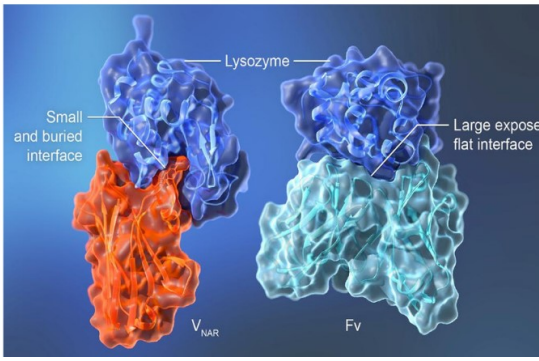
UNIMORE
UNIVERSITÀ DEGLI STUDI DI MODENA E REGGIO EMILIA

Dipartimento di Scienze della Vita

2ND LEVEL MASTER TRAINING PROGRAM IN:

DEVELOPMENT, MANUFACTURING AND AUTHORIZATION OF BIOPHARMACEUTICALS

Academic Year 2021-2022



INTRODUCTION TO THE PROGRAM

The past decade has seen a significant shift in the nature of the products being manufactured and sold by the innovative biopharmaceutical industry.

Nowadays, the global biopharmaceutical portfolio reflects **increased therapeutic competition**, a greater prevalence of the **biological drugs** and **biopharmaceutical products**, expansion in the number of **personalized or targeted drugs**, **advanced therapeutical medicinal products** and **genotype-specific vaccines**.

These changes, paired with the rise of advanced manufacturing technologies and the growing market of biosimilar drugs, are driving biopharmaceutical companies to seek **increasingly specialized employees/ experts** who possess experience and skills in the field, who can also work collaboratively on manufacturing innovation through **partnerships with academic institutions**, diagnostics developers, biopharmaceutical drugs substances manufacturers, and regulatory entities.

OBJECTIVES

The master aims to prepare specialized personnel with a high level of qualification, able to cover various professional positions within the biopharmaceutical drugs world. These professionals will be qualified as:

- **Manager/ Director of laboratories** with biotechnological and pharmacological characterization.
- **Coordinator of development and monitoring programs** of applied biotechnologies in the human health, regarding the industrial development of biopharmaceutical products, the industrial aspects of biotechnological drugs production, the management of scientific and process related data with artificial Intelligence (AI).
- **Expert in management of the regulatory aspects of the market authorizations**, of the ethical and legal implications for the marketing of biopharmaceuticals with aspects of environmental protection and sustainability.

WHO CAN ATTEND THE MASTER

- Graduate students with core competencies in the field of drug development and pharmaceutical, industrial biotechnology and bioengineering.
- PhDs with core competencies in the field of drug development and pharmaceutical biotechnology.
- Corporate personnel who wish to acquire high-level skills in the field of biopharmaceutical product development and manufacturing process including regulatory, ethical and sustainability aspects.

ORGANIZATION

The Master is structured in 1500 hours, for a total of 60 training credits (CFU), of which:

- 240 hours of face-to-face lectures;
- 375 hours of internship;
- 125 hours for the final test.

The remaining hours will be dedicated to individual study, workshops, discussion - individually and in groups - of leading cases, testimonials, company visits, aimed at ensuring the full acquisition of conceptual tools and applications. A 15-hour English course is available for the Master participants who wish to attend it, at the beginning of the course, as an additional benefit.

The Master Training Program will start in **May 2022**. Lessons will take place generally on Fridays (from 9.00 a.m. to 1.00 p.m. and from 2.00 p.m. to 6.00 p.m.) and Saturdays (from 9.00 a.m. to 1.00 p.m.), and will be held in mixed mode (presence / distance).
The Master developes the following topics: 1) Industrial development and manufacturing; 2) Clinical studies of biopharmaceutical products and new concepts in trial design and statistical approaches; 3) Data management in the various industrial processes and exploitation; 4) Regulatory aspects for the market authorizations; 5) Market access and sustainability.

COSTS AND REGISTRATION DETAILS

Application Deadline: April 19, 2022, 1:00 p.m.

Selection process: Qualifications assessment and motivational interview

Master training program enrolment fee:

€ 6'000.00 registration fee

€ 3'500.00 Auditor registration fee

Facilities for recently graduated students:

€ 4'000.00 for students who obtained a degree no more than three years before the application deadline

Enrolment methods and procedures are included in the Admission Announcement available on the website: http://www.masterbiopharmaceuticals.unimore.it/

SCIENTIFIC COMMITTEE

The scientific committee is constitued by of professors, researchers of private and public institutions, corporate directors, personnel managers, and experts with specific skills in pharmaceutical processes and up-front market able to ensure an advanced and multidisciplinary training on the topics covered by the master.

- **Prof. Maria Paola Costi**, PhD, professor of Pharmaceutical Chemistry at Unimore - Director of the Master Program
- **Prof. Maddalena Rossi**, PhD, professor of Chemistry and Biotechnology of fermentation at Unimore - Vice-director of the Master Program
- **Prof. Federica Pellati**, PhD, professor of Pharmaceutical Chemistry at Unimore
- **Prof. Graziella Pellegrini**, PhD, professor of Applied Biology at Unimore and R&D Director at Holostem Terapie Avanzate S.r.l.
- **Dr. Giacomo Capone**, PhD, Healthcare professional - Pharmacist, AIFA
- **Dr. Patrizia Caprari**, PhD, Research Director of Istituto Superiore di Sanità, Rome
- **Dr. Paul M. Selzer**, PhD, Boehringer Ingelheim VetmedicaGmbH
- **Dr. Elvira Marchianò**, PhD, Federchimica, Assobiotec

SOME OF OUR PARTNERS:

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CONTACTS

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For information on the Master program, please contact:
E-mail: master.biopharmaceuticals@unimore.it

Find more information at:
http://www.masterbiopharmaceuticals.unimore.it/

Master training program realized in collaboration with:

Fondazione Marco Biagi