Reference WI – Supplier Proposal for Change, QA128C, for instructions.

# Supplier Change Proposal

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Supplier Proposal for Change (SPC)** | | | | | | |
| Supplier Name:  Supplier Contact Name:  Supplier Email: | | | Terumo Part Numbers - Revisions affected: | | Proposed Implementation Date: | |
| Brief Description of **What** is Changing: | | | | Brief Description of **Why** the change is needed: | | |
| *(Describe in detail WHAT is changing. Provide an outline of the current state and the future state including what documentation would change such as Control Plans, Work Instructions, pFMEA, etc.)* | | | | *(Describe in detail WHY the change is needed (e.g., Increased Capacity, Material Availability, Quality Improvement, Cost Savings, CAPA, Audit Findings, New Processes, New Equipment, etc.)* | | |
|  | | | |  | | |
| |  |  |  | | --- | --- | --- | | Area of Change | Changing | | | Yes | No | | Process Change  *(****Changes related to:*** *Control Plans, Work Instructions, pFMEAs, Sampling Plans, Equipment Add/Remove/Changes, Facility Moves, Validation Changes, Test Method Changes, Tooling Changes, Raw Material)* |  |  | | Sub Tier Supplier Change  *(****Changes related to:*** *New or Alternate Sub-Tier Suppliers)* |  |  | | Design Change  *(****Changes related to:*** *Terumo Prints, Terumo Design Specifications or Other Terumo Related Documents)* |  |  | | N/A  Other: | | | | | | | | | |
| Supplier’s Approval  ***NOTE: The proposed change cannot be implemented until it has been reviewed and properly dispositioned by Terumo.*** | | | | | | |
| Print Name: | Title: | | Date: | | | |
| Comments: | | | | | | |
|  | | **Supplier Completion Stops Here** | | | |  |

# SPC Number:

|  |  |  |
| --- | --- | --- |
| SPC number: | Business Unit: | Date: |

# Impacted Items:

| Item №: | Describe the process(es) that are changing: |
| --- | --- |
|  |  |

# Process Changes: N/A Change does not affect Process Change

## Manufacturing Process N/A Change does not affect the Manufacturing Process

|  |
| --- |
| Is this for new Process / Equipment / Tooling?  **Yes**  **No**  **Process**  **Equipment**  **Tooling**  **Method of Testing** |
| Should the new process/change be validated?  **Yes**  **No**  **If no,**  reviewed process validation criteria per WI – Process Validation, EN021C  Provide rationale: |
| Should the control documentation be updated (Process Flow, PFMEA, Control Plan, WI, Other)?  **Yes**  **No**  **N/A**  If no or N/A, provide rationale: |
| If there is an existing test at Terumo CV – Costa Rica Incoming Quality, will it be impacted by the change?  **Yes**  **No**  If no, provide rationale: |

## Site of Manufacture N/A Change does not affect Site of Manufacture

|  |
| --- |
| Is a transfer plan required?  **Yes**  **No**  If no, provide rationale:  Reviewed transfer plan from the supplier  Does the transfer plan require the processes to be re-validated?  **Yes**  **No**  Verification method:  **If no,** reviewed process revalidation criteria per WI –procedure Process Validation, EN021C  Provide rationale: |

## Raw Material N/A Change does not affect Raw Material

|  |
| --- |
| Is the material equivalent?  **Yes**  **No**  Verification method: |
| Should the material change be validated?   **Yes**  **No**  Verification method:  **If no,**  reviewed process validation criteria per WI – Process Validation, EN021C  Provide rationale: |

# On hand inventory N/A There is no current inventory.

|  |
| --- |
| Is the current inventory going to be used until consumed?  **Yes**  **No**  **N/A**  **If no,**  reviewed current inventory and reject accordantly.  Provide rationale, if required: |

# Sub Tier Supplier Change N/A Change does not affect Sub Tier Supplier Change

|  |
| --- |
| Should the change be validated?  **Yes**  **No**  Verification method:  **If no,** reviewed process validation criteria per WI – Process Validation, EN021C  Provide rationale: |

# Design Change N/A Change does not affect Design

|  |
| --- |
| Is a revision level change required to the top-level object in Matrix?  **Yes**  **No**  Verification method:  If no, provide rationale: |
| Does the change impact any Terumo CV – Costa Rica documents?  **Yes**  **No**  Verification method:  If no, include rationale: |

# Affiliate or Sister Site SPC Leverage N/A

|  |
| --- |
| Is this change already assessed by another Terumo Cardiovascular site?  **Yes**  **No**  **N/A**  Verification method:  Provide rationale: |

# Other N/A

|  |
| --- |
| Should the change be validated?  **Yes**  **No**  **N/A**  Verification method:  **If no,**  reviewed process validation criteria per WI – Process Validation, EN021C  Provide rationale: |
| Other:        **N/A** |

# Review, Approvals, Effectivity and Outcome:

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Completed By:** | | | | | | | | | |
|  | | | | | | | | | |
| Signature Print Name Date  Addition Information/Comments (if applicable): | | | | | | | | | |
| **SPC Board Review** | | | | | | | | | |
| SPC Board Review Date(s):  Disposition:  Approve with CO  Approve without CO  Reject CO # (if applicable): | | | | | | | | | |
| N/A Notes: | | | | | | | | | |
| **Proposed Effectivity** | | | | | | | | | |
| **Lot Number:** | | **Date:** | | | **Purchase Order:** | | **Other – Provide Details:** | | |
| Is a Primary Location Change Needed?  Yes  No | | | | | | | | | |
| Is a Site Evaluation Needed?  Yes  No | | | | | | | | | |
| **SPC Board Approvals:** | | | | | | | | | |
| **Quorum Member** | | | **Printed Name** | | | **Signature** | | | **Date** |
| Product Development rep/Drawing representative: | | |  | | |  | | |  |
| Supply Chain Management Representative: | | |  | | |  | | |  |
| Quality (Design QA) Representative: | | |  | | |  | | |  |
| SQE Management Representative: | | |  | | |  | | |  |
| Manufacturing Engineering Representative | | |  | | |  | | |  |
| Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |  | | |  | | |  |
| *More rows may be added if required. If not, please delete this line.* | | | | | | | | | |
| **SPC Outcome:** | | | | | | | | | |
| Approved without CO: | You can begin immediate implementation of the proposed change(s) no additional documentation from your organization is needed at this time.  You **may not implement** the proposed change(s) until the following information is updated to support the change: Control Plan Work Instructions pFMEA  Other:  The Terumo Change Order Number is: | | | | | | | | |
| Approved with CO: | Terumo needs to make internal changes and you cannot implement the proposed change(s) until the internal changes are completed. You will be contacted when the internal changes are ready to be implemented.  The Terumo Change Order Number(s) is (are):  Terumo needs to make internal changes however the proposed change(s) may be implemented prior to completion of the internal changes.  The Terumo Change Order Number(s) is (are): | | | | | | | | |
| Rejected | The proposed change was rejected and cannot be implemented.  Reason for Rejection: | | | | | | | | |
| **Supplier Acknowledgement:** By signing below you attest that you understand and will follow the SPC Board’s decision. | | | | | | | | | |
|  | | | |  | | | |  | |
| Printed Name / Title | | | | Signature | | | | Date | |

# Effectivity Notes, SPC Closure

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Effectivity Notes:** | | | | | |
| **Lot Number (s)**  **Justification for release:** | | | | | |
| **Closure Information** | | | | | |
| **Action** | **Date** | | **Date** | **Days** | |
| Time to Review  (TTR)  ≤15 business days |  | |  |  | |
| Time to Disposition  (TTD)  ≤5 business days |  | |  |  | |
| Time to Implement (TTI-x) |  | |  |  | |
| **Supplier Quality Representative Review and Approval** | | | | | |
|  | |  | | |  |
| Printed Name / Title | | Signature | | | Date |
| **SQE Management Review and Approval** | | | | | |
|  | | | | | |
| Printed Name / Title | | Signature | | | Date |
|  | |  | | |  |
| N/A **Attachments:** | | | | | |
|  | | | | | |