

DCR INITIATION			
DCR Number			Due Date
Doc ID and Title(s)	QP806_Analysis of Data		
Current version #	12.0	New Version #	
Document Type:	<input checked="" type="checkbox"/> SOP <input type="checkbox"/> Workbook/Checklist <input type="checkbox"/> Tech. Doc	<input type="checkbox"/> Training document <input type="checkbox"/> Form <input type="checkbox"/> Other:	Change Type: <input type="checkbox"/> New <input checked="" type="checkbox"/> Change <input type="checkbox"/> Obsolete
Description of change(s) to document:			
General review of the procedure, update of Technical Support metrics, addition of the review of trends in QC metrics and Post Market Surveillance data.			
Impact Assessment / Risk Analysis:			
Does this change impact any other documents? <input checked="" type="checkbox"/> N/A		<input type="checkbox"/> SOP <input type="checkbox"/> PI <input type="checkbox"/> IFU <input type="checkbox"/> Forms <input type="checkbox"/> Training Material <input type="checkbox"/> Other:	
Is this this change related to a Quality process? <input checked="" type="checkbox"/> N/A		<input type="checkbox"/> Change Control <input type="checkbox"/> NCR <input type="checkbox"/> CAPA <input type="checkbox"/> PMS <input type="checkbox"/> Audit <input type="checkbox"/> Other:	
Types of training to be utilised:		<input checked="" type="checkbox"/> Read and acknowledge <input type="checkbox"/> Presentation <input type="checkbox"/> Notification <input type="checkbox"/> Other:	
Review Required		<input checked="" type="checkbox"/> Operations <input type="checkbox"/> R&D <input checked="" type="checkbox"/> Quality <input checked="" type="checkbox"/> Regulatory <input checked="" type="checkbox"/> Tech. Support <input type="checkbox"/> Other:	
APPROVALS: AUTHORISATION FOR RELEASE AND DISTRIBUTION (Add rows if required)			
Name	Department	Signature	Date
Author/Subject Matter Expert <i>J Morri</i>	<i>QA</i>	<i>[Signature]</i>	<i>05 Aug 22</i>
Document/Process Owner <i>Erin Sauer</i>	<i>QA</i>	<i>[Signature]</i>	<i>09 Aug 22</i>
QA Approval / Delegate			
ISSUANCE (QA/Authorised Issuer to complete)			
New SVN #		Effective Date	
FM401-1 updated?	<input type="checkbox"/> Yes	FM605-12 updated?	<input type="checkbox"/> Yes <input type="checkbox"/> N/A
Superseded version replaced & filed?	<input type="checkbox"/> Yes		<input type="checkbox"/> N/A
Obsolete doc(s) removed from circulation?	<input type="checkbox"/> Yes		<input type="checkbox"/> N/A
QP012 Read & Acknowledgment form initiated?	<input type="checkbox"/> Yes		<input type="checkbox"/> N/A
Workbook Verification Attached?	<input type="checkbox"/> Yes		<input type="checkbox"/> N/A
Authorized Issuer	Name	Signature	Date