

Validation Change Request

Number:		Date:	
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Primary VCR Type: Check one <input type="checkbox"/> Initial <input type="checkbox"/> Change <input type="checkbox"/> Decommission <input type="checkbox"/> Revalidation	VCR Title: Primary Subject Type (Check whichever are relevant) <input type="checkbox"/> Process <input type="checkbox"/> Facilities <input type="checkbox"/> Utilities <input type="checkbox"/> Equipment incl. APC <input type="checkbox"/> Test Method <input type="checkbox"/> Cleaning <input type="checkbox"/> Computer System
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Change Description:

Justification for Change:

Regulatory Filing Impacted? : Yes No because:

Regulatory approvals of protocols required? Yes No Sign and Date: _____

Risk Analysis Impacted? : Yes No because:

Equipment / System Hold Required: Yes No Product Hold Required: Yes No

Equipment / System /Product Release Criteria:

VRB Disposition Approvals:

Approved with Requirements (see page 3 of this VCR) Approved with No Requirements Rejected, because

Function	Name	Signature	Date
<input type="checkbox"/> Initiator			
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			

Validation Deliverables

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Task	Documents / Deliverables (check if Task is required VRB)	Short Description (if required) Short justification (if not required)	Resp.
	<input type="checkbox"/> Validation Change request		
	<input type="checkbox"/> Project/Validation Plan		
	<input type="checkbox"/> Material Assessment		
	<input type="checkbox"/> Technology or Product Transfer Package Plan		
	<input type="checkbox"/> Computer System Validation		
	<input type="checkbox"/> Design Qualification (DQ)		
	<input type="checkbox"/> Installation Qualification (IQ)		
	<input type="checkbox"/> Engineering Evaluation		
	<input type="checkbox"/> Operational Qualification (OQ)		
	<input type="checkbox"/> Performance Qualification (PQ)		
	<input type="checkbox"/> Cleaning Validation (CV)		
	<input type="checkbox"/> Test Method Validation (TMV)		
	<input type="checkbox"/> Review of Biocompatibility, Sterilisation, Stability, Shelf Life		
	<input type="checkbox"/> Other Actions required		
	Validation Closure incl. File review and Validation Master Plan Update		

VCR Amendments- ensure appendix 1 is completed and approved for each amendment

Amendment Number	Date	Amendment Description	Completed: Sign /Date

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Appendix 1

VCR Change Request Amendment / Cancellation

Amendment /Cancellation Information

Amendment Description:
Reason/ Justification for Proposed Amendment:

Protocols/Actions Number	Protocols/Action Type & Description	Person Responsible	Completed: Sign /Date

VRB Disposition Approvals:			
Function	Name	Signature	Date
<input type="checkbox"/> Initiator			
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			
<input type="checkbox"/>			