



RSS Supplier Change Request Form

To be completed by Requestor

Purpose of Change Request (check all that apply):

- Supplier originated request for review and approval of supplier change in processes or specifications
- Roche originated request for supplier implementation of a change
- Change in Intended use of a supplier or material and criticality rating

Date Submitted			
Requestor			
Supplier Name		Roche Vendor No.	
Supplier Contact Information			
Roche Material No.	Material Description:	Supplier Material ID	

Type of Change to Product or Specification (check all that apply and provide details):

<input type="checkbox"/> Changes in manufacturing facility location:
<input type="checkbox"/> Changes in production processes or equipment modifications and moves:
<input type="checkbox"/> Changes in manufacturing quality or testing procedures:
<input type="checkbox"/> Change of components or raw materials, including suppliers or subcontractors:
<input type="checkbox"/> Change in specification target(s) or tolerance(s):
<input type="checkbox"/> Changes in labeling or packaging:
<input type="checkbox"/> Changes in the stability of the product:
<input type="checkbox"/> Changes in software version and/or drivers:
<input type="checkbox"/> Product discontinuation (e.g. End of Life): <Replacement product availability>
<input type="checkbox"/> Change in Intended Use:
<input type="checkbox"/> Other (describe):
Additional details regarding the change:



Change justification (i.e. cost/benefit):

Supplier Change Impact Assessment:

To be completed by Roche Procurement:

Procurement representative:

To be completed by Roche Sequencing Solutions Quality

Date reviewed: [dd-mmm-yyyy](#) | Reviewed by:

Criticality Classification of Supplier:
 One Two Three Four Predefined Four

Rationale for the category assigned: (if criticality is changed):

- Change Impact Assessment: [consider the following](#)
- [Finished goods impacted](#)
 - [Stakeholders](#)
 - [Processes](#)
 - [Orders](#)
 - [And all of the above at any other Roche sites](#)

Risk Assessment:
[Severity](#)
[Probability](#)
[Controls](#)

Risk File References:
[Risk Management File](#)
[dFMEA](#)
[pFMEA](#)

CHANGE REJECTED

REASON:

CHANGE ACCEPTED

CHANGE ORDER NO. : _____

Or N/A and rationale:

Validation and/or acceptance criteria to be jointly determined between RSS and Supplier and documented in Change Order.



Technical Assessment <input type="checkbox"/> N/A (optional)	
Date reviewed: dd-mmm-yyyy	Reviewed by:
Change Impact Assessment: consider the following <ul style="list-style-type: none"> • Finished goods impacted • Stakeholders • Processes • Orders • And all of the above at any other Roche sites 	
Risk Assessment: Severity Probability Controls	
Risk File References: Risk Management File dFMEA pFMEA	
CHANGE REJECTED <input type="checkbox"/>	REASON:
CHANGE ACCEPTED <input type="checkbox"/>	CHANGE ORDER NO. : _____ Or <input type="checkbox"/> N/A and rationale:

RSS Procurement will facilitate communication between the Supplier, RSS Change Review Board and/or RSS Supplier Quality regarding Roche requirements, including the Supplier's requirements (Change Orders, Samples, validation, timing, documentation, etc.)