



### Change Control Tracking Form

(Ref. SOP QMS-180)

#### QMS-180 Quality Assurance Change Control Procedure

#### Section 1 – Initiation Phase

##### 1. Change Details

Change Title:			
Change Control Champion		Department	
Date Initiated	DD / MMM / YYYY	Completion Required	DD / MMM / YYYY
Product Description and Item Code (if applicable)			
Site Affected by Change			
Department/s Affected by Change			
Regulatory Change	Enter appropriate Agency names.		
Details completed by	Champion (initial/date)	DD / MMM / YYYY	

Comments



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#### Detailing of Change / Justification and strategy

Current Situation	
Proposed Situation	
Change Justification	

#### 2. Products Impacted By Change

Product Name / Description	Product Item Code	Market impacted	Registered
			YES / NO
			YES / NO
			YES / NO
			YES / NO
			YES / NO
			YES / NO



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**3. Risk Assessment – as per company Risk Assessment Procedure (refer to PQA-SOP-167 document series)**

Outcome of Change Control Risk Assessment	Major / Minor	Champion (initial/date)	DD / MMM / YYYY
Attach risk assessment to change control		Champion (initial/date)	DD / MMM / YYYY
Comments	If any list below		

**Section 2 – Change Control Package Review**

All Changes		Departments Required as Defined by Change Implications					
Department	Sign	Department	Sign	Department	Sign	Department	Sign
Quality	<input type="checkbox"/>	Commercial	<input type="checkbox"/>	Finance	<input type="checkbox"/>	Information Technology	<input type="checkbox"/>
		Formulation	<input type="checkbox"/>	Maintenance	<input type="checkbox"/>	Production	<input type="checkbox"/>
		Logistics	<input type="checkbox"/>	Quality Control	<input type="checkbox"/>	Safety	<input type="checkbox"/>
		Process Development	<input type="checkbox"/>	Warehouse	<input type="checkbox"/>		
		Purchasing	<input type="checkbox"/>				
		Regulatory	<input type="checkbox"/>				
		Validation	<input type="checkbox"/>				



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**Section 3 – Implementation**

Implementation Strategy	Reference Number (QA Use Only)	Due Date	Responsible



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### Section 4 – Review and Closure

#### 1. Information Provided for change closure

List the first batch where change will occur		
Quality Assurance Associate reviews package and all evidence provided as per plan	YES / NO	<b>Sign &amp; Date</b>
Comments	If more detail is required to close the change control progression, then state it in the comments field.	
Quality Assurance Associate closes change control in the database	YES / NO	<b>Sign &amp; Date</b>
Quality Assurance Associate distributes closure notice to the Site review team	YES / NO	<b>Sign &amp; Date</b>
Change Control file marked as closed and archived appropriately	YES / NO	<b>Sign &amp; Date</b>
Comments	Include the list below; otherwise, mark it as Not Applicable.	