⟨Roche⟩

Supplier Initiated Change Request Form

A. General Information **(Supplier to complete)**

Supplier Name:			
Supplier Contact Completing Form (Name, Function):			
Phone #:			
Email:		**Date Submitted:**	

B. Affected Materials / Service **(Supplier to complete)**

Roche Material Number (if applicable)	Material /Service Description	Supplier Material Number (if applicable)

C. Materials/Stock **(Supplier to complete, if applicable)**

Information concerning materials, if applicable	
Quantity Contract in place y/n, if yes open qty	
Supply Plan Contract in place y/n, if yes open qty	
Price relevant change y/n, if yes elaborate	
Any other commercial implications after change (e.g. different lead time, scrap costs etc.)	

<Roche>

D. <u>Change Request Details</u> (Supplier to complete)

Description of the change (change activities, desired effect):
Proposed timeline for implementation:
Justification/Rationale (Provide rationale for the trigger of change along with testing/validation data to support change):
How do you verify the change? (desired effect and no undesired side effects):

⟨**Roche**⟩

E.   Type of Change (Supplier to complete)

1.	Change of location for manufacturing, assembly, testing, storage, packaging or shipping (include subcontractors).	☐ Yes ☐ No
2.	Change in production equipment, production processes, or process controls, efficiency improvements that affects the validated state. Examples: ● Inspection or measurement system change (includes process, sampling plan and test equipment changes) ● Software or hardware updates that are tied to production controls ● Tooling/assembly fixture refurbishment (major repairs) ● Equipment relocation ● New-alternate/improved processing equipment	☐ Yes ☐ No
3.	Change in product design (e.g. Any change in the physical, functional, and performance characteristics or specifications that uniquely identify a component or device and determine its interchangeability in a system). Examples: ● Material formulation change ● Material performance change ● Testing procedure change ● Regulatory filing ● Change to raw material supplier (direct supplier for Roche or subcontractor to direct supplier for Roche) ● Dating change ● Temperature control method change ● Change to reliability/stability ● Computer/software change ● Change in analytics range ● Change in specification	☐ Yes ☐ No

4.	Change to a raw material or component used to build a product for Roche Examples: ● Reformulation of a raw material or subcomponent ● Change in manufacturing method to produce a raw material (direct supplier for Roche or subcontractor to direct supplier for Roche) ● Second Source ● Change to raw material supplier (direct supplier for Roche or subcontractor to direct supplier for Roche) ● Change in raw material manufacturing location (direct supplier for Roche or subcontractor to direct supplier for Roche	☐ Yes	☐ No
5.	Change to shipping or packaging of product Examples: ● Labeling change ● Container change ● Temperature control method change ● Dating change (expiration/retest)	☐ Yes	☐ No
6.	Product Deletion	☐ Yes	☐ No
7.	General Changes Examples: ● Name change ● ISO Certificate changes ● Ownership change	☐ Yes	☐ No
8.	Change to a service provided to Roche	☐ Yes	☐ No
9.	Other (explain):	☐ Yes	☐ No

F. Impact Assessment to Supplier's Processes/Products/Service (Supplier to complete)

Description	Assessment/Rationale (list impacted documents)
Does the change potentially affect the product/process risk documentation? Check one: ☐ Yes ☐ No	Check All that Apply: ☐ Risk Assessments (Product/Process/Design)/FMEA ☐ Specifications ☐ Test/Inspection Procedures ☐ Manufacturing Instructions ☐ Policies/Procedures List documents potentially impacted or rationale for no potential impact:
Does the change potentially affect the Roche requirements as defined in specification or purchasing requirements? Check one: ☐ Yes ☐ No	Describe potential impact or rationale for no impact.
Does the change potentially impact the validated manufacturing process? Check one: ☐ Yes ☐ No	Describe potential impact or rationale for no impact.
Does the change potentially impact the approved packaging/transportation method for the product? Check one: ☐ Yes ☐ No	Describe potential impact or rationale for no impact.
Does the change potentially impact any business or logistics requirements? Check one: ☐ Yes ☐ No	Describe potential impact or rationale for no impact.
Does the change potentially impact component/part traceability? Check one: ☐ Yes ☐ No	Describe how traceability will be established for the component/part number (e.g. date codes, lot number, site/location code, serial number or any other methods that should establish a beginning point for this change).

Description	Assessment/Rationale (list impacted documents)
☐ Attachment(s)	Identify Attachment(s):
Does supplier plan to provide samples related to the change request Check one: ☐ Yes ☐ No	Describe proposed sampling approach:

G. Change Request acknowledgement (Roche to complete)

Change Request Decision	
Supplier #:	
☐ Rejected	Justification of rejection / comments:

☐ Accepted
 	
    ☐ No Change Request needed by Roche
    ☐ Trigger Change Control Process: Change Record
    ID Number:
	Justification for No Change Request:

☐ I have checked for possible multiple use of the supplier/materials in more than one Roche product and aligned the decision with all applicable Subject Matter Experts for all affected Roche products.	
Signature:	Date:
Name:	Function:

NOTE:

The Change Request (CR) is a request only. No changes are allowed to be implemented before Roche releases a change by a Change Notification (CN) or accept the change without change at Roche.

End of Document