

Dealing with staff training

the « Liège experience »

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INTRODUCTION

- Acquisition of **knowledge, skills and competencies**.
- Result of the teaching of **theoretical and practical skills and knowledge** that relate to specific useful competencies.
- **Mandatory** and management **responsibilities** to set up
- **Personal / professional development & carrier advancement**
- **Beneficial** to both employee & "company "
- **Time & Money** consuming...but it is worth it !
- **Everyone's business** (not only CQ or Human ressource Dpt)

ALL ABOUT TRAINING... !

- i. Recruitment and initial qualification**
- ii. Training plan & job description**
- iii. Initial and continued training**
- iv. Regular competency assessment**
- v. Training records**

What are JACIE requirement for training ?

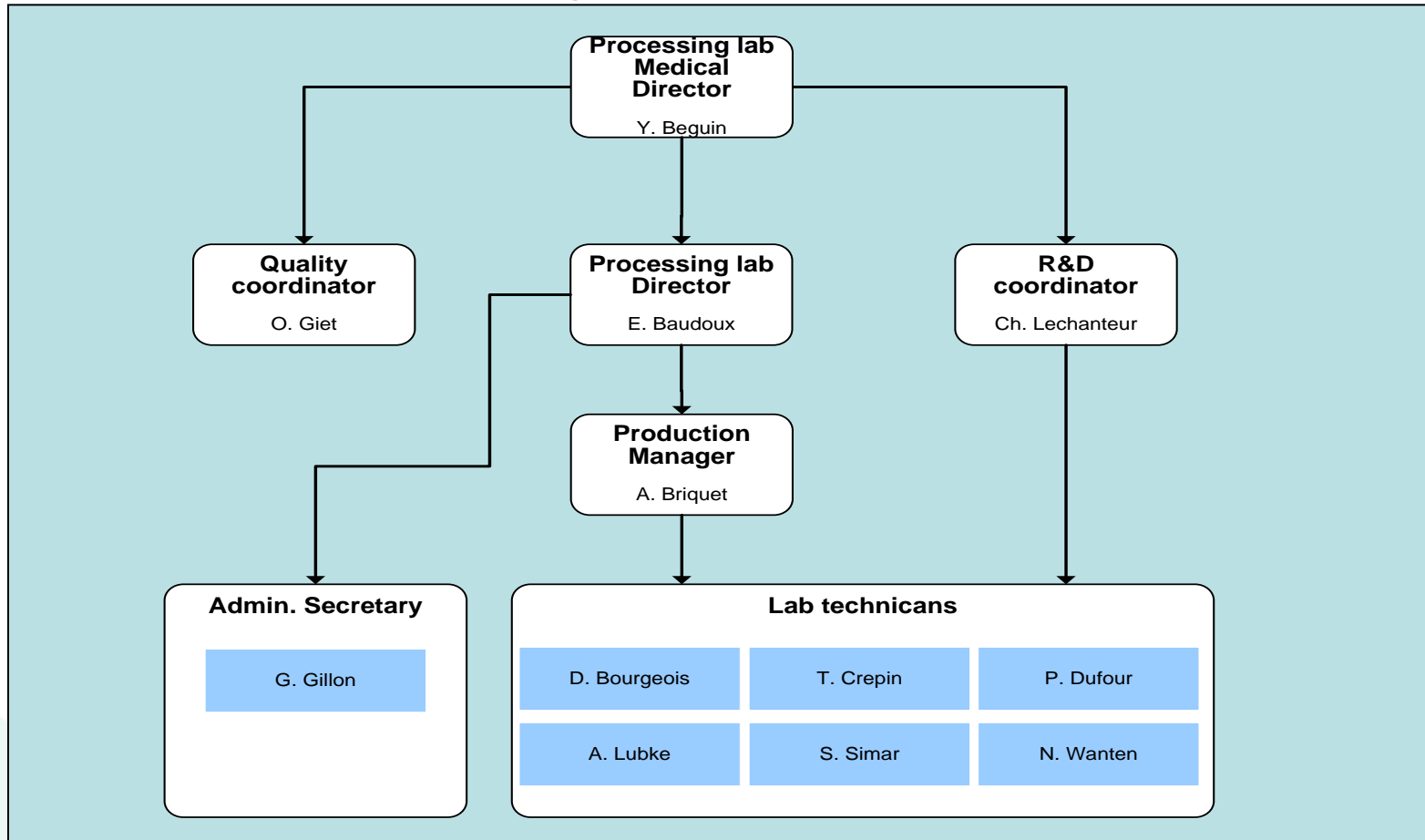
JACIE B4.3, C4.3 & D4.3 :

- Quality Management Plan shall include, or summarize and reference, personnel requirements for each key position...
- Personnel requirements shall include at a minimum:
 - ✓ Current job description for all staff
 - ✓ System to document for each staff member
 - Initial qualifications and
 - Orientation
 - Initial training
 - Competency for each function performed.
 - Continued competency at least annually
 - Provisions for continuing education, training, and retraining.
 - ✓ A description of minimal trainer qualifications.
 - ✓ Procedure for personnel training and competency assessment.

How to deal with all these requirements ?

Organizational flowchart

1. Definition of all required **professional profiles** (as per law and standards requirements)
2. **Job description & organizational flowchart design** : responsibilities – daily tasks, hierarchical relationships...



Example of job description for TECHNICIAN

1. Required qualifications for the position

| | |
|---|-----------|
| Education | |
| Bachelor in clinical biology/chemistry or medical laboratory technologist | MANDATORY |

2. Detailed job description

Tasks **delegated** by the Processing lab Director to technicians are as follows :

▪ Performing operational procedures :

- Reception and qualification for processing of cellular products
- Labeling and traceability requirements
- Cellular product processing : volume reduction / aliquots, cryopreservation / thawing, selection and depletion process, ex vivo culture
- Preparation for transport (including packaging and labelling ad hoc transport containers)

▪ Organizational context and quality management :

- Involved in SOP writing and updates
- Involved in validation studies
- Consumable & reagents stock management
- Involved in maintenance, qualification, and monitoring of equipments and processing facility
- Involved in recording, management and monitoring of quality problems in collaboration with the QC
- Involved in training of new staff / internal audit

| Legend | Assignments |
|--------|---------------------------|
| 1 | Decides |
| 2 | Executes, implements |
| 3 | Participates, co-manages, |

3. Skills responsibilities limits

| Missions | Processing lab Dir | Lab Technicians | Production manager | Quality coordinator |
|--|--------------------|-----------------|--------------------|---------------------|
| Reception, distribution and transport of cellular Products | 1 | 2 | 3 | |
| Labeling and tracability requirements | 1 | 2 | 3 | |
| Cellular product processing | 1 | 2 | 3 | |
| Qualification for Release | 1 & 2 | | | |
| Stock management of cellular products | 1 | 2 | | |
| SOP writing & updates | 1 | 3 | | 2 |
| Validation studies | | 3 | 3 | 1 and 2 |
| Consumable & reagents stock management | | 1 & 2 | 1 | |
| Maintenance, qualification, and monitoring of equipments and processing facility | | 2 | 1 & 3 | 1 |
| Staff training | 1 | 3 | 2 | 2 |
| Board review and audit | 1 & 3 | 3 | 3 | 2 |

RECRUITMENT and INITIAL QUALIFICATION

1. Definition of all required professional profiles (as per law or standards requirements)
2. Job description & organizational flowchart design : responsibilities – daily tasks, hierarchical relationships...
- 3. Selection process : CV review and interview**
- 4. Appointment process of new staff members**
- 5. Initial qualification assessment and set up of required training plans**

INITIAL TRAINING

- For **ALL SOPs** that specific staff member will perform (as defined in the job description)
- Training plans in **4 PHASES** :

| Contents | Actions to follow | Expected results |
|---|---|--|
| Description of theoretical elements referenced in relevant SOPs | <ul style="list-style-type: none"> • 1st phase → Read documentation and review critical items with QC or tutor | <ul style="list-style-type: none"> ✓ Understanding purposes of the process ✓ Review operational modes & critical steps |
| Go into practice | <ul style="list-style-type: none"> • 2nd phase → See process executed by tutor. • 3rd phase → perform process under tutor's supervision | <ul style="list-style-type: none"> ✓ Practical knowledge ✓ Autonomy learning |
| Evaluation | <ul style="list-style-type: none"> • 4th phase → Data review & formal authorization to perform tasks | <ul style="list-style-type: none"> ✓ Autonomy achievement ✓ Part of the stability and achievement of any process |

Example of a training plan

CRYOPRESERVATION & DISTRIBUTION OF CELLULAR PRODUCTS

Necessary knowledge & skills prior to implementation of training plan

| Document # | title |
|------------|---|
| TE0003PRO | Management of reagents and consumables |
| TE0004PRO | Management of equipments |
| TE0007PRO | Circulation of staff members and materials |
| TE0101PRO | Liquid nitrogen: general and safety instructions |
| TE0105PRO | Exposure to infectious risks |
| TE0106PRO | Waste management |
| TE0109PRO | Control of work environment |
| TD0201PRO | Reception and qualification for processing of cellular products |

Part of the initial training plan to set up, firstly

2. Training records

| Document # | Title | 1 st phase | | 2 nd phase | | 3 rd phase | |
|------------|---|-----------------------|-------|-----------------------|-------|-----------------------|-------|
| | | Date / sign | | Date / sign | | Date / sign | |
| | | Trainee | Tutor | Trainee | Tutor | Trainee | Tutor |
| TC0601PRO | Labeling and traceability of cellular products through "Progesa software" | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| TD0301PRO | Cryopreservation of cellular products | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| | | | | ✓ | ✓ | | |
| | | | | | | | |
| TD0701PRO | Distribution of a cellular product | ✓ | ✓ | | | | |

3. Review and approval of training plan completion

| 4 th phase | | | |
|---|---|-----------------------------|-------------|
| Observed results are consistent with "end points" described in SOPs ? | | | Date / sign |
| Tutor | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO | |
| QC / lab Dir | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO | |

CONTINUED TRAINING & EDUCATION

1. Choice of themes :

- ✓ on request of **staff members**
- ✓ By **Management** (Board review)

2. Managed through :

- ✓ In-house training sessions : **journal club, literature review, SOP update...**
- ✓ Attending **meetings / conferences / congresses**
- ✓ Ongoing **education & report, research/scientific articles** commitment
- ✓ **Internship or exchange program** of staff members

3. Documentation & records

- ✓ **Certificate of attendance** : date – sign – contents...
- ✓ Part of the **personal training dossier**
- ✓ **Annual review** by management

COMPETENCY EVALUATION

1. Initial and annual

2. Managed through :

- ✓ **Retrospective statistical analyses** : SOP endpoint achievement...
- ✓ **Mutual cross-audits & tutor approval**
- ✓ **Observation / interviews**
- ✓ **In-house or institutional proficiency surveys**
- ✓ **Use of written tests** (multiple choices questionnaire)
- ✓ **Inspection and internal audit reports**

3. Documentation & records

- ✓ **Annual review & approval** by management
- ✓ **Part of the personal training dossier**

TRAINING MANAGEMENT

1. Applicable to **COLLECTION center & PROCESSING lab** staff members

2. Applicable to **MEDICAL STAFF**, as part of training for
 - ✓ Advanced master of internal medicine
 - ✓ Specialized certificate in hematology

3. Difficult to set up for **NURSING STAFF**
 - ✓ Size of staff
 - ✓ Turnover
 - ✓ Part time personnel
 - ✓ Organizational challenge
 - Alternative solutions to be found
 - Institutional support needed

NURSES TRAINING MANAGEMENT

Solution adopted by ULICE program :

- ✓ **Professional qualification of nurse in ONCOLOGY**
 - 150 hours theory & practice (2-3 days/month) organized by University of Liege
 - Including hematology, HST transplantation & patient care topics (as required by JACIE)
 - Endorsement of the Nurse Dpt & Transplant team
 - Legal & valuable training (Ministerial Decree of 28/01/2009) including exams & awarded by a certificate
 - Professional development / carrier advancement
 - Bonus income for trained nurses
 - Since 2009 : 74 % fully trained, 8% ongoing training and 15% recognized as experts (total nurses staff = 78)
 - http://progcours.ulg.ac.be/cocoon/programmes/TUR_MYONCO.html

- ✓ **In-house training sessions : SOPs update**
- ✓ **Attending meetings (BHS, EBMT...)**

Food for thought

1. Management of temporary work cessation :

- ✓ Specific training plan to regain autonomy and proficiency
- ✓ Manage tutorship supervision
- ✓ At least reading of :
 - Updated SOPs
 - Continued training sessions

2. Not everyone can do everything

→ specialization, reference persons

3. Training & evaluation of tutors ?

4. As for other QM topics, needs **planification and overview** over a defined period (by board review?)

5. Management of > 20 staff members

→ requires computer tools

Conclusions & summary

Training (as trainer or trainee)

- ✓ Part of daily job for all staff members
- ✓ Part of the global quality management
- ✓ Part of the Self-actualization, wellness and personal / professional development inherent to any job

JACIE requirements

- ✓ SOPs for personnel training and competency assessment
- ✓ Training cycle : initial qualifications and continued training - annual performance review - provisions for continued education
- ✓ Management of training records

What JACIE requires about training PLAN – ATTENDING PHYSICIAN?

JACIE B3.4.3 :

- Attending physicians in all Clinical Programs shall have specific training and competency in each of the following areas
- Indications for HPC transplantation
 - ✓ Selection of appropriate patients and preparative high dose therapy regimens.
 - ✓ Pre-transplant patient evaluation, including assessment of appropriate patient eligibility and HPC adequacy with respect to collection
 - ✓ Administration of high-dose therapy.
 - ✓ Administration of growth factors for HPC mobilization and for post-transplant hematopoietic cell reconstitution
 - ✓ HPC product infusion and patient management.
 - ✓ Management of neutropenic fever
 - ✓ Diagnosis and management of infectious and non-infectious pulmonary complications of transplantation
 - ✓ Diagnosis and management of fungal disease
 - ✓ Diagnosis and management of VOD of the liver
 - ✓ Management of thrombocytopenia and bleeding.
 - ✓ ...

What JACIE requires about training PLAN – ATTENDING PHYSICIAN?

JACIE B3.4.3 (continued) :

- ✓ Management of hemorrhagic cystitis.
- ✓ Management of nausea and vomiting
- ✓ Management of pain
- ✓ Management of terminal care patients
- ✓ Diagnosis and management of HPC graft failure
- ✓ Documentation and reporting for patients on investigational protocols.
- ✓ Identification and selection of HPC source, including use of donor registries.
- ✓ Methodology and implications of human leukocyte antigen (HLA) typing.
- ✓ Management of patients receiving ABO incompatible HPC products.
- ✓ Diagnosis and management of cytomegalovirus (CMV) infection and disease.
- ✓ Diagnosis and management of other viral infections in immunocompromised hosts.
- ✓ Diagnosis and management of acute and chronic graft versus host disease.
- ✓ Diagnosis and management of post-transplant immunodeficiencies.
- ✓ Evaluation of chimerism

What JACIE requires about training PLAN – NURSE?

JACIE B3.7 Nurses

- The Clinical Program shall have nurses and nurse supervisors formally trained and experienced in the management of **patients receiving HPC transplants** (B3.7.1)
- Training shall include **hematology/oncology patient care; administration of high-dose therapy, growth factors, and immunosuppressive medications; management of infectious complications associated with compromised host defense mechanisms; administration of blood products** (B3.7.3)
- There shall be written policies for all relevant nursing SOPs, including:
 - **Infection** prevention and control (B3.7.4.1)
 - Administration of the **preparative regimen** (B3.7.4.2)
 - **Transplantation** of HPC (B3.7.4.3)
 - Central venous **catheter care** (B3.7.4.4)
 - **Blood product** transfusion (B3.7.4.5)
 - Transplant nurse **competency evaluation** process (B3.7.4.6)