


**Duke**Medicine


**Pediatric Blood and Marrow Transplant**  
**Adult Blood and Marrow Transplant**  
**Stem Cell Laboratory**

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CQP Audit Schedule for the APBMT Program and STCL

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**COMM-PAS-018 JA1**  
**CQP Audit Schedule for the APBMT Program and STCL**

<b>Program</b>	<b>System/Process Audit (As Applicable)</b>	<b>Frequency</b>
<b>Stem Cell Laboratory (STCL)</b>	<ul style="list-style-type: none"> <li>• Personnel/Training</li> <li>• Facilities</li> <li>• Environmental Monitoring</li> <li>• Equipment Management</li> <li>• Inventory Control/Supply Management</li> <li>• Document Control/Records Management</li> <li>• Process Management and Control</li> <li>• Product Release</li> <li>• Event Management</li> <li>• Quality Improvement</li> <li>• Donor/Recipient/Processing Files</li> <li>• Management of Cellular Therapy Products with Positive Microbial Cultures</li> </ul>	Annually
<b>Adult Blood and Marrow Transplant (ABMT) Apheresis</b>	<ul style="list-style-type: none"> <li>• Personnel/Training</li> <li>• Facilities</li> <li>• Equipment Management</li> <li>• Inventory Control/Supply Management</li> <li>• Document Control/Records Management</li> <li>• Process Management and Control</li> <li>• Event Management</li> <li>• Quality Improvement</li> <li>• TED Forms/Accuracy of Clinical Data</li> <li>• Donor Screening Testing including: <ul style="list-style-type: none"> <li>○ Interim assessment of donor suitability prior to the start of the collection procedure</li> <li>○ Donor eligibility determination prior to the start of the collection procedure</li> </ul> </li> <li>• Chemotherapy Records and Prescription Ordering System Against the Protocol</li> <li>• IEC Therapy Safety Endpoints and Toxicity Management</li> </ul>	Annually
<b>Pediatric Blood and Marrow Transplant (PBMT) Apheresis</b>	<ul style="list-style-type: none"> <li>• Personnel/Training</li> <li>• Facilities</li> <li>• Equipment Management</li> <li>• Inventory Control/Supply Management</li> <li>• Document Control/Records Management</li> <li>• Process Management and Control</li> <li>• Event Management</li> <li>• Quality Improvement</li> </ul>	Annually

Program	System/Process Audit (As Applicable)	Frequency
	<ul style="list-style-type: none"><li>• TED Forms/Accuracy of Clinical Data</li><li>• Donor Screening Testing including:<ul style="list-style-type: none"><li>○ Interim assessment of donor suitability prior to the start of the collection procedure</li><li>○ Donor eligibility determination prior to the start of the collection procedure</li></ul></li><li>• Chemotherapy Records and Prescription Ordering System Against the Protocol</li><li>• IEC Therapy Safety Endpoints and Toxicity Management</li></ul>	

**Signature Manifest****Document Number:** COMM-PAS-018 JA1**Revision:** 01**Title:** CQP Audit Schedule for the APBMT Program and STCL**Effective Date:** 01 Jul 2025

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**Document Release**

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