QUINTESSENCE ENTERPRISES LTD
Vocational Training Centre

Manufacturing of Sterile Pharmaceutical

The Revised EU-PIC/S Annex 1 on sterile manufacturing and an insight on the main requirements and associated difficulties pertaining to the successive steps for terminal sterilization and the aseptic processes.

14 & 15 May 2018
08:30 - 17:15
Nicosia

Course's fee and VAT[1]:
HRDA Beneficiaries:
One Participant 1X€230,00
Two Participants 2X€125,00
Three Participants 3X€100,00
More than 3 participants: €600[2] + VAT
Non HRDA Beneficiaries[3]:
€1000,00 + VAT

Dr Jean-Denis Mallet
GMP Expert Consultant at NNE

Training Methods: Blended learning with face - to - face and asynchronous electronic learning through the internet platform:
www.quintessenceLMS.org

Social networking of Quintessence Enterprises Ltd:

(1) The VAT is calculated over the amount of the total fee (including the subsidy (€1530,00))
(2) Per Person
(3) Company visit not included

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Course Content

Day 1
Introduction
Terminal sterilization & aseptic processing
Why manufacturing sterile products? History and background.
What is sterility – How far can a sterile product be sterile (Sterility validation)
Case study : from controlled bioburdens to acceptable sterility assurance levels
The different classes of sterile products from external to internal dosage forms
The process of quality risk management
The process of root cause analysis and product impact assessment
Essential requirements for non-parenteral and parenteral products
The history of 1970's GMP applied to sterile products (FDA, WHO and PIC/S)
The continual increase of EU-GMP for sterile products (1989, 2001, 2003, 2008)
Evolution of the Media-Fill-Test over the successive editions

Day 2
Day One Summary - Anonymized results from the two mini quiz
Summary on the revision of the Annex 1 (EU-PIC/S)
Scope of the Revised Annex 1
Glossary
Principle
General
Pharmaceutical Quality System with a focus on investigation & CAPAs,
Personnel
Premises
Equipment with a focus on barrier systems
Utilities with a focus on water for injection
Production and specific technologies
Non viable and viable environmental and process monitoring
Quality Control
Setting the limits and evaluation of trends
Rapid microbial methods

Benefits in attending:
- Recognize the institutional framework applied in the European Union, America and Japan to produce sterile pharmaceutical products.
- Distinguish the specific characteristics of different types of sterile pharmaceutical products
- List the parameters that define aseptic processes for the production of sterile pharmaceutical products
- Evaluate and manage the risk of sterile pharmaceutical products .
- Separate the practices involved in the production of parenteral and non-parenteral sterile pharmaceutical products
- Apply techniques to minimize microbial contamination of sterile pharmaceutical products
- Distinguish the cleanliness classes of production areas and the types of air cleanup monitoring equipment .

ΔΗΛΩΣΗ ΣΥΜΜΕΤΟΧΗΣ

Οργανισμός: …… μM* ☐ M* ☐

Οικονομική Δραστηριότητα ……Κίνητρα Συμμετοχής** 1 2 3

Τηλ:…… Φαξ:…….. Email:……..
Άτομο Επικοινωνίας: email: Τηλ:

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Επώνυμο και Όνομα Συμμετεχόντων: email: Κιν. Τηλ.:***

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* μM: Μικρομεσαία Επιχείρηση, M: Μεγάλη Επιχείρηση
** Κυκλώστε: 1. Προσωπική Ανάπτυξη, 2. Νομοθετική Συμμόρφωση, 3. Επιχειρηματική Αριστεία
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ΑνΑΔ