Effective Packaging Training

design cognition

Healthcare Packaging Regulations & Requirements -

A One Day Introductory Course - **1st November 2011**

Pharmaceutical packaging is a very specialised area with its own unique issues and problems. This practical one day workshop will provide delegates with essential information and an appreciation of the information requirements for the successful compilation of the packaging elements of Marketing Authorisation (MA)/ Product Licence (PL) applications. The course is delivered by experts who each have over 25 years experience in Regulatory Affairs and pharmaceutical product and packaging development.

Who should attend

- Packaging Technologists
- Regulatory Trainees
- Packaging and Product Designers
- Project Managers
- Clinicians
- Purchasers & Buyers
- Quality Assurance & Control Personnel
- New Product Development Personnel

Course Content

The European Legislative Framework -
- Understanding the legislation & how to work your way through it

Control of Pharmaceutical Packaging -
- Requirements for each component
- Expectations of the Regulatory Authorities

Marketing Authorisation Applications -
- Which sections apply to packaging components & processes
- What data is required in what format

Basic Data Requirements for Applications -
- Additional data for devices
- How this is generated & captured for the MA
- What other considerations?

How is the Pack Tested? -
- What stability data is required
- Best Practice in generation & supply of data

Labelling & Leaflets -
- Key requirements for pack text
- Readability Guidelines :
  - What they are & how to apply
- Testing requirements & how to ensure best chance of success

Post Licensing & Variations -
- Maintaining the licence
  - What is required

By the end of this interactive course you will have :

1. Appreciate the key data requirements for the justification of the preferred marketing pack for inclusion in a licence application (EU).
2. Have the knowledge to understand the key terms and requirements of each stage of the packaged product elements in the registration process.
3. What is required to maintain and support the packaging of a licensed medicine.

Booking Price £495 + VAT

Fee includes a full set of course documentation as well as refreshments and lunch

Venue: Nottingham, UK. For further details or to register: Email: training@designcognition.com or Telephone: +44 (0)115 846 1914 or Visit: www.designcognition.com/training

(NB places cannot be reserved without full payment)