PhD course in
“SCIENCE OF DRUGS, BIOMOLECULES AND HEALTH PRODUCTS”

Master in
“PHARMACEUTICAL AND REGULATORY STRATEGIES IN MEDICINAL PRODUCTS DEVELOPMENT”

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

University of Parma,
Department of Food and Drug

Room B

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

### DAY 1: MAY 23rd, 2019

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

**Networking Dinner**

### DAY 2: MAY 24th, 2019

<table>
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<td>09.00 - 9.30</td>
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| 9.30 - 10.30 | Factorial DoE: Design of Experiment as essential tool for Quality Risk Management 
*Michele Vitali, PTM Consulting, Sant’Ilario d’Enza (RE)* |
| 10.30 - 11.00 | Case study DoE: drug and packaging interaction during primary packaging change 
*Michele Vitali, PTM Consulting, Sant’Ilario d’Enza (RE)* |
| 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  
*Tiziana Peveri, PTM Consulting, Sant’Ilario d’Enza (RE)* |
| 12.00 - 12.30 | Case Study AQBd: DoE to optimize an analytical method robustness          
*Tiziana Peveri, PTM Consulting, Sant’Ilario d’Enza (RE)* |
| 12.30 – 13.00 | Final Discussion                                                          |
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’ needs, thanks to its technical competencies and its operational experience. PTM Academy has educational and functional streams, always updated on technical and regulatory landscapes.

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 Biopharmaceuticals, 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 chemioterapeutic, oral and nasal drugs.

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