COBBLESTONE

COURSE ID 3101

REVISED!

An Introduction to Current Good Tissue Practice (GTP)

Addressing Human Cell, Tissue, and Cellular and Tissue-based Products (HCT/Ps)

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

- Regulatory Pathways
- Statutes (Section 361 & 351)
- 21 CFR part 1271 (Subparts A – F)
- Core & Non-Core GTP Requirements
- FDA Guidances

about the course

The US FDA's current Good Tissue Practice regulations constitute a significant compliance challenge for the Human Tissue Industry. This course is intended to provide hands-on training for anyone who works for human cell, tissue, and cellular and tissue-based products companies which must comply with CGTP.

In this 90-minute intensive training, we will review the Public Health Service Act (PHS), the federal Food, Drug, and Cosmetic Act (FD&C) and their regulatory authority. Discussion of the regulations and available guidance will be covered including Section 351 and 361 products and determination of minimal manipulation. Deep dive into cGTPs, as outlined in Subpart D, including facilities, environmental controls, equipment, supplies and reagents, recovery, processing and process controls, labeling, storage, receipt, pre-distribution shipment, and distribution. The course will provide tips on how to implement these regulations in a practical format. Participants in this course will gain a detailed understanding of what is required to achieve and maintain compliance with these important regulations.

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

This course is intended for anyone who works for registered human cell, tissue, and cellular and tissue-based product (HCT/Ps) establishments that must comply with CGTP regulations.

It is especially valuable to:

- Executive Directors and CEOs
- MDs and Medical Directors
- Legal Representation
- Laboratory Supervisors and Personnel
- Regulatory Managers and Personnel
- Recovery Personnel
- Q/A Managers and Personnel
- Donor Screeners
- Processing Managers

This training will benefit any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of HCT/Ps, and facilities that engage in contract manufacturing services for a manufacturer of HCT/Ps.

learning objectives

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

- Determine if your establishment is regulated solely under section 361 of the Public Health Services and the regulations in 21 CFR Part 1271 or if your HCT/Ps are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act and/or the federal Food, Drug, and Cosmetic Act.
- Determine if you are required to register and list your product.
- Identify the requirements you must follow if you perform only some manufacturing operations.
- List the "core" GTP requirements that place specific emphasis on procedures and practices to recover, process, store, label, package, and distribute HCT/Ps.
- Explain the additional requirements of reporting and labeling.
- Explain the exceptions to Subpart A.
- Summarize what a quality program consists of.
- Outline and execute a realistic plan for achieving and maintaining compliance with these requirements.

course outline

Review of Learning Objectives

Module 1:

- Regulatory Pathways
  - "361" HCT/Ps
  - "351" HCT/Ps
  - Statutes
  - Section 361 of Public Health Service Act [42 USC 264]
  - Section 351 of Public Health Service Act [42 USC 262]

Module 2:

- Regulations
  - 21 CFR part 1271
  - Subpart A-General Provisions; definitions
  - Subpart B-Registration and Listing
  - Subpart C-Donor Eligibility
  - Subpart D-Current Good Tissue Practice (not reproductive HCT/Ps at this time)

- Subpart E-Additional Requirements: Reporting, Labeling (not reproductive HCT/Ps at this time)
- Subpart F-Inspection and Enforcement

- ” Core” GTP Requirements
  - Donor Eligibility
  - Facilities
  - Environmental Control and Monitoring
  - Equipment
  - Supplies and Reagents
  - Recovery
  - Processing and Process Controls
  - Labeling Controls
  - Storage
  - Receipt, Pre-distribution Shipment and Distribution

Module 3

- Other GTP Requirements (Non-Core)
  - Quality Program
  - Personnel
  - Procedures
  - Process Validation
  - Process Changes
  - Records
  - Tracking
  - Complaint File

- Resources
  - FDA Guidance’s

Question and Answer Session

Assessment Opportunity

course instructor

Ms. Beatrice Huey is a highly experienced Good Tissue Practice Specialist with over 18 years of dedicated service at the University of Arkansas for Medical Sciences in Little Rock. With a remarkable career spanning over 35 years in the healthcare industry, Beatrice has acquired extensive knowledge and expertise in ensuring the highest standards of tissue practice. Her commitment to upholding ethical and safe practices in tissue management has made her an invaluable asset to the University and the healthcare community. Beatrice’s passion for her work and her dedication to improving outcomes make her a trusted and respected professional in her field.

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