



**University Milano - Bicocca**  
**Ph.D. Chemical, Geological and  
Environmental Sciences**  
**Chemical curriculum**



**SEMINAR**

**Thursday July 13, 2023 - 11.00**

**Room U4-06**

**Dott.ssa Benedetta Pasquini**

*Università degli Studi di Firenze*

*Segreteria Scientifica del Comitato Etico di Area Vasta Centro (CEAVC) Regione  
Toscana (Firenze)*

**ANALYTICAL CHEMISTRY FOR THE DEVELOPMENT OF  
NEW MEDICINES: FROM DRUG DISCOVERY TO MARKET**

The research and development of a new drug represent a very complex process. After the initial screening phase, preclinical research and laboratory experiments are carried out. After this, the extensive clinical trial process with human volunteers and patients begins. Before new medicines are available to patients in Europe, they must undergo regulatory evaluations.

The seminar aims to show the contribution of analytical chemistry in preclinical and clinical research to guarantee quality, safety and efficacy, the three prerequisites that any medicinal product must possess at every stage. Crucial topics of regulatory sciences will be addressed: from the Quality by Design in the development and validation of analytical methods for the determination of active ingredients and their impurities up to their evaluation in the European registration dossiers.

The Regulation (EU) n. 536/2014 on clinical trials of medicinal products for human use will be introduced together with real examples of documentation that Authorities are called to evaluate. Finally, the skills required for the emerging professional figures in the regulatory field will be presented, with the final scope of supporting the employability of the participants and facilitate their future transitions towards the labour market.