FDA and State Regulatory Compliance for IVF and Tissue Banking

Welcome to the course on FDA and State Regulatory Compliance for IVF and Tissue Banking. In this course, we will explore the regulatory landscape that governs the handling of human reproductive cells and tissues in IVF labs and tissue banks. Topics include federal and state licensing, donor screening, labeling, distribution, recordkeeping, and adverse event reporting, with special attention to FDA regulations outlined in 21 CFR Part 1271.

Learning Objectives

By the end of this course, participants will be able to:

1. Understand the role of FDA in regulating HCT/Ps in IVF.
2. Identify specific donor screening and eligibility requirements.
3. Implement required labeling and quarantine procedures.
4. Follow proper packaging and shipping protocols.
5. Understand and respond to adverse events and procedural departures.
6. Maintain compliance with both state and international regulations.

FDA Oversight of Reproductive Tissues

Donated reproductive tissues, including sperm, eggs, and embryos, are classified as human cells, tissues, and cellular and tissue-based products (HCT/Ps) and regulated under 21 CFR Part 1271. Establishments involved in recovery, processing, storage, labeling, packaging, or distribution must register with the FDA. The FDA is authorized to inspect these facilities and issue enforcement actions, including shutdowns, if noncompliance is found.

Requirements for Establishments

Any entity handling HCT/Ps must:

Register with the FDA

Be registered with the FDA.

List HCT/Ps

List the specific HCT/Ps handled.

Maintain cGTP Compliance

Maintain compliance with current good tissue practices (cGTP).

Follow Procedures

Follow proper documentation and tracking procedures.

Prepare for Inspections

Be prepared for FDA inspections and respond appropriately to FDA Form 483 observations.

Donor Eligibility Screening

Donor screening includes:

- Reviewing medical records for clinical evidence and risk factors
- Conducting a comprehensive donor medical history interview
- Assessing social behavior and medical treatments
- Performing a physical examination

Communicable disease testing must be conducted by FDA-registered and CLIA-certified labs using FDA-approved donor screening assays.

Required Infectious Disease Testing

FDA requires prospective donors to be tested for:

HIV & Hepatitis

HIV types 1 and 2, Hepatitis B and C

STIs

Syphilis, Chlamydia trachomatis, Neisseria gonorrhoeae

HTLV

HTLV I/II (as applicable)

All test results, along with other screening information, are reviewed to make a donor eligibility determination.

Donor Eligibility Determination

Eligibility must be documented in three parts:

Medical History & Risk Assessment

Donor medical history and risk factor assessment.

Physical Examination

A thorough physical examination.

Infectious Disease Testing

Infectious disease test results.

The determination of donor eligibility is made by a responsible person and documented in a formal record. Donors are classified as:

Eligible: Approved for anonymous and directed donation

Ineligible: Only permitted for directed donation with appropriate counseling and waivers

Directed Donor Exceptions and Waivers

Directed donations from known donors can proceed even if the donor is ineligible, provided:

- The recipient is fully informed of the donor’s infectious disease status
- A written waiver is signed
- A physician provides counseling and explains potential risks

Labeling Requirements for HCT/Ps

Labeling must include:

Unique ID

Unique identification code

Description

Description of the tissue or cells

Establishment Info

Name and address of the establishment

Expiration Date

Expiration date (if any)

Warnings

Biohazard warnings and communicable disease statements where applicable

Examples:

- "FOR AUTOLOGOUS USE ONLY"
- "WARNING: Reactive test results for [disease]"
- "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"

Quarantine and Distribution Controls

Before an HCT/P can be released for distribution:

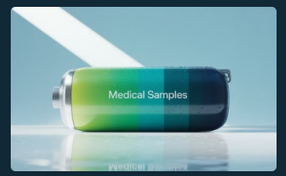
- All manufacturing and tracking records must be reviewed
- Release criteria must be verified and documented
- A responsible person must authorize release

Products must not be distributed if:

- In quarantine
- From an ineligible donor (unless directed)
- Do not meet release criteria

Shipping and Packaging Protocols

Frozen tissue must be:



Shipped Properly

Shipped in properly charged dry shippers.

Packaged Securely

Packaged to prevent contamination and secured with goblets, sleeves, and canes to prevent movement.

Accompanied by Documentation

Accompanied by: authorization forms, freeze/thaw procedures, summary of donor records, description of contents, and tracking number and lab contact info.

Return to Inventory Procedures

Returned specimens may only be added back to inventory if:

- They were stored at a compliant facility
- A Contract Establishment Audit was completed
- Donor eligibility has been confirmed prior to release

Returned HCT/Ps must be logged and reassessed for suitability before use.

Documentation and Recordkeeping

HCT/P documentation must include:

- Donor eligibility statement
- Summary of medical history and testing
- Packaging, shipping, and release forms

Records must be:

Retained

Retained for at least 10 years (longer in some states).

Secure

Secure, confidential, and accessible for audits and inspections.

Contract Establishment Audits

Annually review all contract establishments. Collect:

- FDA and CLIA registration certificates
- Inspection dates, FDA 483s, and resolutions
- State licenses (CA, NY, Canada)

Review the information for compliance with 21 CFR 1271 and applicable tissue bank requirements.

State Regulatory Requirements (Overview)

States have unique licensing and compliance rules:

1

California

Annual registration, SOP review, possible inspections.

2

New York

Registration, inspection, annual advisory meeting.

3

Colorado

Donor age ≥ 21, perpetual records, live birth tracking.

4

Other States

Illinois, Delaware, Oregon, Maryland: Minimal oversight.

International Compliance Requirements

For international work:

Canada

Comply with donor screening and traceability requirements.

United Kingdom

Register with HFEA, use required MD/CD forms, comply with the Code of Practice.

Adverse Event Reporting (SMDA)

Under the Safe Medical Devices Act of 1990:

- Report deaths and serious injuries linked to lab equipment or tissue handling
- Submit reports to FDA and manufacturers within 10 days
- Conduct a Root Cause Analysis

Reporting Process and FDA Form 3500

Steps:

1. Notify

Notify Lab Director and Administrator.

2. Collect

Collect documentation (device records, patient files).

3. Analyze

Conduct Root Cause Analysis.

4. Submit

Submit FDA Form 3500 via MedWatch online or by mail.

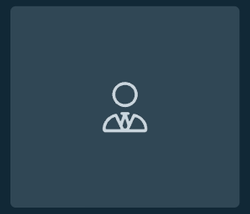
Retain records and confirm receipt with FDA.

Voluntary Reporting Guidelines

Voluntary reporting is encouraged for:

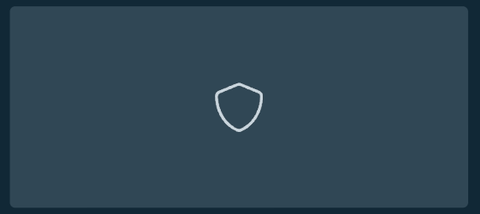
- Product problems (defective packaging, contamination, counterfeit)
- Therapeutic failure
- Any unexpected or suspicious issues

Roles and Responsibilities for Compliance



Lab Director

Ensure compliance, training, licensure renewal.

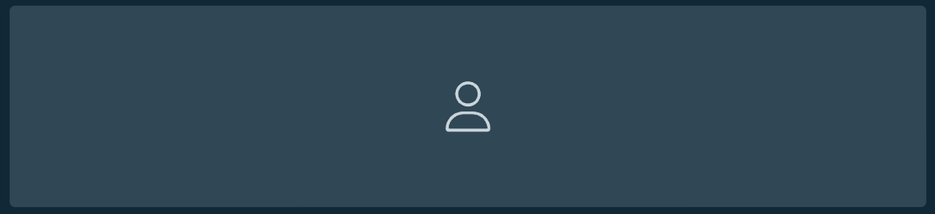


Regulatory Officer

Coordinate inspections, monitor changes.

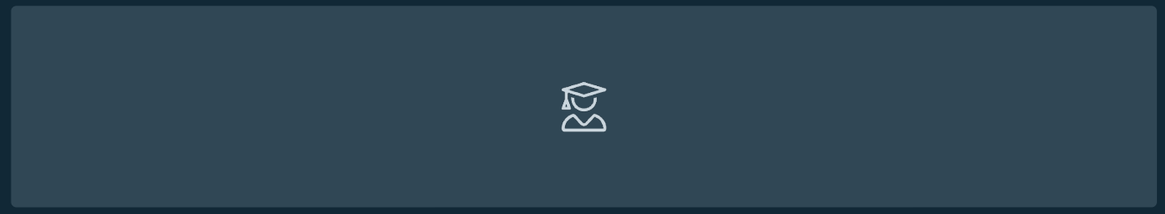
State Licensing Specialist

Maintain state documentation.



Advisory Board

Conduct annual reviews, audit KPIs and SOPs.



All Staff

Remain informed and trained in FDA regulations and procedures.