COBBLESTONE

COURSE ID 2753

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

How It All Comes Together

DIRECTED BY

Esther Sadler-Williams, Managing Director, SimplyESW

90 MINUTE

ACCREDITED COURSE

- Overview of drug development and clinical supply chain
- Introduction to the key principles surrounding packaging, labeling and distribution of clinical supplies
- How to plan for and accommodate change in the clinical supply chain

about the course

Clinical studies are essential to ensuring the safety and effectiveness of new drug products before they are launched. The cornerstone of these studies is the clinical supplies, which must be properly labeled and prepared to ensure patient safety as well as prevent expensive clinical trial delays.

To provide a high-level overview and introduction to the key aspects of designing a clinical supply chain that adapts to the rapidly evolving trial landscape, this 90-minute accredited online training will focus on optimal label and packaging design, as well as global supply logistics. The training will offer examples of strategies that can be employed to ensure the overall supply chain can work flexibly with changes in clinical trial design.

This training is vital to the industry as it underscores the importance of clinical supplies in the drug development process and offers insights into designing a flexible clinical supply chain.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer equipped with a microphone and speakers/headset to fully participate.

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 refresh their knowledge.

This online training will benefit professionals in the following industries:

- Pharmaceutical
- Biotechnology
- Contract Clinical Research
- 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

In addition, this training will benefit, hospital pharmacists involved in Clinical Trials in departments such as:

- Research and Development
- Quality
- Clinical Supplies
- Clinical

learning objectives

Upon completion of this course, 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 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 Randomization important?
- Introduction to Optimal Packaging and Labeling 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

Assessment Opportunity

course instructor

Esther 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 optimize 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

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours or .2 CEUs. For further information, visit www.iacet.org