Response to the External Evaluation Report for
the Program of Study:
MSc Drug Regulatory Affairs

Nicosia
June 21 2018
Introduction

This is the response to the Report of the External Evaluation Committee (EEC) on the evaluation of the MSc Drug Regulatory Affairs Program (Distance Learning) dated May 23\textsuperscript{rd} 2018, which was prepared following the one-day on-site visit of the members of the Committee to the University of Nicosia.

First of all, we would like to thank the External Evaluation Committee for their professionalism in the performance of the tasks entrusted to them. The visit of the Committee to the University of Nicosia and the extensive discussion of all issues relating to the Program under evaluation led to a fruitful dialogue between the members of the Committee, the representatives of the University and the faculty members involved in the program.

The Committee's report has been carefully studied and discussed by the competent bodies of the University.

The EEC 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 EEC «recommends accrediting the MSc Program of Drug Regulatory Affairs provided that the comments listed on page 15 of the report (including the specific comments in Sections 1-5) are sufficiently addressed».

We have taken into consideration and implemented the Committee’s comments/recommendations for further improving the program under evaluation.

The particular and specific recommendations and comments of the Committee and the relevant actions are dealt with in what follows.
Particular and specific recommendations and comments by the Committee and the relevant actions taken

Section 1: Effectiveness of Teaching Work - Available Resources

1.1 Organization of Teaching Work

Comments/Recommendations/Findings

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

Answer/Action

After careful consideration, we fully agree with this recommendation which will be adopted. The admission procedure has now been revised to include a «Candidate Evaluation Form» (Annex 1) which describes the assessment criteria during the interview. We are confident that this procedure ensures that students accepted to the program will have the necessary knowledge and qualifications to meet the high standards of the program.

1.2 Teaching

Comments/Recommendations/Findings

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.

Conclusion/Suggestion 1: The teaching team needs to ensure timely feedback to students on the top of the self-assessment.

Answer/Action

We agree with the panel and we have explicitly added to the “General Assessment Guideline” the responsibility of each instructor to return to the students their work annotated with comments/feedback. Accordingly, feedback should be given within one week for formative assignments and within 2 weeks for summative assignments. Feedback can take the form or annotated comments on the online submitted work and it can be followed by Webex discussion if the student or the instructor feel that additional explanations are needed, or such feedback will be more constructive on a case by case basis.

Please find the amended “General Assessment Guide” in Annex 3.

Comments/Recommendations/Findings

1.2.4 : the teaching team needs to provide consistent criteria for marking (e.g. penalties when word limits are exceeded)
Conclusion/Suggestion 2: The teaching team needs to provide consistent criteria for marking (e.g. penalties when word limits are exceeded)

Answer/Action

We agree with the panel. For this reason additional marking criteria have been added in the “General Assessment Guide” (Annex 3) detailing rules on exceeding word limits or submitting late, if applicable. Accordingly, allowable excess word limits without penalties have been set to 10% for assignments up to 1000 words and 15% for assignments above 1000 words. For summative assignments that exceed these word limits, penalties will apply depending on the % excess words.

Further, instructions with regard to submission deadlines have been clearly indicated as well as penalties that may apply for late submissions.

In addition, since the nature and requirements for each assignment may be different, a more detailed assessment plan will be given for each specific assignment. For this reason, the “General Assessment Guide” has clearly indicated this responsibility of each instructor as per the comments of the panel on the Distance Learning programs p. 31, point 5.7 “the general assessment is consistent but we suggest having a more detailed assessment plan in place for each assignment”.

1.3 Teaching Personnel

Comments/Recommendations/Findings

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.

Answer/Action

We fully agree with this recommendation and we adopt it. We agree that the appointment of a full time staff can be invaluable for the quality of the Program. Thus, the following full-time teaching staff members have been appointed as semester coordinators:

Semester A’: Dr Lefteris Zacharia
Semester B’: Dr Elena Mourelatou
Semester C’: Dr Yiannis Sarigiannis
Comments/Recommendations/Findings

1.3.11 (p. 22) «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».

Answer/Action

The University acknowledges the workload of the Program Coordinator and as soon the program starts he will be granted 3 hours of teaching release per semester.

Section 2: Program of Study and Higher Education Qualifications

2.4 Management of the Program of Study

Comments/Recommendations/Findings

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.

Answer/Action

We fully agree with this recommendation and appropriate corrections and updates have been made to the questionnaire. A new section has been added to the questionnaire regarding the administrative support. This can be seen in the updated questionnaire which was discussed during the last Senate’s meeting on 14/06/2018. (Annex 2).

Section 3: Research Teaching Synergies

Comments/Recommendations/Findings

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 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.

Answer/Action

We value the recommendation of the EEC. Faculty is currently exploring these 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.

Answer/Action
After careful consideration, we fully agree and adopt this recommendation.
ECTS of PHAR-614 are increased to 15. Students in Semester C can choose one out of four electives (PHAR-609, is moved from the section of compulsory to the section of elective courses) and take one compulsory (PHAR-610) and the Postgraduate Assignment.
The Semester C breakdown is now as follows:

<table>
<thead>
<tr>
<th>Course Type</th>
<th>Course Name</th>
<th>Course Code</th>
<th>ECTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective</td>
<td>Product’s Life Cycle Activities</td>
<td>PHAR-609</td>
<td>7.5</td>
</tr>
<tr>
<td>Required</td>
<td>Pharmacovigilance and Pharmacoepidemiology</td>
<td>PHAR-610</td>
<td>7.5</td>
</tr>
<tr>
<td>Required</td>
<td>Post Graduate Assignment</td>
<td>PHAR-614</td>
<td>15</td>
</tr>
<tr>
<td>Elective</td>
<td>Regulation of Herbal Medicinal Products</td>
<td>PHAR-611</td>
<td>7.5</td>
</tr>
<tr>
<td>Elective</td>
<td>Regulation of Medical Devices</td>
<td>PHAR-612</td>
<td>7.5</td>
</tr>
<tr>
<td>Elective</td>
<td>Health Technology Assessment</td>
<td>PHAR-613</td>
<td>7.5</td>
</tr>
</tbody>
</table>

**PROGRAM REQUIREMENTS**

<table>
<thead>
<tr>
<th></th>
<th>ECTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compulsory courses (9)</td>
<td>67.5</td>
</tr>
<tr>
<td>Elective courses (1 out of 4)</td>
<td>7.5</td>
</tr>
<tr>
<td>Postgraduate Assignment</td>
<td>15.0</td>
</tr>
<tr>
<td><strong>Total ECTS</strong></td>
<td>90</td>
</tr>
</tbody>
</table>
Section 4: Administration Services, Student Welfare and Support of the Teaching Work

Comments/Recommendations/Findings

4.2 Infrastructure/Support

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.

Answer/Action

Please see answer below, page 8, point 5.3

Section 5: Distance Learning Programs

Comments/Recommendations/Findings

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.

Answer/Action

We fully agree with this recommendation and appropriate corrections and updates have been made to the questionnaire. This can be seen in the updated questionnaire in Annex 2 (questions 10&11).

Comments/Recommendations/Findings

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

Answer/Action

It is true that the program is based on Academics with experience in conventional teaching courses. The proposed program is a new one, and if accredited, will be the first DL program in Drug Regulatory Affairs in Southern Europe. The program deals with a specialised topic and of course the Academics’ scientific background, knowledge, experience in the field, as well as the nature of their science and teaching experience could not be (and have not been) offered by DL, prior to the development of this program. Consequently, personnel with deep knowledge of the subject matter (in our opinion an extremely important aspect for teaching in such program) and at the same time with extensive experience teaching online courses is rare.

To overcome this limitation the University has established the e-Learning Pedagogical Support Unit (ePSU) dedicated in supporting faculty in online teaching/distance learning. The ePSU will be providing constant support and training in the form of professional development activities.
and one-to-one support to help faculty to improve their distance learning/online teaching skills and successfully adapt to this new, to some faculty, delivery method.

In addition to the support from the ePSU most of the staff members involved in the program have already had the necessary training on DL through training programs already in existence at the University of Nicosia that support faculty in all distance learning programs at the moment. Further, we have reason to expect long term commitment from the recruited personnel, something that will give time to the personnel to improve and refine such skills.

Comments/Recommendations/Findings

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.

(p.11). […]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…]

**General Comment/Suggestion 5 (p. 15):** - 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.

It is recommended the functioning of this Pedagogical Planning Unit as soon as possible.

**Answer/Action**

The University formed the e-learning Pedagogical Unit (ePSU) back in July 2017 Dr. Christos Anagiotos has already signed a contract and will begin working at the University on September 1st, 2018 as the Director of ePSU. We note here that Dr. Anagiotos’ qualifications include a PhD in Adult Education and extensive experience in consulting with faculty about designing and teaching in online and distance learning settings.

One of the first activities of the ePSU will be to help faculty further in their online teaching by providing a number of resources including face-to-face and online workshops, online training (including webinars) and one-to-one consultation with faculty on the topic. The workshops and training will include (but not limited to) topics such as:

- Learners characteristics and needs and how to accommodate them in an online course.
- Common barriers faced by adult learners
- Education theories and practices
- Ways to increase learners’ participation in online threatened discussions/forums, wikis and other interactive tools.
- Creating a learning community in an online course and/or cohort.
- Using learning analytics to understand adult learners

We include here his CV (Annex 4).

Thus we have fully adopted the EEC recommendation.
Comments/Recommendations/Findings

5.3 : 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.

(p.12) “LEARNING ANALYTICS” approaches to support educational or administrative approaches

Answer/Action

We will use distant learning indicators (in the form of learning analytics) by employing existing provisions in the Learning Management System (Moodle) to generate information and support student learning.

Analytics provisions already incorporated in Moodle, will be used to:
- Provide feedback to students on their progress to improve their likelihood of success.
- Provide alerts and reports relating to student activity and progress to teaching and teaching support staff that would enable and inform appropriate intervention strategies to avoid student failure.
- Provide feedback to teaching staff on the effectiveness of their learning designs and teaching practices.
- Provide reports to the program coordinator that will help inform course revisions and curriculum renewal.
- Provide alerts and reports to University officials that would enable and inform appropriate management interventions and professional development strategies.

Regarding the recommendation for “the establishment of 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”.

The University of Nicosia takes seriously this recommendation and has already discussed this during the Senate meeting on 14/06/2017. The Senate decided the creation of this Committee comprising of the following Senate Members:

- Prof. Edna Yamasaki, Vice Rector of Academic Affairs (Chair)
- Prof. Achilles Emilianides, Dean of School of Law
- Assoc. Prof. Kyriakos Felekkis, Head of the Life and Health Sciences Department and Member of the Cyprus National Bioethics Committee.
Comments/Recommendations/Findings

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

Answer/Action

Please see answer to this comment under comment 1.2.4.

Other comments related to Distance Learning

(p.12) [...]Regarding the DIPAE criteria 7.4: There are missing the self-correction guides for self-assessment activities/exercises]

Answer/Action

“Self-Assessment Guide for Assignments” can be found in Annex 5. This Guide is also shown on the Moodle pages of the demo courses.

(p.12) [...] 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)]

Answer/Action

Collaborative learning activities are crucial for the program because of the nature of the field of Regulatory Affairs where collaboration is vital. Even though numerous collaborative learning activities are described in the study guides, the program will be enriched with more such activities. This procedure will be continuous and students will be dealing with real cases from both industry and the regulatory bodies. The expertise and the experience of the staff in regulatory affairs, especially for the members of the faculty staff who come from the industry assure this.

Other comments/conclusions/suggestions

Conclusion/Suggestion 5: Recommendation regarding the GDPR (General Data Protection Regulation) of the European Community, 25 May 2018.

Answer/Action
The University of Nicosia has proceeded to appoint Data Protection Officers (DPO) as per the GDPR who supervise the constant implementation of good practices and the compliance of UNIC procedures with the personal data regulations pursuant to the GDPR. We note that by virtue of the GDPR the system no longer relies on a central organ, i.e. the Office of Commissioner for Personal Data Protection in Cyprus who acts as the supervisory authority, but instead relies on the appointment of DPO’s for large institutions such as the University of Nicosia who consult and oversee the compliance process and who undertake the further communication with the Office of the Commissioner for Personal Data Protection. In view of the above, we consider that the University of Nicosia has undertaken all necessary actions in order to assure compliance with its GDPR obligations, noting of course that compliance is a constant process. We consider that the appointment of a DPO and the changes in the internal and external university policies fully address this recommendation of the external committee. Furthermore, we point out that the Office of the Commissioner already supervises the situation in accordance with the GDPR.
Conclusion

In closing, we would like to thank once again the Program External Evaluation Committee for their positive comments/recommendations, as well as for the constructive discussion we had.

We have seriously considered the Committees’ comments and recommendations. As it is evident in this response, we have fully addressed all the issues raised by the panel and adopted all their recommendations.

We are looking forward to your response and a positive decision regarding the accreditation of the Program, as per the recommendation of the EEC.

Dr Christos Petrou
Program Coordinator
Annex 1

Candidate Evaluation Form

<table>
<thead>
<tr>
<th>Applicant’s Name:</th>
<th>Date</th>
</tr>
</thead>
</table>

Please use this form as a guide to evaluate the applicant’s qualifications for entry to the MSc in Drug Regulatory Affairs (DRA). Check the appropriate numeric value corresponding to the applicant’s level of qualification and provide appropriate comments in the space below.

|---------------|----------------|--------------|------------------|------------|-----------------|

<table>
<thead>
<tr>
<th></th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5</td>
</tr>
</tbody>
</table>

Candidate’s Understanding of the Program:
Assess candidate’s understanding and awareness of the program objectives and expectations.

Relevant Education/Background: Rate the candidate’s knowledge, past working experiences (if any), and relevance of his/her education to entry criteria.

Professional Impression:
Consider self-confidence, maturity, to assess the candidate’s level of professionalism.

Motivation/Initiative:
Assess applicant’s ability to think and act independently, and be goal oriented. Why does this person want to get a MSc in DRA?

Interpersonal/Communication Skills:
Assess ability to express ideas and thoughts clearly, communicate effectively and clearly.

Appropriate Choice:
Assess candidates’ motivation to join the program at the University of Nicosia, including his/her rational for choosing the specific program.

DL program:
Assess the candidates’ awareness of the nature of DL program.

Critical Thinking:
Assess candidates’ ability to think critically, be open minded, and think outside the box.

Candidate’s Enthusiasm:
Overall assessment of candidate’s enthusiasm to a career in DRA and to the program.

Overall impression, Evaluation and recommendation:
Please add appropriate comments below:
Applicant Name:

Comments (Please summarize your perceptions of the candidate’s suitability to the program considering all of the above)

Recommendation:

☐ Accept  ☐ Reject___________  ☐  ☐  ☐
Annex 2: DL Student Evaluation Questionnaire

<table>
<thead>
<tr>
<th>No</th>
<th>Question</th>
<th>Strongly Agree (5)</th>
<th>Agree (4)</th>
<th>Neutral (3)</th>
<th>Disagree (2)</th>
<th>Strongly Disagree (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Course and Material Evaluation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>The study guide contained the weekly learning outcomes and learning material.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Comment box</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>The study guide was clear and directed my learning experience week by week.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Comment box</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>The course material included a variety of online tools to enhance the learning experience.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Comment box</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>The learning materials had sufficient interactivity.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Comment box</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Discussion fora were used as part of my learning activities.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Comment box</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>The videos and multimedia material in the course was useful.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Comment box</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Faculty Evaluation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>The lecturer encouraged group work and interactivity between students (i.e. through fora, wikis, WebEx etc.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Comment box</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Communication with the lecturer:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8a</td>
<td>The lecturer communicated effectively and efficiently in the forum discussions.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8b</td>
<td>The lecturer set convenient online office hours.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8c</td>
<td>The lecturer responded to e-mails in a timely manner.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8d</td>
<td>The lecturer was available to participate in online discussion upon request (i.e. one-to-one Skype meetings, etc.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. The lecturer set convenient hours for WebEx sessions.

10. The lecturer provided timely feedback through the platform.

11. The lecturer provided constructive feedback to assessments.

### Technology and Platform Evaluation

12. There was adequate support on how to use the online platform (instructions and guidelines).

13. Moodle was user-friendly.

14. Accessing and using WebEx was easy and convenient.

15. Accessing and using Student Intranet was easy and convenient.

16. The platform was running uninterrupted.

17. Using the Turnitin antiplagiarism software was easy and convenient.

### Library Evaluation

18. The provision of e-resources and material was adequate.

19. Accessing library e-resources was easy and convenient.

20. Remote (off-campus) access to library e-resources was available on a 24/7 basis.

21. There was adequate support on how to use the library e-resources (instructions and guidelines).
<table>
<thead>
<tr>
<th></th>
<th>Contact with the Distance Learning Administration support via telephone was:</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td>a efficient/timely.</td>
</tr>
<tr>
<td>22</td>
<td>b helpful.</td>
</tr>
<tr>
<td></td>
<td>Comment box</td>
</tr>
<tr>
<td>23</td>
<td>Contact with the Distance Learning Administration support via email was:</td>
</tr>
<tr>
<td>23</td>
<td>a efficient/timely.</td>
</tr>
<tr>
<td>23</td>
<td>b helpful.</td>
</tr>
<tr>
<td></td>
<td>Comment box</td>
</tr>
<tr>
<td>24</td>
<td>Contact with the Distance Learning Technical/LMS support via telephone was:</td>
</tr>
<tr>
<td>24</td>
<td>a efficient/timely.</td>
</tr>
<tr>
<td>24</td>
<td>b helpful.</td>
</tr>
<tr>
<td></td>
<td>Comment box</td>
</tr>
<tr>
<td>25</td>
<td>Contact with the Distance Learning Technical/LMS support via email was:</td>
</tr>
<tr>
<td>25</td>
<td>a efficient/timely.</td>
</tr>
<tr>
<td>25</td>
<td>b helpful.</td>
</tr>
<tr>
<td></td>
<td>Comment box</td>
</tr>
</tbody>
</table>
SCHOOL OF SCIENCES AND ENGINEERING

DEPARTMENT OF LIFE AND HEALTH SCIENCES

MSc IN DRUG REGULATORY AFFAIRS

General Course Assessment Guide
Course Assessment Guide

General

This is a general course assessment guide for courses in the MSc in Drug Regulatory Affairs. As part of the learning experience and evaluation of course mastering, for each course you have to complete:

- Summative assignments
- Formative assignments
- One Final examination.

Details for each of these assessments are found in the study guides of each course, as well as in Moodle under the tab “Formative/Summative assignments” of every week. Formative assignments are usually weekly exercises/quizzes and carry no assessment weight/points, and used for self evaluation. They are however returned to the tutor and the tutor provides feedback to the student.

Summative assessments are graded, and there are usually at least 2 or more summative assessments.

The assessment breakdown and the respective grade allocation is as follows irrespective of the course:

<table>
<thead>
<tr>
<th>Type of assessment</th>
<th>Weight</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summative assessments</td>
<td>40%</td>
<td>According to study guides</td>
</tr>
<tr>
<td>Formative assessments</td>
<td>-</td>
<td>Weekly</td>
</tr>
<tr>
<td>Final exam</td>
<td>60%</td>
<td>To be announced</td>
</tr>
</tbody>
</table>

If there is more than 1 summative assignment, each carries a proportional weight (unless otherwise stated) and the sum of all summative assignments is 40%.

The detailed schedule for the course exercises/quizzes (formative tasks) and assignments (summative assessments) as well as the topics can be found in the study guides and in Moodle under each week’s topic.

Deadlines for summative assignments are at midnight on the day specified in each study guide unless otherwise stated. A minimum of two weeks is provided for each summative assessment unless otherwise stated.

All assignments summative or formative will receive feedback. The instructor is obliged to give feedback to students within one (1) week for formative assignments and within two (2) weeks for summative assignments. Feedback will be in the form of annotated comments on the online submitted work (or track changes where applicable). Additional feedback may be
followed by webex discussion if the student or the instructor feels the need that additional explanations are needed, or that feedback will be more constructive by synchronous interaction.

In addition to this general assessment guide each assignment will be provided with more detailed assessment plan depending on the nature of the specific assignment. The detailed assessment plan can be found under each assignment.
Assignments Guidelines

- Consult each course study guide and/or moodle for the requirements of each summative/formative assignment. For each assignment you are responsible for researching the material or the question posed and prepare a well thought and structured appropriate response.

- Length of responses vary depending on the specific assignment. However they should not exceed 10-15% of the word limit, otherwise a penalty will apply as per the instructions below. Responses with a word limit of 1000 words or more can exceed word limit by no more than 15%, and responses with word limit below 1000 words can exceed word limit by no more than 10% without a penalty. Responses should be double spaced in normal type and font (Arial or Times New Roman size 12) with a minimum of 1” margins. A Front Page should be included with the following information: Course # and title, Students name, Instructor’s name, Date, Semester, etc.

- Each summative assignment should have a proper structure. It should consist of the following sections where applicable:
  
  o Title
  o Aim/Question
  o Introduction/Background
  o Discussion/Analysis
  o Conclusion
  o References

- All papers must be submitted electronically and presented in an orderly fashion under the week assigned. They should be uploaded in the sections under “Summative/formative assessments” of the week assigned.

- All reports/answers should include a bibliography of at least 5 references, if applicable. The references or citations must be shown at a separate reference page at the end of your paper. Members are encouraged to use the Harvard Referencing systems for presenting their bibliography.
Plagiarism is a serious offence and will be marked with ZERO. You can use the “Check your assignment for Plagiarism” available on moodle under “Assignments” in the “General Course Information” to check before submitting.

The assessment criteria for each summative assignment will be as follows:

<table>
<thead>
<tr>
<th>Assessment Criteria</th>
<th>Weight (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical evaluation/ Structure / originality</td>
<td>30</td>
</tr>
<tr>
<td>Content / related subject / completing the tasks/ Conclusion</td>
<td>60</td>
</tr>
<tr>
<td>Evidence of research / references/writing style/format/spelling</td>
<td>10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

Additional notes:

a. For formative assignments that are not graded, if the word limit exceeds 10-15% no feedback will be provided by the instructor and the student will be given one chance to comply with the word limit. In such a case the student will be given the chance to resubmit within 2 days complying with the word limit, otherwise no feedback will be provided.

b. For graded summative assessments, if the word limit exceeds the allowable 10-15% a penalty will apply according to the following table. For summative assessment no chance to resubmit will be given for exceeding the word limit,

<table>
<thead>
<tr>
<th>Word limit exceeded by</th>
<th>Penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>5%</td>
</tr>
<tr>
<td>30%</td>
<td>15%</td>
</tr>
<tr>
<td>40%</td>
<td>25%</td>
</tr>
<tr>
<td>50%</td>
<td>40%</td>
</tr>
<tr>
<td>&gt;50%</td>
<td>Not graded, receives an F</td>
</tr>
</tbody>
</table>

c. Submission deadlines. Please note carefully the deadlines for each assignment. Depending on the discretion of each instructor you may not be able to upload your work after the deadline which is midnight of the due date, or you may be able to submit it within no more than 1 day of the deadline. In the later case a penalty of 5% will apply. After the 1 day late submission grace period no submission will be possible and the student receives a zero on the assignment.
Christos Anagiotos, Ph.D.
Assistant Professor
Adult Education M.S. Program
Department of Leadership Studies and Adult Education
North Carolina A&T State University
1601 E. Market Street, Greensboro, NC 27411
+357 99481511, +1.336.285.4349
christos.anagiotos@gmail.com

EDUCATION

2016  Dual Ph.D. Lifelong Learning and Adult Education & Comparative and International Education
Department of Learning and Performance Systems
Pennsylvania State University, University Park, Pennsylvania, U.S.A.

2011  M.A. Adult Learning – Online Learning focus
Department of Educational Leadership
University of Connecticut, Storrs, Connecticut, U.S.A.

2007  B.A. Education Sciences – Primary Education
Department of Education
University of Cyprus, Nicosia, Cyprus

2003  A.C.C.A. Professional Qualification, Part 1
Diploma in Accounting & Business
Association of Chartered Certified Accountants, Glasgow, Scotland, U.K.

PROFESSIONAL EXPERIENCE

01/2017 - present  Assistant Professor, Tenure Track
North Carolina A&T State University, Adult Education M.S. Program
Teaching graduate courses in the areas of: Adult Education, Adult Learning and Development, Leadership, Assessment and Evaluation, Educational Research.
Conducting research in the areas of online learning, mobile learning, adult education, lifelong learning, comparative education, and workforce education.
Advising graduate students, serving in thesis & dissertation committees, grant writing and serving in administrative positions through committees.

2015-2016  Part-time Faculty
University of Nicosia, Distance Learning, School of Education
Taught Master’s level courses on qualitative research methods (3 semesters, 3 courses per semester).
2013-2014 Multimedia Project Manager & Evaluation Specialist – Graduate Assistant
Pennsylvania State University, World Campus, Media & Learning Design
Coordinated the design and developed of projects, incorporating media in courses in collaboration with faculty, instructional designers, video and media producers and administrators; consulted with faculty to improve teaching with the use of technology; assessed and evaluated learning experience and outcomes in courses using surveys, interviews, focus groups and learning analytics.

2012-2013 Lead Graduate Assistant & Teaching Assistant
Pennsylvania State University, College of Education, Adult Education
Taught online and in-person courses; consulted with faculty about the design of online courses, professional development workshops; conducted research in online learning and professional development; led and coordinated graduate assistants for the program; mentored teaching assistants; held administrative and organizing responsibilities.

2010-2012 Learning Consultant
Chameleon Learning Solutions, Ltd.
Designed, developed and evaluated learning projects; consulted with universities and corporate clients about needs assessment, development of learning programs and quality assurance procedures. Worked remotely on a project basis.

2009-2010 Adult Learning Consultant
Share Point Inc.
Developed and implemented the “Train the trainer” program. This project was part of the Practicum for my M.A. in Adult Learning at the University Of Connecticut.

2008-2010 Online Learning Facilitator - Graduate Assistant
University of Connecticut, Educational Leadership Dpt., Adult Learning Pr.
Worked as teaching facilitator in the School Administrator Preparation Program (UCAPP) hybrid (online and in-person) professional development program; consulted with faculty about technology use in teaching; conducted research in online learning, educational technology, adult learning and higher education; prepared program assessment and evaluation reports.

2007-2008 Elementary School Teacher
Agios Spryridonas Elementary School, Ministry of Education, Cyprus
Taught in the all-day-school science, math and computers in 4th, 5th and 6th grades.

2006-2008 Assistant Producer & TV Reporter
Cyprus Broadcasting Corporation & Cinercon TV Productions
Produced and reported for the youth TV program, “Eimaste do” (Είμαστε δώ)

2006-2007 Production Manager
International Puppet and Mime Festival, Cyprus
Organized and marketed plays, seminars, workshops and exhibitions.
OTHER PROFESSIONAL EXPERIENCES & SKILLS

Service & Leadership
Paper Reviewer for the Adult Learning Journal (2017)
Paper Reviewer for the Comparative & International Education Society’s conference (2014-17)
Vice President of the International Education Student Association, Penn State Univ. (2012-13)
Student Representative of the Adult Education program, Penn State University (2012-13)
Cultural Managing Director-Experimental Laboratory of Creative Expression, University of Cyprus (2004-07)

Language skills
English (fluent)
Greek (native)

IT Skills
NVivo, ATLAS (qualitative data analysis research software)
SPSS, STATA (quantitative data analysis research software)
Sawmill, Google Analytics (Learning Analytics Software)
Moodle, Blackboard, Elluminate, Task Stream & WebCT (learning platforms)
WebEx, Adobe Connect, Skype, Google Hangouts (video conferencing tools)
Google Docs, SharePoint, Wrike & Trello (online collaboration tools)
Photoshop, Camedia Master (image processing)
Windows Movie Maker, Power Producer (video editing)
Inspiration, Kidspiration (educational, instructional program)
Hyperstudio, Model it, Stagecast Creator (educational programming tools)
Second Life (online multiple application program)

PROFESSIONAL MEMBERSHIPS & AFFILIATIONS
American Association of Adult and Continuing Education (AAACE)
Adult Education Research Conference (AERC)
Commission for International Adult Education (CIAE)
Comparative and International Education Society (CIES)
Comparative Education Society in Europe (CESE)
Greek Teachers’ Association of Cyprus (ΠΟΕΔ)
Association of Chartered Certified Accountants (ACCA)

GRANTS, SCHOLARSHIPS & AWARDS
2012-2016 A.S. Onassis Foundation Dissertation Research Grant ($62,600)
2015 Dissertation Research Initiation Grant, Penn State ($600)
2014 Research Grant, Comparative International Education Program, Penn State ($500)
2010 Student Travel Award, American Association for Adult & Continuing Education
2008-2010 Leventis Foundation Grant for Graduate Students ($20,000)
2008-2010 Fulbright Traditional Scholarship for Graduate Studies ($50,000)
2007 Award for highest GPA in the School of Education from the University of Cyprus
2007 Award for excellent teaching performance from the Cyprus Teachers’ Association
2007 Ladommatos Award for Cultural Contribution, University of Cyprus
SAMPLE PUBLICATIONS


Manuscripts in Progress


SAMPLE CONFERENCE PRESENTATIONS (PEER-REVIEWED)


**Anagiotos, C.** (March, 2014). Cypriot, Greek-Cypriot or Turkish-Cypriot: Comparing national identity issues in Cyprus. *Comparative International Education Society Annual Conference (CIES)*.

**Anagiotos, C.** (March, 2013). One country or two? How Greek-Cypriot and Turkish-Cypriot youth learn their national identity. *Comparative International Education Society Annual Conference (CIES)*, Dissertation Mentoring Workshop.


**Anagiotos, C.** (November, 2012). What can we borrow from Neuroscience Brain-research? *Association of Adult and Continuing Education (AAACE) annual conference -Presentation / workshop for the Neuroscience Special Interest Group (SIG)*.


**Anagiotos, C.** & Bell, A. (October, 2010). Recent advances in neuroscience and implications for best practices to support adult learning. *Association of Adult and Continuing Education (AAACE) annual conference*. 
SCHOOL OF SCIENCES AND ENGINEERING

DEPARTMENT OF LIFE AND HEALTH SCIENCES

MSc IN DRUG REGULATORY AFFAIRS

Self-Assessment Guide for Assignments
Self-Assessment Guide for Assignments

For each course in the MSc in Drug Regulatory Affairs there are a number of self-assessment activities given almost every week as described in the study guide and in the online platform. The self-assessment activities for all courses may include written essay assignments, as well as quizzes. The aim of these self-assessment activities is to determine whether or not the learning objectives/outcomes have being met and mastered.

The nature of the courses in the MSc in Drug Regulatory Affairs is such that in most cases the answers to assignments are based on critical thinking and applying what has been learned. For all assignment feedback from the instructor will be given, but in addition, and before an assignment is turned in, self-assessment should also be done by each student. This will help identify the weaknesses and strengths and improve the learning experience.

**Note:** In addition to this “self assessment guide” please consult the “General assessment guide” regarding details on format, and rules that apply for assignments.

**Critical Thinking Rubric**

In assessing assignments a Critical Thinking Rubric is usually used which can help the student to assess the assignment before being turned in. In this regard after self-evaluation, changes can be made to improve the assignment. The Rubric helps define critical thinking in some detail. Most critical thinking tasks that instructors want their students to perform will be characterized by several if not all of the criteria described in the Rubric (shown below).

The Rubric not only defines the key dimensions of critical thinking, it also illustrates for students the typical performance levels on each dimension from “limited or no proficiency” to “high proficiency.” With practice and guidance students should be able to self-assess the assignments in order to determine the level of mastering and whether the objectives of the course/assignment have been met. Not each task in a course may require all criteria, but instructors can point their students to the ones that are important for a given assignment.

The critical thinking Rubric works best with a student assignment that reflect most of the assignments of the MSc in Drug Regulatory Affairs and that:

- Presents an open-ended, ill-defined problem which has more than one appropriate answer.
• Requires the student to develop a meaningful argument supported by evidence and followed by a conclusion.

• Is related to course readings or other sources that the student ought to consider as he or she critiques arguments from the literature and/or develops arguments of his or her own.

The Rubric’s criteria include aspects of critical thinking which are:

1. ISSUE/S: Identifies and concisely explains the problem/question at issue

2. CONTEXT: Recognizes the influence of the context on different stakeholders and the issue

3. OWN PERSPECTIVE: Presents the student’s own perspective and position related to the issue

4. OTHER PERSPECTIVES: Considers other salient perspectives and positions relevant to the issue

5. ASSUMPTIONS: Evaluates the key assumptions behind the claims and recommendations made

6. EVIDENCE: Evaluates the quality of supporting data/evidence and provides additional data as needed

7. IMPLICATIONS: Evaluates conclusions, implications, and consequences
## Critical Thinking Rubric

<table>
<thead>
<tr>
<th>Rating (1,2,3,4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No/Limited Proficiency (1 point)</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>1. Identifies &amp; explains ISSUES</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>2. Recognizes stakeholders and CONTEXTS (i.e., cultural/social, scientific, economic, ethical, personal experience)</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>3. Frames personal responses and acknowledges other PERSPECTIVES</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>4. Evaluates ASSUMPTIONS</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>5. Evaluates EVIDENCE</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>6. Evaluates</td>
</tr>
<tr>
<td><strong>IMPLICATIONS</strong>, conclusions, and consequences.</td>
</tr>
</tbody>
</table>
Self-evaluation questions

In addition to consulting the rubric for guidance and self-assessment students can also answer self-evaluation questions to determine if the level of mastering, or expectations have been realized, and if changes are needed.

Typical questions include:

- I am most satisfied with the following aspect of this assignment:
- I am least satisfied with the following aspect of this assignment:
- I incorporated feedback from my previous assignment into this one in the following ways:
- What I have learnt from undertaking this assignment:
- If I were marking this assignment myself, according to the Marking Criteria, I think a fair mark for it would be:
- Did I spent as much time as needed?
- What do I now understand about the subject?
- What are my strongest and weakest points? What did I do to improve the weak points?