



**UNIVERSITÀ
DI PARMA**

DIPARTIMENTO DI SCIENZE
DEGLI ALIMENTI E DEL FARMACO

PHD COURSE ON SCIENCES OF DRUGS, BIOMOLECULES AND HEALTH PRODUCTS.
MASTER IN PHARMACEUTICAL AND REGULATORY STRATEGIES IN MEDICINAL PRODUCTS DEVELOPMENT.

TWO DAYS SEMINAR ON:

**QUALITY BY DESIGN IN PHARMACEUTICAL DEVELOPMENT:
THEORY AND CASE STUDIES**

Campus, University of Parma
Pharmacy Building, Padiglione 08
Room G

Parma, December 9-10, 2019

Lecturers:

Associate Professor D.M.Rekkas, *Head, Department of Pharmacy, National and Kapodistrian University of Athens, Greece*

Dr. S.N.Politis, *R&D Director (Non Respiratory), Elpen SA, Greece*

Organized by: Prof. Emeritus Paolo Colombo, PlumeStars srl, in collaboration with Advanced Accelerator Applications (A Novartis Company)



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DAY 1: MONDAY DECEMBER 9TH, 2019

9.30 - 10.00	Welcoming, introduction of participants
10.00 - 11.00	The Quality Guidelines, D.M.Rekkas
11.00 - 11.30	Coffee Break
11.30 – 13.00	Quality by Design, Knowledge Management and Statistical Thinking, D.M.Rekkas
13.00 - 14.30	Lunch
14.30 - 15.30	Design of Experiments, D.M.Rekkas
15.30 - 16.00	Mixture and Factorial designs: Theory and Practice-Case studies I, <i>D.M.Rekkas, S.N.Politis</i>
16.00 - 16.30	Coffee Break
16.30 - 17.30	Discussion- Question and Answers
20.00 - 23.00	Dinner all together

DAY 2: TUESDAY DECEMBER 10TH, 2019.

09.30– 11.00	Mixture and Factorial designs Theory and Practice-Case studies II, <i>D.M.Rekkas, S.N.Politis</i>
11.00 - 11.30	Coffee Break
11.30 - 13.00	Quality Risk Management in pharmaceutical product and process development, <i>S.N.Politis</i>
13.00 - 14.00	Lunch
14.00 – 15.30	Statistical Process Control and Capability Analysis – Theory and Practice-Case Studies, <i>S.N.Politis</i>
15.30 - 16.00	Coffee Break
16.00 - 17.00	Discussion- Questions and Answers. Case studies proposed by the participants