makingeducation

ANNEX 1
CHAPTER AND TOPICS

GPIE EIPG

THE EIPG - EUROPEAN INDUSTRIAL PHARMACISTS GROUP - ORGANIZES A PROFESSIONAL TRAINING COURSE ON THE PRODUCTION OF STERILE PRODUCTS

WHAT ARE THE LEARNING OUTCOMES

1. To understand thoroughly the requirements of Annex 1
2. To be guided in the interpretation of critical requirements
3. To learn how to implement the requirements in terms of equipment, procedures, and training, with examples

WHO ARE THE TEACHERS

An international panel of professionals selected by EIPG among the top Annex1 experts

WHO IS THE COURSE ADDRESSED TO

Industrial pharmacists and other professionals working in the pharmaceutical sector who are interested in the manufacture of sterile medicinal products

HOW MUCH DOES IT COST

Price reserved for members of EIPG associations
- € 300 for the single module
- € 1.800 for the complete course

Price for non-members of EIPG associations
- € 400 for the single module
- € 2.500 for the complete course

8 TRAINING WEBINARS

- 8 LIVE STREAMING MEETINGS
- 24 HOURS OF TRAINING
- HIGHLY QUALIFIED EUROPEAN TEACHERS
- DOWNLOADABLE STUDY MATERIALS
- END OF COURSE CERTIFICATE

SCIENTIFIC DIRECTOR

PIERO IAMARTINO

President of EIPG

ITALY

FACULTY

FRANCESCO BOSCHI

Sr. Manager Technical Services - Global Microbiology and Aseptic Support Team (MAS) Pfizer
ITALY

WALID EL-AZAB

Co-founder & Managing Director QP Pro Services
Extensive expertise in GMP of sterile products
BELGIUM

TRACY MOORE

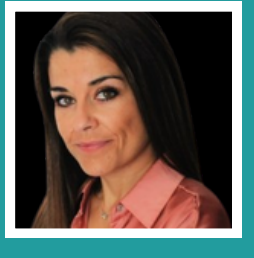
Founder and CEO at TM Pharma Group Ltd and former MHRA Expert EU GMDP inspector
UK

PATRIZIA MUSCAS

Sterility Assurance Director, Global TS.MS Eli Lilly and Company
ITALY

STAN O'NEIL

Managing Director The Compliance Group
Assistant Professor Trinity College Dublin
Honorary Associate Professor Royal College of Surgeons In Ireland
iRELAND



MARTA RODRIGUEZ

Quality Assurance Leti Pharma
Expert in Quality Assurance, GXP Compliance, Regulatory Affairs & Pharmacovigilance
SPAIN

MARK THOMPSON

Managing Director MTL Projects Ltd
Expert in pharmaceutical engineering, especially in sterile product manufacturing
UK

MODULE 1

21ST FEBRUARY 15.00 - 17.30 (CET)

WALID EL-AZAB
MARTA RODRIGUEZ

ENROLL MODULE 1:

CLICK HERE

Annex 1 Chapters and Paragraphs considered:

2. Principle
General principles as applied to the manufacture of sterile products - CCS (**2.1 – 2.7**)

3. Pharmaceutical Quality System (PQS)
Highlights the specific requirements of the PQS when applied to sterile products (**3.1 – 3.2**)

7. Personnel
Guidance on the requirements for specific training, knowledge and skills. Also gives guidance regarding the qualification of personnel. (**7.1 – 7.18**)

MODULE 2

28TH FEBRUARY 15.00 - 17.30 (CET)

TRACY MOORE

ENROLL MODULE 2:

CLICK HERE

Annex 1 Chapters and Paragraphs considered:

4. Premises
General guidance for premises design and qualification:

- Barrier Technology Isolators and RABS (**4.1 – 4.22**)
- Cleanroom and clean air equipment qualification (**4.23 – 4.32**)
- Disinfection of cleanrooms (**4.33 – 4.36**)

MODULE 3

6TH MARCH 15.00 - 17.30 (CET)

MARK THOMPSON

ENROLL MODULE 3:

CLICK HERE

Annex 1 Chapters and Paragraphs considered:

5. Equipment
General guidance on the design and operation of equipment. (**5.1 – 5.9**)

6. Utilities
Guidance regarding the special requirements of utilities such as water, gas and vacuum. (**6.1 – 6.22**)

MODULE 4

13TH MARCH 15.00 - 17.30 (CET)

WALID EL-AZAB
STAN O'NEIL

Annex 1 Chapters and Paragraphs considered:

8. Production and specific technologies PART 1

- Terminally sterilized products (**8.1 – 8.6**)
- Sterilization (**8.34 – 8.49**)
- Sterilization by heat and moist heat sterilization (**8.50 – 8.65**)
- Dry heat sterilization (**8.66 – 8.70**)
- Sterilization by radiation and with ethylene oxide (**8.71 – 8.78**)

ENROLL MODULE 4:

CLICK HERE

MODULE 5

20TH MARCH 15.00 - 17.30 (CET)

STAN O'NEIL

Annex 1 Chapters and Paragraphs considered:

8. Production and specific technologies PART 2

- Aseptic preparation and processing (**8.7 – 8.18**)
- Finishing of sterile products (**8.20 – 8.33**)
- Filter sterilization (**8.79 – 8.95**)

ENROLL MODULE 5:

CLICK HERE

MODULE 6

27TH MARCH 15.00 - 17.30 (CET)

TRACY MOORE

Annex 1 Chapters and Paragraphs considered:

8. Production and specific technologies PART 3

- Form-Fill-Seal and Blow-Fill-Seal (**8.96 – 8.120**)
- Lyophilization (**8.121 – 8.126**)
- Closed systems (**8.127 – 8.130**)
- Single use systems (**8.131 – 8.139**)

ENROLL MODULE 6:

CLICK HERE

MODULE 7

10TH APRIL | 15.00 - 17.30 (CET)

STAN O'NEIL

Annex 1 Chapters and Paragraphs considered:

9. Environmental and process monitoring PART 1

- General (**9.1 – 9.13**)
- Environmental monitoring - total particle (**9.14 – 9.21**)
- Environmental and personnel monitoring (**9.22 – 9.31**)

ENROLL MODULE 7:

CLICK HERE

MODULE 8

17TH APRIL | 15.00 - 17.30 (CET)

PATRIZIA MUSCAS
FRANCESCO BOSCHI

Annex 1 Chapters and Paragraphs considered:

9. Environmental and process monitoring PART 2
Aseptic process simulation (**9.32 – 9.49**)

10. Quality Control
Guidance on some of the specific Quality Control requirements relating to sterile products **(10.1 – 10.11)**

ENROLL MODULE 8:

CLICK HERE

FULL COURSE ENROLL:

CLICK HERE

SCIENTIFIC COMMITTEE

GPIE
EIPG

ORGANIZING PROVIDER

makinglife

MakingLife srl
Via Pascoli 60
20133 Milano
02 80897963
info@makinglife.it