UNIMORE
UNIVERSITÀ DEGLI STUDI DI MODENA E REGGIO EMILIA
Dipartimento di Scienze della Vita

In collaborazione con
Fondazione Marco Biagi

POST-GRADUATE -
2° LEVEL MASTER PROGRAM IN

Development, manufacturing & authorization of biopharmaceuticals

A.Y. 2024-2025

APR. 2025 - MAR. 2026
ONLINE

Introduction to the Program

The past decade has seen a significant shift in the products manufactured and sold by the innovative biopharmaceutical industry.
Nowadays, the global biopharmaceutical portfolio reflects **increased therapeutic competition**, a greater prevalence of 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** 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.
The teaching program of the 3rd Edition has been implemented with concepts in **Human Space Flight and Space Medicine**, a look at the need for a new way of thinking about drugs. A second concept is about **AI and data use, refinement, and management in the pharmaceutical industries**.

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 human health, regarding the industrial development of biopharmaceutical products, the industrial aspects of biotechnological drug production, and 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 fields 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, and **testimonials**, aimed at ensuring the full acquisition of conceptual tools and applications.

The Master's teaching program will start in April 2025. Classes will be held **online**, in live streaming, and will generally occur on Fridays (9.00 a.m. - 1.00 p.m. - 2.00 p.m. - 6.00 p.m.) and Saturdays (9.00 a.m. - 1.00 p.m.).
Once every 4-6 weeks students will be invited to join a class that will take place in Modena in-person and simultaneously online.

The Master develops the following topics: 1) Development and manufacturing; 2) Clinical studies; 3) Data management and exploitation; 4) Regulatory; 5) Market access and sustainability.

Costs and registration details

Please read more about the application procedure and the selection process on the call for admission to the master program (Art. 3).

Application Deadline: **February 20th, 2025 - 1:00 p.m.**

- **Registration fee**: € 6,000.00
- Reduction for **recently graduated students**: € 4,000.00

It is possible to register for one or more modules of the Master's program with the following options:

- Registration fee to attend as **auditor to the entire Master Program**: € 4,000.00;
- Registration fee to attend **module I - Development and Manufacturing**: €1,700.00;
- Registration fee to attend **module II - Clinical Studies**: €500.00;
- Registration fee to attend **module IV - Regulatory**: €1,500.00;
- Registration fee to attend **module V - Market Access and Sustainability**: €500.00.

Please read more about how to apply as an auditor in the call for admission to this master program and online, at: www.masterbiopharmaceuticals.unimore.it/admission/

Scientific Committee

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

- **Prof. Maddalena Rossi**, PhD, professor of Fermentation Chemistry and Biotechnology of fermentation at Unimore – Director of the Post-graduate 2nd Level Master Programme
- **Prof. Maria Paola Costi**, PhD, professor of Pharmaceutical Chemistry at Unimore – Vice-Director of the Post-graduate 2nd Level Master Programme
- **Prof. Graziella Pellegrini**, PhD, professor of Applied Biology at Unimore and Coordinator of Cellular Therapy at the Regenerative Medicine Center of the University of Modena and Reggio Emilia
- **Dr. Giacomo Capone**, PhD, Healthcare professional – Pharmacist, AIFA
- **Prof. Dr. Paul M. Selzer**, PhD, Boehringer Ingelheim Vetmedica GmbH
- **Dr. Elvira Marchianò**, PhD, Federchimica, Assobiotec

Stage

The **375-hour internship** will begin once lectures are over and will take place during weekdays, following the company's working hours. The internship can be carried out at some selected companies among the list of the master's partners, located in **Italy** or **abroad**. Please visit the master's website to see the updated list of partners. Please note that some partners may require a specific profile to accept candidates.
Read more on: www.masterbiopharmaceuticals.unimore.it/partners/

Contacts

For information about teaching and to become partner, please contact:

Prof. Maria Paola Costi
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For information about the Master program and how to apply, please contact:

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Phone: +39 059 205 6026/6036

Find more information at:

www.masterbiopharmaceuticals.unimore.it