HCT/P Deviations and Reporting

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Subpart E – Additional Requirements for Establishments Described in 21 CFR 1271.10

- 21 CFR 1271.330  Applicability
- 21 CFR 1271.350(a) – Adverse Reaction Reports
- 21 CFR 1271.350(b) – Reports of HCT/P Deviations
Subpart E – Additional Requirements

Applicability [21 CFR 1271.330]

Nonreproductive HCT/Ps described in 21 CFR 1271.10(a) and regulated solely under PHS Act Section 361

- Not Applicable
  - Reproductive HCT/Ps (semen, oocyte, embryo)
  - HCT/Ps that are drugs, devices and/or biologics
HCT/P Deviation Reporting
[21 CFR 1271.350(b)]
HCT/P Deviation Means an Event:

• That represents a deviation from applicable regulations in this part or from applicable standards or established specifications that relate to the prevention of communicable disease transmission or HCT/P contamination; or

• That is an unexpected or unforeseeable event that may relate to the transmission or potential transmission of a communicable disease or may lead to HCT/P contamination

[21 CFR 1271.3(dd)]
HCT/P Deviation Reporting

All HCT/P deviations related to a distributed HCT/P

- Must be investigated by the manufacturer
- Must report any such HCT/P deviation
  - That occurred in that facility or in a facility that performed a manufacturing step for the facility under contract, agreement, or other arrangement
  - Only those related to core CGTP requirements

[21 CFR 1271.350(b)]
Manufacture

• *Manufacture* means, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging or distribution of any human cell or tissue and the screening or testing of the cell or tissue donor.

[21 CFR 1271.3(c)]
Distribution

• *Distribution* means any conveyance or shipment (including importation or exportation) of an HCT/P that has been determined to meet all release criteria, whether or not such conveyance or shipment is entirely intrastate.

[21 CFR 1271.3(bb)]
Core CGTPs
21 CFR 1271.150(b)

- Requirements directly related to preventing the introduction, transmission, or spread of communicable diseases
- Other requirements support the core CGTPs
Core CGTPs
21 CFR 1271.150(b)

- Facilities
- Environmental control
- Equipment
- Supplies & reagents
- Recovery
- Processing and process controls
- Labeling controls
- Storage
- Receipt, pre-distribution shipment, and distribution
- Donor eligibility determinations, donor screening and donor testing
When Must I Report HCT/P Deviations?

You must report each such HCT/P deviation *that relates to a core CGTP*…within 45 days of the discovery of the event.

[21 CFR 1271.350(b)(3)]
Who Must Report HCT/P Deviations?

- Establishments that manufacture HCT/Ps
  - The HCT/P deviation occurred in your facility
  - The HCT/P occurred in a facility that performed a manufacturing step for you under contract, agreement, or other arrangement
How Do I Report HCT/P and Biological Product Deviations?

Report on Form FDA 3486, electronically or by mail to:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71-G112
Silver Spring, MD 20993-0002

Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271

Draft Guidance for Industry
December 2015
HCT/P and Biological Product Deviation Reporting


- Regulations: 21 CFR 600.14, 606.171, 1271.350(b)
- FDA Form 3486 - PDF format
- Electronic Form
- Instructions for completing forms
- Deviation Codes for HCT/Ps & other biological products
- Product Codes for deviation reporting purposes
- Summary Reports
Questions About HCT/P Deviation Reporting?

• Email account for questions about HCT/P deviations:
  – HCTP_Deviations@fda.hhs.gov

• Contact CBER’s Division of Inspections and Surveillance
  – Sharon O’Callaghan (240) 402-9037
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Consumer Affairs Branch (CAB)
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Manufacturers Assistance and Technical Training Branch (MATTB)
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