Document Change Request Form

To Be Filled Out By Employee Requesting Document Change
Type of document being changed or created: SDS
(Quality Manual, Procedures Manual, Form, Template, Log, Label, SOP, Protocol, PI)

Document Name: SDS 40065

New Version #: 2

Details of Change: Update to new SDS template

Reason for Change: VWR product add (requires WHMIS-compliant SDS)

Who should be notified internally: N/A

Who should be notified externally: N/A

Change Request made by: L. Roberts

Date of Request: 3/20/20

When this section is completed, electronically sign your name below, save the file as a PDF, discard the Word document, and email the PDF to the owner of the Key Process to which the document you are wishing to revise pertains (or the most relevant Biotium employee concerned). Once the owner of the Key Process approves the revision you may make the revision.

X 

Lori Roberts
Director, Bioscience

To be filled out by Owner of Key Process to which the document pertains
If you approve the change being requested sign below and make any notifications and perform any trainings required as a result of the document change. Submit the form to the owner of Process 0: Document Control and Records once notifications and trainings are complete.

Signature: _____ Name: _____ Date: _____

Summary of notifications and trainings:

To be filled out by the owner of Process 0: Document Control and Records

If you approve the change being requested sign below and make any further QMS document changes that are necessary. Enter file name at top of page and retain the completed form as a record.

Signature: _____

Summary of further QMS Changes:

Document Changes and Notifications Required After Document Revision

After *CREATING* a new ISO Form, Template, Register, Log, Label, or SOP:

--immediately notify Quality Management Representative or Director of Product Manufacturing if creation of the new document was not discussed previously
--add document to The Master Form Register (OPR001) under the appropriate Key Process
--add document to the Process Description Form (OPF023) for that Key Process
--if the new document is an SOP, add SOP to the Employee Training Register (HRR002), train all relevant employees and have them update their Employee Training Record (HRF011) with Head of HR
--if the new document is not an SOP, add it to the Authorized Signature Register (HRR001) showing which employees will be allowed to use/approve/author/edit the form
--careful consideration should be taken as many forms, Templates, Registers, SOP's etc may be affected by the creation of the new document and may also need to be revised

After changing a controlled ISO Form:

--update version # for the ISO Form in the Master Form Register (OPR001)
--remove any hard copies of the now obsolete form that may possibly be in circulation
--update any related ISO documents that may refer to the ISO Form being changed, if needed
--update Product Launch Checklist (PDF002) with changes, if needed

After changing a controlled ISO Template:

--update version # for the ISO Template in the Master Form Register (OPR001)
--update any related ISO documents that may refer to the ISO Template being changed, if needed
--update Product Launch Checklist (PDF002) with changes, if needed
--set timeline for protocols which have been created using the Obsolete Template to be changed over to obey the New Template, with Director of Product Manufacturing or Quality Management Representative

After changing an ISO Register:

--ISO registers are meant to be edited without the document needing to be revised, i.e. given a new version #
--consult with Quality Management Representative or Director of Product Manufacturing if change to register is so drastic that it may require a new version #

After changing a controlled SOP:

--update version # for the SOP in the Master Form Register (OPR001)

--update version # for the SOP in the Employee Training Register (HRR002), train all relevant employees and have them update their Employee Training Record (HRF011) with Head of HR
--update any related ISO documents that may refer to the SOP being changed, if needed
--update Product Launch Checklist (PDF002) with changes, if needed

After changing a Product Information Sheet (PSF006) or SDS (PSF008):
--make sure the document is being revised using the most up to date Template Version #
--the product information sheet or SDS on the website must be replaced with the updated version
--notification that the PI has been updated must be included in the next monthly distributor newsletter if the change is one a distributor should be made immediately aware of
--notification of SDS change is only required if new hazards have been listed

After changing a maintenance/inspection Log or Label:
--all hard copies of the log or label must be removed from their physical locations and replaced with the updated version
--obsolete logs must be filed in the expired calibration certificates binder. Obsolete labels must be shredded
--hard copies of logs must be stamped as controlled
--update any related ISO documents that may refer to the Log or Label being changed, if needed

After changing a Protocol that was created from an ISO Template:
--make sure the protocol is being revised using the most up to date Template Version #
--if a change to a chemical structure or another type of significant change is being made to a product formulation that may affect downstream production protocols used by other departments at Biotium, those departments should be notified so that the proper downstream changes can be made to their protocols
--if the protocol being changed relates to a licensee product, consult directly with Business Manager to see if the licensee needs be notified of the change (as per the licensee agreement)

After changing a Process Description (OPF023):
--a Process Description should only be changed by the owner of the process in question, the Quality Management Representative or the Director of Product Manufacturing
--careful consideration should be made as many forms, Templates, Registers, SOP's etc within that process may be affected by this change and may also need to be revised

After amending the Quality Manual:
--the change should be added to the Table of Amendments contained within the Quality Manual
--the revision # of the manual does not need to be updated
--all employees should be notified of the changes, no official retraining needed, because document is only being amended

After amending a Procedures Manual:
--the change should be added to the Table of Amendments contained within PRM00
--the revision # of the manual does not need to be updated
--all employees trained on this procedure (see HRR002) should be notified of the changes, no official retraining needed, because document is only being amended