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Chapter 6: Third Party Agreements

Philosophy

FACT - accredited organizations must demonstrate control over and knowledge of all aspects of its activities. When activities are outsourced to third party vendors/service providers, it can be challenging to maintain that same level of control. For that reason, third-party agreements are necessary; it can be difficult to maintain control when an activity or product is in the hands of another facility. While management of third party agreements may pertain more to collection and processing, it can be used in the clinical setting when the patient care activity is transferred to a non-FACT accredited center before such time as the patient is ready for discharge.

QM Principles

Agreements should clearly define roles and responsibilities for all critical tasks. All such agreements should be dated and reviewed on a regular basis, and include provision for the maintenance of records following termination of the agreement. If an organization interacts with third parties for the procurement, processing, or testing of cellular therapy products, it must have policies and procedures for establishing and maintaining written agreements. Agreements such as these should contain references to quality management concepts.

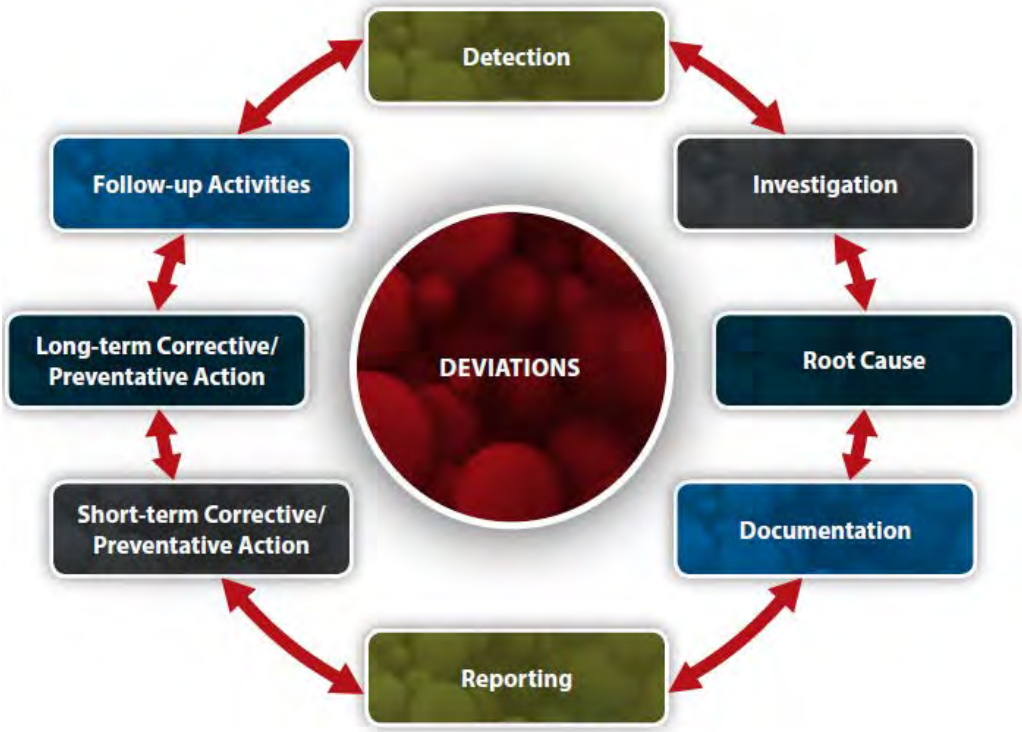
> *Example: Some combined adult and pediatric programs do not have a pediatric ICU within the facility. In that case, negotiations must take place and agreements must be written for patients who are transferred in case of emergency. It is not only imperative that contracts be written, but you must also ensure that policies are being followed as per the written agreement. The program may wish to develop a nursing education program within the transplant facility that addresses training nurses from other facilities to care for the transplant patients. An effective education program assesses initial training as well as continued competency.*

Organizations need to not only ensure that agreements exist with entities outside of the main organization that participate in product collection, testing, storage, transport, or other critical services that might affect the quality of the product, but also to ensure that they are followed. While the Program/Facility Director is responsible for all agreements and compliance from all parties, Quality Management personnel should verify that quality agreements exist and are satisfactorily documented. It is also important that the quality agreements are periodically reviewed and updated to meet changing requirements after the first acceptance. Some organizations perform an annual review; however others may have a different defined period. Agreements need to be reviewed to ensure they are still meeting both parties' requirements. Both parties mutually determine how they will ensure compliance with written agreements.

> *Example: The NMDP has such agreements with facilities that perform unrelated donor transplants. If the organization has the processing and collection facilities within the institution, it is not necessary to have such an agreement. In that case, there should be a memo stating that other than the NMDP, there are no other organizations to whom services are provided.*

Managing Deviations

To effectively manage deviations, organizations must incorporate the tasks illustrated by the diagram below into their processes. Generally, there is an intuitive order to the requirements; however, different situations may require ordering completion of these steps differently, and they are often performed concurrently.



Deviations from approved practice could have major consequences to the recipient, donor, or institution. All personnel should be encouraged to report anything which may affect the quality of the product or the safety of a donor or recipient. This can be as simple as asking three simple questions – *What Happened, What Immediate Action was Taken, and What Might be Done to Prevent Recurrence of the Problem.*

Documents and records are important for investigation of deviations because these investigations are frequently retrospective.

The most important action of the deviation management and reporting process is preventing re-occurrence. While there is no set timeline for investigation, review and analysis, this should be undertaken quickly so that potential repeat of the issue is avoided. While all deviations must be reported through an internal detection system, some may have to be reported to authorities outside the department or even to regulatory agencies due to laws and regulations.

Investigation and analysis with a proposed preventative action are required for reports that must be submitted to CBER, FDA or to the IRB and FDA during the IND annual report. The same process must be completed in order to expect prevention of re-occurrence. In many organizations this work is completed by a centralized program service so that all processes; screening, collections, processing and clinical transplant can be reviewed objectively. This objectivity is more likely to identify the true root cause and lead more quickly to needed corrections.

Common Citations for supplies lacking validated labels

A commonly cited deficiency concerning supplies is lack of validated labels. Documentation should exist which demonstrates that labels in use were checked against an approved template, were approved for use, maintain integrity during use, remain affixed or attached as required, are readable, do not contain any blank data points, included all of the required elements as listed on the label table in the FACT-JACIE Standards, Appendix II and III). Validation of the labeling process should demonstrate completeness and correctness of each data point, as well as the accuracy of data as shown by traceability and traceability of the product from donor to recipient, or final disposition. A periodic audit of labels in use can document that this process – the supply which is necessary - is in control.

Product Disposal

The control of cellular product disposal must be defined to protect the product and product records from inadvertent disposal or destruction. The facility must have a system to document the final disposition of all products and must be able to account for all products that are no longer in inventory.

Facilities should define product expiration, disposition of expired products and supplies, and disposal methods. Agreements between facilities or consent between the facility and the customer should define approval required for product transfer, disposal, or destruction.

In some facilities, products and supplies deemed unsuitable for clinical use may be released for research purposes. Product and materials, specifically biohazardous, chemical, or toxic materials, must be disposed according to waste agencies regulations.

- Facility policies and procedures must detail when products can be disposed and what process must be followed for product disposal.
- Length of storage and reasons for disposal must be defined in agreements between the processing facility and the customer.
- Protocols should state duration and conditions of storage and indications for disposal.
- Records of final disposition must be complete and readily available for review.

Examples of disposal review and audits

- *Review disposal agreements or patient consents regarding product storage and disposal.*
- *Review discard records and waste policy for proper disposal of biological products.*
- *Review patient records for notification and approval of recipient physician to dispose products.*
- *Verify that facility policies define criteria for product disposal. Examples include: product expired, product no longer needed by customer, customer approved product disposal, product was contaminated or did not meet release criteria.*
- *Review protocol agreements for record retention and follow up.*