

TWO DAYS SEMINAR

April, 22nd-29th, 2021

QUALITY BY DESIGN IN PHARMACEUTICAL AND FOOD SUPPLEMENT DEVELOPMENT THEORY AND CASE STUDIES

LECTURERS:

D.M.Rekkas, PhD, Associate Professor and Director Pharmaceutical Technology, Dpt.of Pharmacy, University of Athens, Hellas.

S.N.Politis, PhD, R&D Director, ELPEN Pharmaceuticals S.A, Hellas.

KEY SUBJECTS:

Quality by Design - Quality Guidelines - Design of Experiments - Quality Risk Management- Statistical Process Control (SPC) & Control Charts – Process Capability Analysis (PCA) - Practical Examples - Discussion of the Case Studies as Proposed by the Participants.

This seminar will be delivered remotely through the Zoom platform

Organized by: *Prof. Emeritus Paolo Colombo, PlumeStars srl*

In collaboration with:

DAY 1: THURSDAY APRIL 22nd , 2021

The first day will be focused on delivering the body of knowledge required to understand the application of QbD and related Quality Quidelines.

09.00 - 09.15	Welcome Address by <i>Prof. P.Colombo and Dr.F. Nembri</i> Introduction of the Lecturers and the Participants
09.15 - 10.00	The Quality Guidelines – ICH Q8, Q9 and Q10. <i>D.M.Rekkas</i>
10.00 - 10.15	Q&A
10.15 - 11.00	Quality by Design, Knowledge Management and Statistical Thinking. <i>D.M.Rekkas</i>
11.00 - 11.15	Q&A
11.15 - 12.00	Design of Experiments I. <i>D.M.Rekkas</i>
12.00 - 12.15	Q&A
12.15 - 13.00	Lunch Break
13.00 - 13.45	Design of Experiments II. <i>D.M.Rekkas</i>
13.45 - 14.00	Q&A
14.00 - 15.30 <i>With a 10 min break at 14.40</i>	Statistical Process Control, Control Charts and Capability Analysis Theory and Applications. <i>S.N.Politis</i>
15.30 - 16.00	Q&A – Discussion

DAY 2 THURSDAY 29th, 2021:

The second day of the seminar will be focused on real life application examples and on analysis of 3 case studies as they were proposed in advance by SFI team.

09.00 - 09.45	Mixture and Factorial Designs: Theory and Practical Examples <i>D.M.Rekkas, S.N.Politis</i>
09.45 - 10.00	Q&A
10.00 - 10.45	Application of the QbD regulatory framework on CTD compilation: A practical example – Part one <i>S.N.Politis</i>
10.45 - 11.00	Q&A
11.00 - 11.45	Application of the QbD regulatory framework on CTD compilation: A practical example – Part two <i>S.N.Politis</i>
11.45 - 12.00	Q&A
12.00 - 12.45	Lunch Break
12.45 - 15.45	Analysis and discussion of the 3 case studies as proposed by the SFI team. <i>(10 minutes breaks every hour or as decided with the participants)</i>
15.45 -16.00	Closing Remarks by Professor P.Colombo and Dr.F.Nembri