of programs of study of institutions of higher education, by the External Evaluation Committee.

**DIRECTIONS:** Note what is applicable for each quality standard/indicator.

1. Applicable to a minimum degree
2. Applicable to a non satisfactory degree
3. Applicable to a satisfactory degree
4. Applicable to a very satisfactory degree
5. It applies and it constitutes a good practice

**It is pointed out that, in the case of standards and indicators that cannot be applied due to the status of the institution and/or of the program of study, N/A (= Not Applicable) should be noted and a detailed explanation should be provided on the institution’s corresponding policy regarding the specific quality standard or indicator.**

### Members of the External Evaluation Committee

NAME	TITLE	UNIVERSITY / INSTITUTION
Marie Louise De Bruin	Professor	University of Copenhagen
Angelique Dimitracopoulou	Professor	University of the Aegean
Dimitrios Lamprou	Professor	Queen's University Belfast
Dionysios (Dennis) Douroumis	Professor	University of Greenwich
Ioanna Zacharia	Student Representative	University of Cyprus

**Date and Time of the On-Site Visit: 23 May 2018**

**Duration of the On-Site Visit: 9h**

1. EFFECTIVENESS OF TEACHING WORK – AVAILABLE RESOURCES						
1.1	Organization of teaching work	1	2	3	4	5
1.1.1	The student admission requirements to the program of study, are based on specific regulations which are adhered to in a consistent manner.			X		
1.1.2	The number of students in each class allows for constructive teaching and communication, and it compares positively to the current international standards and/or practices.					X
1.1.3	The organization of the educational process safeguards the quality implementation of the program's purpose and objectives and the achievement of the learning outcomes. Particularly, the following are taken into consideration:					
1.1.3.1	The implementation of a specific academic calendar and its timely publication.					X
1.1.3.2	The disclosure of the program's curricula to the students, and their implementation by the teaching personnel					X
1.1.3.3	The course web-pages, updated with the relevant supplementary material					X
1.1.3.4	The procedures for the fulfillment of undergraduate and postgraduate assignments / practical training			X		
1.1.3.5	The procedures for the conduct and the format of the examinations and for student assessment					X
1.1.3.6	The effective provision of information to the students and the enhancement of their participation in the procedures for the improvement of the educational process.				X	
1.1.4	Adequate and modern learning resources, are available to the students, including the following:					
1.1.4.1	facilities					X
1.1.4.2	library					X
1.1.4.3	infrastructure					X

	1.1.4.4	student welfare						X
	1.1.4.5	academic mentoring						X
1.1.5	A policy for regular and effective communication, between the teaching personnel and the students, is applied.							X
1.1.6	The teaching personnel, for each course, provide timely and effective feedback to the students.							X
1.1.7	Statutory mechanisms, for the support of students and the communication with the teaching personnel, are effective.							X
1.1.8	Control mechanisms for student performance are effective.				X			
1.1.9	Support mechanisms for students with problematic academic performance are effective.							X
1.1.10	Academic mentoring processes are transparent and effective for undergraduate and postgraduate programs and are taken into consideration for the calculation of academic work load.							N/A
1.1.11	The program of study applies an effective policy for the prevention and detection of plagiarism.							X
1.1.12	The program of study provides satisfactory mechanisms for complaint management and for dispute resolution.							X

Justify the answer you have provided and note the additional comments you may have on each standard / indicator.

1.1.1: More clarity on the procedure and entry criteria into the program is required (e.g. bachelor grades and interview criteria).

1.1.3.4: the general procedures are sufficiently described. The panel recommends improving and provide more details of how to deliver the various assignments.

1.1.8: the student performance mechanisms could be analyzed by distant learning analytical indicators. Some existing provision in the Moodle platform have to be calibrated and used. Students have also raised the issue and they recommend that it should be improved further (this applies to paragraph 5.4 as well).

Note, additionally:

α) the expected number of Cypriot and International Students in the program of study.

The anticipated numbers from Cyprus is 20 students per academic year and 10-20 from abroad.

β) the countries of origin of the majority of students.  
The targeted countries are Cyprus, Greece, Italy and Middle East

γ) the maximum planned number of students per class-section.  
The maximum number of students per class is 30 and will be split in 15 if more students are registered.

1.2	Teaching	1	2	3	4	5
1.2.1	The methodology utilized in each course is suitable for achieving the course's purpose and objectives and those of the individual modules.					X
1.2.2	The methodology of each course is suitable for adults.					X
1.2.3	Continuous-formative assessment and feedback are provided to the students regularly.				X	
1.2.4	The assessment system and criteria regarding student course performance, are clear, adequate, and known to the students.				X	
1.2.5	Educational activities which encourage students' active participation in the learning process, are implemented.				X	
1.2.6	Teaching incorporates the use of modern educational technologies that are consistent with international standards, including a platform for the electronic support of learning.					X
1.2.7	Teaching materials (books, manuals, journals, databases, and teaching notes) meet the requirements set by the methodology of the program's individual courses, and are updated regularly.				X	

Justify the answer you have provided and note the additional comments you may have on each standard / indicator.

1.2.3: the course provides self-assessment options for the students on a weekly basis and what they describe as 2-3 summative assessments on which a feedback will be provided for each course.

The teaching team needs to ensure timely feedback to students on the top of the self-assessment.

1.2.4: the teaching team needs to provide consistent criteria for marking (e.g. penalties when word limits are exceeded)

1.2.5: The course includes discussion forums with the active participation of academics but also student chat forums. the panel suggest that the teaching team introduces more collaborative assignments for students to enhance participation (e.g. case studies)

1.3	Teaching Personnel	1	2	3	4	5
1.3.1	The number of full-time academic personnel, occupied exclusively at the institution, and their fields of expertise, adequately support the program of study.					X
1.3.2	The members of teaching personnel for each course have the relevant formal and fundamental qualifications for teaching the course, as described by the legislation, including the following:					
1.3.2.1	Subject specialization, preferably with a doctorate, in the discipline.					X
1.3.2.2	Publications within the discipline.					X
1.3.3	The specializations of Visiting Professors adequately support the program of study.					X
1.3.4	Special Teaching Personnel and Special Scientists have the necessary qualifications, adequate work experience and specialization to teach a limited number of courses in the program of study.					X
1.3.5	In every program of study the Special Teaching Personnel does not exceed 30% of the Teaching Research Personnel.			X		
1.3.6	The teaching personnel of each private institution of tertiary education, to a percentage of at least 70%, has recognized academic qualification, by one level higher than that of the program of study in which he/she teaches.					X
1.3.7	In the program of study, the ratio of the number of courses taught by full-time personnel, occupied exclusively at the institution, to the number of courses taught by part-time personnel, ensures the quality of the program of study.			X		

1.3.8	The ratio of the number of students to the total number of teaching personnel is adequate for the support and safeguarding of the program's quality.					X
1.3.9	The academic personnel's teaching load does not limit the conduct of research, writing, and contribution to the society.				X	
1.3.10	Future redundancies / retirements, expected recruitment and promotions of academic personnel safeguard the unimpeded implementation of the program of study within a five-year span.					X
1.3.11	The program's Coordinator has the qualifications and experience to efficiently coordinate the program of study.					X

Justify the answer you have provided and note the additional comments you may have on each standard / indicator.

1.3.5. The percentage of the specialized teaching personnel exceeds 60% due to the nature of the course. However, this is acceptable at this stage.

1.3.7: the teaching team has an excellent track record and the panel feels that they have the expertise to support the program. However, of the 18 teachers only 6 are full – time academic staff with major obligation in other programs. In addition, 4 out of the 10-compulsory course depend on external special scientists.

The panel encourages to appoint one of the full-time teaching staff members per semester to oversee the quality and support the special scientists in the academic teaching.

1.3.11: the panel is confident that the program Coordinator has strong experience to coordinate the program (including the MPharm). We advise some teaching relief when the program is accredited.

<b>2. PROGRAM OF STUDY AND HIGHER EDUCATION QUALIFICATIONS</b>						
<b>2.1</b>	<b>Purpose and Objectives and learning outcomes of the Program of Study</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
2.1.1	The purpose and objectives of the program of study are formulated in terms of expected learning outcomes and are consistent with the mission and the strategy of the institution.					X
2.1.2	The purpose and objectives of the program and the learning outcomes are utilized as a guide for the design of the program of study.					X
2.1.3	The higher education qualification and the program of study, conform to the provisions of their corresponding Professional and Vocational Bodies for the purpose of registration to these bodies.					N/A
2.1.4	The program's content, the methods of assessment, the teaching materials and the equipment, lead to the achievement of the program's purpose and objectives and ensure the expected learning outcomes.				X	
2.1.5	The expected learning outcomes of the program are known to the students and to the members of the academic and teaching personnel.					X
2.1.6	The learning process is properly designed to achieve the expected learning outcomes.				X	
2.1.7	The higher education qualification awarded to the students, corresponds to the purpose and objectives and the learning outcomes of the program.					X
<p>Justify the answer you have provided and note the additional comments you may have on each standard / indicator.</p>						

2.2	Structure and Content of the Program of Study	1	2	3	4	5
2.2.1	The course curricula clearly define the expected learning outcomes, the content, the teaching and learning approaches and the method of assessing student performance.				X	
2.2.2	The European Credit Transfer System (ECTS) is applied and there is true correspondence between credits and workload per course and per semester for the student either he / she studies in a specific program or he/she is registered and studies simultaneously in additional programs of studies according to the European practice in higher education institutions.					X
2.2.3	The program of study is structured in a consistent manner and in sequence, so that concepts operating as preconditions precede the teaching of other, more complex and cognitively more demanding, concepts.					X
2.2.4	The higher education qualification awarded, the learning outcomes and the content of the program are consistent.					X
2.2.5	The program, in addition to the courses focusing on the specific discipline, includes an adequate number of general education courses.					N/A
2.2.6	The content of courses and modules, and the corresponding educational activities are suitable for achieving the desired learning outcomes with regards to the knowledge, skills, and abilities which should be acquired by students.					X
2.2.7	The number and the content of the program's courses are sufficient for the achievement of learning outcomes.				X	
2.2.8	The content of the program's courses reflects the latest achievements / developments in science, arts, research and technology.					X
2.2.9	Flexible options / adaptable to the personal needs or to the needs of students with special needs, are provided.				X	
<p>Justify the answer you have provided and note the additional comments you may have on each standard / indicator.</p> <p>2.2.5: doesn't apply to MSc programs</p>						

Note the expected number of students who will be studying simultaneously at another academic institution, based on your experience so far, regarding students who study simultaneously in the programs of your institution.

2.3	Quality Assurance of the Program of Study	1	2	3	4	5
2.3.1	The arrangements regarding the program's quality assurance define clear competencies and procedures.					X
2.3.2	Participation in the processes of the system of quality assurance of the program, is ensured for					
	2.3.2.1 the members of the academic personnel					X
	2.3.2.2 the members of the administrative personnel					X
	2.3.2.3 the students.					X
2.3.3	The guide and / or the regulations for quality assurance, provide detailed information and data for the support and management of the program of study.					X
2.3.4	The quality assurance process constitutes an academic process and it is not restricted by non-academic factors.					X

Justify the answer you have provided and note the additional comments you may have on each standard / indicator.

The policy of the University of Nicosia is satisfactory. It should apply to all members of the program and the dimensions of the program.

2.4	Management of the Program of Study	1	2	3	4	5
2.4.1	Effective management of the program of study with regard to its design, its approval, its monitoring and its review, is in place.					X
2.4.2	It is ensured that learning outcomes may be achieved within the specified timeframe.				X	

2.4.3	It is ensured that the program's management and development process is an academic process which operates without any non-academic interventions.					X
2.4.4	The academic hierarchy of the institution, (Rector, Vice-Rectors, Deans, Chairs and Programs' Coordinators, academic personnel) have the sole responsibility for academic excellence and the development of the programs of study.					X
2.4.5	Information relating to the program of study are posted publicly and include:					
2.4.5.1	The provisions regarding unit credits					X
2.4.5.2	The expected learning outcomes					X
2.4.5.3	The methodology					X
2.4.5.4	Course descriptions					X
2.4.5.5	The program's structure					X
2.4.5.6	The admission requirements			X		
2.4.5.7	The format and the procedures for student assessment				X	
2.4.6	The award of the higher education qualification is accompanied by the Diploma Supplement which is in line with the European and international standards.					X
2.4.7	The effectiveness of the program's evaluation mechanism, by the students, is ensured.				X	
2.4.8	The recognition and transfer of credit units from previous studies is regulated by procedures and regulations which ensure that the majority of credit units is awarded by the institution which awards the higher education qualification.					N/A

Justify the answer you have provided and note the additional comments you may have on each standard / indicator.

2.4.7: a questionnaire is provided to the students at the end of the course which includes questions on course material evaluation, faculty evaluation, technology & platform evaluation and library evaluation (e-resources, journals). The panel noted that there are not questions about administrative support.

In the case of practical training, note:

- The number of credit units for courses and the number of credits for practical training
- In which semester does practical training takes place?
- Note if practical training is taking place in a country other than the home country of the institution which awards the higher education qualification

2.5	International Dimension of the Program of Study	1	2	3	4	5
2.5.1	The program's collaborations with other institutions are compared positively with corresponding collaborations of other departments / programs of study in Europe and internationally.					N/A
2.5.2	The program attracts Visiting professors of recognized academic standing.					X
2.5.3	Students participate in exchange programs.					N/A
2.5.4	The academic profile of the program of study is compatible with corresponding programs of study in Cyprus and internationally.					X

Justify the answer you have provided and note the additional comments you may have on each standard / indicator.

2.5.4: to our knowledge there is no such a program in Cyprus.

Also, comment on the degree the program compares positively with corresponding programs operating in Cyprus and abroad in higher education institutions of the same rank.

2.6	Connection with the labor market and the society	1	2	3	4	5
2.6.1	The procedures applied, so that the program conforms to the scientific and professional activities of the graduates, are adequate and effective.					X
2.6.2	According to the feasibility study, indicators for the employability of graduates are satisfactory.					X
2.6.3	Benefits, for the society, deriving from the program are significant.				X	

Justify the answer you have provided and note the additional comments you may have on each standard / indicator.

3. RESEARCH WORK AND SYNERGIES WITH TEACHING						
3.1	Research - Teaching Synergies	1	2	3	4	5
3.1.1	It is ensured that teaching and learning have been adequately enlightened by research.			X		
3.1.2	New research results are embodied in the content of the program of study.					N/A
3.1.3	Adequate and sufficient facilities and equipment are provided to support the research component of the program of study, which are available and accessible to the personnel and the students.					N/A
3.1.4	The results of the academic personnel's research activity are published in international journals with the peer-reviewing system, in international conferences, conference minutes, publications etc.					X
3.1.5	External, non-governmental, funding for the academic personnel's research activities, is compared positively to the funding of other institutions in Cyprus and abroad.					X
3.1.6	Internal funding, of the academic personnel's research activities, is compared positively to the funding of other institutions in Cyprus and abroad.					X
3.1.7	The policy for, indirect or direct, internal funding of the academic personnel's research activity is satisfactory.					N/A
3.1.8	The participation of students, academic, teaching and administrative personnel of the program in research activities and projects is satisfactory.					N/A
3.1.9	Student training in the research process is sufficient.			X		
<p>Justify the answer you have provided and note the additional comments you may have on each standard / indicator.</p> <p>3.1.1: drug regulatory affairs is an applied discipline. However, regulatory sciences, particular the subtype where tools and standards are developed that can facilitate regulatory decision making, offers the opportunity to do research. The panel</p>						

encourages the program faculty to explore the possibilities to identify topics where their current “basic” research activities align with regulatory procedures for drug approval and regulatory decision making.

3.1.9: The panel noticed that the research project credits are not adequate to standard MSc programs. We recommend increasing the credit of the Post Graduate Assignment (PHAR-614) to 15 ECTS and align with other programs at the University of Nicosia.

#### 4. ADMINISTRATION SERVICES, STUDENT WELFARE AND SUPPORT OF TEACHING WORK

4.1	Administrative Mechanisms	1	2	3	4	5
4.1.1	There is a Student Welfare Service that supports students with regards to academic and personal problems and difficulties.					X
4.1.2	Statutory administrative mechanisms for monitoring and supporting students are sufficient.					X
4.1.3	The efficiency of these mechanisms is assessed on the basis of specific criteria.			X		

Justify the answer you have provided and note the additional comments you may have on each standard / indicator.

4.1.3: the panel could not find the specific criteria of such mechanisms.

4.2	Infrastructure / Support	1	2	3	4	5
4.2.1	There are suitable books and reputable journals supporting the program.					X
4.2.2	There is a supportive internal communication platform.					X
4.2.3	The facilities are adequate in number and size.					X
4.2.4	The equipment used in teaching and learning (laboratory and electronic equipment, consumables etc) are quantitatively and qualitatively adequate.					X
4.2.5	Teaching materials (books, manuals, scientific journals, databases) are adequate and accessible to students.					X

4.2.6	Teaching materials (books, manuals, scientific journals, databases) are updated regularly with the most recent publications.					X
4.2.7	The teaching personnel are provided with training opportunities in teaching method, in adult education, and in new technologies on the basis of a structured learning framework.			X		
<p>Justify the answer you have provided and note the additional comments you may have on each standard / indicator.</p> <p>4.2.7: the teaching personnel have received training in new technological platforms (Webex, Moodle), usage of equipment and a written guideline on how to organize the course in a weekly basis (DL Handbook, 2018) but they haven't received any training in DL pedagogical approaches.</p>						
<b>4.3</b>	<b>Financial Resources</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
4.3.1	The management and allocation of the financial resources of the program of study, allow for the development of the program and of the academic / teaching personnel.					N/A
4.3.2	The allocation of financial resources as regards to academic matters, is the responsibility of the relevant academic departments.					N/A
4.3.3	The remuneration of academic and other personnel is analogous to the remuneration of academic and other personnel of the respective institutions in Cyprus.					N/A
4.3.4	Student tuition and fees are consistent to the tuition and fees of other respective institutions.					N/A
<p>Justify the answer you have provided and note the additional comments you may have on each standard / indicator.</p> <p>The panel didn't have sufficient information to access this section</p>						

The following criterion applies additionally for distance learning programs of study.

5.	DISTANCE LEARNING PROGRAMS	1	2	3	4	5
5.1	Feedback processes for teaching personnel with regards to the evaluation of their teaching work, by the students, are satisfactory.			X		
5.2	The process and the conditions for the recruitment of academic / teaching personnel, ensure that candidates have the necessary skills and experience for long distance education.		X			
5.3	Through established procedures, appropriate training, guidance and support, are provided to teaching personnel, to enable it to efficiently support the educational process.			X		
5.4	Student performance monitoring mechanisms are satisfactory.			X		
5.5	Adequate mentoring by the teaching personnel, is provided to students, through established procedures.				X	
5.6	The unimpeded long-distance communication between the teaching personnel and the students, is ensured to a satisfactory degree.				X	
5.7	Assessment consistency, its equivalent application to all students, and the compliance with predefined procedures, are ensured.				X	
5.8	Teaching materials (books, manuals, scientific journals, databases) comply with the requirements provided by the long-distance education methodology and are updated regularly.					X
5.9	The program of study has the appropriate and adequate infrastructure for the support of learning.					X
5.10	The supporting infrastructures are easily accessible.					X
5.11	Students are informed and trained with regards to the available educational infrastructure.					X
5.12	The procedures for systematic control and improvement of the supportive services are regular and effective.				X	

5.13	Infrastructure for distance education is comparable to university infrastructure in the European Union and internationally.					X
5.14	Electronic library services are provided according to international practice in order to support the needs of the students and of the teaching personnel.					X
5.15	The students and the teaching personnel have access to the necessary electronic sources of information, relevant to the program, the level, and the method of teaching.					X
5.16	The percentage of teaching personnel who holds a doctorate, in a program of study which is offered long distance, is not less than 75%.					X

Justify the answer you have provided and note the additional comments you may have on each standard / indicator.

5.1: there is a feedback process for teaching personnel with regards to the evaluation of their teaching work by the students via the DL evaluation questionnaire they provide at the end of the course. There are 8 questions regarding the overall academic performance but what is missing is a question for the students to assess the quality of the feedback/comments provided by the academics regarding the student assignment.

5.2: there is no recruited personnel for DL and the program is based on academics with experience in conventional teaching courses.

5.3: there is a lack of sufficient training mechanisms. The Rector should initiate the process for the appointment of the appropriate personnel to establish the pedagogical planning unit for DL programs.

5.4: the student performance mechanisms could be analyzed by distant learning analytical indicators. Some existing provision in the Moodle platform have to be calibrated and used. Students have also raised the issue and they recommend that it should be improved further.

5.6: the program is designed to use a range of communication tools in order to facilitate proper student communication.

5.7: the general assessment is consistent but we suggest having a more detailed assessment plan in place for each assignment.

If the following apply, note “√” in the appropriate space next to each statement. In case the following statements do not apply, note what is applicable:

The maximum number of students per class-section, should not exceed 30 students.	X
The conduct of written examinations with the physical presence of the students, under the supervision of the institution or under the supervision	X

of reliable agencies which operate in the countries of the students, is compulsory.	
The number of long distance classes taught by the academic personnel does not exceed the number of courses taught by the teaching personnel in conventional programs of study.	X

**The following criterion applies additionally for doctoral programs of study.**

6.	DOCTORAL PROGRAMS OF STUDY	1	2	3	4	5
6.1	The provision of quality doctoral studies is ensured through Doctoral Studies Regulations.					N/A
6.2	The structure and the content of a doctoral program of study are satisfactory and they ensure the quality provision of doctoral studies.					N/A
6.3	The number of academic personnel, which is going to support the doctoral program of study, is adequate.					N/A
6.4	The doctoral studies' supervisors have the necessary academic qualifications and experience for the supervision of the specific dissertations.					N/A
6.5	The degree of accessibility of all interested parties to the Doctoral Studies Regulations is satisfactory.					N/A
6.6	The number of doctoral students, under the supervision of a member of the academic personnel, is apt for the continuous and effective feedback provided to the students and it complies with the European and international standards.					N/A
6.7	The research interests of academic advisors and supervisors are satisfactory and they adequately cover the thematic areas of research conducted by the doctoral students of the program.					N/A
<p>Justify the answer you have provided and note the additional comments you may have on each standard / indicator.</p> <p>Note the number of doctoral students under the supervision of each member of the academic personnel of the program and the academic rank of the supervisor.</p>						

### FINAL REMARKS – SUGGESTIONS

The panel examined thoroughly the Program Specifications, the relative documents, the facilities and had extensive discussions with academics, students and technical support staff. The panel recommends accrediting the MSc Program of Drug Regulatory Affairs provided that the major issues listed on page 15 of this report are sufficiently addressed. The program will start in January 2019 and the panel believes that there is sufficient time to respond and comply with the above recommendations.

#### Names and Signatures of the Chair and the Members of the External Evaluation Committee:

Name:	Signature:
Marie Louise De Bruin	
Angelique Dimitracopoulou	
Dimitrios Lamprou	
Dionysios (Dennis) Douroumis	
Ioanna Zacharia	

Date: 24th May 2018