Chapter 17

Training Programme

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Cell therapy guidelines and standards, for staff training and quality control, are outlined in the European Union (EU) Directives and by other international agencies [1–5]. In addition to staff qualifications and training, the directives also require documented evidence of the qualifications of the trainers [4].

Educational activities aimed at developing staff knowledge and skills [6] are fundamental for safe and effective cell therapy. Such educational activities can facilitate the manufacturing of a cost-effective product while improving overall process and improve management. Appropriately trained staff have more self-confidence, a greater sense of accomplishment and ability to fulfil personal goals, and better communication and leadership skills [7]. High-quality and motivated cell therapy staff are indispensable regarding developing and maintaining an effective QM system. Therefore, it is advantageous for cell therapy staff to have continuous training and receive competency evaluations at regular intervals.

Types of Education

FACT-JACIE has established international standards for cell therapy, including the following training and education requirements for personnel.

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Orientation Training

This includes activities to introduce new employees to their colleagues and the treatment centre. The aim, history, philosophy, rules and procedures of the centre should be reviewed with all new staff. Information about human resources policies to include business hours, staff support services, payroll procedures, overtime requirements and benefits are provided, together with information on the physical capacity of the organisation. Specific orientation training for staff working in cell therapy should cover general therapeutic principles for each area involved in cellular therapy as well as the functionality of the cellular therapy clinical units within the centre. All training should be clearly defined in the standard operating procedures. To facilitate orientation, a handbook could be provided to all personnel to ensure compliance (Table 17.1).

Initial Training

After attending a general facility orientation, initial hands-on training of new personnel should begin. It is especially important that personnel, who will be performing critical procedures, clearly understand the work that they will be undertaking.

Table 17.1 Example orientation training programme for new personnel in a cell therapy unit

Days	Topic	Trainer
First day	Meet colleagues Roles and responsibilities Payroll and human resource requirements policy Benefits package Dress code regulations Organisation, mission and vision	Unit director Technician Personnel manager
Second day	Bone marrow centre/vision, mission, values Quality management system Organisation chart Working hours Training courses/certification Procedures/bonuses/policy violations Standard operating procedure and other forms and booklets Promotion of the hospital Transportation/housing/services Patient rights/satisfaction	Unit director Technician Quality control manager Personnel manager
Third day	General operating principles of the unit Employee, donor, patient, and product safety Workflow processes	Unit director Technician

Initial training should focus on relevant scientific and technical material, organisational structure, the QM system, health, and safety rules, and ethical, legal, and regulatory policies [4].

Moreover, the initial training should allow sufficient time to grasp the concept and application of the treatment processes at various interval of patient care. For processes where minimising error is critical, training should be repeated, at specific intervals with assigned knowledge and skills sign-offs, to ensure that personnel fully comprehend the content.

Continuous Education

Continuous staff training, both personally and professionally, is essential to ensure that both staff and the department keep abreast of the latest developments in cellular therapy [4]. Centers can develop and apply their own continuous education programs or use methods based on international standards. New developments in cell therapy occur constantly, and training will facilitate the adoption of new methods and processes by personnel. Continuous training is a dynamic process that ensures that the centre itself is committed to continuous growth and development.

According to FACT-JACIE, key personnel should participate in a minimum of 10 hours of educational activities related to cell therapy annually, and continuing education should include, but not be limited to, activities related to hematopoietic stem cell therapy. Appropriate continuing education activities [4] include the following:

- Annual meetings of professional societies presenting information which is directly related to cell therapy
- Presentation of papers at scientific meetings
- Participation in webinars and online tutorials

Training Methods

Theoretical Education

All cell therapy centres should provide theoretical training with a predetermined purpose, method, and content (Table 17.2).

Table 17.2 Planned training to be delivered over a 6-month period in a clinical unit

Center name		(Year)				Date:../.../.....					
						Page number:					
						Revision no.:					
						Revision date:					
						Application date:					
No.	Subject	Date	Place	Duration	Trainer	Trainees	Aims and objectives of education	Method and material of education	Training assessment (competency)	Qualification criterion	Date of training
1	Hematology/ oncology patient care		Clinical unit	60 Min	Transplant doctor	Stem cell transplant nurses	To raise awareness	Oral presentation	Exam	80	
2	Recognition of cellular therapy and emergency Management		Clinical unit	60 Min	Senior nurse	Stem cell transplant nurses	Rapid control of complications	On-site training	Observation	Not available	
PREPAED						QUALITY MANAGER					
Name and surname :						Name and surname :					
Title:						Title:					
Signature:						Signature: Date					

Practical Training

Mistakes made during cell therapy can be fatal to patients and may also lead to product loss. Thus, practical training should be provided to personnel involved in all relevant procedures but especially those considered critical.

Rotation Training

Rotation of personnel between departments and roles will enhance experience, skills, and knowledge. The aim is to familiarise employees with the functions, rules and procedures of all departments included in the rotation cycle. Rotation training constitutes a holistic approach to the training of new personnel, who will engage in activities involving a variety of disciplines.

Conferences

Given the rapid advances in cell therapy treatments and methods, information exchange at the international level is essential to remain up to date. This can be accomplished through attendance at relevant courses and conferences.

Case Training

Case training requires personnel to analyse cases, identify problems and discuss possible solutions with their colleagues; this process allows personnel to readily apply their knowledge and skills.

Online Training

The information and technologies available through the internet have become indispensable tools for modern education. Online training has increased dramatically due to ease of access and the possibility of training many people in a single session. In addition, participants can provide feedback and their proficiency can be assessed automatically [8].

Standard Operating Procedure (SOP) Training

Cell therapy personnel should be familiar with the SOPs in a QM system. Personnel should be trained in the use of these documents so that they can be effectively applied, when needed.

Unplanned Training

Unplanned training may be required to address repeated errors, following an inspection by an auditor, or in response to events occurring on a particular day. The location and timing of unplanned training are inherently undefined but should be recorded by the QM system, as required.

Trainer Qualifications

The most important factor in the effectiveness of training is the trainer. International standards for cell therapy do not specify the qualifications required by a trainer. However, he or she should have sufficient skills, experience and knowledge of the topic to be taught and should be able to demonstrate specific competencies on request by auditors. Centres should not only employ qualified educators but also define their own training methods according to their QM plans. The effectiveness of the trainer should be assessed using a survey of training participants.

Determination of Training Needs

The training of personnel starts by determining their needs. The required training should then be delivered in accordance with legal and institutional requirements. The training required for maintenance of unit activities (e.g. SOP training) should consider not only what is needed to perform the tasks required by that unit but also the necessity to develop new skills [1–4].

The types of training needed by employees can be assessed by means of surveys, interviews, observation and performance tests. Ideally, a training commission should be created by each centre to determine training parameters including duration, location, method and certification (Table 17.2).

After training needs have been determined, a training programme should be planned and discussed with trainers. Decisions should then be made regarding who should participate in the training, and its format, delivery date/time and location.

Training programmes should be run once or twice a year, although this will depend on the identified needs and capacity to deliver training. All training should be operationally and clinically focused on the cellular therapy programme.

Documentation of Training

As discussed above, training should be conducted in accordance with the training programme. If a training session does not take place in accordance with the plan, the reason for this should be documented; postponing the session until the next training period should also be considered.

All training activities should be documented in accordance with the QM system. Every stage of the training procedure should be recorded and archived, according to the regulations and standards of the individual centre.

Training Evaluation

Evaluation of the quality and outcomes of training are essential to assess how much information has been imparted to personnel. Clear and quantitative assessments facilitate determination of the effectiveness of the training.

The criteria used in training evaluations should be defined in the training plan. Significant work aimed at quantifying the learning that occurs during training has been carried out by Kirkpatrick, who assessed four different areas: (i) participants' responses to education, (ii) learning efficacy, (iii) participants' behaviour after training and (iv) training outcomes [9].

The optimal methods for evaluating training outcomes for key therapy personnel should be determined to ensure patient/donor/product safety. Indirect evaluation methods, including product effectiveness and patient outcomes, can also be used.

In addition, training sessions should be recorded to allow subsequent evaluations thereof, whether by testing or observing the participants.

Conclusion

Training is a critical part of any QM system and can contribute to continued progress in the field of cell therapy. International standards have defined the training required for key cell therapy personnel. Within this framework, all centres should establish their own procedures for conducting and evaluating training. The procedures should be dynamic and meet the needs of the individual unit.

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