DukeMedicine

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

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DOCUMENT TITLE:
Supplier Risk Assessment

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COMM-PAS-017 JA1
Supplier Risk Assessment

1 PURPOSE

1.1 To provide guidance for assessing the level of risk and/or potential risk for APBMT and/or STCL supplier and for determining the type and frequency of supplier qualifications.

2 INTRODUCTION

2.1 Suppliers are selected according to their ability to reliably provide high-quality supplies/services that meet requirements and expectations. Supplier qualification is based on a Quality Management System (QMS) that ensures that any goods, supplies, services, or components coming from a supplier are produced and delivered under a set of controls that ensure their predetermined standards are met. The objective is to preempt quality problems, prevent defects, and guarantee consistent quality through effective management and monitoring of suppliers.

2.2 All suppliers are qualified, but suppliers providing critical materials/services that have the potential to affect quality should be qualified before use. Once qualified, the periodic evaluation of all suppliers' performance (requalification) described in this procedure helps to ensure suppliers are continuing to meet requirements.

3 SCOPE AND RESPONSIBILITIES

3.1 This job aid (JA) applies to the APBMT Clinical Quality Program (CQP) when determining the type and frequency of supplier qualifications.

3.2 The CQP, in collaboration with the Program and Facility Medical Directors, is responsible for determining the type and frequency of supplier qualifications.

4 DEFINITIONS/ACRONYMS

4.1	APBMT	Adult and Pediatric Blood and Marrow Transplant Program
4.2	CQP	APBMT Clinical Quality Program
4.3	JA	Job Aide
4.4	QMS	Quality Management System

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 The CQP will complete an initial COMM-PAS-017 FRM2 *Supplier Impact Assessment* for every supplier.

8.2 Based on the results of the initial COMM-PAS-017 FRM2 *Supplier Impact Assessment*, perform a risk assessment using this form based on the following risk matrix and identify the risk grade (Z, A, B, C, D, or E).

8.3 Assess any potential negative patient impact by considering the impact on patient safety if the supply/service failed.

8.4 When assessing the likelihood of supply/service failure, consider the following factors:

8.4.1 The complexity of the supply/service

8.4.2 The size and history of the supplier

8.4.3 The relation of the supply/service to the supplier's core business

8.4.4 The reputation of the supplier

8.4.5 Relevant certifications

8.4.6 The overall historical integrity issues of the supply/service

Likelihood of Material/Service Failure That Would Not Be Readily Detected	**HIGH** ↑ **LOW**	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 → **HIGH**				
			Potential Patient Negative Impact				

8.5 Based on the risk grade, determine the appropriate level of initial qualification and the appropriate level of requalification:

Risk Grade	Qualification Required [1]	Requalification Frequency
Z	☐ **Initial** Impact Assessment	☐ Review the assessment **biennially**
A	☐ **Initial** Impact Assessment ☐ **Initial** Questionnaire	☐ Review the assessment **biennially** ☐ **Repeat** Questionnaire, *(if significant change to material/process)*
B	☐ **Initial** Impact Assessment ☐ **Initial** Questionnaire	☐ *Assessment review based on updated questionnaire* ☐ **Biennial** Questionnaire
C	☐ **Initial** Impact Assessment ☐ **Initial** Questionnaire	☐ *Assessment review based on updated questionnaire* ☐ **Annual** Questionnaire
D	☐ **Initial** Impact Assessment ☐ **Initial** Questionnaire ☐ **Initial** Audit	☐ *Assessment review based on updated questionnaire* ☐ **Annual** Questionnaire ☐ **Quadrennial** Audit
E	☐ **Initial** Impact Assessment ☐ **Initial** Questionnaire ☐ **Initial** Audit	☐ *Assessment review based on updated questionnaire and audit report* ☐ **Annual** Questionnaire ☐ **Biennial** Audit

8.6 At the time of supplier requalification, regardless of method, this risk assessment should be reviewed in conjunction with the review of the documentation on file. Any changes to the risk grade should be documented as detailed in COMM-PAS-017 *Supplier Qualification*, and updated qualification documentation should be pursued as necessary.

8.7 Appendix 1 provides a visual overview of initial qualification activities, followed by details on the requalification cycle for all risk grades detailed in Section 8.5 above.

[1] Any supplier designated as critical may have a Quality Agreement (or equivalent). See COMM-PAS-017 *Supplier Qualifications.*

9 RELATED DOCUMENTS/FORMS

9.1 COMM-PAS-017 Supplier Qualifications

9.2 COMM-PAS-017 FRM1 Supplier Questionnaire

9.3 COMM-PAS-017 FRM2 Supplier Impact Assessment

10 REFERENCES

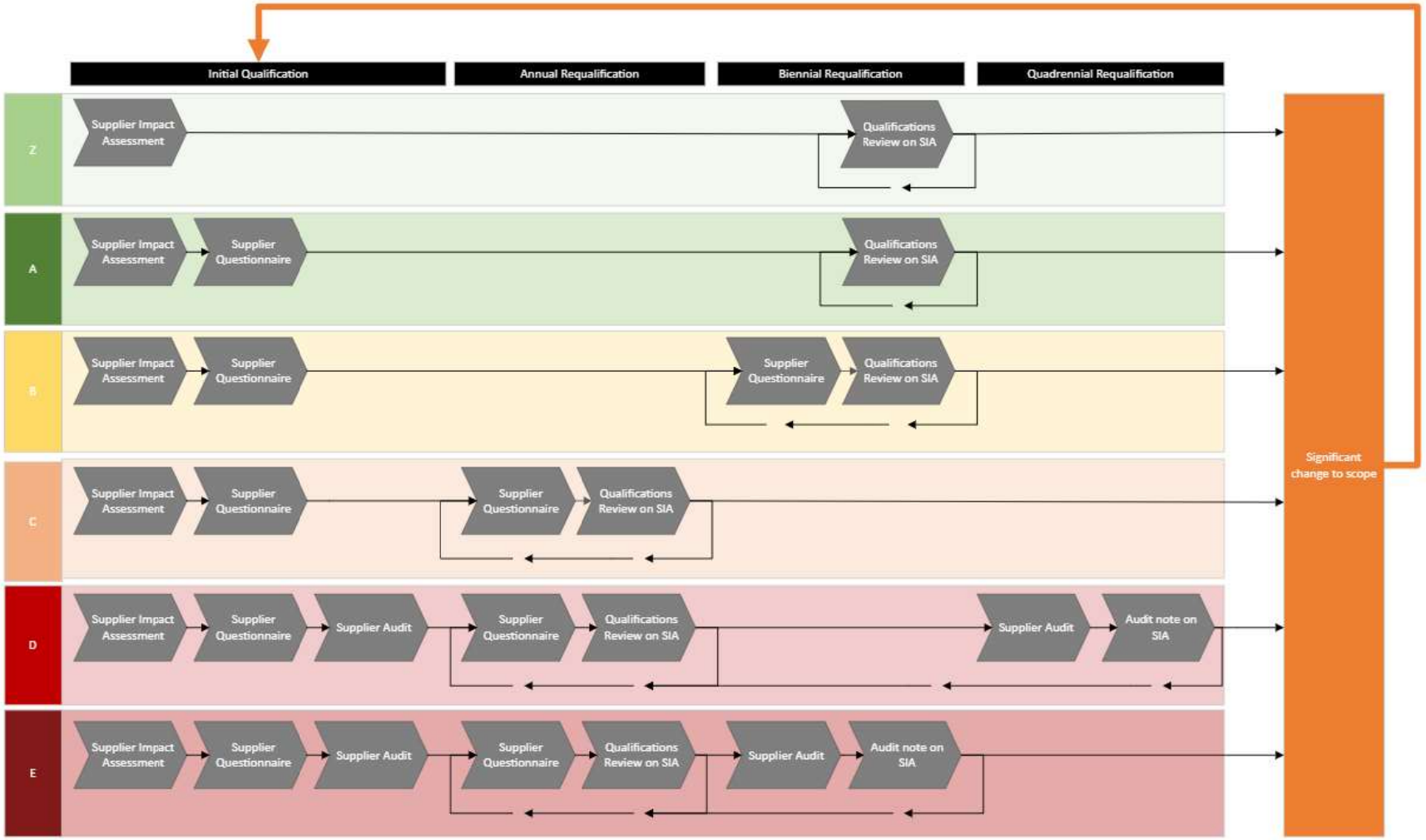
10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition

10.2 21 CFR Parts 211.22, 606, 1271.210

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	M. Christen	• New document

Appendix 1 Initial Qualification and Re-Qualification Cycle [2]



[2] Any supplier designated as critical may also receive a Quality Agreement (or equivalent). See COMM-PAS-017 *Supplier Qualifications.*

Signature Manifest

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