Chapter 7

Personnel Requirements Including Job Descriptions

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Introduction

Workforce is central to safe and effective delivery of cellular therapy. Staff organisation and collaboration are essential for successful outcomes [1]. It is important to define the roles of key personnel and their support personnel, thus ensuring that tasks are uninterrupted. The number of personnel should be determined in accordance with demand, as well as the nature of the respective centre's activity. Cellular therapies are unique, in that they require many personnel with varying qualifications and competencies to work as a team. For these therapy centres to achieve their goals, employees must work together harmoniously; this requires communication and collaboration among employees [2].

To establish mutual understanding and cooperation between components of hematopoietic stem cell transplantation (HSCT) programs, it is imperative to establish a centralised and active communication network. Motivation is another factor that ensures effective and efficient employees. Training, organisation, management, and development of personnel should all be prioritised within the quality management plan, alongside regulations that ensure the occupational safety and health of workers for all processes [2–5].

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Organisational Structure and Organisational Chart

The organisational structure is a coordination system that enables individuals to realise their goals by combining their respective efforts, knowledge and abilities through collaborating with others, as well as through development and execution of a structure considered most suitable to achieve a specific goal. While developing the organisational structure in cellular therapy centres, the hierarchy, collaboration and communication of all units both within and outside the centre must be easily understood [3–5].

The organisational chart should define, maintain and work with the optimal number of staff in the quality management system. Each level in the chart should consider the tasks, capabilities, responsibilities, and communication networks shaped within the framework of business processes and corporate systems. The scheme should reflect quality management, along with clearly defining the roles, authority, responsibilities and duties of all employees [3–5].

In centres that provide cellular therapy services, organisational charts should never be made for individuals; they should be developed for units as a whole. This includes the organisational structure of all units involved, such as clinical units, cell processing, peripheral blood or bone marrow collection units, other disciplines (e.g., consultants), supporting units (e.g., medical/nutritionist) and administrative units (e.g., transportation unit and housekeeping), alongside all units with a service level agreement. Organisational charts should be developed in accordance with targets, systems and processes; staff should be chosen for positions within the chart, based on their qualifications, competencies and training. This is necessary, as the performance of a centre is directly influenced by its organisational structure [3–5].

The quality management system should be able to accommodate fluctuations in personnel and cover planned and unplanned unavailability to maintain operations on a day-to-day basis, e.g. illness, annual leave and departures [1–5]. Succession planning for key position should also be considered, e.g. quality manager (1). Education, quality and motivation of personnel are the most important factors for ensuring well-organised human resources and quality awareness within cellular therapy centres.

Key Personnel

All personnel involved in the planning, management and control of critical activities, both directly and indirectly, in the field of cellular therapies should be defined as key personnel. For example, these personnel would include individuals performing stem cell collection, processing and freezing procedures. This definition will determine in advance when and what individual cellular therapy centres can provide, along with the personnel available within the centres.

It is necessary to ensure that personnel designated and appointed conform to the requirements and qualifications of the job to be undertaken. In addition, the experience and abilities of individuals should be considered during the selection; those selected should be trained in accordance with their duties. Designated key personnel should remain unchanged wherever possible; supervisors of key personnel should be trained to an equivalent standard, such that where key personnel are not available, those supervisors may step into the role as necessary [3–6].

Personnel Competency

Haematopoietic cellular therapies have complex and dynamic treatment pathways. All employees working in the field of cellular therapy should therefore be developing and improving skills and knowledge through continuous training [6]. As such, competencies of employees should be measured and recorded regularly within the quality management plan (Standards B3, C3, CM3, D3) [5]. The ability of employees to work effectively provides an indicator of the quality of training, its relevance to the requirements of employees in their respective roles and whether the system is working correctly with expected results. Various methods can be used to measure the adequacy of employees for a given role. A table completed through measurement or observation can be used; electrical monitoring systems can also be used (Table 7.1).

Responsibility and Task Awareness

Once recruited, personnel are given powers and responsibilities required to perform in their given roles. Individuals must know and understand their role, to whom and to what extent they have authority, and to what extent they can give instructions to others who rely on them. To achieve this, job descriptions should include relevant duties, necessary qualifications, responsibilities and authority.

Use of Effective Communication

Cellular therapy centres function as a multidisciplinary unit with other components within the same hospital and/or program, as well as with other centres both inside and outside of the country. To achieve this objective, interaction, cooperation between units and a common language are proven elements for success in the field. It is vital for all personnel involved in the process to possess good communication skills and be able to use communication resources effectively. Communication meetings with all personnel and key personnel involved in the processes should be

Table 7.1 Sample personnel performance form

Example of personnel competency evaluation form	
Evaluated employee: Name and surname: Unit of work: Start date of work:	Evaluator (director/supervisor) Name and surname: Signature: Date: Score:
1	Adherence to both written and verbal communication standards of the institution (including compliance with working hours and dress code)
2	Knowledge, adoption and implementation of institution's quality policy and objectives
3	Identification of business priorities, including effective use of time and resources
4	Communication and collaboration with superiors and other team members
5	Adherence to patient, donor, product and occupational safety rules
6	Collaboration with others in tasks requiring teamwork, providing support and meeting deadlines
7	Possession of effective communication skills; protection of confidentiality for patient donors and medical records
8	Willingness to undergo further training and self-development
9	Attention to detail; timely recognition and resolution of problems
10	Comprehension of working role; ability to perform appropriately; leadership potential
Total score (all questions scaled from 1 to 10): 0–20: Very unsuccessful; 21–30: unsuccessful; 31–60: moderately successful; 61–80: successful; 81–100: very successful	
Employee strengths:	
Employee weaknesses:	

scheduled regularly. These multi-unit meetings should be recorded and presented within annual reports [3–5].

All personnel should undergo annual appraisal of performance and other key aspects of their work and relationships with others in the team, with appropriate action taken in order to promote team work and good practice and maximise quality for product safety and, ultimately, patient and donor benefit [7–8].

Job Descriptions

The roles of personnel included in the organisational chart of cellular therapy centres must be clearly defined in advance. Processes within cellular therapy centres are complex; as such, any errors that may occur must be minimised. Accordingly, European Union Directive 2006/86/EC states that all personnel working in the field

of cellular therapies should have clear, documented and up-to-date job descriptions; moreover, their duties and responsibilities should be clearly documented and understandable [9].

International standards also require that current job descriptions be documented within the audits and that employees have received training for their respective job descriptions [5]. If employees have been given responsibility for a critical procedure, they must possess sufficient competencies to fulfil this responsibility. In addition, the level of authority should not be less than or greater than that required for the responsibility; the task designation of the employee should be sufficiently detailed in the job description. This should detail the positions of employees within the organisational chart [3–5].

Job descriptions must be written, understandable, and clear. When employees read their job descriptions, they should not have to guess or interpret meanings beyond those which are written. Job descriptions should be concise, define the current position and possess a dynamic structure. They should not restrict the employees in their tasks, but should allow the employees' experience to inform the work that each member performs. While creating a job definition, it is necessary to determine the nature of the proposed task and who will write the task description. The author should be competent and knowledgeable regarding the task and how it will function. When the definition of the task is initially formed, ideas should be collected from employees by means of interview or survey. It may also be useful to examine job descriptions created for similar positions in other institutions [10].

When a job definition is created, it should be properly documented. All job descriptions should be reviewed and approved by the relevant centre or unit director. The director should convey the final definition of the task to the relevant personnel; the relevant personnel should then be trained accordingly. The personnel must be confirmed to fully understand the content of the job description. An examination, observation or similar method can be used for this confirmation [10].

The structure of the job description may vary among centres; however, all job descriptions within an organisation should have a standardised appearance [10].

The following topics should be included:

- *Job title* – name of the position.
- *Salary grade/level/range* – compensation levels, groups or pay ranges, into which jobs of the same or similar worth are placed, including minimum and maximum pay bands.
- *Reports to* – title of the position this job reports to.
- *Date* – date when the job description was written or last reviewed.
- *Summary/objective* – summary and overall objectives of the job.
- *Essential functions* – essential functions, including how an individual is to perform them and the frequency with which the tasks are performed; the tasks must be part of the job function and be required to perform the job.
- *Competency* – knowledge, skills and abilities.
- *Supervisory responsibilities* – direct reports, if any, and the level of supervision.

- *Work environment* – the work environment; temperature, noise level, inside or outside, or other factors that will affect the person's working conditions while performing the job.
- *Physical demands* – the physical demands of the job, including bending, sitting, lifting and driving.
- *Position type and expected hours of work* – full time or part time, typical work hours and shifts, days of week and whether overtime is expected.
- *Required education and experience* – required education and experience based on job-related requirements and consistent with the requirements of the centre.
- *Preferred education and experience* – preferred education and experience based on job-related requirements and consistent with requirements of the centre.
- *Additional eligibility qualifications* – additional requirements such as certifications, cellular therapy-specific experience and experience working with specific items of equipment.
- *Other duties* –.

Signature lines Signatures are important in validating the job description. They indicate that the job description has been approved and that the employee understands the requirements, essential functions and duties of the position. Signatures should include those of the supervisor and of the employee [10].

Personnel File

Personnel files should be created for uninterrupted monitoring of all key personnel in the quality management system. When no longer required, these files should be archived in a secure area for the period specified in the quality plan. Personnel files are confidential and should therefore be kept with controlled access. These files include personal education information, training participation and personnel qualification evaluations. Related documents should be included; when the employee leaves the unit, their file should be retained [3–5].

Conclusion

An important responsibility of directors working in cellular therapy centres is to understand and define the roles and responsibilities of employees so that their objectives are best met. This enables directors to better distribute workload to personnel appropriately, whilst maintaining safety and efficiency. The collection of personnel or staff satisfaction surveys at regular intervals is recommended. The results should be evaluated at the quality committee meetings or similar groups with the goal of optimising ongoing processes and operations as well as workforce well-being.

A continuously improving quality management system incorporating the correct personnel with clear roles, responsibilities, training, competency and working relationships will ensure that processes are effective and efficient and maintain safety and quality for the programme. Processes are numerous and diverse; personnel should have continuous development of skills and qualifications, and key personnel should continuously contribute to the training, competency and personal development of new and existing personnel. Continuity and robustness of operations should be supported by cross-cover arrangements and succession planning. All of these aspects are covered by FACT-JACIE standards and the accreditation process, which should be used as an opportunity to review personnel and their functions, and, where necessary, identify deficiencies or weaknesses, undertake corrective actions or highlight issues to the accreditation organisation and external inspectors during the accreditation process.

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