



Organigram - Organizational Chart



Southampton – June, 2016

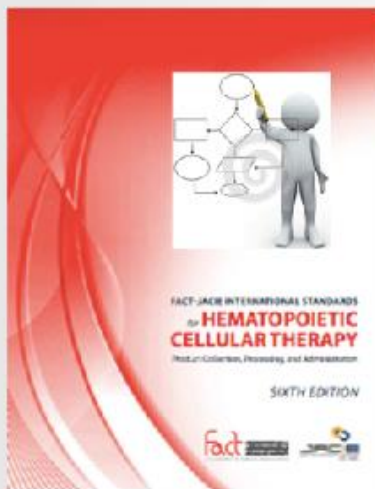
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Standard B4.3

“The Quality Management Plan shall include, or summarize and reference, an organizational chart of key positions and functions within the cellular therapy program, including clinical, collection, and processing.”

C4.3 (Apheresis Collection Facility) and D4.3 (Processing Facility)



EXERCISES



WHO & HOW?

EXERCISE 1

Objective: Identify the key positions within the cellular therapy program, for a facility that consists of an Adult Clinical unit, Collection unit (BM & APH), and Processing unit

Material: International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration. Sixth Edition

Timeline: Group Exercise: 5 minutes

Outcome: List of key positions for each unit of the cellular therapy program

GROUP A

Debbie	Anderson
Nicole	Da Silva
Michelle	Farrar
Pamela	Trippick
Matthias	Klammer

GROUP C

Ranjeet	Babbra
Alanna	McVeigh
Amit	Patel
Noel	Ryman
Tracey	Parker
Marisa	Pereira

GROUP B

Karen	Benn
Simon	Hack
Michael	Uhrig
Sylwia	Simpson
Rachael	Wyre

GROUP D

Shaheena	Mian
Daniel	Piper
Jacqueline	Fritzsche
Pramila	Krishnamurthy
Oscar M	Pello

Key positions – Cellular Therapy Program

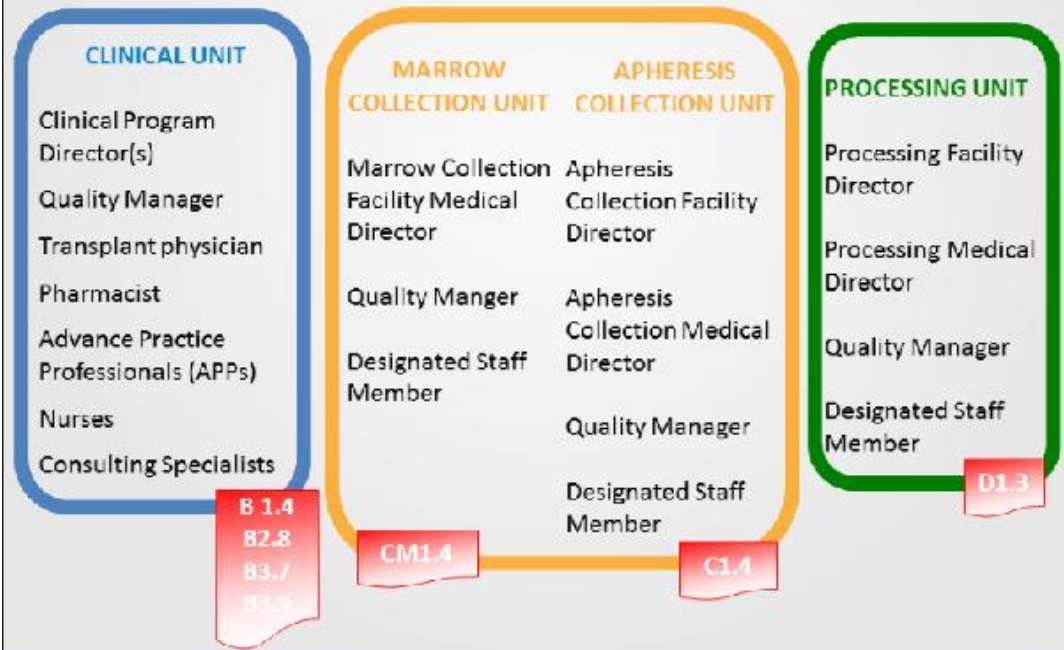


CONSULTING SPECIALIST

B3.9

- B3.9.1.1 *Surgery.*
- B3.9.1.2 *Pulmonary medicine.*
- B3.9.1.3 *Intensive care.*
- B3.9.1.4 *Gastroenterology.*
- B3.9.1.5 *Nephrology.*
- B3.9.1.6 *Infectious disease.*
- B3.9.1.7 *Cardiology.*
- B3.9.1.8 *Pathology.*
- B3.9.1.9 *Psychiatry.*
- B3.9.1.10 *Radiology.*
- B3.9.1.11 *Radiation oncology with experience in large-field (e.g., total body or total lymphoid) irradiation treatment protocols, if radiation administered.*
- B3.9.1.12 *Transfusion medicine.*
- B3.9.1.13 *Neurology.*
- B3.9.1.14 *Ophthalmology.*
- B3.9.1.15 *Obstetrics/Gynecology.*
- B3.9.1.16 *Dermatology.*
- B3.9.1.17 *Palliative and end of life care.*

Key positions – Cellular Therapy Program

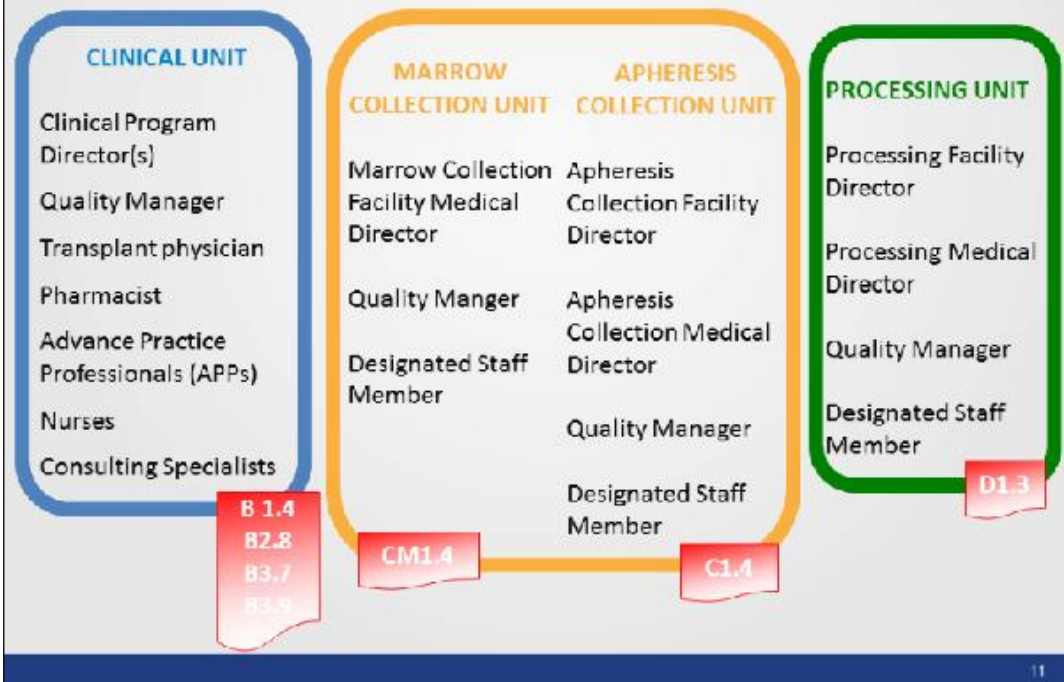


DESIGNATED STAFF MEMBER

C1.4

- *C1.4 The Apheresis Collection Facility shall have an Apheresis Collection Facility Director, an Apheresis Collection Facility Medical Director, a Quality Manager, and at least one (1) additional designated staff member. This team shall have been in place and performing cellular therapy product collections for at least twelve (12) months preceding initial accreditation.*

Key positions – Cellular Therapy Program



EXERCISE 2

Objective: Prepare organizational chart for a cellular therapy program of a facility that consists of an Adult Clinical unit, Collection unit (BM & APH), and Processing unit.

Material: List of key positions for each unit of the cellular therapy program (Exercise 1).

Timeline: Group Exercise: 15 minutes

Outcome: Organigram of a cellular therapy program.
Presented by the group representative.

WHAT

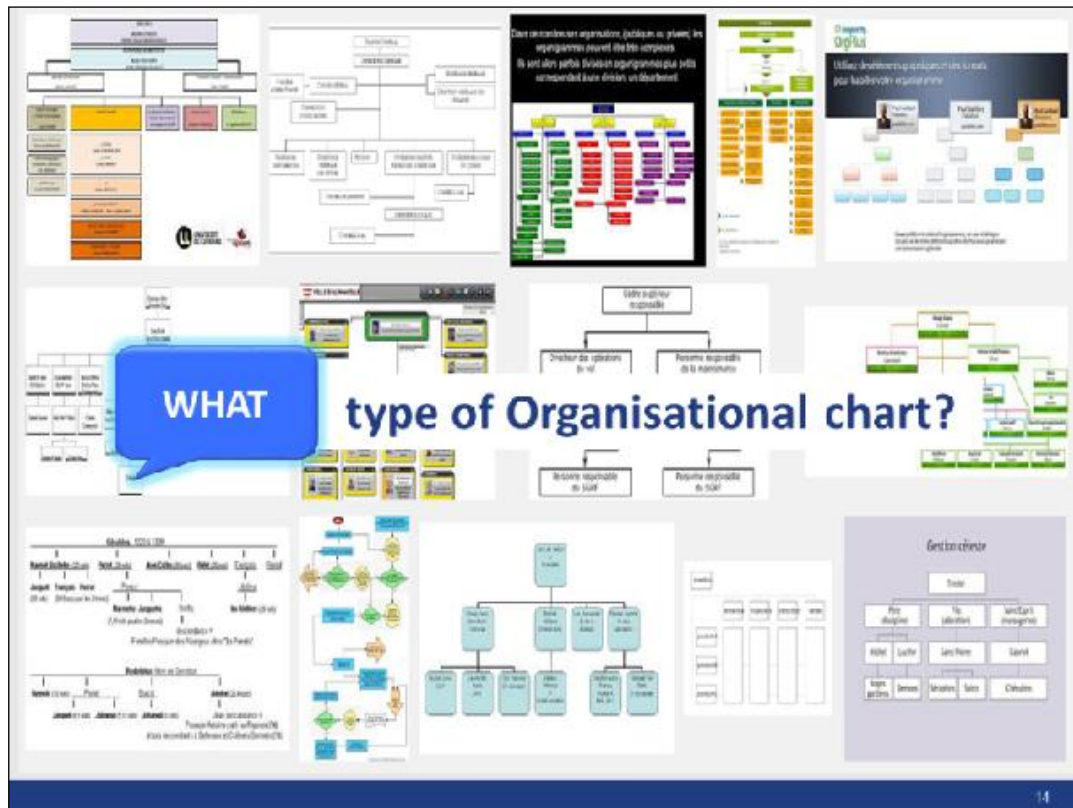
is an organizational chart?

“An **organizational chart** (often called

- **organization chart**
- **org chart**
- **organigram(me)**
- **organogram**)

is a [diagram](#) that shows the [structure](#) of an organization and the [relationships](#) and relative ranks of its parts and positions/jobs”

http://en.wikipedia.org/wiki/Organizational_chart



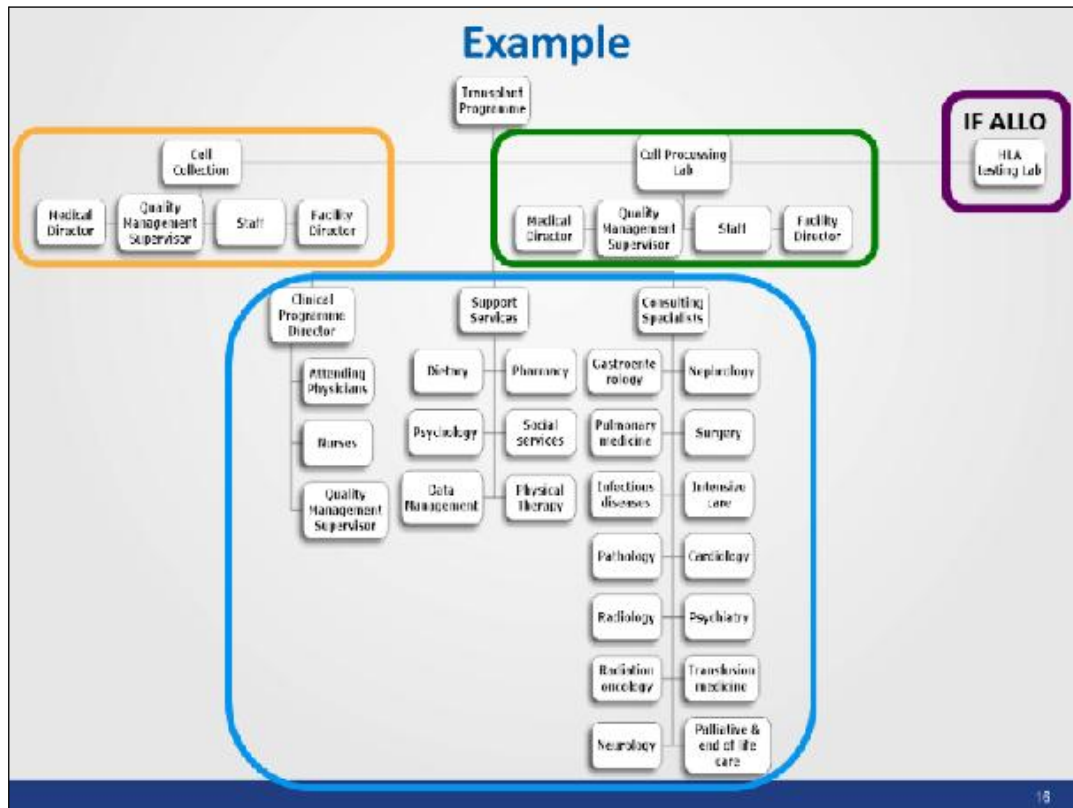
EXERCISE 2

Objective: Prepare organizational chart for a cellular therapy program of a facility that consists of an Adult Clinical unit, Collection unit (BM & APH), and Processing unit.

Material: List of key positions for each unit of the cellular therapy program (Exercise 1).

Timeline: Group Exercise: 10 minutes

Outcome: Organigram of a cellular therapy program.
Presented by the group representative.





Organizational Chart



WHAT

to review in an organigram?

- Key positions
- Relationships between departments
- Does it portray the reality?
 - Tools: Interview and Supporting documentation

HOW

should it be?

Clear & Concise

- Invaluable tool for management

Clear responsibilities, titles and lines of authority

- Facilitate team organisation

Distributing & sharing

- Communicate valuable organisational information to employees
- Sharing organisation strategic vision and responsibilities, dependencies and relationships

HOW

should not it be?

- Too simplistic or too complicated
- Not isolated but linked
- Steep Hierarchies
- Roles not defined



WHY

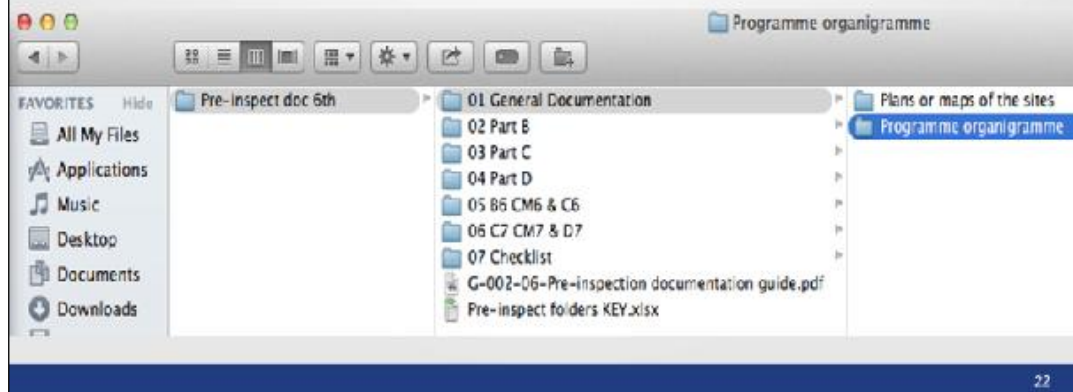
is important for the inspection?

- Key document to prepare the agenda timetable
- It can be used as the guiding theme for the inspection:
 - understanding responsibilities
 - areas to be inspected
 - interrelationship between departments
 - document control pathways

WHERE

to find it?

- Email: [dropbox link](#)
- Pre-inspection documentation folder: General Documentation



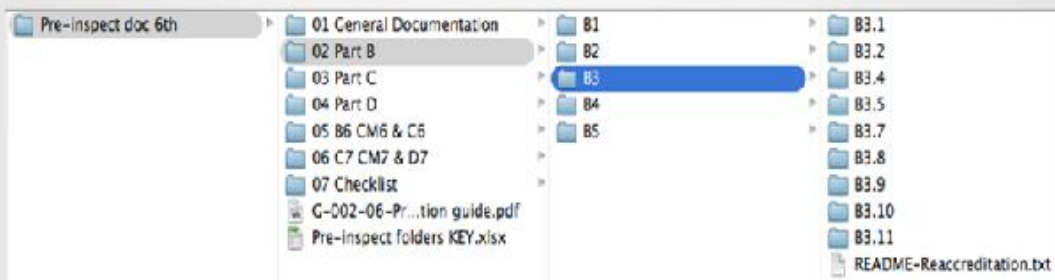
WHERE

to find it?

- Pre-inspection documentation folder:

- Part B: B3 Personnel
- Part C & D: CM3, C3 & D3

B3 Personnel
B3.1 Clinical Programme Director
B3.2 Attending Physicians
B3.4 Physicians-in-training
B3.5 Advanced Practice Providers/Professionals
B3.7 Nurses
B3.8 Pharmacists
B3.9 Consulting Specialists
B3.10 Quality Manager
B3.11 Support Services Staff



WHEN

to use it?

PRE-INSPECTION

INSPECTION

POST-INSPECTION

Identification key personnel
Inspection timetable

Verification

Report Writing

“Difficulties” encountered by inspectors

- The organigram provided by the facility is not updated.
- Names are not included in the organigram so specific persons can not be identified (it is not a requirement)
- The information provided in the organigram does not correspond with the CVs provided in the pre-inspection documentation.

Organizational Chart

- Essential tool in any organisation
- Key document for inspector
- Effective QMS requires clearly defined organisation with clear responsibilities
- Basis for communication, management and setting up Quality Management System



THANK you for listening!