

A thin, light blue line starts from the left edge of the page, slopes upwards to the right, and then curves downwards to the right, ending near the top right corner.

# EXAMPLE OF UNIDIRECTIONAL CHAIN OF CUSTODY FORM FOR SHEET FOR IEC PRODUCTS WITH COLLECTION, MANUFACTURING, RECEIPT AND INFUSION AT DISTINCT SITES

Disclaimer: This example is just one of many potential examples of a chain of custody form for a cellular therapy product being shipped from apheresis collection to another site for manufacturing. A similar chain of custody form could be used for shipping from manufacturer to the storage site, and from the storage site to the infusion site.

The general expectation is that the immune effector cell (IEC) program tracks a cellular therapy product through each link in the chain of custody from collection from the donor to the eventual recipient infused. The chain of custody must be managed in a manner that clearly documents entities in control of the product at each change in custody and protects viability and integrity of the product. The format and information included in chain of custody processes may vary for each site and type of product. If this example is used, the program is responsible for updating it as new information becomes available.

**CHAIN OF CUSTODY RECORD**

<b>SECTION A: PRODUCT INFORMATION</b>			
To be completed by Chain of Custody Initiator.			
Initiator Name: _____		Unique Product Number: W.....	Collection Date:
<b>Collection Facility</b> <b>Institution XXX</b> Email: _____ PHONE: XXX-XXX-XXX FAX: XXX-XXX-XXX		Bag Number:	
Type of Product: <input type="checkbox"/> T Cells, Apheresis <input type="checkbox"/> Other Cells, Apheresis _____		<b>Shipping Temperature</b>	
Product State: <input type="checkbox"/> Fresh		[ ] 2-8 °C [ ] Other _____	
Product(s) and Documentation Packed For Shipping By: _____		Date:	Time
Ship & Deliver To: ATTN: XXX Manufacturing Facility XXX Address Tel: XXX XXX-XXX Fax: XXX XXX-XXX Email:		Courier: XXX Job #:	

<b>SECTION B:</b>	
<b>FACILITY INFORMATION PERTAINING TO PRODUCT COLLECTION, PROCESSING &amp; INFUSION</b>	
<b>1. Collection Facility Name &amp; Address:</b>	<b>3. Infusion Facility Name &amp; Address:</b>
XXX	XXX
<b>2. Processing Facility Name &amp; Address:</b>	<b>4. Other:</b>
XXX	XXX

<b>SECTION C: PRODUCT TRANSFER RECORDS:</b>			
Signatures indicate transfer/acceptance of products to/from designated authorized personnel.			
<b>From Institution XXX (Product Relinquished)</b>		<b>To Courier XXX (Product Accepted)</b>	
Signature:		Signature:	
Date:	Time:	Date:	Time:

**CHAIN OF CUSTODY RECORD**

<b>From Courier XXX (Product Delivered)</b> Signature:		<b>To Manufacturing Facility XX (Product Received)</b> Signature:	
Date:	Time:	Date:	Time:

<b>Section D: Remarks.</b> To be completed by Manufacturing Facility XXX staff member receiving the apheresis product. Fax (XXX-XXX-XXXX)/Email this document back to Initiator of this Chain of Custody on completion.			
Primary Container: correct product received, bag intact	<input type="checkbox"/> Acceptable	<input type="checkbox"/> Unacceptable	<input type="checkbox"/> Other: Specify:
Product Quality (Physical Inspection): no hemolysis, clotting or clumping	<input type="checkbox"/> Acceptable	<input type="checkbox"/> Unacceptable	<input type="checkbox"/> Other: Specify:
Secondary Container (Shipper): intact, unopened	<input type="checkbox"/> Acceptable	<input type="checkbox"/> Unacceptable	<input type="checkbox"/> Other: Specify:
Temperature of Inner Container at receipt		°C	
Label Quality: intact, legible, not frayed or stripped	<input type="checkbox"/> Acceptable	<input type="checkbox"/> Unacceptable	<input type="checkbox"/> Other: Specify:
Product ID Matches Order	<input type="checkbox"/> Yes <input type="checkbox"/> No*		
<b>All Required Documents Are Included:</b>			
<i>DISTRIBUTION &amp; TRANSPORT RECORD</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No*		
Waybill	<input type="checkbox"/> Yes <input type="checkbox"/> No*		
Infectious Disease Monitoring (IDM) paperwork provided by XXX facility and within 7 days of apheresis collection	<input type="checkbox"/> Yes <input type="checkbox"/> No*		
<i>PRODUCT INFORMATION SHEET</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No*		
* If any of these conditions are not met please call XXX-XXX-XXXX			
Product inspected by: Print Name:	Date:	Time:	