QUINTESSENCE ENTERPRISES LTD
Vocational Training Provider

Global Competitiveness Strategies through Regulatory Compliance & Best Practices in GMP

How to make use of your advantage of best GMP compliance to enter the global market in the pharmaceutical sector?

May 10&11, 2010
Limassol

Course Fee

HRDA Beneficiaries
SMEs:~ €150-300* + ΦΠΑ
LEs:~ €250-500* + ΦΠΑ
Non HRDA Beneficiaries:
€650 + VAT

David R. Buckley
GMP/GLP Consultant

*The approved fee by the HRDA is €2000. The due fee by each participant depends on his/her company cost . How to calcualate the exact fee? Please call in 22466500.

For more details:
www.quintessence.com.cy

Quintessence Enterprises Ltd
Kennedy Business Center,
12 -14 Kennedy Avenue, Office 208
1087 Nicosia, Cyprus
Tel.:+357 22466500
Fax:+357 22560260
E:mail:quintessence@cytanet.com.cy
website: www.quintessence.com.cy

Course Content

The Global Regulatory GMP-scene.
Changes in the PIC/S.
Revision of PE009-09 Annex 1 for Sterile manufacturing, environmental monitoring, room classification, hygiene zones, particle counting,
Changes to Eudralex Vol 4 during 2009-09-12
WHO New revised GMP guidelines
Review of cleaning validation requirements
Practical – setting up matrixes of products, calculation of cleaning validation results.
The GMP of powders and tablets.
Tablet development in practice.
Beyond GMP, ICH Q10 – complying with the requirement for Quality System:Setting up a three level quality system, Policies, Technical Guides, Manufacturer's manuals, Training requirements
GMP Audit Process review. Six steps to successfully surviving GMP audits
Current most common US FDA inspection findings
Process validation review and Matrix validation - Design of experiment (DOE)
Fractional Designs, Screening experiments, Resolution of a design, Building an appropriate model.
Practical – Process validation studies using Matrix validation and Design of experiment (DOE).
How to Audit Active Pharmaceutical Ingredient Manufacturers
Why audit API Manufacturers? EU Directive 2004/27/EC (Regulator's view)
What are the requirements?
What role should secondary manufacturers play?
Product Transfers and Technology Transfers. Intellectual Property, Technology, Techniques. Regulatory Considerations
Variation Procedures, Types of Variations
Human challenges

Course Benefits: Delegates will be able to:

- Understand the benefits of best compliance to GMP regulations and, as a result of this, how to penetrate the global market with innovative pharmaceutical products.
- Set up the strategy to develop the competitiveness of the Cyprus pharmaceutical industry in the global market.
- Develop new products based on modern experimental design schemes.

APPLICATION FORM

Company :……

Tel……. Fax:…….. Email:……..

Name and surname	email	Mobile Phone
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Τα προγράμματα εγκρίθηκαν από την ΑνΑΔ. Οι επιχειρήσεις που συμμετέχουν με εργοδοτούμενούς τους, οι οποίοι ικανοποιούν τα κριτήρια της ΑνΑΔ, θα τύχουν της σχετικής επιχορήγησης.

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ΑνΑΔ