DUKE

DOCUMENT NUMBER: COMM-QA-019 FRM2

DOCUMENT TITLE:

Change Control Request (No Effectiveness Check) FRM2

DOCUMENT NOTES:

Document Information

Revision: 02	**Vault:** COMM-QA-rel
Status: Release	**Document Type:** COMM-QA

Date Information

Creation Date: 29 Oct 2019	**Release Date:** 30 Oct 2020
Effective Date: 30 Oct 2020	**Expiration Date:**

Control Information

Author: LE42	**Owner:** LE42
Previous Number: COMM-QA-019 FRM2 Rev 01	**Change Number:** COMM-CCR-134

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Change Control Request Number:
Initiator:
Date Request Initiated:

Instructions to Initiator: Complete Sections I and II by checking applicable items and providing explanation where requested (*To be completed on the First Route*).

TAB 1: "Section I – Type of Change"

Document Changes (If selected, Fill out below items)

☐ **N/A**

☐ **New Document Title(s):**

☐ **Existing Document(s):** ☐ **Revise** ☐ **Archive**

New Title for Existing Document(s):

Existing Document Number, Title(s) and Revision Number:

Collaborators for New or Revised Document(s):

Document Training Requirements:

Development of Training Tools Required? Yes ☐ **No** ☐

☐ **Checklist**

☐ **Quiz**

☐ **Other (specify)**

MasterControl Job Codes Requiring Training:

☐ Specify job codes requiring training:

☐ **Revised Documents Only -** Previously established job codes for this document have been reviewed and are appropriate for this version.

Comments:

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Process Changes (If selected, Fill out below items)

☐ **N/A**

Does change affect qualification status of Process? **Yes** ☐ **No** ☐

Summarize Process Change (*How do individual changes described within Section I impact the overall process***):**

Comments:

Equipment Changes

☐ **N/A**

(If selected, Provide Equipment Information at the prompts below.)

☐ **New Equipment** (*Name, Serial Number*)

☐ **Critical** ☐ **Non-Critical**

☐ **Replacing**

☐ **Decommission Equipment**

☐ **Existing Equipment Change or Move**
Equipment: ☐ **Critical** ☐ **Non-Critical**
Does change affect qualification status of equipment? **Yes** ☐ **No** ☐

☐ **Equipment Repair** (*Name, Serial Number*)

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Software Changes

☐ **N/A**

☐ **New Software** (*Software Type, Name, and Version Number*)

☐ **Software Change (Upgrade/Replacement)**

Replacing/Upgrading

Material Specification Form Changes (*Critical MSPECs Only***)**

☐ **N/A**

☐ **New MSPEC Number**

Replacing MSPEC Number

Quality Documents available

Service Provider Changes

☐ **N/A**

(If selected, Provide Service Provider Name, Type of service provided, and Criticality at the prompts below.)

☐ **New Service Provider** (*List Name*)

☐ **Critical** ☐ **Non-Critical**

☐ **Replacing** (*List Name*)

☐ **Service Provider Removed**

☐ **Service Provider Scope/Process Change (detail in description of change)**

Process Change Alters Criticality: ☐ **Yes** ☐ **No**

Facility Changes

☐ **N/A**

(If selected, Provide Facility Shutdown dates and/or Layout Change at the prompts below.)

☐ **Facility Shutdown**

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☐ **Facility Shutdown Date**

☐ **Proposed Facility Start Up Date**

☐ **Facility Layout Change**

Does Change Involve New Equipment: ☐ **Yes** ☐ **No**

Rooms/Areas Impacted

Other, Explain:

☐ **N/A**

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TAB 2: Section I - Description and Reason for Change

Description of Change(s):
Reason for Change(s):
Comments:
Is this Change associated with and/or a direct result of a Deviation and Investigation, Adverse Event, Complaint, or, Validation? **If yes, explain:** **Associated event number:**

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TAB 3: "SECTION II – IMPACT AND RISK ASSESSMENT"

Select all System/Areas Affected by the Change Control Request:

☐ ABMT	☐ COMM	☐ Inventory	☐ QSU
☐ APBMT	☐ Equipment	☐ MC3 Research/PD	☐ STCL
☐ CCBB Admin	☐ Facility Utilities	☐ MPACT	☐ Other:
☐ CCBB Collections	☐ GMP Clinical	☐ PBMT	
☐ CCBB Lab	☐ GMP Lab	☐ MC HTML Forms	☐ Project/ Product Affected:

Select any additional items required before change is implemented:

- ☐ Analytical Validation Number
- ☐ Equipment Qualification Number
- ☐ External Reporting Required
  - ☐ List/Describe external reporting entity
  - ☐ Copy of Communication/Notification Required
  - ☐ Sponsor Approval of Change Required
- ☐ Process Validation Number
- ☐ SCR Number for EMMES change
- ☐ Supplier/Service Provider Qualification
- ☐ HTML Form Assessment
- ☐ Computerized System Applicability Assessment (If applicable to facility/area affected - *Robertson GMP Laboratory*)
- ☐ Risk Assessment Exercise/Report per COMM-QA-080
  - ☐ If Risk Assessment Included, Specify Tool Utilized/Explain
- ☐ Other, explain

List all other documents, as applicable, that also reference the same SOP, process, document, or other item that is the focus of this change:

Place these documents into collaboration for updates (under a new CCR):
List New CCR #

Documents not placed in collaboration, but will be updated at next MC designated review cycle:

Affected Documents, but will not be placed into collaboration, (include rationale/justification):

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Risk Assessment (See *COMM-QA-077 Risk Assessment Procedure*):
Severity Assessment Score (S):

Severity Assessment Rationale (S):

S	Severity	Definition	Anticipated Harm to the Patient	GMP Non-compliance	Impact on Product
1	Negligible	Insignificant	None	None	No perceived impact on product
2	Marginal	At the outer or lower limits, minimal for requirements	Minimal	Minor	Unlikely impact on product, SQIPP not likely to be affected
3	Moderate	Within reasonable limits, transient or persistent	Transient or persistent, not life threatening	Significant	May indirectly impact product quality/SQIPP
4	Serious	Very important	Permanent, life threatening	Major	High likelihood of impacting product quality/SQIPP
5	Critical	Abnormal, unstable, unfavorable	May cause or contribute to death	Serious	Evidence of Product Impact, SQIPP affected

Probability Assessment Score (P):

Probability Assessment Rationale (P):

P	Probability	Definition (Occurrence)	Definition (Recurrence)
1	Rare	Not likely to happen, nearly impossible	Extremely unlikely to recur
2	Low	Occurrence is hardly likely, but possible	Unlikely to recur
3	Occasional	May occur sometimes	Likely to recur sometimes
4	Probable	Repeated occurrence, high likelihood of occurrence	Recur at moderate rate
5	Frequent	Will happen for certain, a regularly observed event	Likely to recur regularly

Detectability Assessment Score (D):

Detectability Assessment Rationale (D):

D	Detectability	Definition	Examples
1	High	Control system in place; automated detectability certain	Automatic detection system that is a direct measure of the failure
2	Good	Control system is in place with a high probability to detect the issue or its effects	SOP driven process that facilitates a direct measure of the failure
3	Moderate	Control system in place could detect the issue or its effects	SOP driven process that is NOT directly measuring or assessing the failure
4	Fair	Control system in place with a low probability to detect the issue or its effects	Non-SOP driven process for detection of direct measure of the failure
5	Low	No control system in place to detect the issue.	No ability to detect the failure or no SOP-driven process to indirectly detect the failure

COMBINED CHANGE CONTROL RISK ASSESSMENT SCORE:

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RISK ASSESSMENT SUMMARY/CONCLUSION:

If one risk parameter is scored a 5 and no effectiveness check is completed, justification is required as detailed in COMM-QA-077.

☐ **N/A**

Risk Assessment Summary/Conclusion:

Image of Table 4 From COMM-QA-077

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TAB – "Section III - Regulatory Affairs Review"–

Change(s) Associated with a Licensed Product ☐			
RA	**Classification**	**Reporting Type**	**Time of Document Release**
☐	Major	PAS	Wait for FDA feedback. **Confirm release date with RA.**
☐	Moderate	CBE 30	30 Days after FDA Receipt of Supplement. **Confirm release date with RA.**
☐	Moderate	CBE 0	Immediately after FDA Receipt. **Confirm release date with RA.**
☐	Minor	AR	Effective immediately. No confirmation required from RA.
☐	N/A		
RA Comments:			

Change(s) Associated with a Master File or an Investigational Product Under an IND ☐		
RA	**Reporting Type**	**Time of Document Release**
☐	Amendment	**Confirm release date with RA.**
☐	Annual Report	Effective immediately. No confirmation required from RA.
☐	N/A	
RA Comments:		

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TAB 4 – "SECTION IV – Final Approval To Implement"
(*To be completed on the Second Route*)

All requirements noted in Sections II and III met to implement change (ex. Qualification, Validation, Regulatory Submission, External Reporting)? ☐ Yes ☐ No* *If no, explain:
Projected Implementation (Effective) Dates for New or Revised Document(s):
Comments:

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TAB – "Attachments"

ATTACHMENTS

SUBMIT ☐

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TAB – "Change Control Form Routing"

Change Control Plan Approval (First Routing)

Initiator will:

- Populate the appropriate CCR section.
- Route CCR for first routing.

First routing steps are as follows:

1) Initiator
2) Medical Director (MD)
3) Regulatory Affairs (RA)
4) Quality (QA)*

*An email notification is sent that the plan is approved and initiator can proceed with next steps (collaboration, validations, etc.).

Change Control Implementation Approval (Second Routing)

Initiator will:

- HOLD the CCR at the initiator step until ready to implement the change.
- Review RA comments and ensure all requirements to implement have been met
- Once all requirements have been met and ready to implement the change, route CCR for second routing.

Second routing steps are as follows:

5) Initiator
6) Quality (QA)
7) Final Quality (QA) Approval*

*An email notification is sent that change is approved for implementation, CCR is complete.

Signature Manifest

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All dates and times are in Eastern Time.

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Author

Name/Signature	Title	Date	Meaning/Reason
Lisa Eddinger (LE42)		26 Oct 2020, 09:29:51 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		26 Oct 2020, 10:04:29 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Richard Bryant (RB232)		26 Oct 2020, 10:36:09 AM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		27 Oct 2020, 09:21:49 AM	Approved

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		27 Oct 2020, 10:18:57 AM	Approved