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GOOD PACKAGING & PRINTING PRACTICES FOR PHARMACEUTICAL INDUSTRY

Recommendations to enhance the capabilities in the Packaging Sector in Jordan

Final Report

June 11, 2009

This publication was produced for review by the United States Agency for International Development. It was prepared by Peter Spokowski /DAI

GOOD PACKAGING & PRINTING PRACTICES FOR PHARMACEUTICAL INDUSTRY

Recommendations to Enhance the Capabilities in the Packaging Sector in Jordan

Final Report

USAID JORDAN ECONOMIC DEVELOPMENT PROGRAM

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BEARINGPOINT, INC.

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EXECUTIVE SUMMARY

1. PHARMACEUTICAL PACKAGING AND PRINTING CAPABILITIES IN JORDAN OVERVIEW

Packaging and Printing are both important industries within the manufacturing sectors in Jordan and the world. They are the most prominent sectors in Jordan; and their importance come from the nature of packaging being inter-twined with all industries both large and small, which makes it an integral part for food, cosmetics, agriculture, chemicals and others.

Printed packaging plays a vital role in successfully marketing the product. It serves as a means of protecting the product, as well as providing information about the contents, and is a key component in marketing the product.

Almost all manufacturing industries in Jordan use printed packaging for their products. This is most evident when examining the market share of Jordan's pharmaceutical, beverage, processed foods, agriculture and other products for export and local consumption.

In its efforts to bridge the gap between demand and supply to enhance the competitiveness of the Jordanian industry and better positioning in the global value chain, SABEQ conducted two focus groups targeted for the pharmaceutical and printing industries (bottles, cartons and leaflets).

One of the combined focus groups conducted was with the pharmaceutical sector and representatives from printing industries; where the issue of "best printing quality" was presented. The Jordanian Association of Pharmaceutical Manufacturers & Medical Appliances ensure the importance of quality and upgrading the local packaging and printing companies to meet & exceed cGMP specifications mandated by the global pharmaceutical industry.

The pharmaceutical sector was chosen due to its contributions to Jordan's economy; as it contributes in excess of 8.0% of Jordan's total exports; and 75% of its annual sales is directed to exports.

Jordanian printing companies are a significant part of packaging suppliers who are serving the pharmaceutical industry with labeling for cartons, leaflets, bottles, aerosol containers and other package components essential to the pharmaceutical trade industry.

Therefore, the main activity objectives completed were:

- Identify gaps between the pharmaceutical and printing companies.
- Promote global good printing practices.
- Maintain a process to ensure quality of printing and consistency in meeting or exceeding the Jordan Food and Drug Administration (JFDA) regulations.

FOCUS GROUPS OUTCOMES

1. Specific pharmaceutical and printing companies were selected for on-site operations capabilities related to printed package material composites. Many quality-printing issues were presented by each company for discussion. The resolution for all issues is to establish a corporate packaging printing guideline to share with each printing company to meet industry and regulatory practices.
2. Interviews were conducted with key personnel to ascertain a level of skills, knowledge and abilities with printed pharmaceutical material compositions. The interviews identified the "technical gap" of incompatible personnel assigned to the packaging and printing process.
3. Identify main obstacles facing printing companies to meet and exceed JFDA regulation standards. Discussions with each printing company revealed a lack of "technical communication" pertaining to JFDA and global quality printing standards.
4. Review Jordanian Food and Drug Standards and Global Packaging Industry Regulations to suggest areas of improvement for the quality of printed packaging materials. SABEQ's translation of the JFDA printing regulations only describes a printing "process record" and does not address "technical quality" of printed matter.
5. Identify gaps, suggest solutions and upgrading requirements. Twenty-seven major Package Printing Gaps were identified and discussed in detail with each pharmaceutical and printing company. Solutions and upgrading requirements will be difficult to obtain without full cooperation from each industry or by government legislation.
6. Conduct a two-day workshop with pharmaceutical and printing companies and obtain participant consensus on the quality of printing and consistency in delivering. The workshop was presented to 30 attendees who listened to presenters but were not active participants. The attendees primarily expected to receive immediate solutions to their printing process failures without proper education or assigned technical internal resources. The attendees were handed examples of packaging materials printing specifications to apply to their internal packaging process. Additionally; the moderator requested SABEQ to order the USA-FDA code of federal regulations; and distributed copies to each attendee for their procedural process application and reference information. Unfortunately; given these specifications and handbooks will assist each pharmaceutical and printing company, their internal application may not occur due to interpretation, knowledge and skilled internal resources.
7. Some Jordan printers have excellent modern industry capabilities and equipment. However, the pharmaceutical purchasing departments will seek the least cost effective (process controlled) printer with numerous errors occurring in the deliverable order. Errors include mis-counting, color degradation, text flooding, excessive glue and contamination. These errors are a result of improper process controls; which adversely, impact the cGMP's expected in the pharmaceutical industry. These error discrepancies are acceptable with other non-regulated industries. It is recommended that the Jordan printers need to self-educate and regulate their industry (GMP), to align with the pharmaceutical industry mandated JFDA printing process controls and guidelines. Jordan printers should collaborate with pharmaceutical companies by conducting "frequent" printing workshops at each manufacturing site. An independent certified (CPP) packaging engineer consultant / instructor should champion these workshops.
8. A guideline on the packaging printing process and controls to ensure the quality of printing among different parties is not obtainable at this time. The 30 attendees were informed of our intention to create such a "guideline", specifically requested to contribute

to the preparation. The participants were not interactive when prompted. In fact, they may not have been a qualified target group, with the necessary knowledge, skills or abilities to create a "general" guideline. The moderator was able to obtain some data points to consider for preparing a draft guideline. The process & control points to be considered are; packaging label specifications, receipt inspection, storage and handling, label design, sampling plans, record maintenance, and label testing. However, each point requires an independent process and not a "general" guideline. General printing guidelines (processes and controls) are currently identified in JFDA and other global regulations (ISO & FDA/CFR manuals). The need to create a separate guideline will not service the prevailing printing / pharmaceutical discrepancies or issues.

STRATEGY RECCOMENDATIONS

A. Recommend that the Jordan Food and Drug Administration should consult directly with the pharmaceutical and printing industries to review the current "global" printed quality standards and specifications. Recommend establishing a pharmaceutical and printing industry sub-task group to champion amending current printing process standards and establish enforcement codes with (non-compliance) penalties.

B. Jordan Chamber of Industry in coordination with the vocational training corporation has commenced establishing a printing and packaging academy technical center of excellence. Recommend that the Jordanian universities or technical trade schools be encouraged to educate undergraduates in all technical fields of packaging technology, and establish a packaging engineer degree for research & development, packaging equipment, packaging materials and material handling and distribution of finished packaged products.

C. Recommend continued efforts to recruit global Packaging Subject Matter Experts to conduct 60-day technical packaging training modules on all aspects of package commodities. A training certificate should be awarded to each participant; and an annual packaging re-fresher module should be initiated to maintain "certification standards".

D. Communication and image of Pharmaceutical printing is flat-lined; I recommend a series of continuous improvement printing seminars, and development of a "memo of understanding" on the process to ensure the quality of printing among the different packaging industries. I highly recommend the development of a "fishbone" diagram to identify all accountable resources in processing a printed component. This will prevent negative technical gaps between clients and printing companies.

E. Workshop attendees completed an evaluation form with a consensus of the following suggested recommendations: that the pharmaceutical and printing industry require regulated printing standards, collaborative process engagement, a packaging engineer, training video's and instructional modules, effective communication linkages, and legal contractual controls.

F. The moderator recommended the purchase of some global packaging materials, component specification software programs to assist in the proper research, and development of all printed materials composites to avoid common packaging printing errors. For the past ten years, these software programs have been utilized daily at the leading global pharmaceutical and printing companies. However; this software is too technical to apply, and requires appropriate internal (educated) resource staffing (i.e. packaging engineers). The use of this software will eliminate many of current packaging and printing issues within the Jordanian manufacturing sectors.

APPENDICES

Appendix 1: "Good Packaging & Printing Practices for Pharmaceutical Industry" Workshop & Exhibition presentation

Appendix 2: "Good Packaging & Printing Practices for Pharmaceutical Industry" Workshop & Exhibition Materials

Appendix 2: "Good Packaging & Printing Practices for Pharmaceutical Industry" Workshop & Exhibition Attendance List

APPENDIX 1: "GOOD PACKAGING & PRINTING PRACTICES FOR PHARMACEUTICAL INDUSTRY" WORKSHOP & EXHIBITION PRESENTATION

Global Packaging Printing Practices

HOW TO ?

Pharmaceutical Print / Text Development

- **Who?** The Owners (Marketing, Legal, Regulatory Affairs, Quality Assurance, Packaging Engineer, Strategic Planners, Purchasing, Document Control, Graphics and Supplier's)
- **What?** Labels, Leaflets, Cartons
- **When?** Cosmetic Workmanship Standard Delivery
- **Where?** Prime Plant / Contractor / Supplier
- **Why?** Cost Avoidance and Savings
- **GAPS!** Identified and shared
- **Solutions & Recommendations!** Moving Forward
- **Impact!** Benefits

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Internal Process
WHO?

- **Marketing & Graphics** create the brand text data and visual graphics
- **Legal** considers all text data for corrective content, errors and omissions.
- **Regulatory Affairs** prepares JFDA submittal documentation.
- **Quality Assurance and Document Control** validates print application for internal process controls.
- **Packaging Engineer** is primary point of contact to insure "technical" form, fit and functionality with all internal & external owners.
- **Purchasing, Planners & Suppliers** agree to timely forecasted deliverables contractual terms and delivery dates.

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Technical Delivery Specifications
Labels, Leaflets and Cartons
WHAT ?

- **Physical Properties** (per "validated" approved packaging design & material specifications)
- **Chemical Properties** (per21CFR 1771520 & 1630 for raw materials)
- **Biological Properties** (per DIN EN 868-1"bioburden levels)
- **Supplier Packaging Requirements** (TBD with Client)
- **Technical Documentation** (Certificates of Analysis / Compliance)
- **Statement of Storage Conditions** (per packaging component specification)
- **Client Audit of Suppliers** (per cGMP's and FDA regulatory compliance CFR parts)
- **Delivery Conditions:** Supplier Responsibilities per agreed Client Specifications
- **Transportation** (per certified testing acceptance by client)
- **Delivery** (per approved P.O. agreements and arrangements)
- **Right to Refuse** (per contractual agreements with principals)
- **Changes & Authorizations** (mandatory per contractual P.O. and technical specifications from client)

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Cosmetic Workmanship Standards
Labels, Leaflets, Cartons
WHEN?

- **General Requirements:** Client & Supplier Inspection per approved AQL's, and rework agreements.
- **Label Component Requirements:** Detailed material, graphic and text approved specifications with illustrations or picture frames.
- **Technical Delivery Specifications:** Labels, Cardboard Boxes, Workmanship and Package & Label Rework Process. **Handout Examples (drafts).**
- **Acceptance Criteria:** Material, Dimensions, Seals, Cosmetics, Adherence, Verification, Creases, Dents, Depressions, Scuffing, Gluing, Alignment, Count, Rips / Tears, Windows, Contamination (dirt particles), Discoloration, Graphics and Text.
- **Records and Definitions:** References, Location, Responsibility, Accountability per Client, Supplier and Regulatory Agencies (JFDA, FDA, ISO, CFR, cGMP's, EU, Asian, SOP and PO).

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Prime Plant / Contractor
WHERE?

- **Supplier Location:** Performance of printing deliverables
- **Prime Manufacturing Site:** Performance of finished packaged (printed) products.
- **Third Party Contractors:** Performance of secondary finished packaged (printed) products.

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Cost Avoidance and Savings
WHY?

- Enhanced Reconciliation
- Prevent Rework
- Shrink Additional Resources
- Reduced Storage of rejects
- Eliminate Repeat Production runs

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Package Printing of
Labels, Leaflets, Cartons & Containers
GAPS !!

- Contamination
- Insufficient planning forecasts
- Traceability and Record control is minimal
- Incomplete Packaging Specifications
- Printer production lot mix-ups.
- Submitted C of A incomplete
- Counting errors: Validation issues between principals
- Supplier modifying approved Designs without approval
- Late Deliveries from Suppliers
- Supplier un-approved substitution of Raw materials
- Pantone Color Deviation
- Poor Communication between Client & Supplier
- Lack of formal Jordan regulations or guidelines for Packaging components
- Quality dependant on costs
- Client lack of knowledge of Supplier capabilities
- Bar Code errors
- Minimal Design controls between Client & Supplier
- Suppliers do not understand GMP's
- Minimal Supplier packaging material testing capabilities
- Minimal Supplier Internal Quality Control procedures
- Improper Segregation
- Minimal Formal Procedures at Suppliers
- Lack of Formal GMP training at Suppliers & Clients
- Packaging components are unclean (internal & external)
- Process Flow diagram (fishbone)

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Solutions & Recommendations!!

- Enhanced Communication (production planning, CAPA's, supply issues, delays, etc.)
- Mutual Co-operation and customer involvement
- Combine Education (Bar Code & GMP's skills training) on site sessions
- Employ Proper Resources (Packaging Engineer, student internships)
- Develop Detailed Comprehensive Component & Printing Technical Specifications
- Create Engineered Drawings for Print and Package Components
- ***Develop and Implement Joint Procedure Guidelines & Process Flow Diagrams to ensure quality of printing and consistency in delivering to meet or exceed JFDA regulations***
- Establish annual "Best Practices Awards" for Suppliers & Clients
- Attend "quarterly" Packaging & Printing workshops and certification modules
- Establish a Jordan Technical Center of Packaging Excellence
- Create a Packaging "Hot Line" call center
- Build a Packaging Reference library
- Perform first article inspection at each supplier production runs
- Printing equipment upgrades (counters & vision systems)
- Minimize technical intervention by purchasing

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IMPACT !!

- Cost Savings: Better pricing
- Cost Avoidance: Reduced rejects and re-work by 25-35% ($150,000+)
- Skills, Knowledge and Ability improvements
- Global Recognition
- Meet and Exceed 2010 Environmental and Sustainable regulations to reduce packaging carbon waste footprint
- Better Product Branding
- Increased customer market revenue (profits)

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Thank You !

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APPENDIX 2: "GOOD PACKAGING & PRINTING PRACTICES FOR PHARMACEUTICAL INDUSTRY" WORKSHOP & EXHIBITION MATERIALS

1. Introduction

This technical delivery specification deals with the order, the control and the delivery of cardboard boxes used for secondary packaging of sterile implants, bone substitute and other materials.

Medtronic Sofamor Danek Deggendorf GmbH is abbreviated as MSDD in this document.

2. Definitions

2.1 Associated Documents

EU – Directive 94/62/EC

Ready to be printed (RTP):

Document, which is approved from both sides (MSDD and manufacturer of the cardboard box) and according to how the production (printing and cutting) has to be performed.

This document will be used for the incoming inspection of the delivered product to the MSDD plant (refer to the form FL208-x where each product type is reported on a RTP).

2.2 Terms

Batch number

The batch number is a number given by the supplier to the product in order to assure the complete traceability of the product history.

Package unit

A package unit is the smallest package for the product.

One package unit corresponds to 175 cardboard boxes.

3. Product Specification

3.1 Physical Properties

Material:	GC1 350 g/m² Kasuar; cardboard box folded or not-folded
Size:	defined in the RTP
Color boxes:	defined in the RTP, for example:

BLUE for the name "Medtronic" in the logo Medtronic Sofamor Danek (Pantone 301 or C100%-M45%-Y0%-K18%). Filed under MSDHorizColor_CMYK.tif and MSDVert_CMYK.tif.

GRAY for the name "Sofamor Danek" in the logo Medtronic Sofamor Danek (Pantone cool gray 8 or C0%-M0%-Y0%-K43%). Filed under MSDHorizColor_CMYK.tif and MSDVert_CMYK.tif.

BLACK for all written text parts and icons (C0%-M0%-Y0%-K100%).

pms

A DOMINANT COLOR for the product logo and the "recall band" on the cover of the box (defined by Pantone No. or Cx%-Mx%-Yx%-Kx%) when needed.

Additional specification for white cardboard boxes without print:

- Pasted lined and shiny outer surface (Faltschachtel außen mit Dispersionslackierung vollflächig).
- Type of cardboard box: 42 B.

Deleted: ganzflächig kaschiert und glänzend beschichtet

3.2 Chemical Properties

Heavy metals according to EU – Directive 94/62/EC.

3.3 Biological Properties

Not applicable.

3.4 Packaging

The cardboard boxes are delivered in boxes, which are packed and fixed on a palette.

Each container should have a label chosen in a way to assure that it cannot be damaged or lost during transport and storage. The label should contain the following information:

- Name of the product
- Manufacturer and/ or supplier
- Batch number/ number of certificate
- Number of pieces
- Retest date/ minimum shelf life
- Storage conditions

In case the above listed items are not completely documented on the label, the supplier has to provide a delivery document, which contains the information missing on the certificate (see chapter 6.3).

4. Technical Documentation

4.1 Certificate

The supplier needs to provide a certificate, which describes and affirms all of the following items:

- Order number and date
- Supplier reference and name of the product
- Reference number of this Technical Delivery Specification (TLB021, Rev. 12)

TLB 021-12.doc

Deleted: 1
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- Number of certificate/ supplier's internal order number
- Supplier and/ or manufacturer
- Retest date/ minimum shelf life
- Delivered quantity
- Test results of the batch (see product specification in section 3.1, 3.2 and 3.3)

In case the above listed items are not completely represented on the certificate, the supplier has to provide a delivery document, which contains the information missing on the certificate (see chapter 6.3)

4.2 Statement of Storage Conditions

The supplier has to provide at least once a document, which describes the storage under which the minimum shelf life can reliably be achieved:

Temperature:	5 – 35 °C
Humidity:	50 - 80 % rH, store protected from direct light.
Min. shelf life:	4 years, if not packaged in automatic packaging device.

5. Audit

MSDD keeps the right to perform regular quality audits at the supplier's manufacturing plant in order to check the above-mentioned documents and tests. The manufacturing plant should be open for audit all the year. A date has to be fixed in advance by written statement after mutual agreement.

6. Delivery Conditions and Supplier's Responsibilities

6.1 Order Intake and Order Confirmation

MSDD provides the supplier with an official order for the product or process as specified in this Technical Delivery Specification.

When the order is accepted, the supplier needs to comply with following procedure:

- Provide a written confirmation of order and confirm a delivery date
- Produce and deliver to MSDD a product in compliance with this TLB.

6.2 Transportation

The integrity of the product including its packaging should be maintained on the way of transportation to MSDD.

6.3 Delivery

A delivery note needs to be sent with the product. It should summarize all the following information:

- Delivery note, stating
  - Order number
  - Name of the product
  - Name of manufacturer and/ or supplier
  - Number of certificate/ supplier's internal order number
  - Quantity delivered including number of boxes
- Documentation as described in section 4.

No invoice will be paid to the supplier if one of the documents is missing or cannot be obtained after delivery of the product.

6.4 Right to Refuse

MSDD keeps the right to perform a verification of the delivered product in house in order to check compliance of the delivered product with this TLB.

If a deviation is noticed during the verification, the delivered product will be sent back to the supplier. No invoice will be paid and the order will be considered as not completed. The supplier will have to provide a new batch.

6.5 Changes

The supplier or the manufacturer of the product or process described in this specification has to keep MSDD informed by an official letter in case of:

- Intended changes in the manufacturing or packaging procedure
- Intended change of manufacturer or manufacturing location
- Intended changes in the technical specification
- Any other intended change, which can have an effect on the quality of the specified product or process.

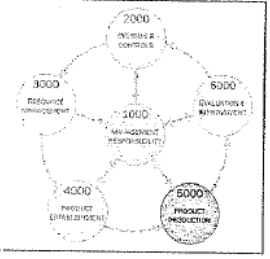
Global Instruction

WI GQ 143

Package & Label Rework Process

Document ID: GQ143 Version: A

Effective Date: 1/28/2009 Owner: Peter Spokowski



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Package & Label Rework Process

PURPOSE

The purpose of this document is to describe the process for controlling rework projects that are limited to packaging and/or labeling.

SCOPE

This document is designated for use at the following business locations:

- MDT Spinal and Biologics Bartlett Manufacturing
- MDT Spinal and Biologics Distribution Center
- MDT Spinal and Biologics Memphis Headquarters
- MDT Spinal and Biologics Memphis Manufacturing

The information in this document applies to MSB employees involved in the processing of package and label reworks.

RESPONSIBILITIES

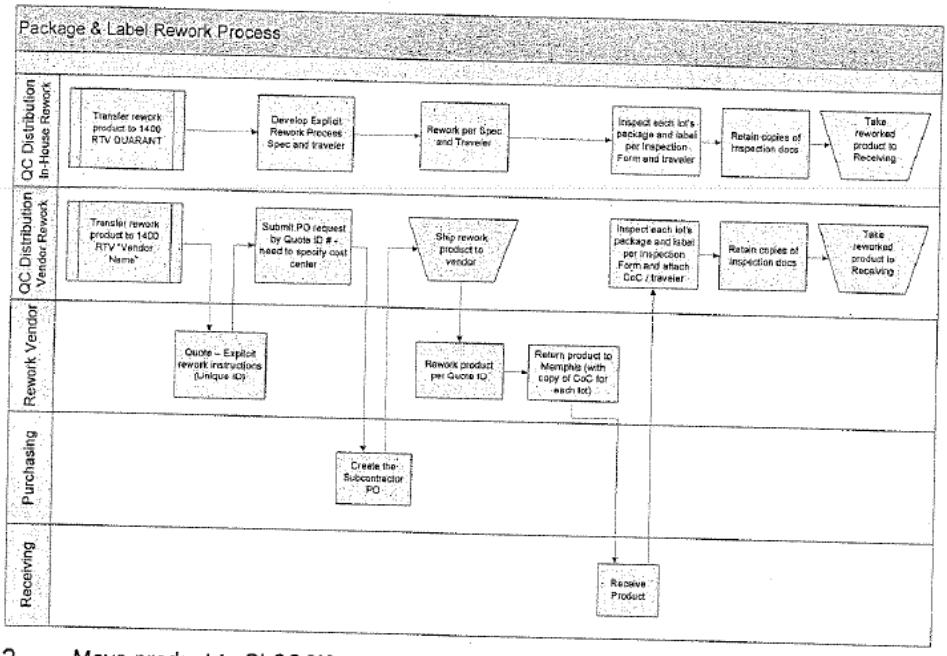
Indicator [1]	Function or Role	Summary of Responsibilities
[A]	QC Distribution	Responsibilities include: • Creating purchase requisitions • Shipping, inspection of reworked product
[B]	Purchasing	Create subcontractor purchase order
[C]	Receiving	Receive product in SAP

[1] **Responsibility Indicators** are used throughout this document to highlight responsibilities for each affected function or role.

Package & Label Rework Process

INSTRUCTION

1 Process Flow



2 Move product to SLOC [A]

2.1 Transfer parts/lots to be reworked to SLOC 1400 RTV "Vendor name".

2.2 Retain a list (spreadsheet) of part / lot/ qty.

3 Request for Quotation [A]

3.1 Contact rework vendor with a request for quotation.

3.2 Provide explicit rework instructions – including new lot numbering strategy.

- Existing lot plus one unique alpha character (unique to rework at hand)

3.3 Specify the components will be provided to vendor and which components vendor will need to acquire, if any.

3.4 Provide number of CFNs and number of lots involved.

3.5 Provide requirements to be on the certificate of conformance (CoC).

3.6 Request that the vendor provide the traveler / router or list components used on the CoC.

3.7 Vendor will provide process spec with the quote.

4 Create Purchase Requisition [A]

4.1 When the quote is received from the rework vendor, email copies to interested parties (Quality manager, Marketing, PD, Planning, Purchasing, etc.).

4.2 Ensure the quotation has a unique quote ID.

4.3 If the quote is acceptable, proceed to section 4.5.

4.4 If the quote is not acceptable, discuss requirements with interested parties and go to section 3.1.

4.5 Create the purchase requisition using SAP transaction ME51N.

- 4.5.1 Complete the requisition with the required fields.
- 4.5.2 Use Item Category Type "L" to designate that this is a subcontractor PO request.
- 4.5.3 Enter the Cost Center to that will pay for the rework cost.
- 4.5.4 Enter the unique quote ID in the text field.
- 4.5.5 Specify a QC Distribution employee for the reworked product to be shipped to.
- 4.5.6 Enter the part /lot/ qty to be reworked.
- 4.5.7 Save the requisition.
- 4.5.8 Email the Purchaser the requisition number and an electronic copy of the quote.

5 Create the Subcontractor PO [B]

5.1 Once the purchase requisition is approved in SAP, the PO can be created.

5.2 Copy and paste the quote into the PO in SAP.

6 Ship Product to Vendor [A]

6.1 Pack the product by part / lot in accordance with QI005, Instructions for Returning Quarantine Product.

6.2 Ship the product using the agreed upon shipping method - FDX, UPS, courier, etc. Retain shipping information at least until the entire shipment is confirmed to have arrived at vendor.

7 Product Receipt [C]

7.1 Receive the reworked product into SLOC NEW as the new lot numbers.

7.2 Inform QC Distribution that the product is in-house, and move the product to the Quality area for inspection.

8 Product Inspection [A]

8.1 Review the certificate of conformance (CoC) for each lot.

8.2 Inspect product by lot, completing GQF143, Package and Label Rework Inspection Form for each lot.

- Attach the CoC to the inspection form for each lot.
- Attached the vendor's traveler for each lot (if component info is not provided on CoC).
- Please add inspection characteristics using lines 7-10, if needed.

8.3 Quarantine any rejected quantities and contact QC supervisor for appropriate disposition.

8.4 File the GQF143, Package and Label Rework Inspection Form, CoC, and traveler for each lot as the DHR.

8.5 Alert the Receiving dept that reworked product will be brought to their area.

8.6 Move product to Receiving dept for putaway and bring appropriate transfer documents.

9 In-House Reworks [A]

9.1 If the rework is to be done in-house by MSB personnel, sections 3-7 should be omitted.

9.2 An explicit rework process specification must be developed and approved by the interested parties before the rework begins.

- A traveler or router must be developed and approved listing steps performed, by whom and when.

9.3 All necessary components must be procured.

9.4 Rework the product per the explicit rework process specification and complete the traveler as steps are performed.

9.5 Go to Section 8 for product inspection.

- NOTE: There will be no CoC for this rework. The in-house traveler should be included in the DHR.

RECORDS

The following records will be maintained according to the retention standards defined by regulatory agencies, applicable Medtronic Corporate Policies, and record retention procedures:

- Inspection form
- Certificate of Conformance
- Receipt of reworked product - stored in SAP

DEFINITIONS

Terminology, abbreviations, and acronyms are defined in the context of the document.,

REFERENCES

GQF143, Package and Label Rework Inspection Form 4
QI005, Instructions for Returning Quarantine Product 4

Package & Label Rework Process

REVISION HISTORY

Version	Originator	Description of Change	Date
A	Robert Cassady	Initial release of document	1/28/09

Material #:		Description:		PO #:	
New Lot # :		Drawing Rev:		PO Qty:	
				Criteria Revision	A

Item	Characteristic	Method/Gaging	AQL.	Acc. Qty.	Rej. Qty.	Date	Comments
1	Certificate of Conformance matches quote	Visual	100%				
2	Labels match master print and label verbiage	Visual	1.0				
3	Labels are legible and free of damage	Visual	1.0				
4	Carton matches print	Visual	1.0				
5	Inspect carton for damage	Visual	1.0				
6	Inspect wrap / packaging for damage	Visual	1.0				
7							
8							
9							
10							

NOTE: Make sure all fields are complete. If a field is not applicable, put N/A.

Inspected By: (Name)	Date:	Qty Accepted:	Qty Rejected:

Quality Assurance Approval: Note – This approval cannot be the same as the inspector.		Date:

Type of Inspection Key and Abbreviation List	
I	In-Process / Manufacturing
R	QC Receiving
F	QC Inspect Final

Material #:		Description:		WO/PO #:	
New Lot # :		Drawing Rev:		WO/PO Qty:	
				Criteria Revision	A

Revision History Page

Revision	Prepared By	Description of Change	Effective Date
A	Robert Cassady	Initial release	

[LB]

	Technical Delivery Specification **Labels for Packaging of Sterile Implants**	Revision : 04 Page 1 of 5 **TLB 025**

listen. respond. deliver.

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	Writer	Approver	Release
Department :	NT	NT	QM
Name :	Reif	Dr. Früh	Wechsler
Date :			
Signature :			

1. Introduction

This technical delivery specification deals with the order, the control and the delivery of white or pre-printed product labels.

Medtronic Sofamor Danek Deggendorf GmbH is abbreviated as MSDD in this document.

2. Definitions

2.1 Associated Documents

Ready to be printed (RTP):

Document, which is approved by both sides (MSDD and manufacturer of the labels) and according to which the production (printing and cutting) has to be performed.

This document will be used for the incoming inspection of the delivered product in the MSDD plant (refer to form FL208-x where each product type is reported on a RTP).

2.2 Terms

Batch number

The batch number is a number given by the supplier to the product in order to assure the complete traceability of the product history.

Package unit

A package unit is the smallest package for the product.

One package unit corresponds to one roll with a defined amount of labels.

3. Product Specification

3.1 Physical Properties

Detailed information is defined in RTP.

The label is white or pre-printed with up to 8 colors.

The product is provided on a roll with an inner diameter of 76 mm. The product consists of high-gloss paper 83 g, white shining with permanent glue and is winded on the roll in a defined rolling scheme.

3.2 Chemical Properties

Not applicable.

3.3 Biological Properties

Not applicable.

3.4 Packaging

The product is delivered on rolls which are packaged in PE bags.

Each container should have a label chosen in a way to assure that it cannot be damaged or lost during transport and storage. The label should contain the following information:

- Name of the product
- Manufacturer and/ or supplier
- Batch number
- Number of pieces/ units
- Retest/ minimum shelf life
- Storage conditions

In case the above listed items are not completely represented on the certificate, the supplier has to provide a delivery document, which contains the information missing on the certificate (see chapter 6.3)

4. Technical Documentation

4.1 Certificate

The supplier needs to provide a certificate, which describes and affirms all of the following items:

- Order number and date
- Supplier reference and name of the product
- Batch number
- Reference number of this Technical Delivery Specification (TLB025, Rev. 04)
- Supplier and/ or manufacturer
- Manufacturing date
- Retest date/ minimum shelf life
- Delivered quantity
- Test results of the batch (see product specification in section 3.1, 3.2 and 3.3)

In case the above listed items are not completely represented on the certificate, the supplier has to provide a delivery document, which contains the information missing on the certificate (see chapter 6.3)

4.2 Statement of Storage Conditions

The supplier has to provide at least once a document, which describes the storage conditions under which the minimum shelf life can reliably be achieved:

Temperature:	5 -35 °C
Humidity:	20 ± 90 % rH, store protected from direct light.
Min. shelf life:	4 years

5. Audit

MSDD keeps the right to perform regular quality audits at the supplier's manufacturing plant in order to check the above mentioned documents and tests. The manufacturing plant should be open for audit all the year. A date has to be fixed in advance by written statement after mutual agreement.

6. Delivery Conditions and Supplier's Responsibilities

6.1 Order Intake and Order Confirmation

MSDD provides the supplier with an official order for the product or process as specified in this Technical Delivery Specification.

When the order is accepted, the supplier needs to comply with following procedure:

- Provide a written confirmation of order and confirm a delivery date
- Produce and deliver to MSDD a product in compliance with this TLB.

6.2 Transportation

The integrity of the product including its packaging should be maintained on the way of transportation to MSDD.

6.3 Delivery

A delivery note needs to be sent with the product. It should summarize all the following information:

- Delivery note, stating
  - Order number
  - Name of the product
  - Name of manufacturer and/ or supplier

- Batch number
- Quantity delivered including number of containers

- Documentation as described in section 4.

No invoice will be paid to the supplier if one of the documents is missing or cannot be obtained after delivery of the product.

6.4 Right to Refuse

MSDD keeps the right to perform a verification of the delivered product in house in order to check compliance of the delivered product with this TLB.

If a deviation is noticed during the verification, the delivered product will be sent back to the supplier. No invoice will be paid and the order will be considered as not completed. The supplier will have to provide a new batch.

6.5 Changes

The supplier or the manufacturer of the product or process described in this specification has to keep MSDD informed by an official letter in case of:

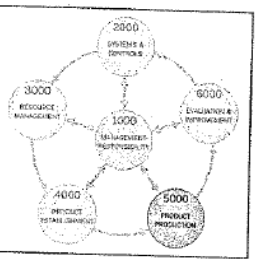
- Intended changes in the manufacturing or packaging procedure
- Intended change of manufacturer or manufacturing location
- Intended changes in the technical specification
- Any other intended change which can have an effect on the quality of the specified product or process.

Global Instruction

Cosmetic Workmanship Standards for Sterile Product Packaging

Document ID: PKG085 Version: A (Draft)

Effective Date: Owner: ~~Chris Bagacin~~ Peter Spokowski



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Cosmetic Workmanship Standards for Sterile Product Packaging

INSTRUCTION

1 General Requirements

1.1 Packaging components and complete unit packages must be inspected per the Medtronic manufacturing site inspection defect detection method.

1.2 Packaging components must be free of tears or deformed areas (creases or pulls).

2 Sterile Package Component Requirements (for incoming inspections follow current "on-site" approved sampling plan)

2.1 PETG BLISTERS

2.1.1 **Blister Scratches:** A total of six or more micro defect scratches per the entire surface of the blister, excluding the sealing flange, which can be detected using the standard defect detection methods. Any minor or major scratch is not acceptable.

2.1.2 **Blister Gels (fisheyes):** A fisheye or gel is defined as an inconsistency in the blister material that looks like a very small area of thickened plastic caused by the presence of inconsistencies in the plastic sheet or contaminants during the forming process. Maximum of three (3) gels per entire blister surface. The maximum diameter allowable is 1.0mm (0.040 in)

2.1.3 **Blister Container Surface and Contaminant:** The inner blister must be free from loose particles and dirt. Reference section 7.8 for outer blister particle acceptance. Both outer and inner blisters must be free from discoloration, holes, cracks, tears, creases, scuffmarks, or localized thickening and or thinning (areas thicker or thinner than the surrounding areas) sufficient to impair functionality of the blister.

2.1.4 **Blister Material:** Foreign particles imbedded into the blister material that can be felt but do not stop a G0025 (include MSDD equivalent) and are smaller than 0.25mm² (0.0004 in²) Ref: Medtronic TAPPI Dirt Estimate Chart, are acceptable. Imbedded foreign particles that cannot be felt with a G0025 are also allowable providing they are less than 0.25mm² (0.0004 in²) Ref: Medtronic TAPPI Dirt Estimate Char, and not in the sealing flange. There can be no more than one occurrence per plane and no more than 2 occurrences on the entire surface of the blister.

2.1.5 **Blister Cut Edges:** Die cut tray edges shall not have any nicks or angel hairs present.

2.1.6 **Blister Dimensions:** The blister tray must meet all print dimensions.

2.1.7 **Blister Seals:** The tensile seal strength of the blister (ASTM F88, "Standard Test Method for Seal Strength of Flexible Barrier Materials"). Seal strength and material seal widths are determined by manufacturing site material specifications.

2.2 TYVEK LIDS

2.2.1 **Tyvek Lid Dimensions:** The Tyvek lids must meet all print dimensions.

2.2.2 **Tyvek Lid Material:** The Tyvek lid material must be free of any damage and/or contamination (i.e. holes or perforations).

2.2.3 **Tyvek Lid Seals:** The seal strength of the Tyvek Lid (ASTM F88 "Standard Test Method for Seal Strength of Flexible Barrier Materials"). Seal strength and material seal widths are determined by manufacturing site material specifications.

2.3 TYVEK POUCHES

2.3.1 **Pouch Dimensions:** The pouches must meet all print dimensions.

2.3.2 **Pouch Material:** The pouch material must be free of any damage and/or contamination.

2.3.3 **Pouch Seals:** The seal strength of the pouch seal (ASTM F88 "Standard Test Method for Seal Strength of Flexible Barrier Materials"). Seal strength and material seal widths are determined by manufacturing site material specification.

2.4 POLYBAGS

2.4.1 **Pouch Dimensions:** The pouches must meet all print requirements as specified.

2.4.2 **Pouch material:** The polybags must be free of any damage and/or contamination (i.e. loose particles or dirt) (Add comment regarding carbon marks)

2.5 LABELS

2.5.1 **Label Cosmetics:** The labels applied to the package shall be free from smudges, smears, fold, or creases.

2.5.2 **Over-labeling:** If an error is found on a package label or the original label is unreadable or damaged, label ~~"SHOULD NOT"~~ be over labeled with a new label. The sterile package must be torn down and reworked per normal processing procedures. (Is not permitted unless agreed upon by the appropriate facility, marketing, Packging, Reg, and Quality departments). . (Move to Final Packaging section)

2.5.3

2.5.4 **Label Adherence:** All outer edges of labels must be completely attached to the surface of which they are adhered. Bubbles, air spaces, or non-adhered surfaces under a label are not to be more than 5% (five percent) of the label surface as viewed from the printed surface side of the label. (Move to Final Packaging section)

2.5.5 **Label Verification:** If a labeling error is found on a device, the entire job must be re-verified to assure that other devices did not get labeled incorrectly.

2.6 Cartons and Boxes:

2.6.1 **Creases:** Creases that will be visible when the box or carton is fully assembled are not acceptable. If the crease is on an inner flap that will be not visible when the box is fully assembled, it is acceptable. A maximum of 2 MICRO Defects are allowable per box or carton (clarify). (Also specified at Packaging Inspection stage) (Bring up with Japan content)

2.6.2 **Dents, Depressions, and Scuffs:** Micro and minor dents, depressions, or scuffs that are visible on the outside of the fully assembled box or carton are acceptable. A maximum of 5 micro and/or minor dents are allowable. An additional 2 dents, depressions, or scuffs are allowable up to a size of 3.2mm (0.125 in) long by 2.0mm (0.079 in) wide. No dent, depression, or scuff is allowable if it is more than 1.0mm (0.040 in) deep or if it punctures the box or carton material. If the dent, depression, or scuff will not be visible when the box or carton is fully assembled it is acceptable providing it does not puncture the box or carton material. (Bring up with Japan content)

2.6.3 **Gluing:** Visible glue on the outside of the box or carton is not acceptable. It is also not acceptable to have tears on the inside of a box or carton caused by over gluing a box or carton seam.

2.6.4 **Alignment:** All mating joints of a box or carton should align properly. Any box or carton that does not align correctly may not function properly and therefore is not acceptable.

2.6.5 **Rips and Tears:** Ripped or torn material on a carton or box that has been completely removed is not acceptable on any location on the carton or box. Rips or tears on a portion of the box or carton that will not be visible when the box or carton is fully assembled is acceptable providing the ripped or torn material is still attached to the box or carton and the length of the tear or rip is less than 10mm (0.394 in). There is only 1 occurrence allowable per box or carton.

2.6.6 **Carton Windows:** Carton window material must be present. A carton with windows shall have a maximum of 2 micro defects (particles or fibers) visible through the window. The carton window shall also be fully adhered to the inside of the carton as to not detach during normal material handling.

2.6.7 **Discolorations:** Discolorations and/or colored lines on boxes or cartons are acceptable provided they are no bigger than 2.00mm² (.0031in²) Ref: Medtronic TAPPI Dirt Estimate Chart.

2.6.8 **Graphics:** Graphics must be placed so that labels will not cover any required graphic when applied. Graphics must also be uniform throughout an entire lot.

3 Acceptance Criteria for In Process Inspection

3.1 Sterile tray and pouch seals must be inspected 100%.

3.2 Micro scratches in packaging components are acceptable. Refer to individual packaging component definitions for size and occurrences.

3.3 Micro and minor pits/indentations that do not go through the wall of the packaging component are acceptable. Refer to individual packaging component definitions for size and occurrences.

3.4 Particles within the seal that are less than 0.25mm², that are not organic in nature, are acceptable providing there is at least a cumulative seal width of 3.175mm (1/8 in) for trays and 4.763mm (3/16 in) for pouches maintained (see Figure 1). The particle must not protrude outside the seal and must not be moveable inside the seal. No more than 2 occurrences per completed package.

3.5 A total of 2 micro fibers or 1 minor fiber is allowable in the seal provided the above diagram (see Figure 1) is satisfied for minimum seal width of pouches or trays. The fiber also can not protrude outside the seal or be movable inside the seal.

3.6 Products, implants and instruments, which have up to three layers of single thickness poly bag material on top of them, are acceptable.

3.7 Minor spottiness or inconsistencies in the seal are acceptable providing there is at least a cumulative, 3.175mm (1/8 in) for a tray and 4.763mm (3/16 in) for a pouch, seal is maintained.

3.8 Particles less than 0.25mm² are acceptable in the outer blister or outer pouch. A maximum of 2 occurrences per complete package is allowable.

3.9 Once a lid is sealed onto a packaging tray the lids shall be free of folds or creases within or touching the seal area. Large fibers in the lid that travel through the seal area are acceptable so long as they show a darker coloration indicating an acceptable seal.

3.10 A maximum of 3 voids are acceptable per Tyvek lid provided they are not larger than .8mm² (.0012in²) Ref: Medtronic TAPPI Dirt Estimate Chart, they are not closer than .025in of each other and the seal still measures at least 3.175mm (1/8in) on either side of the void.

3.11 A maximum of 2 micro fibers are allowable in the outer blister or outer pouch.

4 Completed Packages for Final Inspection

4.1 Organic materials (ex. hair) of any kind are not acceptable on any component within the package.

4.2 Any fiber or particle that protrudes from the seal of the package is not acceptable.

4.3 Products, implants and instruments, which cannot be clearly seen due to having more than three layers of single thickness poly bag material between the implant or instrument and clear outer window is not acceptable when product visibility is required. (Address change to clarify see Packaging Assembly drawing)

4.4 Spottiness and inconsistencies in the seal are not acceptable if a cumulative seal, of at least 3.175mm (0.125 in) for trays and 4.763mm (3/16 in) for pouches, is not maintained. The cumulative seal shall not be comprised of more than 3 separate segments of sealed distance.

4.5 Poly bag cut edges must be free of any loose fibers.

4.6 Particles and fibers are not allowable inside or on the polybag. However, a total of 3 micro and/or minor defects are allowed in the bag providing they are colorless not holes. (Clarify that only 3 total defects allowed)

4.7 Carton window material must be present. A carton with a window shall have a maximum of two micro defects (particles or fibers) visible through the window. The carton window shall also be fully adhered to the inside of the carton as to not detach during normal material handling. (Check with Japan)

5 REWORK

5.1 If a complete package is rejected, it may be reworked. New packaging supplies must be used when reworking a complete package.

5.2 All blisters and Tyvek lids may only be used once. If a seal has been broken in any way, a new blister and seal must be used in its place.

5.3 Packaging materials that are not within specification are rejected as scrap and cannot be reworked.

RECORDS

The following records will be maintained according to the retention standards defined by regulatory agencies, applicable Medtronic Corporate Policies, and record retention procedures:

Inspection records are retained in accordance with "Control of Quality Records", located at each Medtronic Global Quality Department manufacturing site..

Cosmetic Workmanship Standards for Sterile Product Packaging

DEFINITIONS

Inspection Defect Detection Method
At a distance of 12 inches; use the unaided normal eye or corrected vision, scan each package or material (without a magnification instruments) in each plane for 1 to 3 seconds, for a maximum of 15 seconds unless clarification is necessary. Use only light provided in each inspection area (Reference 2000 to 7000 lux). Magnification instruments and additional inspection time is only to be used for clarification, not detection.

Cover Sheet
The first sheet from a blister mold, processed during each new supplier run, provided to MSB by the supplier for certain blister products and used by CEA personnel to determine mold defects. Remove any coversheet references once new 0237692/693 mold is approved by all MSD manufacturing sites (note: only the 692/693 trays use the "cover sheets").

CEA
Controlled Environment Area

Particle
A very small piece or part. (See Tappi Dirt Chart and Defect Classification)

Fiber
An elongated polymer remnant.

Defect Classification
Defects are classed according to their prominence or size and the ability to detect them per defect detection and their ability to be detected with a 0.20mm (0.008 in) radius tip pin (G0025). Note: "G0025" is an item identifier number assigned by Warsaw calibration department.

All defects shall be classified as follows:

Micro Defect
The term describes a defect up to 0.15mm (0.006 in) wide and up to 1.6mm (0.062 in) in length. It can be seen but cannot be detected with a G0025. Defects are classed according to their prominence or size and the ability to detect them per defect detection and their ability to be detected with a 0.20mm (0.008 in) radius tip pin (G0025).

Minor Defect:
The term describes a defect that is up to 0.25mm (0.010 in) wide and up to 3.2mm (0.125 in) in length. It can be seen and detected with G0025.

Major Defect:
The term describes a defect that is larger than .25mm (0.010 in), wide by 3.2mm (0.125 in) in length, which is clearly visible, distinctly felt and will stop a G0025.

Mold Defect:
Describes a defect that is inherent from the molding process at the supplier level. These defects are acceptable provided that a quality representative has accepted the "Cover Sheet" and AQL sample of the supplier lot/job in question per I-8.2-002 (Quality Control Inspection for Sterile Product). CEA personnel will have access to the "cover sheet" and will be allowed to compare blisters of that supplier lot number in order to clarify the acceptability of a defect. Not all supplier part numbers, or lot numbers, will have a "cover sheet". Only 692 / 693 trays have cover sheets.

APPENDIX 2: "GOOD PACKAGING & PRINTING PRACTICES FOR PHARMACEUTICAL INDUSTRY" WORKSHOP & EXHIBITION ATTENDANCE LIST

Workshop and Exhibition on
"Good Packaging & Printing Practices for Pharmaceutical Industry"
May 27-28, 09 - Landmark Hotel

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