


DukeMedicine


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

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Supplier Impact Assessment

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Duke Cancer Institute
SUPPLIER IMPACT ASSESSMENT

The Quality Management System (QMS) requires qualifying information and periodic monitoring of suppliers. An impact assessment is sufficient to qualify some suppliers based on the level of criticality of supplies or services provided. This Supplier Impact Assessment Form will be completed internally, considering the supplier's history with the organization, the ability to consistently produce the supply/service, and previous complaints filed with the supplier. The CQP will review this information to determine the level of risk associated with the supplier.

Internal Use Only	
Completed By:	Date Completed:
Supplier Name:	Contact Name/Title:
Supplier Address:	Phone: Fax: Email: Web Address:
Supply/Service Name/Number:	Description:
Associated Change Control Request (CCR) number(s):	

Question	Yes	No	Comments
1. Has the supplier been qualified previously by CQP? If yes, provide the type of qualification and date in the comments.	<input type="checkbox"/>	<input type="checkbox"/>	
2. Is the supplier considered critical? If yes, a quality agreement may be required; verify and date in comments.	<input type="checkbox"/>	<input type="checkbox"/>	
3. Does CQP have a quality agreement with the supplier?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Does any group under the purview of the CQP have prior experience with the supplier?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Have there been complaints submitted by CQP to the supplier in the past?	<input type="checkbox"/>	<input type="checkbox"/>	
6. Have there been any applicable recalls associated with the supplier?	<input type="checkbox"/>	<input type="checkbox"/>	

SUPPLIER IMPACT ASSESSMENT

Question	Yes	No	Comments
7. Does the supplier currently have the ability to supply the required supply/service?	<input type="checkbox"/>	<input type="checkbox"/>	
8. Supply/Service Used by:			
<input type="checkbox"/> ABMT	<input type="checkbox"/> APBMT		
<input type="checkbox"/> PBMT	<input type="checkbox"/> STCL		

Likelihood of Material/Service Failure That Would Not Be Readily Detected	HIGH	5	A	B	C	D	E
	↑	4	A	B	C	C	D
		3	Z	A	B	C	C
		2	Z	A	A	B	B
		1	Z	Z	Z	A	A
			1	2	3	4	5
LOW	<div style="text-align: center;"> LOW HIGH </div>						
Potential Patient Impact							

Grades		Z	A	B	C	D	E
9. Recommended impact grade (see COMM-PAS-017 JA1):		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	Provide rationale for assignment of risk grade.						
11.	Has the risk grade for this supplier changed since the first impact assessment was completed? If yes, please explain. <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A						
12.	Type of initial qualification required? (check all that apply) <input type="checkbox"/> Supplier Questionnaire <input type="checkbox"/> Audit: <input type="checkbox"/> Desk <input type="checkbox"/> On-site <input type="checkbox"/> No additional qualification <input type="checkbox"/> Other: _____						
13.	Type of re-qualification required? (check all that apply) <input type="checkbox"/> Supplier Questionnaire (Frequency: <input type="checkbox"/> Annual <input type="checkbox"/> Biennial) <input type="checkbox"/> Audit: <input type="checkbox"/> Desk <input type="checkbox"/> On-site (Frequency: <input type="checkbox"/> Biennial <input type="checkbox"/> Quadrennial) <input type="checkbox"/> Biennial Review of Supplier Qualifications <input type="checkbox"/> Other: _____						
Quality Manager/Director Approval:						Date:	

SUPPLIER IMPACT ASSESSMENT

Internal Use Only: Review Section (if applicable)					<input type="checkbox"/> N/A	
Criticality	<input type="checkbox"/> Critical	<input type="checkbox"/> Non-critical	Risk Grade	<input type="checkbox"/> Z	<input type="checkbox"/> A	<input type="checkbox"/> B
				<input type="checkbox"/> C	<input type="checkbox"/> D	<input type="checkbox"/> E
Qualifications on File	<input type="checkbox"/> Supplier Impact Assessment			<input type="checkbox"/> Quality Agreement		
	<input type="checkbox"/> Supplier Questionnaire			<input type="checkbox"/> Memo to File		
	<input type="checkbox"/> Audit Report			<input type="checkbox"/> Other: _____		
Review Date	Notes			Reviewer		
				Name		
				Title		
				Signature		
				Next Review Due Date		
				Name		
				Title		
				Signature		
				Next Review Due Date		
				Name		
				Title		
				Signature		
				Next Review Due Date		
				Name		
				Title		
				Signature		
				Next Review Due Date		

Signature Manifest**Document Number:** COMM-PAS-017 FRM2**Revision:** 01**Title:** Supplier Impact Assessment**Effective Date:** 01 Jul 2025

All dates and times are in Eastern Time.

COMM-PAS-016 FRM1--COMM-PAS-018**Author**

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Document Release

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