


Deviation Notification Investigation Request

1. Deviation Information <i>(Completed by BMS)</i>		BMS Deviation Number:	
Apheresis Site Name:			
Date Deviation Discovered:			
Date Deviation Occurred:			
Apheresis Site Investigation Due Date:			
MNC Collection Information			
JOIN(s):		Select applicable collection type:	
		Commercial: <input type="checkbox"/> Clinical: <input type="checkbox"/> Healthy Donor: <input type="checkbox"/> Pediatric: <input type="checkbox"/>	
Description of Deviation			
Expected Results:			
			
<p>9.4.6. Affix the verified Shipping Address Label (Attachment C) to the side of the MNC Shipping Container.</p>			
Actual Results:			
<p>JOIN 8XR8-HP6P6 arrived at BMS Manufacturing without the shipping label affixed to the shipping container. Product bag label had a rip that obscured patient DOB.</p>			
Apheresis Site Notification issued to:		Name(s):	
		Email(s):	
Apheresis Site Notification issued by:		Name:	Date:

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2. Apheresis Site Investigation <i>(completed by Apheresis site)</i>		Apheresis Site Deviation Number: <input type="checkbox"/> N/A	
Note: Apheresis site can submit a final internal Investigation report to BMS instead of completing this report. If utilizing an Internal report, it should contain the information requested in Section 2 of this report.			
Investigation Summary:			
Root Cause attributed to:			
Materials: Raw Material, API, Intermediates, Components, etc.		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Method/Procedures: Standard, Policy, SOP, WP, Regulations, Processes, etc.		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Environment: Temperature, Humidity, Location, Time, etc.		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Equipment: Apheresis Machines, Tools, Chambers, Computers, Controllers, etc.		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Personnel: Operator, Technician <i>(If personnel error determined to be "Human Error" check applicable Category below or N/A)</i>		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Human Error: <input type="checkbox"/> N/A		Check Category	
<ul style="list-style-type: none"> Decision - Inappropriate decisions and/or behavior 		<input type="checkbox"/>	
<ul style="list-style-type: none"> Training - Lack of skills and/or knowledge 		<input type="checkbox"/>	
<ul style="list-style-type: none"> Omission - Knowledgeable but missed step/action/info. 		<input type="checkbox"/>	
<ul style="list-style-type: none"> Inconsistency - Has knowledge, but method/practice has not been standardized 		<input type="checkbox"/>	
<ul style="list-style-type: none"> Application - Knowledgeable but implemented the action/information incorrectly 		<input type="checkbox"/>	
Investigation Completed By (Print Name):			

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Immediate Corrective Actions:	
Document Immediate Corrective Actions or check N/A:	<input type="checkbox"/> N/A
Corrective Action/Preventive Action (CAPA):	
Was CAPA initiated?	<input type="checkbox"/> Yes <input type="checkbox"/> No If no, explain why?
	If yes, document CAPA/CAPAs: Implementation Date:
Effectiveness Check:	
Is an Effectiveness Check required?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, describe effectiveness check:
	EC Date:
Investigation Final Report Completed By:	
Print Name:	Title:
Signature:	Date:

Send the completed Investigation Report to:
BMS Apheresis Operations at apheresis@celltherapy360.com and
QA Patient Operations at mg-na_gapops@bms.com.