

DOCUMENT NUMBER: COMM-QA-002	FRM2
DOCUMENT TITLE: Supplier Impact Assessment FRM2	
DOCUMENT NOTES:	
Document Information	
Revision: 04	Vault: COMM-QA-rel
Status: Release	Document Type: COMM-QA
Date Information	
Creation Date: 27 Apr 2023	Release Date: 16 May 2023
Effective Date: 16 May 2023	Expiration Date:

Previous Number: COMM-QA-002 FRM2 Rev 03 Change Number: COMM-CCR-216

Owner: BS76

Control Information

Author: ADR35



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 Co	Completed:			
Supplier Name:	Contact	Nan	ne/Ti	tle:	
Supplier Address: Product/Service Name/Number:	Phone: Fax: Email: Web Ac		s:		
Associated Change Control Request (CCR) num	nber(s):				
		Yes	No	Comments	
1. Has the supplier been qualified previously by If yes, provide type of qualification (e.g. questionnaire or audit) and date in comments					
2. Is the supplier considered critical? If yes, a q agreement is required.	uality		П		
3. Does QSU have a quality agreement with the supplier?	e				
4. Does any group under the purview of the Qu Systems Unit have prior experience with the supplier?	•				
5. Have there been complaints submitted by QS the supplier in the past?	SU to				
6. Have there been any applicable recalls assoc with the supplier?	iated				

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7	. Does the supplier currently have the ability to supply the required product/material/service?											
8	. Product/Se	ervice Use	ed by:									
	IAPBMT IABMT IPBMT			\square R	CBB obertson TCL	GMI	P Labo	ratory	7			
N S F V R	ikelihood of Iaterial/ ervice ailure That Vould Not Be eadily etected	HIGH	5 A B C 4 A B C 3 Z A B 2 Z A A A 1 Z Z Z Z 1 2 3						D E C D C C B B A A A A 4 5 HIGH			
					Po	tentia	l Patiei	nt Imp	act			
							Z	A	В	С	D	E
9. R	ecommended	d impact g	grade (see COM	M-QA-002 JA	A 1):							
11.	If yes, p	lease expl				npac	t assess				eted?] N/A	
12.	☐ Sup _l ☐ Aud	olier Ques it: Des additional	cation required tionnaire k On-site qualification	? (check all th	at apply)							
13.	Supp Aud	olier Ques it: Des nial Revie	on required? (cl tionnaire (Frequ k On-site (Frew of Supplier (uency: Ann requency: C Qualifications	ual Bi Biennial			nnial)				
Qual	ity Manager/	Director A	Approval:					Date):			

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InfoCard #: COMM-QA-002 FRM2 Rev. 04 Effective Date: 16 May 2023



SUPPLIER IMPACT ASSESSMENT

Internal	Internal Use Only: Review Section (if applicable)									
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Signature Manifest

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All dates and times are in Eastern Time.

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Document Release

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