Johnson & Johnson

ISSUED

Consumer Group

Type : Form
Title : CHANGE REQUEST FORM (CR)
Number : FM-010353

Revision	4		
Issued Date	2012-11-14	Expiration Date	None
Spec Should not be Issued Before Date	NA	Effective Timeline (days)	0
Geographical Scope	Local	Specification Category	Permanent
Review Interval (Months)	0		

Related Information

SCO	**SCO-495892**

Organizations(refer to the Organizations section in GSS)

Organization Type	Organization Name
Franchise	Oral Care
Form Type	Batch Record Form
Region	North America
Specification Type	Form
Manufacturing Location	Haina

Revisions

Rev	State	Description of Change	Reason for Change	Revised By	Issued Date	Expiration Date
0	Obsolete	First Issue	New	Unknown Unknown	2011-09-17	None
1	Obsolete	1-Include Matrix from QSP-000436 on section 2 2-Eliminate Approver "Impacto realizado por" on section 2 3-Change Section 3: Include Approvers from CCRB meeting	Meet requirements from QSP-000436 Rev 4 (Change Management) and improve the Change Management Process and changes on SOP-006527	Unknown Unknown	2012-02-06	None
		Eliminate Section 0, include Change Control Number in all pages of the document. Modify Section 2 to separate Matrices for the Changes from				

2	Obsolete	Deliverables. Deliverables classified depending on their source (QSP Deliverables - Local Deliverables). Add clarification regarding Approval requirements in Section 3.	Change Control Process Improvement.	Lilliam Jimenez	2012-05-14	None
3	Obsolete	Add new task: 1-Master Data update in SAP	Add the guideline for changes that include APR in Reference Information	Unknown Unknown	2012-08-06	None
4	Issued	- Se le agrego en la sección de Local Deliverables: - Review Job Description. - Review Personnel Skills.	-Como parte de CAPA-003971 de Human Error.	Dulce Mieses	2012-11-14	None

Approvals

Approver	Role	Responsibilities	Date/Time
Valenzuela Yudelka	Training	Haina	2012-11-14 04:14:30 PM GMT-5:00
Ramos Noelia	Quality Assurance	Oral Care,Haina,Form,Batch Record Form	2012-11-12 06:09:19 AM GMT-5:00

Global Attributes

ERP Code	NA
Reference	NA

Content

Name	Format	File Size
FM-010353.docx	generic	158059

Reference Documents

Name	Description
Doc-0452238	Document Change Request
Doc-0452239	DOCUMENT CHANGE REQUEST, Attachment I – QSP-000436
Doc-0452240	NA
Doc-0452241	Attachment I QSP-000436
Doc-0452243	NA

Related Specifications

Number	Type
QSP-000436	Quality System Procedure
SOP-006527	Standard Operating Procedure

CHANGE REQUEST FORM (CR)

Change Control Number _____ Permanent _____Temporary_____

This number will be assigned by the ETQ system when the Global Change Control (GCC) is created.

Section 1. Initiation- To be completed by the Initiator/ Change Owner (CO)

Change Description *(What specific changes to the current conditions will be made that prevent the unacceptable outcome referenced in the rationale?):*	
Justification *(i.e. Rational and clear justification of the change):*	☐ Cost reduction ☐ New Product/Process ☐ Regulatory/Compliance ☐ Improvement of Product/Process ☐ Raw Material changes ☐ Other_____
Change is a result of	☐ Audit/Inspection (Specify) _____ ☐ CAPA (Provide #) _____ ☐ NC (Provide #) _____ ☐ Continuous Improvement Program (specify details) _____ ☐ Extension / Expansion of Product / Line ☐ Innovation ☐ Other _____
Affected by this change	☐ Product (Finished, WIP) ☐ Raw Material ☐ Component ☐ Packaging/ Labeling Material ☐ Policy/Procedure ☐ SOP ☐ Others _____
Is product affected? (*Yes, identify the affected product and attach list)*	☐ Yes ☐ No

Register the information below to move to Section 2

Function	Name	Signature / Date
Initiator / Change Owner(CO)		

Note: This form must be attached to the change in the ETQ System.

CHANGE REQUEST FORM (CR)

Change Control Number _____

This number is assigned by the ETQ system when the Global Change Control (GCC) is created.

Section 2. Selection of Deliverables –

A.1 NEW/CHANGE TO PRODUCT-PROCESS	Check the box if applies
Change category • *Product Formulation* • *Product Transfer* • *Release of New Product* • *Introduction of a current product to a new market* • *Process Change*	• *Re-work* • *Master Batch Records* • *Labeling* • *Manufacturing process* • *Others*	☐ Yes ☐ N/A

A. Matrix from QSP-000436

Product Modifications - Engineered Products	Type of Change (APR, CR, DCR)	Change Request Form Required (if applicable)	Specification Change	Risk Analysis	Design Control Approval	Environmental Evaluation	Safety Assessment	Preclinical clearance	Clinical Evaluation	Quality Assurance Clearance	Product & Process Development	Validation	Packaging clearance	Micro Clearance	Analytical/ Stability	Tox Clearance	Sterile Product Section	Claim support	Regulatory clearance	Right to market
Oral Care																				
Completely New Product (Code / SKU)	APR																			
Change in Brush Handle or Bristle Resins or Colorants OR Floss Material or Floss coating	APR		X			X	X			X	X	X	X		X	X		X	X	
Change in Handle Molding Process	CR	B	X			X				X	X	X			X			X		
Change in Bristle Mfg. Process, Tufting, Trimming, Attachment	CR	B	X			X				X	X	X			X			X		
Change in Floss Coating and/or winding process	CR	B	X			X	X			X	X	X	X		X			X	X	X
Change in FG Test Methods or Acceptance Criteria	CR	B	X							X	X	X			X				X	
Change in Product Performance Claims	CR	B					X				X				X			X	X	
Change in Packaging Material / Components	CR	B	X			X				X	X		X		X	X			X	
Change in Mfg. Site	APR		X							X	X	X								
Change in Pkg. Graphics	CR	B	X							X			X						X	

X Guidelines indicate this deliverable will likely be required in the change plan.
D Depends, should be considered during change plan development.

Reference: QSP-000436

Process Modifications - Engineered Products	Type of Change (APR, CR, DCR)	Change Request Form Required (if applicable)	Specification Change				Design Control Approval Form	Risk Analysis	Micro Clearance		Analytical	Product & Process Development	Environmental clearance	Quality Assurance Clearance				Preclinical and clinical clearance			Regulatory Assessment			Packaging clearance	Stability
			Product	Process	RM	C&G			R&D	QA (bioburden)				Quality Plan	IQ/OQ	PQ	Supplier Qualification	MID/ Tox	Safety summary	Clinical evaluation	Right to market	Claim support	Regulatory clearance (one per marketing		
Existing product on other line	CR	B										X			X	X			X						
Existing product on new technology	APR			X			X	X	X	X	X	X	X	X	X	X					X		X		X
Speed increase	CR	B		X												X									
Parameter change - critical	APR			X				X				X		X	X	X							D		
Parameter change - critical - humidity level	APR			X				X	X	X	X	X	X	X	X	X									X
Parameter change - others	CR	B		X				X				X		X	D	X									

X Guidelines indicate this deliverable will likely be required in the change plan.
D Depends, should be considered during change plan development.

Reference: QSP-000436

CHANGE REQUEST FORM (CR)

Change Control Number _____

This number is assigned by the ETQ system when the Global Change Control (GCC) is created.

PROCESS MODIFICATIONS/ADJUSTMENTS	Type of Change (APR, CR, DCR)	Change Request Form Requred (if applicable)	Document Update: (FGS, BMS, Component Spec., MF)	SAP UpdateBOM and Master Data	Environmental Evaluation	Safety Assessment	Toxicology Assessment	Packaging Qualification	Process Validation	Cleaning Validation	Stability	Analytical Testing Required	Change to Electronic Label Verification (ELV)	Regulatory Clearance
1. CRITICAL PROCESS PARAMETER CHANGE	APR		X						X		X	X		
2. REDUCE or INCREMIXING TIME BY <30% OF CURRENT SPEC.	CR	F	X									X		
3. CHANGE OF MIXING SPEEDS ΛΕΣΣ ΤΗΑΝ 15% OF CURRENT SPEC.	CR	F	X									X		
4. CHANGE OF EMULSIFICATION TEMPERATURE WHERE: *TEMPERATURE IS REDUCED < 5° C *TEMPERATURE IS INCREASED < 10° C	CR	F	X									X		
5. CHANGE OF HOMOGENIZATION SPEED BY < 15% OF CURRENT SPEC.	CR	F	X									X		
6. CHANGE OF HOMOGENIZATION TIME BY< 25% OF CURRENT SPEC.	CR	F	X									X		
7. CHANGE OF MATERIAL HEATING TEMPERATURE WHERE: *TEMPERATURE IS REDUCED < 5° C *TEMPERATURE IS INCREASED < 10° C	CR	F	X									X		
8. CHANGE OF PHASE HEATING TEMPERATURE. *TEMPERATURE IS REDUCED < 5° C *TEMPERATURE IS INCREASED < 10° C	CR	F	X									X		
9. INCORPORATION OF FILTRATION STEP WITH NO IMPACT ON AESTHETICS	DCR		X									X		
10. CHANGE OF PHASE ADDITION RATE (FOR EMULSIFICATION ONLY) < 15% OF CURRENT SPEC.	CR	F	X						X		X	X		
11. CHANGE OF CLEANING PROCEDURE	CR	F	X		X	X				X		X		
12. CHANGE OF CLEANING AGENT/SOLUTION/SANITIZER	CR	F	X		X	X				X		X		
13. CHANGE OF PROPELLER/MIXER DESIGN/DIMENSIONS/ BATCH TANK WITHIN THE MAIN PHASE.	CR	F	X						X		X			
14. CHANGE OF MATERIAL SEQUENCE ADDITION FOR NONCRITICAL PROCESS	DCR		X											
15. CHANGE OF PHASE ADDITION SEQUENCE	CR	F	X						X		X			
16. INCORPORATION OF A NEW PHASE FOR NON-PROCESS SENSITIVE PRODUCT	APR		X						X		X			
17. REMOVAL OF A PHASE	CR	F	X											
18. INCORPORATION OF RECIRCULATION STEP	DCR		X									X		
19. INCORPORATION OF HOMOGENIZATION STEP WITH NO IMPACT ON AESTHETICS	CR	F	X									X		
20. NEW BATCH SIZE WITH NEW TANK	CR	F												
21. NEW BATCH SIZE WITHIN CURRENT TANK	CR	F	X						X					
22 CHANGE IN HOMOGNISER/PREMIX/ PUMPS/TANKS	CR	F	X						X		X			
23. IMPLEMENTING A CIP PROCESS FROM MANUAL COP PROCESS	CR	F	X							X				
24. SWITCHING FROM CHEMICAL TO HEAT OR HEAT TO CHEMICAL SANITIZATION	CR	F	X		X	X	X			X				
25. INCREASING CONTACT TIME OF SANITIZER	DCR		X							X				
26. SWITCHING SUPPLIER OFCHEMICAL SANITIZER	DCR		X											

X Guidelines indicate this deliverable will likely be required in the change plan.
D Depends, should be considered during change plan development.

Reference: QSP-000436

CHANGE REQUEST FORM (CR)

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B.1 NEW/CHANGE TO EQUIPMENT

Check the box if applies ☐ Yes ☐ N/A

Change category

- *Equipment modifications*
- *Modification to equipment parts*
- *Parts with product contact*
- *Others*

B. Matrix from QSP-000436

EQUIPMENT MODIFICATIONS/ADDITIONS	Type of Change (APR, CR, DCR)	Change Request Form Required (if applicable)	Document Update: (FGS, BMS, Component Spec., MF)	User Requirements	Drawings Update	Environmental Evaluation/ Safety Assessment	Product Impact Analysis	Supplier Audit / FAT / SAT	IQ, OQ and PQ	Cleaning Validation	Lab Testing (Including pH, Conductivity, Bioburden Testing)	PM Update	Calibration Update	Regulatory Clearance
1. PURCHASE/RELOCATION OF PRODUCT CONTACT/INSPECTION EQUIPMENT	CR	G	X	X	X	X	X	X	X	X	X	X	X	
2. PURCHASE/RELOCATION OF NON-PRODUCT CONTACT EQUIPMENT	CR	G	X		X	X	X	X				X	X	
3. PURCHASE OF MANUFACTURING PRINTER	CR	G	X	X					X					
4. MODIFICATION TO CONTROL CIRCUITRY, PIPING OR CONFIGURATION OF PRODUCT CONTACT EQUIPMENT	CR	G	X	X	X	X	X	X	X	X	X		X	
5. INCREASE/DECREASE AN EXISTING CONVEYORS LENGTH (WITH NO MODIFICATION TO EXISTING CONTROLS)	CR	G			X							X		

X Guidelines indicate this deliverable will likely be required in the change plan.
D Depends, should be considered during change plan development.

Reference: QSP-000436

C.1 NEW/CHANGE TO MATERIAL

Check the box if applies ☐ Yes ☐ N/A

Change category

- *Material*
- *Component*
- *Material Supplier*

C. Matrix from QSP-000436

Raw Material Modifications - Engineered Products Including: Wound Care, Oral Care, Wipes, Powders, Cotton	Type of Change (APR, CR, DCR)	Change Request Form Required (if applicable)	Specification Change				Design Control Approval Form	Risk Analysis	Micro Clearance		Analytical	Product & Process Development	Environmental clearance	Quality Assurance Clearance				Preclinical and clinical			Regulatory Assessment			Packaging clearance	Stability
			Product	Process	RM	C&G			R&D	QA (bioburden)				Quality Plan	IQ/OQ	PQ	Supplier Qualification	MID/ Tox	Safety summary	Clinical evaluation	Right to market	Claim support	Regulatory clearance (one per marketing country)		
New Supplier	CR	C		X	X		X	X	X	X	X	X	X	X		X	X	X	X	D	X		X		X
Supplier process change	CR	C			X		X	X	D	D	D	X		X		X		D	D						D
Supplier New Plant / new line (current technology)	CR	C			X		X	X	X	X	D	X		X		X	X	X	X						D
Feedstock change (same materials, different supplier)	CR	C			X		X	X	D	D	D	X		X		X		D	D						D
Basis weight reduction	CR	C		X	X		X	X			D	X	X	X		X							D		D
Slit width reduction	CR	C		X	X		X	X			D	X	X	X		X							D		
Raw material packaging	CR	C			X																			X	
Acceptance criteria	DCR				X																				
Test method change	DCR				X																				

X Guidelines indicate this deliverable will likely be required in the change plan.
D Depends, should be considered during change plan development.

Reference: QSP-000436

CHANGE REQUEST FORM (CR)

Change Control Number _____

This number is assigned by the ETQ system when the Global Change Control (GCC) is created.

RAW MATERIAL MODIFICATIONS/ADJUSTMENTS	Type of Change (APR, CR, DCR)	Change Request Form Requred (if applicable)	Document Update: (FGS, BMS, Component Spec., MF)	SAP UpdateBOM and Master Data	Analytical Testing	Residual Solvent from Vender	Raw Material Questionnaire (RMQ)1	Microl Testing	Supplier Audit Questionnaire	Certificate of Analysis(C of A)	Stability Testing	Test Method Transfer/ Validation	Toxicology Review	Patent/Claims Review	Environmental/Safety Assessment Required	Regulatory Clearance
1. NEW SUPPLIER ACTIVE INGREDIENT	CR	D	X	X	X	X	X	*	*	X	X	*	*	*	*	
2. NEW SUPPLIER FILM FORMING/VISCOSITY BUILDING AGENT	CR	D	X	X	X	X	X	*	*	X	X	*	*	*	*	
3. NEW SUPPLIER FOR ALL OTHER RAW MATERIALS	CR	D	X	X	X	X	X	*	*	X	*	*	*	*	*	
4. ROTATION FROM MAIN VENDOR TO SECONDARY RAW MATERIAL VENDOR (OR SECONDARY TO MAIN)**																
5. RAW MATERIAL MANUFACTURING LOCATION CHANGE	CR	D	X	X	X	X		*	*	X	*		*	*	*	
6. RAW MATERIAL MANUFACTURING PROCESS CHANGE	CR	D	X		X	X	*	*	*	X	*		*	*	*	
7. RAW MATERIAL SPECIFICATION CHANGE	DCR		X													
8. PURCHASE OF NEW (TO J&J) RAW MATERIAL FROM AN EXISTING APPROVED VENDOR	APR		X	X	X	X	X	*	X	X	X	X	X	X	X	
9. CHANGE IN CHEMICAL CONTAINER MATERIAL/CONTAINER TYPE.	DCR															
10. CHANGE IN CHEMICAL CONTAINER SIZE.	DCR															
11. RAW MATERIAL USED IN A CLASS II MEDICAL DEVICE OR CLASS 1 MEDICAL DEVICE WITH 510(k)	CR***		X	X	X	X	X	X	X	X	X	***	***	***	***	

* Determined based on material and formulation that it goes in
** If both suppliers are qualified then nothing is required
*** Change Request must also comply with QSP-000381
X Guidelines indicate this deliverable will likely be required in the change plan.

Reference: QSP-000436

FORMULATION MODIFICATIONS/ADJUSTMENTS	Type of Change (APR, CR, DCR)	Change Request Form Requred (if applicable)	SAP UpdateBOM and Master Data	Document Update: (FGS, BMS, Component Spec., MF)	Copy Update	Microbiological Evaluation	Safety Assessment	Toxicology Assessment	Package Compatibility	Packaging Qualification (includes Functional and Deco Testing)	Process Validation	Cleaning Validation	Stability C= ConcurrentP = Prospective	Analytical Testing/ Lab Testing	Regulatory Clearance	Technical Justification
1. REMOVAL OR ADDITION OF A RAW MATERIAL	APR		X	X	X	X	X	X	X			X	X		X	X
2. CHANGE IN CONCENTRATION OF EXISTING RAW MATERIAL ≤ 2%	APR		X	X	X		X	X	X			X	X		X	X
SPECIFICATION (PROCESS CAPABILITY CHANGES)	CR	F	X	X		X								X	X	X

X Guidelines indicate this deliverable will likely be required in the change plan.
D Depends, should be considered during change plan development.

Reference: QSP-000436

CHANGE REQUEST FORM (CR)

Change Control Number _____

This number is assigned by the ETQ system when the Global Change Control (GCC) is created.

COMPONENT MODIFICATIONS/ADJUSTMENTS	Type of Change (APR, CR, DCR)	Change Request Form Required (if applicable)	Supplier Audit Required	Stability C= Concurrent P = Prospective	Compatibility w/ Product	Line Trial	Document Update: (FGS, BMS, Component Spec., MF)	Regulatory Clearance	Notify International Marketing Companies	Enviro/nmental/Safety/Toxicology	SAP UpdateBOM and Master Data	Change to Electronic Label Verification (ELV)	Packaging Qualification (includes Functional and Deco Testing)	USP Container Testing
1. CHANGE IN COMPONENT TYPE (TUBE TO BOTTLE, BOTTLE TO JAR ETC…)	APR		Consider	1xP	X	Consider	X	X	X	X	X	X	X	
2. CHANGE IN RESIN FAMILY (PRIMARY PKG)	APR			1XP	X	Consider	X	X		X	X		X	
3. CHANGE IN RESIN FORMULA (PRIMARY PKG)	CR	E		1XC	X	Consider	X			X			X	X
4. CHANGE IN CLOSURE TYPE (PRIMARY PKG)	CR	E		1XP	X	Consider	X		X	X	X		X	
5. CHANGE IN LABEL MATERIAL (PRIMARY PKG)	CR	E			X	Consider	X			X	X		X	
6. CHANGE TO STERILE BARRIER	APR			1XP	X	Consider	X		X	X	X		X	
7. CHANGE IN COMPONENT MATERIAL - OTHER CONSUMER TAKE-AWAY COMPONENTS	See QA			Consider	X	Consider	X		X		X	X	X	
8. CHANGE IN PRODUCT SIZE	APR			1XP		Consider	X		X		X	X	X	
9. CHANGE OF COMPONENT VENDOR	CR	E	Consider	Consider	X	Consider	X				X		X	
10. CHANGE IN MOLD (PRIMARY PACKAGING)	CR	E				Consider	X						X	
11. CHANGE IN PACK OUT CONFIGURATION	CR	E					X		X		X		X	

X Guidelines indicate this deliverable will likely be required in the change plan.
Consider Depends, should be considered during change plan development.

Reference: QSP-000436

D.1 MISCELLANEOUS CHANGES — **Check the box if applies**

Change category

- *Test Method*
- *Specifications*
- *SOP, FM,*
- *Product Discontinuance*
- *Others*

☐ **Yes** ☐ **N/A**

D. Matrix from QSP-000436

Miscellaneous Changes	Type of Change (APR, CR, DCR)	Change Request Form Required (if applicable)	Validation	Analytical/ Stability	Technical Justification	Supplier Approval	Monitoring Program	Ship Testing	Letter to File	Regulatory Clearance
Test Method Terminology Changes	CR	H			X					
Test Method Major Changes 1) Significant Modifications to methods parameters	CR	H	X							
Test Method Moderate Changes 1) Change of injection size 2) Modify gradient slightly, pH, % soln	CR	H	X							

CHANGE REQUEST FORM (CR)

Change Control Number _____

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Chemical Specification Changes 1) Supplier Name 2) Limit/Range Changes 3) TM Changes(assay) 4) Grade	CR	H			X	X	X			
Chemical Specification Changes 1) Remove a Test 2) TM Changes (Viscosity, acid value)	CR	H				X	X			
Chemical Specification Changes 1) Change in Test Frenquency	CR	H					X			
Chemical Specification Changes 1) Name Change 2) Typographical 3) Packaging Size	DCR									
Product Specification Expiration Date Changes	CR	H		X						
Product Specification Storage and Ship Control	CR	H	X-P					X		
Product Specification AQL Levels	CR	H			X					
Product Discontinuation	CR	H							X	
SOP, QSP, WWSP Procedural change Only - **A change that does not impact product, process, test method or other specifications or testing*	DCR									

X Guidelines indicate this deliverable will likely be required in the change
D Depends, should be considered during change plan development. Reference: QSP-000436

E.1 NEW/CHANGE TO FACILITIES	**Check the box if applies**
Change category • *Manufacturing location* • *Installation of services such as water, clean steam, sources of air filters, etc.* • *Installation Diagrams (Resulting of another change)* • *Others*	☐ **Yes** ☐ **N/A**

F.1 NEW/CHANGE TO SOFTWARE	**Check the box if applies**
Change category • *Software* • *Others*	☐ **Yes** ☐ **N/A**

G.1 NEW/CHANGE TO CALIBRATIONS	**Check the box if applies**
Change category • *Tolerance changes* • *Changes to specification of instruments used in the process* • *Decreased calibration frequency* • *Others*	☐ **Yes** ☐ **N/A**

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SELECT ALL THE DELIVERABLES THAT APPLY			
QSP Deliverables			
Analytical Testing	☐ Yes ☐ N/A	Packaging Assessment	☐ Yes ☐ N/A
Authorization for Product Release (APR)	☐ Yes ☐ N/A	Packaging Qualification	☐ Yes ☐ N/A
Assess Impact on Product Quality (parameters, samples, contact product, pollution prevention) Product Impact Analysis	☐ Yes ☐ N/A	Product/Process Development	☐ Yes ☐ N/A
BOM Update	☐ Yes ☐ N/A	Quality Assurance Evaluation	☐ Yes ☐ N/A
Calibration Update/ Equipment Calibration/ Certification	☐ Yes ☐ N/A	Quality Plan	☐ Yes ☐ N/A
Certificate of Analysis (C of A)	☐ Yes ☐ N/A	Regulatory Clearance/ Approval	☐ Yes ☐ N/A
Change to Electronic Label Verification (ELV)	☐ Yes ☐ N/A	Residual solvent from Vendor	☐ Yes ☐ N/A
Claim Support	☐ Yes ☐ N/A	Right to Market	☐ Yes ☐ N/A
Create or revise Drawings/Layout (electrical, water, etc,)	☐ Yes ☐ N/A	Risk Analysis	☐ Yes ☐ N/A
Create/Update inspection plans in SAP	☐ Yes ☐ N/A	Ship testing	☐ Yes ☐ N/A
Master Data Update in SAP **	☐ Yes ☐ N/A	Verification of Test Method	☐ Yes ☐ N/A
Design Control Approval Form	☐ Yes ☐ N/A	Stability Analysis	☐ Yes ☐ N/A
Environmental/ Safety Assessment (Job permits, LOTO, Guards, Ergonomic, chemical, MSDS, etc)	☐ Yes ☐ N/A	Supplier Approval	☐ Yes ☐ N/A
Evaluate the Update/Creation of documents (SOP's, FM's, CG, RM, FP, Visual standards, etc)	☐ Yes ☐ N/A	Supplier Audit (FAT,SAT if applicable)	☐ Yes ☐ N/A
Evaluation of the cleaning method / Cleaning Validation	☐ Yes ☐ N/A	Supplier Qualification	☐ Yes ☐ N/A
Lab Testing (Including pH, Conductivity, Bioburden Testing)	☐ Yes ☐ N/A	Technical Justification	☐ Yes ☐ N/A
Letter to File	☐ Yes ☐ N/A	Toxicology Assessment	☐ Yes ☐ N/A
Master Data update in PQMS/PLS	☐ Yes ☐ N/A	Update or create PM (Preventive maintenance) MAXIMO	☐ Yes ☐ N/A
Microbiology testing	☐ Yes ☐ N/A	User requirements	☐ Yes ☐ N/A
Monitoring program	☐ Yes ☐ N/A	Validation (IQ, OQ, PQ) as applicable	☐ Yes ☐ N/A
Notify International Marketing Companies	☐ Yes ☐ N/A	Others	☐ Yes ☐ N/A
Local Deliverables			
Add GCC characteristic/feature in SAP for inspection lots affected by the change	☐ Yes ☐ N/A	Create equipment profile in ETQ	☐ Yes ☐ N/A
Approval of Inks	☐ Yes ☐ N/A	Create record to external company (if applicable)	☐ Yes ☐ N/A
Approval of Samples or Art	☐ Yes ☐ N/A	Curriculum Update in ComplianceWire	☐ Yes ☐ N/A
Approval of the plates in decorator	☐ Yes ☐ N/A	Review Job Descriptions	☐ Yes ☐ N/A
Assess Impact on facilities: space requirements, energy, water, compressed air, gas, etc.	☐ Yes ☐ N/A	Review Personnel Skill	☐ Yes ☐ N/A
Assess operational and productivity impact of the equipment.	☐ Yes ☐ N/A	Depletion of inventory -MDA	☐ Yes ☐ N/A
Assessment of the Mix Ups prevention System: Cameras, UPC Insert, dispenser and other sub-systems (ELV Update)	☐ Yes ☐ N/A	Evaluate calibration tools and specification needs	☐ Yes ☐ N/A

CHANGE REQUEST FORM (CR)

Change Control Number _____

This number is assigned by the ETQ system when the Global Change Control (GCC) is created.

Evaluate capital requirements, labels and asset depreciation	☐ Yes ☐ N/A	Evaluate Device Master Record (DMR)	☐ Yes ☐ N/A
Check the spare parts needed to be created in MAXIMO and in stock/warehouse	☐ Yes ☐ N/A	Evaluate impact on the insurance requirements	☐ Yes ☐ N/A
Evaluation Labeling requirements (country of origin, etc.)	☐ Yes ☐ N/A	Notification of change to supplier	☐ Yes ☐ N/A
First Article Inspection (FAI)	☐ Yes ☐ N/A	Notify the Change of Chemical specifications to RMC- Skillman	☐ Yes ☐ N/A
Inclusion of the Supplier and the new component in the Approval List of Suppliers	☐ Yes ☐ N/A	Order Creation in ETQ	☐ Yes ☐ N/A
Material test in the plant	☐ Yes ☐ N/A	Parameters development	☐ Yes ☐ N/A
Mode Code (Create Item Number, Country of Origin)	☐ Yes ☐ N/A	Perform RDO (Research Development Outline)	☐ Yes ☐ N/A
Modify equipment master list	☐ Yes ☐ N/A	Require equipment manuals	☐ Yes ☐ N/A
MSDS	☐ Yes ☐ N/A	Training* (Contractor, Manufacturing u other personnel)	☐ Yes ☐ N/A
Facility			
Area Cleaning Verification	☐ Yes ☐ N/A	Review manuals	☐ Yes ☐ N/A
Area quarantine/clearance	☐ Yes ☐ N/A	Review of instruments that may require the development of a Calibration Plan	☐ Yes ☐ N/A
Assess the need for changes / adjustments to the consumption of public services such as energy, water, compressed air	☐ Yes ☐ N/A	Service agreements for contractors	☐ Yes ☐ N/A
Conductivity	☐ Yes ☐ N/A	Verify that all construction materials meet GMP design requirements	☐ Yes ☐ N/A
Contractor Safety Assessment	☐ Yes ☐ N/A		
Software			
Compliance Analysis IT Management	☐ Yes ☐ N/A	Risk Assessment (FMEA) IT Management	☐ Yes ☐ N/A
Compliance Plan IT Management	☐ Yes ☐ N/A	System Design and/or Configuration Specification	☐ Yes ☐ N/A
Compliance Report IT Management	☐ Yes ☐ N/A	System Test Protocol IT Management	☐ Yes ☐ N/A
Data Conversion/Migration Protocol IT Management	☐ Yes ☐ N/A	System Test Report IT Management	☐ Yes ☐ N/A
Functional Specification	☐ Yes ☐ N/A	Traceability Matrix IT Management	☐ Yes ☐ N/A
Retirement Plan IT Management	☐ Yes ☐ N/A	User Acceptance Test Report IT Management	☐ Yes ☐ N/A
Retirement Report	☐ Yes ☐ N/A	User Requirements Specification IT Management	☐ Yes ☐ N/A

*** Specify the personnel to be trained, request to the training department as specified in the SOP-009417.**
**** Note: This transaction is a process control. GCC can be closed. Product cannot be dispositioned until the APR is closed- as per section 7.0 of SOP006527 and the master data updated accordingly**

Comments/ Other Deliverables:

CHANGE REQUEST FORM (CR)

Change Control Number _____

This number is assigned by the ETQ system when the Global Change Control (GCC) is created.

Section 3. Approval

Obtain approval by the Departments listed below. The correspondent functional area consents that the impact of the change in that area is considered.
Required: Change Owner (CO), Change Control Coordinator, Quality Assurance, Technical Assurance/ Validation and the manager of the area affected by the change.

Function	Name	Signature/Date
Change Owner (CO)		
CC Coordinator		
Quality Assurance		
Technical Assurance/ Validation		
Engineering		
Manufacturing		
Supply Chain		
EHS		
Other_____		
Other_____		

End of the Document

Ref. SOP-006527