13th Annual FDA and the Changing Paradigm for HCT/P Regulation

Quality Audits
Linda Martin
Vice-President Tissue and Support Services
Quality Audits

Objectives

- FDA Requirements
- Accrediting Programs
- Organizational Audits Internal to One OPO
We Are Mid-America Transplant

• Organ, tissue and eye procurement organization (OPO)
• Not for profit 501c3
• 160 employees
• Audited by numerous entities and programs
We Are Mid-America Transplant

- Full service eye bank
- Tissue procurement
- Infectious disease testing laboratory on-site
- Procurement suites on-site/99% cases on-site
2016 Snapshot of Activity

1380  MS Donors
890  Skin Donors
275  Heart for Valve Donors
1200  Ocular Donors
635  Domestically Distributed Corneas
FDA

Regulation of Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Ps)
FDA Inspections

- Ensure registration compliance
- **Goal:** Establish donor-eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCTPs
- Approximately every two years
  - Section 1271.160
    - Quality Program
      - Appropriate procedures to ensure compliance with all applicable core CGTPs
      - Ensuring appropriate corrective actions relating to core CGTPs requirements, including reaudits of deficiencies
FDA Inspection

– Mid-America Transplant Experience

• FDA Audit 12/28/16 – 1/4/17
Industry Audits

- FDA
- CLIA/CAP
- AATB
- EBAA
- Processor(s)
CAP/CLIA

Laboratory

Peer Inspectors

2-year Cycle

On-site
AATB

- Accredited
- Level A
- Level B
- Denial
- Audit report with findings/requirements

Contract Inspectors

3-year Cycle
EBAA

Peer Inspectors

3-Year Cycle (depending on audit)

• Three year/one year/denial
• Audit report with findings/requirements
Processor

Processor Staff

Bi-annual or processor specific

Audit report/findings with timeline
How hard could it be?

**Compliance Dashboard**

### Accreditation and Regulatory Compliance Dashboard - 2016

<table>
<thead>
<tr>
<th>Type</th>
<th>FDAd</th>
<th>AATSB</th>
<th>EBDA</th>
<th>ACPO</th>
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### Last Survey

- Oct 14
- Aug 14
- July 12-13, 2016
- Jan 15
- May 15
- Jun 15
- Apr 14
- Jul 15
- Feb 15
- Jul 16
- n/a
- 15-Dec Desk Audit
- Oct 15
- May 8, 2016 Desk Audit
- Aug 15
- Sep 13
- 5-May-16
- 16-May-16

### Next Survey

- Results Received
- On-site portion completed

### Schedule of External Audits

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<th>Stericycle</th>
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**Key:**
- Green: Full Compliance
- Red: Action Plan Required/Partial Compliance/Awaiting Results
- Blue: Deficiencies/Action Plan Required
- Purple: Full Compliance & Best Practices Identified
- Yellow: Audit Due within Calendar Year
External Audit Preparation

- Review prior audit findings
- AATB/EBAA/CAP
  - Cross walks
  - Group preparation meetings weekly or bi-monthly nine months prior
External Audit Preparation, Continued

• Staff point of contact
• Access (Document/EMR Portal)
• SOPs
• Utilize resources available
Internal Audits

Managers consulted prior to launching for the year

The list continues to expand

Audit Scheduled (or Unscheduled) → Audit Conducted → Findings Summarized → CAPAs/Deviations Filed → Report Provided to Management → Summary Provided to Staff
## Audit Schedule

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### Bi-Weekly Systems Audit

- System Audit: Complete Audit
- Reporting: SSN/Password
- Anually
- Anually
- Anually
- Anually

### Monthly Systems Audit

- System Audit: Complete Audit
- Reporting: SSN/Password
- Anually
- Anually
- Anually
- Anually

### Quarterly Systems Audit

- System Audit: Complete Audit
- Reporting: SSN/Password
- Anually
- Anually
- Anually
- Anually

**Note:** The table above outlines the audit schedule for various tasks and activities across different months and frequencies. Each entry specifies the type of audit, the tasks involved, the data completed, and the records used. The schedule covers monthly, bi-weekly, quarterly, and annual tasks, ensuring comprehensive monitoring and auditing of various systems and processes.
<table>
<thead>
<tr>
<th>Referral Number</th>
<th>Tissue Receiving Site</th>
<th>Process</th>
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<td>Open review and certification document (Yes, No, or NA).</td>
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### Document of Self-Mutilation or Informed Consent

#### 1. Chart Audits - Document of Self-Mutilation or Informed Consent (Peritoneal GP Form)

- Y, Auth
- Y, Auth
- Y, FPA
- Y, Auth
- Y, Auth
- Y, FPA
- Y, FPA
- Y, FPA
- Y, FPA
- Y, FPA
- Y, Auth
- Y, Auth

#### 2. Chart Audits - Document of Self-Mutilation or Informed Consent (Abdominal GP Form)

- Y, Auth
- Y, Auth
- Y, FPA
- Y, Auth
- Y, Auth
- Y, FPA
- Y, FPA
- Y, FPA
- Y, FPA
- Y, Auth
- Y, Auth
- Y, Auth

#### 3. Chart Audits - Document of Self-Mutilation or Informed Consent (Abdominal Intra-Peritoneal Form)

- Y, Auth
- Y, Auth
- Y, FPA
- Y, Auth
- Y, Auth
- Y, FPA
- Y, FPA
- Y, FPA
- Y, FPA
- Y, FPA
- Y, Auth
- Y, Auth

### AATF Brand - Required Document

#### 1. Chart Audits - Document of Self-Mutilation or Informed Consent (Peritoneal GP Form)

- Y, Auth
- Y, Auth
- Y, FPA
- Y, Auth
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- Y, Auth

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- Y, Auth
- Y, Auth
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- Y, Auth

#### 4. Chart Audits - Document of Self-Mutilation or Informed Consent (Abdominal Intra-Peritoneal Intra-Peritoneal Form)

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### Technical Records Review

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### Open Review and Certification Document

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### Donor Physical Assessment Form

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### Donor Risk Assessment Interview

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### Reference

- Chart Audits
One Tissue Bank’s Approach to Audits

• Split Quality/Regulatory and Performance Improvement
• Embrace the audit findings
• Audit the audit findings
• ‘Close the loop’
Quality Software

• Document control
• Equipment/maintenance
• Training
SUMMARY

Quality Audits – Industry

Goal

Safe, effective, high quality tissue meeting all regulatory and industry requirements...
Questions