



**Call for the International Two-Year University Level 2 Master in
"PHARMACOVIGILANCE"
Academic year 2017/2018
English language course**

The University of Camerino,

- GIVEN** the University By-Laws, issued with the University President's decree n. 194 of July 30, 2012 and published in the Official Gazette of the Italian Republic – General Series – First Part, n. 200 of August 28, 2012;
- GIVEN** the "Regulations for the establishment and functioning of university master programs, postgraduate specialization courses and professional development courses," promulgated in D. R. n. 9 of 12/11/2013;
- GIVEN** resolution n. 78 of 22/03/2017 of the School of Medicinal and Health Product Sciences;
- GIVEN** the minutes of the Master Commission of 16/05/2017;
- GIVEN** the resolutions of the Academic Senate n. 38 of 31/05/2017
- GIVEN** the decrees for the activation of the UNICAM master programs, for academic year 2016/17, n. 157 of 1/06/2017;

ACTIVATES

the International University Level 2 Master in "PHARMACOVIGILANCE"

GOALS AND OBJECTIVES

All medicinal products in the Western countries are subject to a strict testing and assessment of their quality, efficacy and safety before being authorised. Once placed on the market they continue to be monitored so to assure that any aspect which could impact the safety profile of a medicine is detected and assessed and that necessary measures are taken. This monitoring is called pharmacovigilance.

Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines. It is a key public health function. In summary, pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.

A unique characteristic of the Master, developed to meet the needs of working professionals, is its e-learning format for the theoretical part of the program. The face-to-face and practical parts of the formation will be conducted in a series of intensive internships performed in Rome.

PROFESSIONAL PROFILE

Working in pharmacovigilance is highly competitive and challenging. There is a growing need for qualified professionals for the pharmaceutical industry, regulatory authorities and academia. The postgraduate Master Course in Pharmacovigilance of the University of Camerino will provide high level formation for professionals who will work in the field.

PROGRAM OF STUDIES						
Title of the activity	Discipline	ECTS	Hours of e-learning formation	Structure of the credit		
				Number of hours face to face lessons	Number of hours alternative didactics	Number of hours individual study
Introduction to the Course and the Use of the E-learning Platform		3		15	30	30
Ethics and Regulatory Aspects of Medicinal Products Research, Development and Marketing authorizations (2 modules)	MED/43 MED/44	4	20	10	10	60
Bio-informatics and statistics	INF/01	2	16			34
History of Pharmacovigilance	BIO/14	2	15		5	30
Pharmacovigilance legislation	MED/43	5	50	5	15	55
Medical literature monitoring		2	15		5	30
Good Pharmacovigilance Practice (2 modules)	BIO/14	8	50	20	30	100
Medication Errors	BIO/14 MED/43	2	15		5	30
Risk and Signal Management	BIO/14 MED/43	2	15		5	30
Additional Monitoring of Drug Safety	BIO/14 MED/43	2	15		5	30
Post Authorization Safety Studies	BIO/14 MED/43	4	20	10	10	60
EUDRA Vigilance and Pharmacovigilance System (2 modules)	BIO/14 MED/43	8	50	20	30	100
Patient registres	BIO/14 MED/43	2	15		5	30
Pharmacovigilance of non pharmaceutical compounds	BIO/14 MED/43	4	20	10	10	60
			316	90	165	679
Internship to gain practical skills for pharmacovigilance		6	150			
Final examination and Thesis		4	100			
	Total hours		1500			

TEACHERS OF THE MASTER

Teachers of the Master will be enrolled after a public selection performed by the Master's Scientific Council.

STRUCTURE OF THE MASTER

The Master is composed of 14 units, each of which is in turn formed of one or more modules, for a total of 16 modules. A module includes a series of lessons, most of which employ e-learning, and a library in which learners can find carefully selected reference material that would otherwise be difficult to obtain. Each module is followed by an on-line test.

In addition to modules, there will be *case studies* that focus on some practical aspects of the management and practice of cosmetic medicine. There will also be on-line *forum* sessions in which a teacher guides discussion about a topic on the basis of preparatory material she or he will have previously sent to students. Other teachers will also participate in the discussion.

Before presentation and defence of the thesis, the student must pass a face-to-face exam on the fundamental content of the program of studies. At the end of the Master, the student must present and discuss her or his Master's thesis, as one of the requirements to earn the degree.

At the end of the program, participants will receive the two-year university level two Master degree.

INTERNSHIP (*obligatory*)

In addition to face-to-face lessons, e-learning and practical activities, there will be a six week internship in Rome

ADMISSION REQUIREMENTS

The Master is open to applicants who are employed, unemployed, or have never been employed, and who have a degree in Medicine and Surgery or in Pharmacy or Pharmaceutical Sciences.

All participants in the Master must have the computer skills and familiarity with internet use needed to follow the interactive e-learning lessons. They must have a multi-media personal computer with broadband service, and possess sufficient knowledge of scientific English.

Enrolment in the Master is not possible for those who in this academic year are already enrolled in an undergraduate, master, specialization, or doctoral degree program, or another course involving a year-long commitment (Law 270/2004, art. 5, c. 2).

UNIVERSITY DEGREE PROGRAM GROUPS

- | | |
|--|--|
| 1. <input type="checkbox"/> Agriculture | 9. <input type="checkbox"/> Education |
| 2. <input type="checkbox"/> Architecture | 10. <input type="checkbox"/> Literature |
| 3. <input checked="" type="checkbox"/> Pharmaceutical Chemistry | 11. <input type="checkbox"/> Languages |
| 4. <input type="checkbox"/> Economics-Statistics | 12. <input checked="" type="checkbox"/> <u>Medicine</u> |
| 5. <input type="checkbox"/> Physical Education | 13. <input type="checkbox"/> Politics-Sociology |
| 6. <input type="checkbox"/> Geology-Biology | 14. <input type="checkbox"/> Psychology |
| 7. <input type="checkbox"/> Jurisprudence | 15. <input type="checkbox"/> Sciences |
| 8. <input type="checkbox"/> Engineering | |

TERMS AND MODALITIES OF THE ENTRANCE TEST

If the number of applicants exceeds the maximum number of students allowed in the program, evaluation of the curriculum will be followed by a personal interview, which will count 30% in formulating the ranking of applicants. Previous documented activity in the area of the Master will serve as a preferential requisite for admission.

APPLICATION DEADLINE

31 January 2018

THE MASTER PROGRAM BEGINS

9 March , 2018

THE MASTER PROGRAM ENDS

January, 2019

NUMBER OF STUDENTS PER CLASSMinimum **15**Maximum **30****EXAMINATIONS**

For each module conducted through e-learning there will be an on-line test. At the end of the of the Master, students must pass a face-to-face examination to confirm that they have mastered the fundamental aspects developed during the year.

FEES for the Master:

A. FULL FEE	€ 3.200,00
B. FULL FEE WITH REQUIRED SIMULTANEOUS TRANSLATION FOR FRONTAL LECTURES	€ 3.600,00
C. REDUCED FEE FOR STUDENTS WITH DISABILITIES	€ 2.560,00
D. REDUCED FEE FOR STUDENTS WITH DISABILITIES WITH REQUIRED SIMULTANEOUS TRANSLATION FOR FRONTAL LECTURES	€ 2.880,00

PAYMENT INSTALLMENTS (MAXIMUM 2 INSTALLMENTS)

	First Installment By 31 January 2018	Second Installment By 31 July 2018
A. FULL FEE	€ 1.800,00	€ 1.400,00
B. FULL FEE WITH REQUIRED SIMULTANEOUS TRANSLATION FOR FRONTAL LECTURES	€ 1.800,00	€ 1.800,00
C. REDUCED FEE FOR STUDENTS WITH DISABILITIES	€ 1.800,00	€ 760,00
D. REDUCED FEE FOR STUDENTS WITH DISABILITIES WITH REQUIRED SIMULTANEOUS TRANSLATION FOR FRONTAL LECTURES	€ 1.800,00	€ 1.080,00

The payment of the second installment made after the above mentioned deadline will be charged with an additional fee of € 25.00.

The non-payment of the second installment, within thirty days after the above deadline will automatically result in the loss of the right to participate in the activities of the Master as well as to achieve the university Master Diploma.

APPLICATIONS

Applications addressed to the Rector of the University of Camerino, should be sent online by the deadline. Information and news about the application process, as well as possible modifications to the document of the competitive selection can be found at <http://www.unicam.it/reginfo/iscrizionemaster>. In case of difficulties, applicants can contact the Master's secretariat. For organizational reasons, once applicants have completed the application online, they are advised to send a copy of the application to master.pharmacovigilance@unicam.it. Help with the application process is available by phone from Monday to Friday, 10:00 to 12:30, and by e-mail at master.pharmacovigilance@unicam.it

The following documents must be sent with the application:

- a. signed declaration (Attachment A) available together with the application form;
- b. copy of a valid identification document;
- c. curriculum vitae in European format;
- d. other degrees and certificates useful for the selection.

ISSUING OF THE DIPLOMA

At the conclusion of the Master, only those who are up to date with their fee payments and have attended at least 75% of the face-to-face lessons will be able to take the final examination. Having passed the final examination, they will receive the University of Camerino Diploma for the University II Level Master.

After the application deadline, an applicant who decides against starting the Master will not be able to receive reimbursement for the amount paid.

Application to the Master entails tacit consent to the publication of personal data and results of the selection examination on the website of the Master, in line with D.L. 196 of June 30, 2003.

EVALUATION OF THE MASTER PROGRAM

Before the conclusion of the course, students must fill out the **Evaluation Form** provided by the Director of the Master or available on the UNICAM web site 'quick link' – MASTER E CORSI POST-LAUREA [MASTER AND GRADUATE COURSES], then MODULISTICA [FORMS].

DIRECTOR OF THE MASTER

Prof. Francesco Amenta tel. +39-0737-403311 and e-mail: francesco.amenta@unicam.it

SCIENTIFIC COUNCIL

Director	Prof. Francesco Amenta	Full professor	BIO/16
Vice Director	Dr. Alessandro Allegrini		
Member	Prof. Roberto Ciccocioppo	Full professor	BIO/14
Member	Prof. Seyed Khosrow Tayebati	Associate professor	BIO/16
Member	Prof. Daniele Tomassoni	Associate professor	BIO/16

ADMINISTRATIVE SECRETARIAT:

Administrative Secretariat of the Scuola di Scienze del Farmaco e Prodotti della Salute [School of Pharmaceutical and Health Product Sciences]

ORGANIZATIONAL SECRETARIAT FOR THE COURSE: (*information about application to the Master, information for course programs, dates, etc*)

Camerino: Scuola di Scienze del Farmaco e dei Prodotti della Salute [School of Medicinal and Health Product Sciences], Centro Ricerche Cliniche, Telemedicina e Telefarmacia [Center for Clinical Research, Telemedicine and Telepharmacy]

Dr. Isabel Pirillo

tel. +39-0737-403326 and e-mail: master.pharmacovigilance@unicam.it

**S.A.S. [SCHOOL OF ADVANCED STUDIES]- POLO DI ALTA FORMAZIONE
(*bureaucratic information*)**

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