

Our FACT-JACIE Standards Compliance



FACT-JACIE Standards are designed to provide minimum guidelines for programs, facilities, and individuals performing cellular therapy or providing support services for such procedures. It is the responsibility of these organisations and individuals to ensure that all areas comply with the standards.

Relevant Standards

- **FACT:** Foundation for the Accreditation of Cellular Therapy
- **JACIE:** Joint Accreditation Committee
- **FACT-JACIE:** International Standards for Hematopoietic Cellular Therapy (Product Collection, Processing and Administration) 7th Edition



Applicability

World Courier as a transport provider is not eligible to be certified under these standards. However, as there are sections that focus on Product Transportation and Shipping, a gap analysis was conducted to confirm that World Courier is compliant with the requirements.

During the gap analysis, the relevant sections of the standards reviewed were:

- CM 10 Marrow Collection Facility Standards - Cellular Therapy Product Transportation and Shipping
- C10 Apheresis Collection Facility Standards - Cellular Therapy Product Transportation and Shipping
- D10 Processing Facility Standards - Cellular Therapy Product Transportation and Shipping

Outcome

The gap analysis indicates that World Courier is compliant due to the following:

- There is a Standard Operating Procedure (SOP) on the handling of Cell/Gene Therapy OPS E003 Cell/Gene Therapy
- There is evidence that relevant staff have been trained on this SOP and training records are available for review in the Training Resource Centre
- There are qualification reports for the various types of packaging including dry shippers
- All relevant staff are aware of the requirements of a specific Cell/Gene Therapy project and that, the available tools, Cell/Gene Therapy Project Statement of Work and Cell/Gene Therapy Lane Mapping are to be used
- SOP CORP C001, Performance Qualification of Shipping Container and Lane Risk Assessment used to assess the suitability of shipping containers and shipping lanes
- Notifications sent out when pick-ups and deliveries are completed
- Work Instruction WI-Ops-E011 Using and Documenting Security Seals is used to ensure security of each shipment. This is also covered in SOP OPS E005, Shipment Handling and Cargo Preparation

To learn more about our quality standards, and how to utilize our logistics platform, please contact your local World Courier representative.