

**DUKE****DOCUMENT NUMBER:** COMM-QA-002 FRM2**DOCUMENT TITLE:**

Supplier Impact Assessment FRM2

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SUPPLIER IMPACT ASSESSMENT

The Quality Management System 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 taking in to account the supplier's history with the organization, the ability to consistently produce the supply, and previous complaints filed with the supplier. QSU will review this information in order to determine the level of risk associated with the supplier. This document is for internal use only.

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

	Yes	No	Comments
1. Has the supplier been qualified previously by QSU? If yes, provide type of qualification (e.g. questionnaire or audit) and date in comments.	<input type="checkbox"/>	<input type="checkbox"/>	
2. Is the supplier considered critical? If yes, a quality agreement is required.	<input type="checkbox"/>	<input type="checkbox"/>	
3. Does QSU have a quality agreement with the supplier?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Does any group under the purview of the Quality Systems Unit have prior experience with the supplier?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Have there been complaints submitted by QSU 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"/>	

7. Does the supplier currently have the ability to supply the required product/material/service?	<input type="checkbox"/>	<input type="checkbox"/>	
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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"/> C <input type="checkbox"/> D	<input type="checkbox"/> B <input type="checkbox"/> E	
Qualifications on File	<div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Supplier Impact Assessment <input type="checkbox"/> Supplier Questionnaire <input type="checkbox"/> Audit Report </div> <div> <input type="checkbox"/> Quality Agreement <input type="checkbox"/> Memo to File <input type="checkbox"/> Other: _____ </div> </div>				
Review Date	Notes	Reviewer			
		Name			
		Title			
		Signature			
		Next Review Due Date			
		Name			
		Title			
		Signature			
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		Name			
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		Next Review Due Date			

Signature Manifest**Document Number:** COMM-QA-002 FRM2**Revision:** 04**Title:** Supplier Impact Assessment FRM2**Effective Date:** 16 May 2023

All dates and times are in Eastern Time.

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Document Release

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