



**UNIVERSITÀ
DI PARMA**

DIPARTIMENTO DI SCIENZE
DEGLI ALIMENTI E DEL FARMACO

PhD course in
"SCIENCE OF DRUGS, BIOMOLECULES AND HEALTH PRODUCTS"

Master in
"PHARMACEUTICAL AND REGULATORY STRATEGIES
IN MEDICINAL PRODUCTS DEVELOPMENT"

**SAVE THE DATE!
May 23-24, 2019**



Workshop on

THE IMPORTANCE OF STATISTICS IN QUALITY BY DESIGN

How to use statistical tools
in a risk-based approach
to optimize formulation
and development

Organized by



Informed decisions
for better process.



STELLAR MEDICINES
FOR RARE DISEASES

**University of Parma,
Department of Food and Drug**

Room B

**Parco Area delle Scienze 27/A,
43124 Parma (Italy)**



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How to use statistical tools in a risk-based approach to optimize formulation and development

Agenda

DAY 1: MAY 23rd, 2019

09.30 - 10.00	Welcoming, introduction of participants
10.00 - 11.00	Opening Lecture: Quality by Design and the Pharmaceutical Industry 4.0 <i>D.M.Rekkas, Head, Dpt. of Pharmacy, University of Athens, Greece</i>
11.00 - 11.30	Coffee Break
11.30 - 13.00	Decision and risk in a QbD approach <i>Paolo Mazzoni, PTM Consulting, Sant'Ilario d'Enza (RE)</i>
13.00 - 14.30	Lunch
14.30 - 15.45	Risk management during development process <i>Paolo Mazzoni, PTM Consulting, Sant'Ilario d'Enza (RE)</i>
15.45 - 16.15	Coffee Break
16.15 - 17.00	Statistical tools during development process <i>Michele Vitali, PTM Consulting, Sant'Ilario d'Enza (RE)</i>
17.30 - 18.00	Final Discussion
Networking Dinner	

DAY 2: MAY 24th, 2019

09.00 - 9.30	Welcoming, introduction of participants
9.30 - 10.30	Factorial DoE: Design of Experiment as essential tool for Quality Risk Management <i>Michele Vitali, PTM Consulting, Sant'Ilario d'Enza (RE)</i>
10.30 - 11.00	Case study DoE: drug and packaging interaction during primary packaging change <i>Michele Vitali, PTM Consulting, Sant'Ilario d'Enza (RE)</i>
11.00 - 11.30	Coffee Break
11.30 - 12.00	Analytical Quality by Design: how to use Quality by Design to develop and validate analytical methods <i>Tiziana Peveri, PTM Consulting, Sant'Ilario d'Enza (RE)</i>
12.00 - 12.30	Case Study AQbD: DoE to optimize an analytical method robustness <i>Tiziana Peveri, PTM Consulting, Sant'Ilario d'Enza (RE)</i>
12.30 - 13.00	Final Discussion



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Companies



Informed decisions
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Founded in 2002, PTM Consulting works for leading pharmaceutical companies in Europe and the United States by applying the concepts and principles of Quality and Design, Process Validation, Product Validation, Lean Manufacturing, Transfer of Technology, Quality Risk Management to the early and full development phases -up process, industrialization and life-cycle management.

PTM Consulting provides solutions for the improvement and optimization of business products and processes from the early stages of development to the industrial ones, achieving the desired quality targets, minimizing cost and time development through an efficient and effective project management.

Through the Academy, PTM organizes and supplies educational courses customized on customers need, thanks to its technical competencies and its operational experience PTM Academy has educational and functional stream, always updated on technical and regulatory landscape.



STELLAR MEDICINES
FOR RARE DISEASES

PlumeStars s.r.l. is an innovative start-up company established in September 2013, specialized in drug delivery to lung for the treatment of respiratory diseases, stemming from a patent of the University of Parma.

The patented technology claims the molecular deposition of fatty acids on drug microparticles, to improve their aerodynamic behavior for aerosol administration. In particular, the company focuses on the development of antibiotics to treat lung infections in patients affected by Cystic Fibrosis.

Recently, PlumeStars acquired experience in developing novel orphan medicines. Pharmaceutical technologies applied to different APIs for innovative medicines with primary interest in inhalation. Amikacin & Tobramycin powders for inhalations in cystic fibrosis, Cisplatin films for local delivery in mesothelioma recurrences, Thalidomide powder for oral and nasal delivery in Hereditary Hemorrhagic Telangiectasia, are EMA and FDA designed orphan medicines assigned to PlumeStars.

PlumeStars collaborates with the University of Parma and the Interdepartmental Center for Innovation in Health Products Biopharmanet, to organize workshops, seminars and short courses in research skills for doctoral students and business company. Subject courses deal with the innovative pharmaceutical technology research and biopharmacy. Specialized courses focus on orphan medicines, antibiotics for inhalation, implantable chemioterapic, oral and nasal drugs.

PRIVACY POLICY

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