JACIE

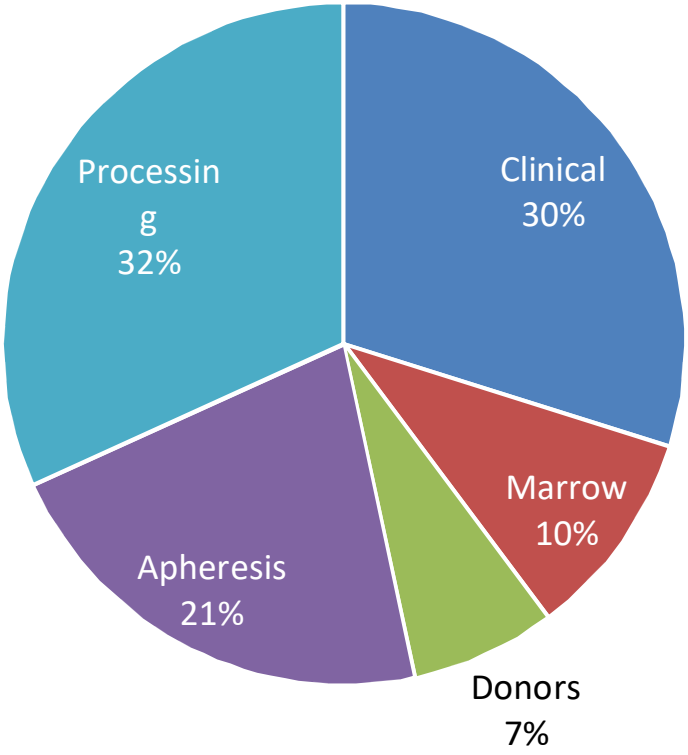
Common Non-Compliances 5th Edition

Based on presentation by Carole Charley,

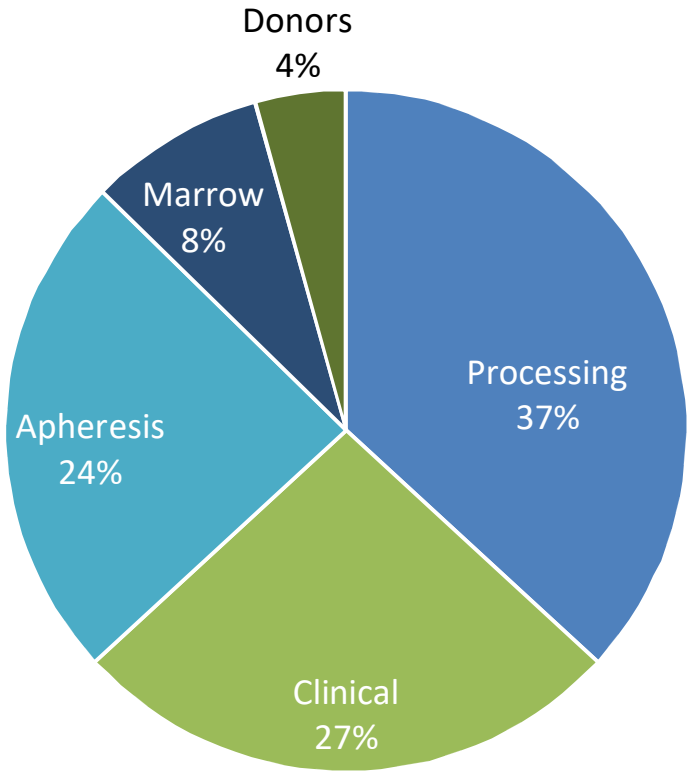
JACIE Report Assessor, at EBMT 2016 Valencia

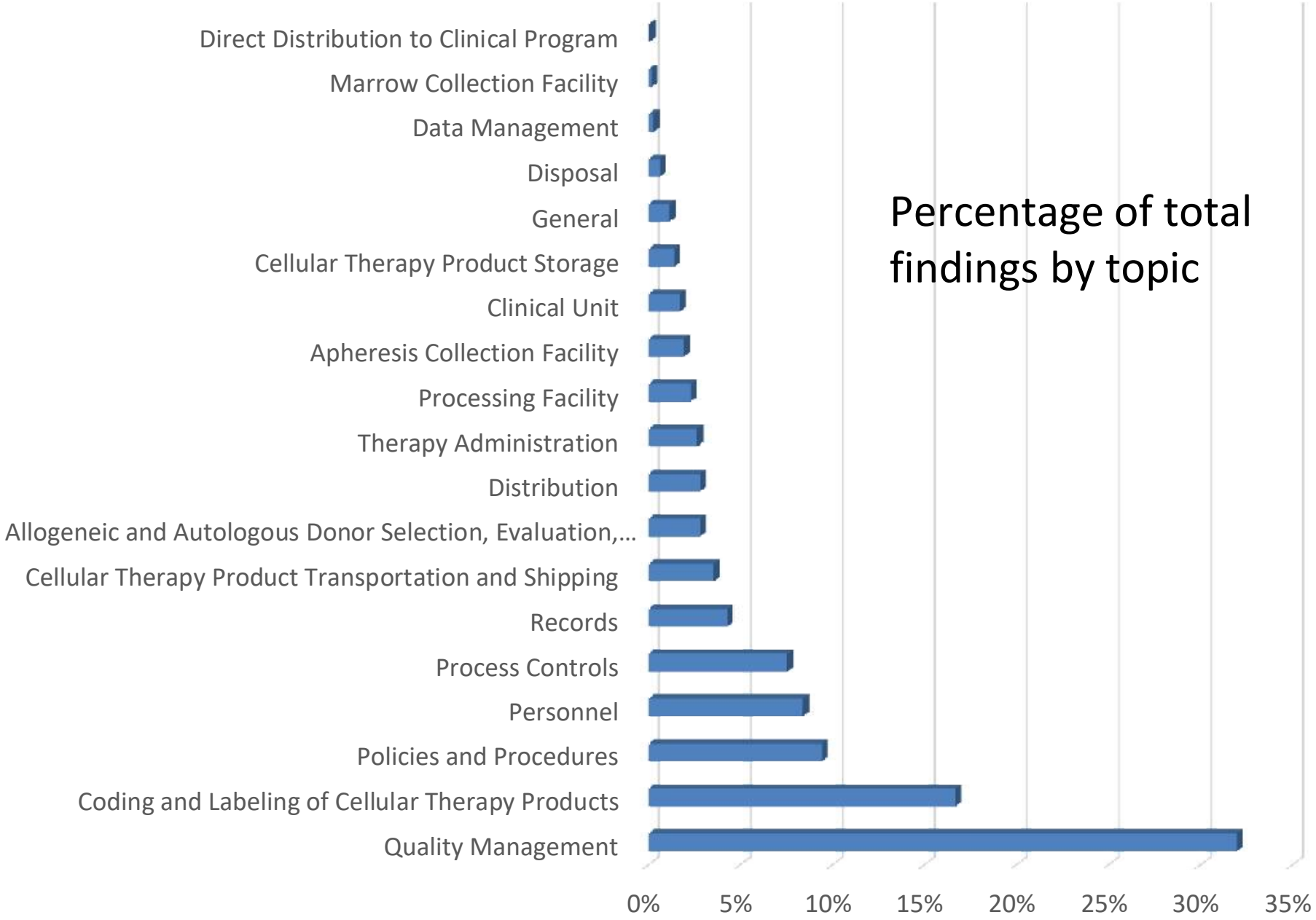
- 87% (146/168) of reports based on the 5th Edition have been analysed

Distribution of total items from reports



Distribution of total items from reports showing full/partial deficiencies




Percentage of total findings by topic
Direct Distribution to Clinical Program
Marrow Collection Facility
Data Management
Disposal
General
Cellular Therapy Product Storage
Clinical Unit
Apheresis Collection Facility
Processing Facility
Therapy Administration
Distribution
Allogeneic and Autologous Donor Selection, Evaluation,...
Cellular Therapy Product Transportation and Shipping
Records
Process Controls
Personnel
Policies and Procedures
Coding and Labeling of Cellular Therapy Products
Quality Management
0%
5%
10%
15%
20%
25%
30%
35%

B03: PERSONEL

- 103 Standards









B03: PERSONEL : Education

Over 60+/103 standards

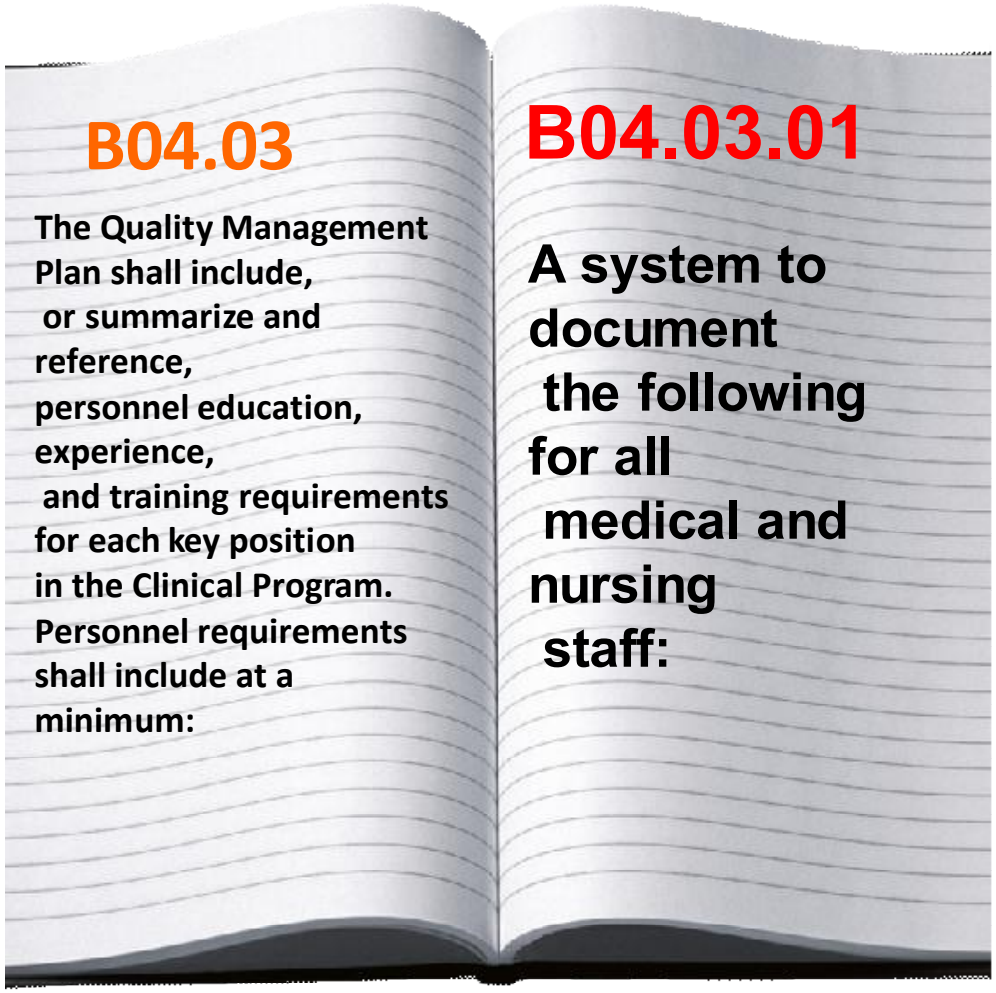
Lack of evidence for:

- ✗ Attending physicians participate in educational activities
- ✗ Mid level practitioners participation
- ✗ Training in donor evaluation & management
- ✗ Nurses formally trained & experienced

?

B03/B04: PERSONNEL Education

- QMP



✗ Continued competency at least annually.

Across all facilities

D04 Quality Management
Lack of evidence

Processing

D04.14.1 (15) *Critical procedures to be validated or verified shall include at least the following processing techniques, cryopreservation procedures, labeling, storage, and distribution.*

D.04 (10) *The Quality Management Plan shall include, or summarize and reference, policies and procedures for establishment and maintenance of written agreements with third parties whose services impact the cellular therapy product.*

✗ Agreements shall be dated, reviewed, and renewed on a regular basis.

C04/D04 Quality Management

Quality Management Plan

Collection

- ✗ Should describe the minimal trainer qualification and a uniform plan of staff training
- ✗ Should include or summarize the procedure to implement policies

Collection & Processing

- ✗ Should include maintenance of written agreements and to include all responsibilities and reviewed on a regular basis

- Number of standards: B=71/CM=2/C=76/D=81

B04 Quality Management

✗ Review of outcome analysis and product efficacy shall include at a Minimum

Clinical

✗ For HPC products, overall and treatment-related morbidity and mortality at 100 days and 1 year after transplantation.

✗ For other cellular therapy products, the criteria for product efficacy and/or the clinical outcome shall be determined and shall be reviewed at regular time intervals.

C0/D04 Quality Management

✗ Review of outcome analysis and product efficacy shall include at a Minimum

Processing D4.07

- ✗ A process for documentation of engraftment
- ✗ Other products efficiency

B4/C4/D4
QUALITY MANAGEMENT

CLINICAL

✗ The clinical Program Director or designee shall report on quality management activities, at a minimum, quarterly

B4/C4/D4

QUALITY MANAGEMENT

The Clinical Program shall periodically audit at a minimum

- ✗ Accuracy of MEDA DATA
- ✗ Verification of chemotherapy drug and dose against the orders and the protocol
- ✗ Collection and analysis of data related to the audit shall be reviewed, reported, and documented, at a minimum, on an annual basis

The Collection & Processing facilities shall periodically audit at a minimum:

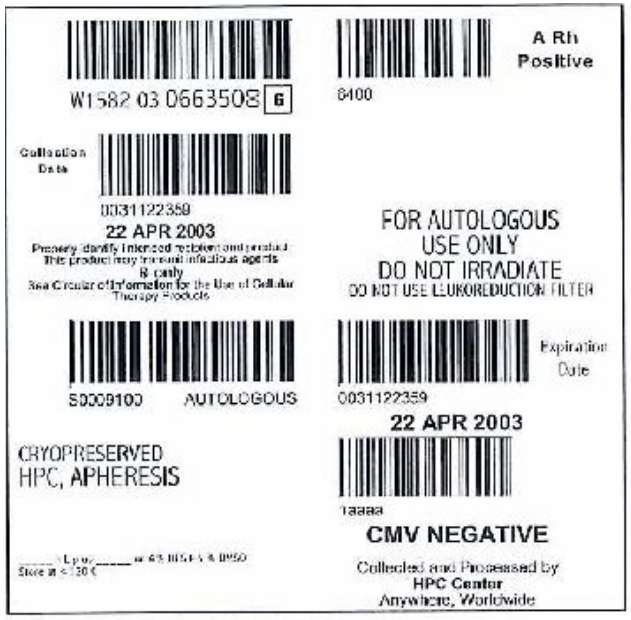
- Collection

✗ Documentation that external facilities meet the written agreements

- Processing (16)

✗ Audits shall include documentation that external facilities performing critical contracted services have met the requirements of the written agreements

C07/D07: LABELLING



Processing

✗ Each label shall bear the information in the Cellular Therapy Product Labeling Table in Appendix I codes

✗ Misuse of biohazard labels

Collection & Processing

✗ Use of ISBT 128 labelling and codes

✗ Plan to implement plan for ISBT 128

<u>New EU Regulations:</u>

Single Euro Coding system

OVERVIEW

	Clinical	Collection	Processing
Personnel	x		
QMS	x	x	x
Process control			x
Labeling		x	x
Records			x
Product Storage			x
Transport & Shipping			x

Challenge of working with a QMS: Evidence

- Effective documentary evidence that each standard is compliant
  - Complete training and competencies records
  - QMP to describe all processes
  - QMS to carry out processes described in QMP
  - Carry out all audits required including external audits & follow up of corrective measure
  - Document outcome analysis
  - Agreements to include responsibilities