

Baxter Tracking Number:	
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### Section A. Change Request

To be completed by Supplier or Baxter Personnel.  
Steps 1-11 are to be completed at original change request submission.

Step 1. Supplier Identification <i>Complete Information below.</i>	
Supplier Company Name:	
Multiple Supplier Site Impact?	<input type="checkbox"/> Yes, Identify supplier sites / addresses requesting this change. <input type="checkbox"/> See Attached
Street Address:	
City / State / Province:	
Country:	
Zip Code:	

Step 2. Supplier Change Assessment Checklist	
<p>In order to enable Baxter to determine if any proposed change to supplier product(s) or service(s) will have any effect on the safety and/or efficacy of any Baxter product(s), supplier must notify Baxter in writing prior to making a change in the following aspects of the product(s). <u>Based on the type of SNC being submitted, the supplier should provide data indicated below.</u> (at a minimum including the underlying data points establishing that the post-Change Product meets the Specifications and an identification of the test methods used to generate such data points).</p> <ul style="list-style-type: none"> <li>• Specification compatibility, comparison, gap analysis</li> <li>• Supplier Validation, verification, commissioning report</li> <li>• Safety &amp; regulatory review</li> <li>• Mold approval</li> <li>• Supplier declaration of no change to: design, material, process, or testing</li> <li>• Supplier own assessment report</li> <li>• For suppliers who maintain drawings and/or specifications which are under Baxter's Design Control, provide a copy of the updated drawings and/or specifications with this form.</li> </ul> <p>Due to supplier resource commitment, supplier validation evidence may be provided after the original SNC submission. If evidence is not available when submitting this change proposal, the supplier is requested to provide a plan and timeline to validate the change.</p> <p>For additional guidance for Notifications of Change, please see <a href="http://www.baxter.com/partners-suppliers/suppliers/forms">http://www.baxter.com/partners-suppliers/suppliers/forms</a>.</p> <p><b>Check all that apply:</b></p>	
<input type="checkbox"/> Supplier Name Change <i>Supplier: please provide supply chain verification form, GQT-11-01-01</i> <input type="checkbox"/> Operating under SAME Quality System <i>GQF-11-03-01Administrative Update Request Form must be used</i> <input type="checkbox"/> NEW Quality System <i>Baxter approval process must follow GQP-11-01 in addition to the SNC process.</i>	<input type="checkbox"/> Physical Change in Location or address - Refer to GQP-11-01 for process requirements. Supplier: please provide supply chain verification form, GQT-11-01-01. <input type="checkbox"/> Purchase Order location(s) only <input type="checkbox"/> Headquarters or Sales Office(s) only <input type="checkbox"/> Manufacturing/Service Location
<input type="checkbox"/> Raw Material Change (Composition)	<input type="checkbox"/> Design Change
<input type="checkbox"/> Raw Material Change (Source)	<input type="checkbox"/> Change in Labeling and/or Packaging
<input type="checkbox"/> Raw Material Discontinuation	<input type="checkbox"/> Change in subcontractors for distribution, producing, processing or testing
<input type="checkbox"/> Change in Method or Equipment of manufacturing, producing, processing, or testing	<input type="checkbox"/> Change in quality documentation such as COA, COC, etc.
<input type="checkbox"/> Other. If other, please describe:	

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**Step 3. Baxter Part Number(s)** *Enter applicable Baxter Part Numbers or attach list.*

Part Numbers:		<input type="checkbox"/> See Attached
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**Step 4. Supplier Part Identification** *Enter applicable information or attach list.*

Supplier Part Number and Trade Name Description. Also include the Supplier manufacturing facility.		<input type="checkbox"/> See Attached
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**Step 5. Baxter Receiving Facilities** *Parts identified in step 4. Enter applicable information or attach list.*

Facilities that have received the part numbers (listed in step 4) during the previous 3 years. Alternately, please attach a Ship-To history.		<input type="checkbox"/> See Attached
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**Step 6. Requested Date of Change**

<i>Enter the date the supplier is requesting to implement the change.</i>	
<i>Is the above date flexible? Y/N</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>Is there a final date when approval is needed from Baxter? If yes, provide date and rationale:</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>
<i>If Baxter needs more information about this change proposal, who is the appropriate contact person?</i>	

**Suppliers must receive Baxter approval, via this approved form, prior to shipping impacted materials to Baxter facilities for production use & release.**

NOTE: Materials, impacted by a SNC project that are identified as a Notify Only or are an Administrative Closure project, may be used in production and distributed to customers, because these types of changes are identified as not impacting the quality of Baxter's finished product.

**Step 7. Proposed Change**

<i>Enter description of proposed change(s).</i>
Description of Change:

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<b>Step 8. Reason for Change</b>	
<ul style="list-style-type: none"> <li>• Explain why changes are being proposed.</li> <li>• Provide rationale, when appropriate, for why the change is appropriate, justified, or needed. (Explain why it is acceptable to make the proposed changes.)</li> </ul>	
Reason for Change:	<input type="checkbox"/> See Attached Data
<p>How does this Change benefit Baxter?</p> <p>Is the product or process change request a result of actions: <span style="float: right;">Information not available <input type="checkbox"/></span></p> <ul style="list-style-type: none"> <li>• to reduce customer complaints or to respond to a customer complaint? Yes <input type="checkbox"/> No <input type="checkbox"/></li> <li>• to respond to an FDA or other regulatory request? Yes <input type="checkbox"/> No <input type="checkbox"/></li> <li>• to achieve cost savings (in raw materials, components, process, other)? Yes <input type="checkbox"/> No <input type="checkbox"/></li> <li>• Other benefit? (explain below) Yes <input type="checkbox"/> No <input type="checkbox"/></li> </ul> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin-left: auto; margin-right: auto;"> <p style="color: blue; font-size: small;">If yes to any, please describe details below.</p> </div>	
Explain here:	<input type="checkbox"/> See Attached Data

<b>Step 10. Completed By</b> <i>Record information below for completion of Steps 1-10 proceed to Step 11.</i>				
Name (Print)	Title	Signature	Date	Phone

<b>Step 11. Notification</b>
<p><i>Submit this Form with applicable Ship-To history or Supplier manufacturing facility location(s) to Baxter Healthcare at <a href="mailto:SNC@Baxter.com">SNC@Baxter.com</a></i></p>

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**Section B. Disposition and Approval for Closure**

*This section for Baxter Use Only*

<b>Step 12. Submission for Closure</b> <i>12A-12E To be completed by Project Lead or designee--Check all applicable boxes.</i>		
<b>12A.</b>	<input type="checkbox"/> Accept Change <input type="checkbox"/> Reject Change <input type="checkbox"/> Administrative Closure	
<b>12B.</b>	<input type="checkbox"/> Full Closure: all Baxter plants and parts listed in the GQF-11-03-04, and all impacted product lines  <input type="checkbox"/> Partial Closure, list site(s) or part(s):	
<b>12C.</b>	<i>How was this change evaluated in Change Control?</i> <input type="checkbox"/> Minor Change * <input type="checkbox"/> Moderate Change * <input type="checkbox"/> Major Change * <input type="checkbox"/> N/A <i>*Or equivalent</i>	
<b>12D.</b>	<i>Enter any applicable tracking numbers related to this change.</i> <input type="checkbox"/> None <input type="checkbox"/> NSR #: <input type="checkbox"/> Change Control Number/Record Number:	
<b>12E.</b>	Summary/Rationale for closure type:	
<b>12F.</b>	Name (Print)	Signature

**Submit to Supplier Quality for further processing at [SNC@Baxter.com](mailto:SNC@Baxter.com)**

<b>Step 13. Disposition</b> <i>To be completed by Supplier Quality member of the CCT--Check only one box.</i>		
<input type="checkbox"/> Accept Change <input type="checkbox"/> Reject Change <input type="checkbox"/> Administrative Closure		
<b>Additional Information</b> <i>Enter any additional information or comments.</i>		
Information or comments:		<input type="checkbox"/> N/A
<b>Supplier Notice of Change Complete and Approved</b>		
<input type="checkbox"/> Full Closure	<input type="checkbox"/> Partial Closure	Included Facilities or parts:
<i>This approval indicates that the Requirements in GQP-11-03 have been met.</i>		
Name (Print)	Signature	Date

**Note: Once Full Closure has been approved this SNC is closed. Any post-implementation change control activities and local purchasing system updates should be completed as appropriate.**