Educational Needs for Cell Processing Facility Personnel

42

Boris Calmels

Training on ATMP processes and procedures is systematically provided by the sponsor after site certification/accreditation.

Chain of Identity (COI) and Chain of Custody (COC) are the most crucial items to understand to ensure traceability and identification of a cellular product; for commercial ATMPs, the COI and COC are usually managed through a dedicated secure web-based platform.

In the autologous setting, cell processing staff is involved in most of the on-site ATMP stages, from collection to administration: the information flow between all protagonists must be well established to allow for timely delivery of information.

Pivotal training steps for cell processing staff:

- before apheresis: receipt of empty shipper (if apheresis is shipped after cryopreservation) and materials.
- after apheresis completion: control of product label, sampling, cryopreservation, and/or packaging for transportation of fresh or frozen apheresis to the manufacturing site.

The responsibility for subsequent steps might be shared with or fulfilled by the hospital pharmacy, depending on local regulations.

- after manufacturing completion and prior to initiating lymphodepletion: receipt of shipper, conformity of transport temperature, frozen bag integrity, and transfer of frozen product to on-site storage.
- the day of infusion: transport of bag(s) to the thawing site, clinical ward (if bedside), or cell therapy facility (recommended) if localized near the infusion site (thawed ATMPs need to be infused asap).

B. Calmels (✉)

Cell Therapy Facility, Institut Paoli-Calmettes, Marseilles, France

e-mail: calmelsb@ipc.unicancer.fr

Frozen bag handling and thawing require expertise and must be performed by experienced, i.e., cell processing staff, whenever possible: this will also relieve training of unexperienced staff, especially regarding the risks associated with liquid nitrogen exposure, and anoxia or handling of accidental bag failures.

One of the many challenges of training is to become used to the quantity and variety of forms associated with each step of the ATMP circuit; consequently, mock (training) runs organized by sponsors are pivotal for staff training.

Key Points

- Chain of Custody (COC) is crucial to ensure traceability through the multiple steps and stakeholders in the supply chain.
- Information that flows between all protagonists must be well defined.
- Frozen bag handling and thawing should be performed by skilled cell processing staff.

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