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Supplier Risk Assessment JA1

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SUPPLIER RISK ASSESSMENT

1 PURPOSE

1.1 To provide guidance for assessing the level of risk/potential risk for suppliers/vendors and for determining the type and frequency of supplier/vendor qualifications.

2 INTRODUCTION

2.1 Suppliers are selected according to their ability to reliably provide high-quality materials/products that meet the manufacturer's defined requirements and expectations. Supplier qualification is based on a Quality Management System (QMS) that ensures that any goods, materials, 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 Critical materials that have the potential to affect quality should be qualified before use and should be obtained from suppliers who can meet defined requirements. Once suppliers are qualified, periodic evaluation of supplier performance helps to ensure the supplier's continued ability to meet requirements.

3 SCOPE AND RESPONSIBILITIES

3.1 This JA applies to the Quality Systems Unit (QSU) when determining the type and frequency of supplier/vendor qualifications.

3.2 The QSU, in collaboration with the Program/Medical Director, is responsible for determining the type and frequency of supplier/vendor qualifications.

4 DEFINITIONS/ACRONYMS

4.1 JA – Job Aide

4.2 QSU – Quality Systems Unit

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 QSU will complete an initial COMM-QA-002 FRM2 *Supplier Impact Assessment* for every supplier.

8.2 Based on the results of the initial Impact Assessment, perform a risk assessment for the material/service based on the following risk matrix and identify the material/service risk grade (Z, A, B, C, D, or E).

8.3 Assess the potential patient impact by considering the impact on patient safety if the material/service failed.

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

8.4.1 The complexity of the material/service

8.4.2 The size and history of the supplier

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

8.4.4 The reputation of the supplier

8.4.5 Relevant certifications (e.g. ISO)

8.4.6 The overall historical integrity issues of the material/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 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]	Frequency
Z	•Supplier Impact Assessment	•Initial impact assessment to be reviewed biennially
A	•Supplier Impact Assessment •Supplier Questionnaire	•Initial impact assessment •Initial Questionnaire, then only if significant change to material or manufacturing process. •Impact assessment to be reviewed biennially.
B	•Supplier Impact Assessment •Supplier Questionnaire	•Initial impact assessment •Biennial Questionnaire •Impact assessment to be reviewed based on updated questionnaire
C	•Supplier Impact Assessment •Supplier Questionnaire	•Initial impact assessment •Annual Questionnaire •Impact assessment to be reviewed based on updated questionnaire
D	•Supplier Impact Assessment •Supplier Questionnaire •Audit	•Initial impact assessment •Annual Questionnaire •Quadrennial Audit •Impact assessment to be reviewed based on updated questionnaire and audit report
E	•Supplier Impact Assessment •Supplier Questionnaire •Audit	•Initial impact assessment •Annual Questionnaire •Biennial Audit •Impact assessment to be reviewed based on updated questionnaire and audit report

8.6 At the time of supplier requalification, regardless of method, this risk assessment should be reviewed in conjunction with review of the documentation on file. Any changes to the risk grade should be documented as detailed in COMM-QA-002, and updated qualification documentation 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 must also receive a Quality Agreement (or equivalent). See COMM-QA-002 *Supplier Qualifications.*

9 RELATED DOCUMENTS/FORMS

9.1 COMM-QA-002 Supplier Qualifications

9.2 COMM-QA-002 FRM1 Supplier Questionnaire

9.3 COMM-QA-002 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 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT) and Netcord. International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection and Release Current edition

10.3 U.S. Food and Drug Administration. Vaccines, Blood & Biologics. 7342.001 – Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors. Completion Date: January 31, 2019.

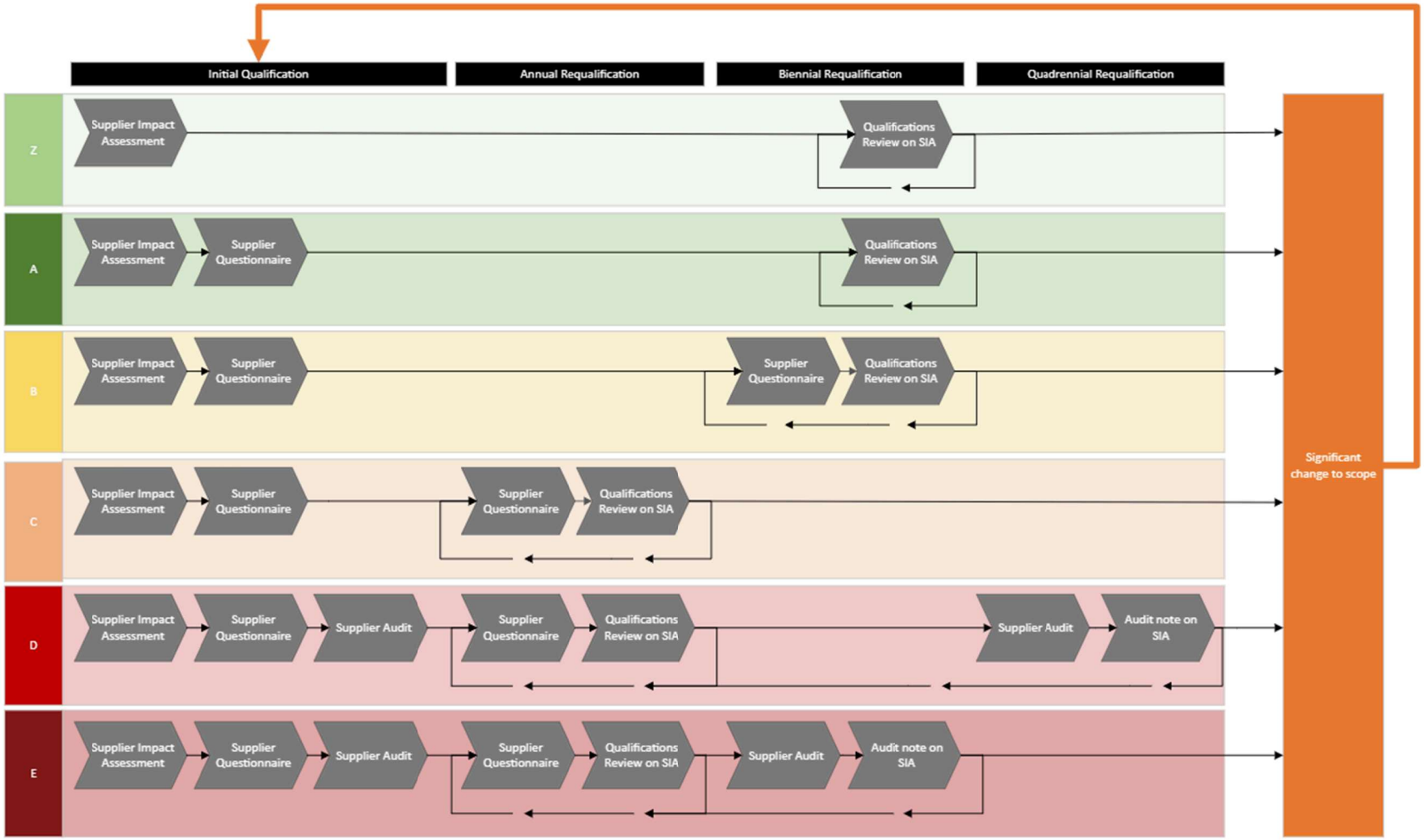
10.4 21CFR Part 820.50, Purchasing Controls

10.5 21 CFR Parts 211.22, 606, 1271.210

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	Austin Rudisill	a. Minor language clarifications throughout. b. Revised to include specifics on new risk grade of E c. Revised table in step 8.5 to include color coding, more specifics on all qualification required per risk grade, and also what is required at each frequency per risk grade. d. Added footnotes on quality agreements. e. Added Appendix 1: Initial Qualification and Re-Qualification Cycle flow chart.

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



[2] Any supplier designated as critical must also receive a Quality Agreement (or equivalent). See COMM-QA-002 *Supplier Qualifications.*

Signature Manifest

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