

An Introduction to the Preparation, Packaging and Labelling of Clinical Trial Supplies

How It All Comes Together

Course ID # 2753



who should attend

The introductory training will provide an overview of the key procedures and techniques involved in the preparation of clinical trial supplies. The training is intended for those who are new to clinical supplies or individuals who may interact with clinical supplies personnel /third party providers and want to understand the clinical supply chain or re-fresh their knowledge.

This online training will benefit professionals in the following industries:

- Pharmaceutical
- Biotechnology
- Contract Clinical Research (CRO)
- Contract Clinical Packaging and Logistics

Thus, it will be of interest to those in the following Job Functions:

- Packaging
- Clinical Manufacturing
- Clinical Trial Label Design
- Clinical Research Associate
- Logistics
- Quality Assurance/Quality Control
- Interactive Voice Response Systems- IVR/IWRS
- Hospital Pharmacists Involved in Clinical Trials

In Departments such as:

- Research and Development
- Quality
- Clinical Supplies
- Clinical

learning objectives

Upon completion of this training, you will be able to:

- Define the key elements of the clinical supply chain and the scope of activities required to provide clinical trial supplies;
- Specify the core principles around label design and packaging for multinational studies;
- Identify strategies that can be employed to optimize global clinical supply logistics

course description

The aim of this 90-minute accredited online training is to provide a high level overview and introduction to the key aspects involved in designing a clinical supply chain which is fit for today's rapidly evolving trial landscape. Emphasis will be placed on the optimal design for labels, packaging and global supply logistics.

Examples will be provided of strategies that can be employed to ensure the overall supply chain can work flexibly with changes in clinical trial design.

course outline

Review of Learning Objectives

Module 1:

- Overview of the Drug Development Process
- Description of a Typical Clinical Supply Chain

Module 2:

- Why is Blinding and Randomisation important?
- Introduction to Optimal Packaging and Labelling Design

Module 3:

- Distribution of Clinical Supplies and Global Logistics
- Overview of Cold Chain Distribution Principles
- Summary of design strategies to accommodate change

Question and Answer Session

course director

Esther Sadler-Williams, Managing Director, SimplyESW

Ms. Sadler-Williams is currently Managing Director, of her own Clinical Supply training and consultancy company – SimplyESW, an organisation that supports clients in enhancing team skills as well as conducting improvement projects to optimise clinical supply chain delivery.

Prior to this, Ms. Sadler-Williams was Senior Director of Strategic Alliance Development and Innovation for Catalent Pharma Solutions. Catalent acquired Aptuit CTS in February 2012, a company which had previously acquired Almedica where Ms. Sadler-Williams was a founder member of the European facility. Almedica provided contract services for clinical supplies including packaging, labelling and distribution.

accreditations/recertifications for this course



The Center for Professional Advancement has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 2201 Cooperative Way, Suite 600, Herndon, VA 20171. In obtaining this approval, The Center for Professional Advancement has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. The Center for Professional Advancement is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEU will be awarded for participation in The Center for Professional Advancement's courses at the rate of .1 CEU per contact hour. CEU will be awarded only upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. This course offers a total of 1.5 contact hours or .2 CEUs (CEUs rounded up).

tuition and registration

TUITION– Single Rate: U.S.\$295.00 per person Group Rate: U.S.\$245.00 per person

Register at www.cfpa.com. Enter **Course ID# 2753** into **Search**. To register click **Register Now**.

For Questions and Information call Customer Service at 732-613-4500.

Please Note: Multiple participants are not authorized to share access provided to a single registrant, a single dedicated seat license must be purchased for each individual. CfPA reserves the right to cancel access or collect the group rate payment if this requirement has been violated. Only registered participants will receive accreditation.

courses of interest

- **CGMPs for Pharmaceutical Life Cycle Management**
course ID# 2474
- **CMC Writing and Submission Strategies: A Global Regulatory Approach**
course ID# 1989
- **Early Drug Development**
course ID# 2854
- **Ensuring Data Integrity: A Multi-Disciplinary Approach**
course ID# 2349
- **How to Conduct Robust Root Cause Investigations for CAPA**
course ID# 2089
- **Non-Clinical Safety Assessment: A Journey through Drug Development**
course ID# 2817
- **Preparation, Packaging and Labeling of Clinical Trial Materials**
course ID# 858
- **Quality Management and Compliance in the Pharmaceutical and Related Industries**
course ID# 224

terms and conditions

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