

Organigram - Organizational Chart

Who?

Where?

How do I know if
it is adequate?

What do I have
check on an
organigram?

How?

Why?

When?

Is it really a key
document for
the inspection?

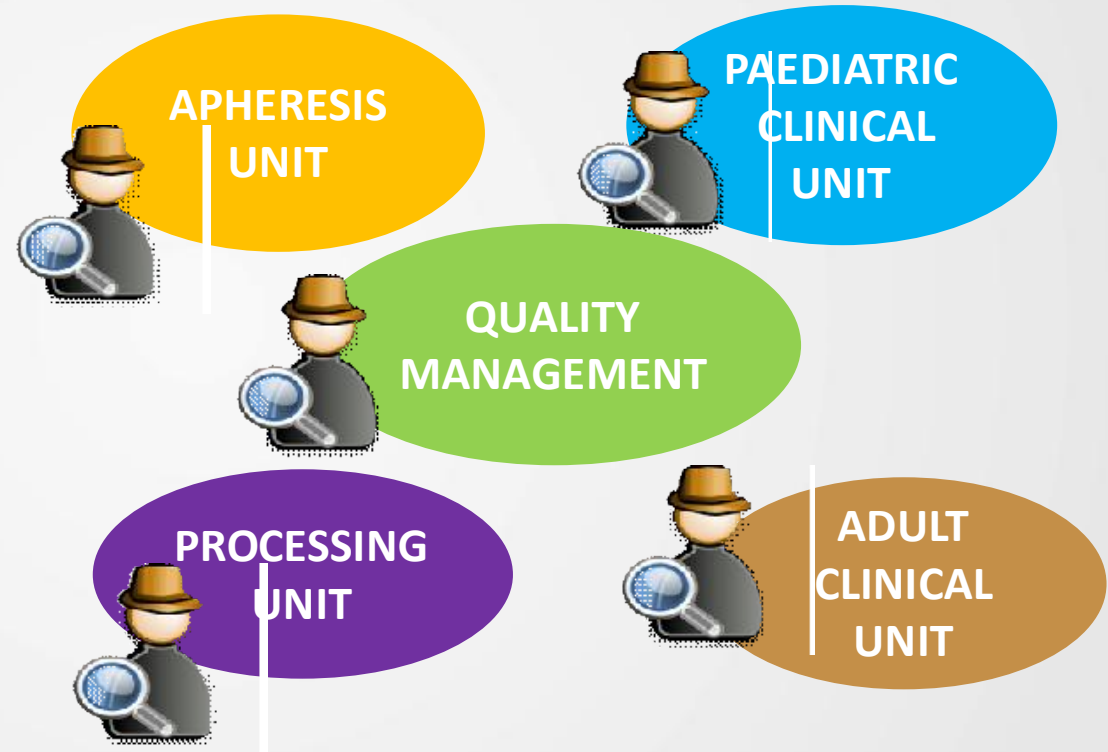
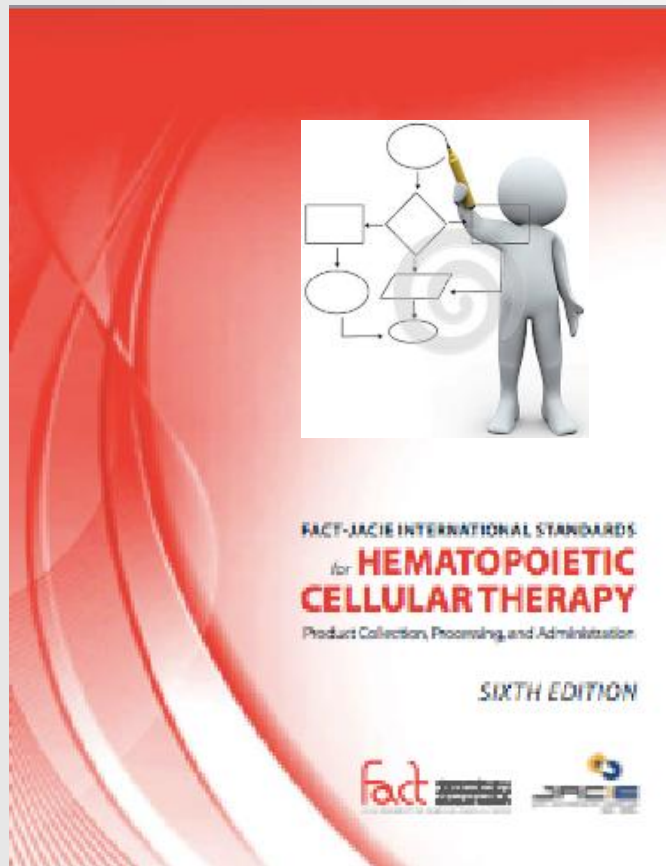
What?



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:

Individual Exercise: 5 minutes

Outcome:

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

Key positions – Cellular Therapy Program

CLINICAL UNIT

Clinical Program Director(s)
Quality Manager
Transplant physician
Pharmacist
Advance Practice Professionals (APPs)
Nurses
Consulting Specialists

B 1.4
B2.8
B.3

MARROW COLLECTION UNIT

Marrow Collection Facility Medical Director

Quality Manager

Designated Staff Member

CM1.4

APHERESIS COLLECTION UNIT

Apheresis Collection Facility Director

Apheresis Collection Medical Director

Quality Manager

Designated Staff Member

C1.4
C3

PROCESSING UNIT

Processing Facility Director

Processing Medical Director

Quality Manager

Designated Staff Member

D1.3
D3

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

CLINICAL UNIT

Clinical Program Director(s)
Quality Manager
Transplant physician
Pharmacist
Advance Practice Professionals (APPs)
Nurses
Consulting Specialists

B 1.4
B2.8
B.3

MARROW COLLECTION UNIT

Marrow Collection Facility Medical Director

Quality Manager

Designated Staff Member

CM1.4

APHERESIS COLLECTION UNIT

Apheresis Collection Facility Director

Apheresis Collection Medical Director

Quality Manager

Designated Staff Member

C1.4
C3

PROCESSING UNIT

Processing Facility Director

Processing Medical Director

Quality Manager

Designated Staff Member

D1.3
D3

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

CLINICAL UNIT

Clinical Program Director(s)
Quality Manager
Transplant physician
Pharmacist
Advance Practice Professionals (APPs)
Nurses
Consulting Specialists

B 1.4
B2.8
B.3

MARROW COLLECTION UNIT

Marrow Collection Facility Medical Director
Quality Manager
Designated Staff Member

CM1.4

APHERESIS COLLECTION UNIT

Apheresis Collection Facility Director
Apheresis Collection Medical Director
Quality Manager
Designated Staff Member

C1.4
C3

PROCESSING UNIT

Processing Facility Director
Processing Medical Director
Quality Manager
Designated Staff Member

D1.3
D3

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 grup representative.



WHAT

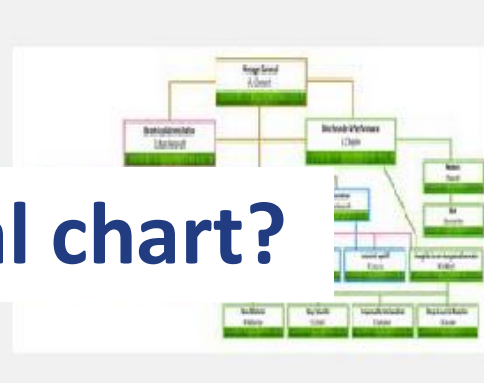
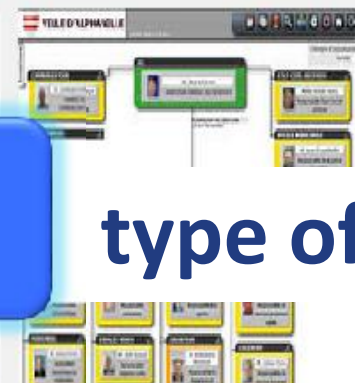
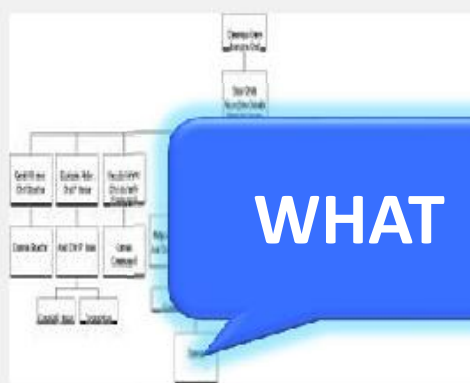
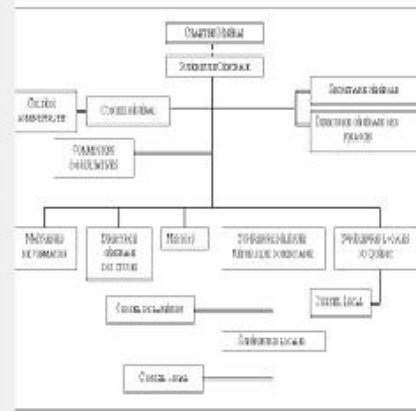
is an organizational chart?

“An **organizational chart** (often called

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

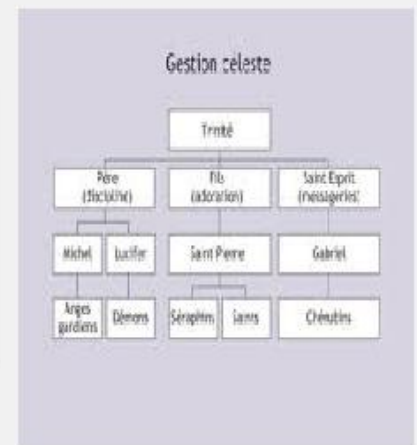
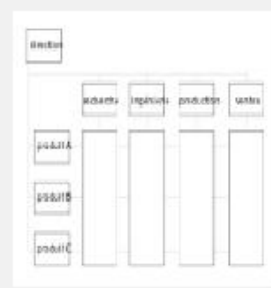
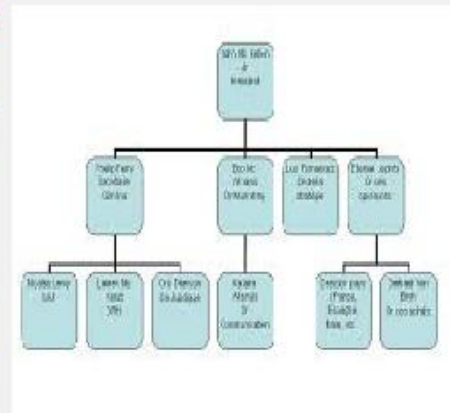
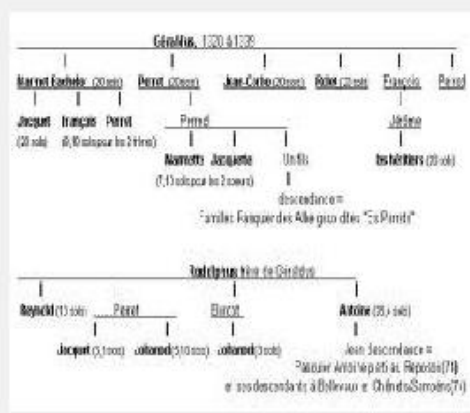
is a [diagram](#) that shows the [structure](#) of an organization and the [relationships](#) and relative ranks of its parts and positions/jobs”

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



WHAT

type of Organisational 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 grup representative.

GROUP 1

Fereshta Aslami-Zarbi
Marie-José Claessen
Monique Grommé
Noud Hendricks
Anna Popp
Tanja Netelenbos

GROUP 2

Jacco Besteman
Ginette Balk
Miranda van Harmelen
Chantal Vermeiden-Meenhorst
Marianne Lucassen
Stela Radojska

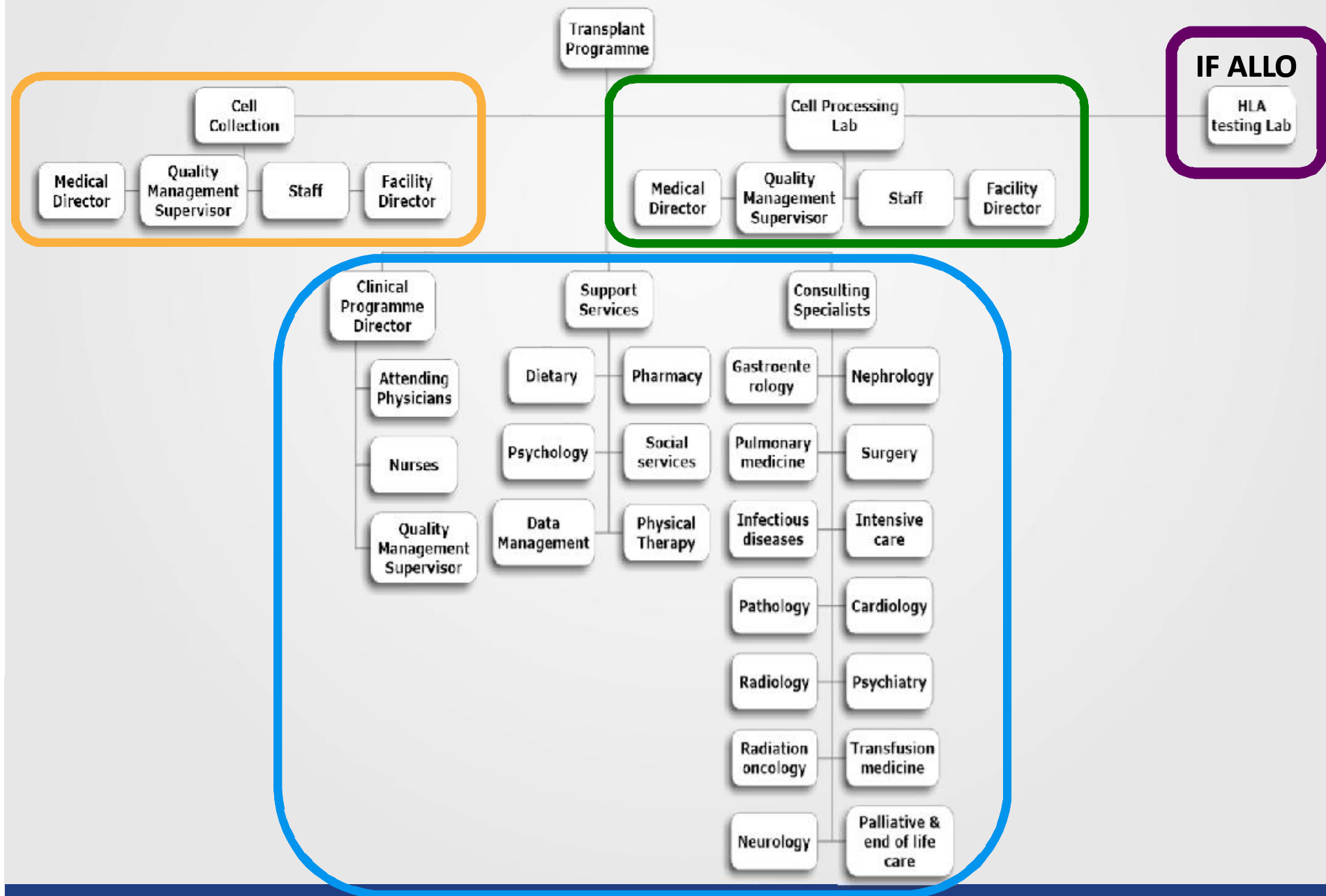
GROUP 3

Sylvia Haan
Kristin de Bruijn
Dinie Hoentjen
Yvonne Westerman
Patty van Tiel
Bas van Haren

GROUP 4

Marielle van Roosmalen
Monique Oosterwijk
Marco de Groot
Léon Kant
Carlijn Voermans
Margreet Knobben

Example





Organizational Chart



WHAT

to review in an organigramme?

- 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

A green speech bubble with a white border and a small tail pointing towards the bottom left. The word "WHY" is written in white, bold, uppercase letters inside the bubble.

WHY

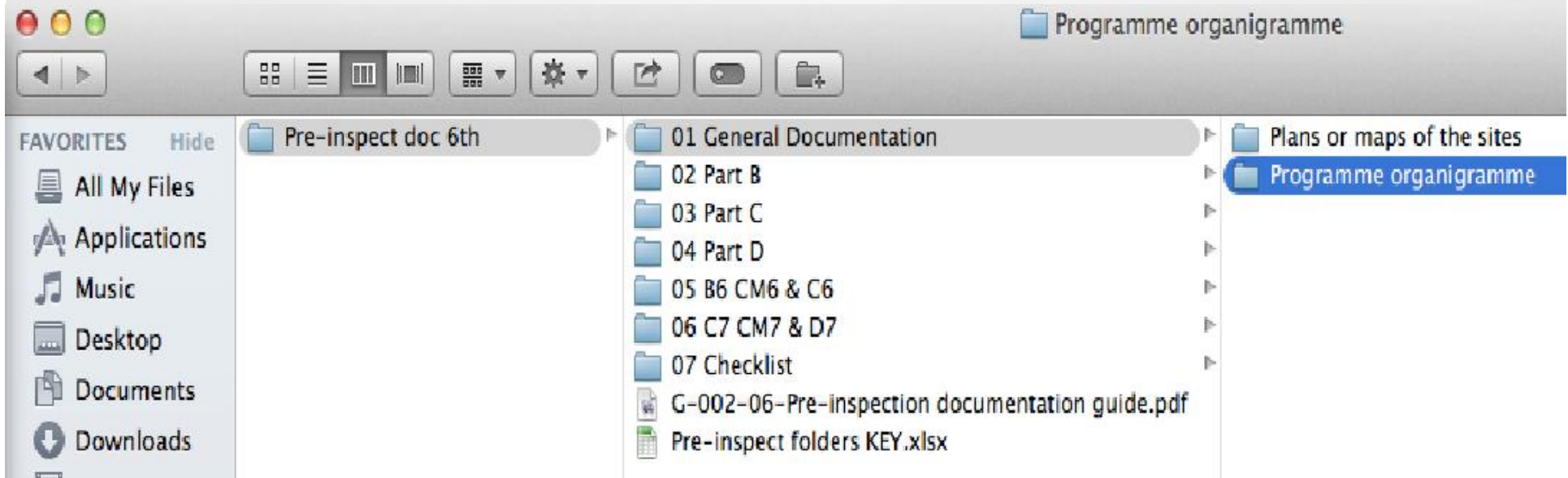
is important for the inspection?

- 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

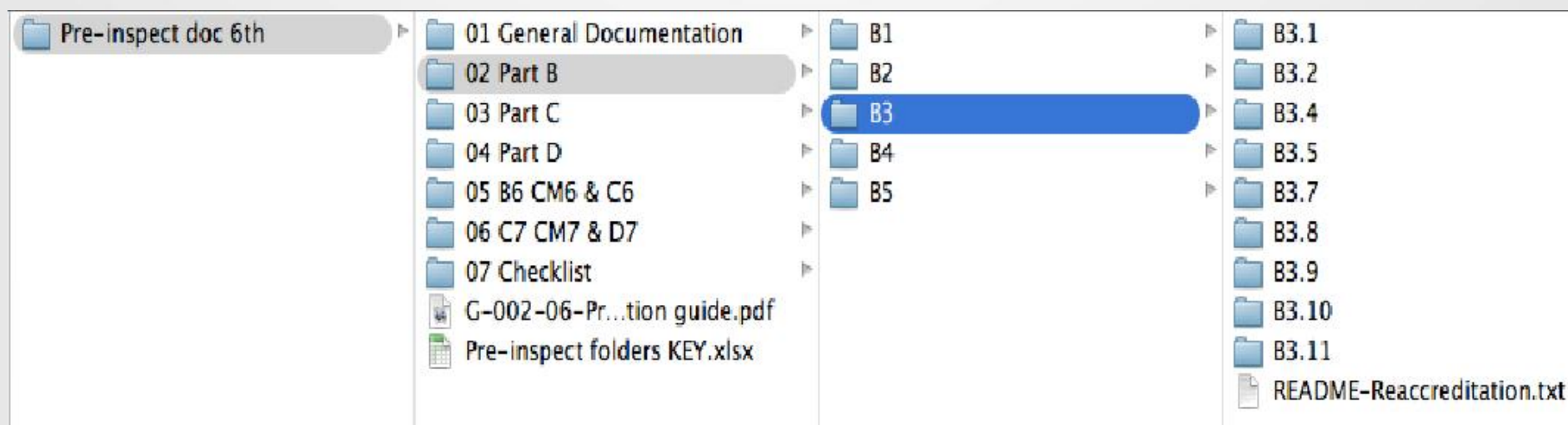


WHERE

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 organigramme provided by the facility is not updated.
- Names are not included in the organigramme so specific persons can not be identified (it is not a requirement)
- The information provided in the organigramme 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 !