A Case Study of the Challenges of Global Labeling and its Impact on the Supply Chain

Medical Device Supply Chain Council
October 2nd, 2013
Agenda

Today’s Discussion Items

- Company Overview
- Hidden challenges of growth thru acquisition
- The impact labeling localization has on the Global Supply Chain
- How do we turn the ship?
- Global labeling Controls and Lean Labeling Localization
- Putting the pieces together
- The path to postponement
- Future opportunities…
Company Profile

Boston Scientific (NYSE: BSX) is a worldwide developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties.

Innovation Leader
- One of the world’s largest medical device companies
- 15 manufacturing facilities worldwide
- Portfolio of more than 13,000 products

Locations
- Corporate HQ: Natick, MA
- Regional HQs: Paris, Tokyo
- Major Tech. Centers: MN, CA, IRL, CRI
- Website: www.bostonscientific.com

People
- CEO & President: Mike Mahoney
- 24,000 Employees
- Sales forces in more than 40 countries

Financials
- $7.1 Billion Revenue (’12)
- $1.0 Billion Adjusted Net Income\(^1\) (’12)
- NYSE: BSX

1. Excluding acquisition, litigation, divestiture, restructuring and other charges
Interventional Cardiology technologies diagnose and treat coronary artery disease and other cardiovascular disorders.

Cardiac Rhythm Management products treat irregular heart rhythms and heart failure, and protect against sudden cardiac arrest.

Urology/Women’s Health products treat various urological and gynecological disorders such as kidney and bladder stones, stress urinary incontinence, pelvic organ prolapse and excessive uterine bleeding.

Neuromodulation therapies use microelectronic implantable technologies to manage chronic neuropathic pain.

Electrophysiology products use technologies such as mapping catheters, radiofrequency energy and cryogenics to diagnose and treat heart rhythm disorders.

Endoscopy technologies diagnose and treat diseases of the digestive system, airway and lungs.

Peripheral Interventions products treat vascular system blockages in areas such as the carotid and renal arteries and the lower extremities.
Although BSC successfully achieved its goal of obtaining “strategic mass” and top line growth via acquisitions, it created significant Ops labeling challenges in the years ahead…
Packaging and Labeling “State of Affairs”…

As a result, across 17 manufacturing plants and 6 divisions, BSC was faced with…

- Mass proliferation of packaging & labeling component sizes, styles, designs…
- Over 20 different labeling systems
- Multiple labeling review and approval processes
- Non-standard software / hardware platforms
- Source data issues
- Inconsistent naming conventions
- Labeling in various states of compliance
BSC Labeling Background

Since 1998, BSC multilingual policy has provided translations for 11 languages...

- English
- Spanish
- French
- German
- Italian
- Dutch
- Japanese

- Danish
- Greek
- Portuguese
- Swedish

4 – Electronically

Not Readily Available

7 - Multilingual Core

Label – All 11 Languages
1. **Lack of brand recognition…**

2. **Field Actions –** in 2004, 34% of all field actions were labeling related.

   “Pretty boxes are nice, but I have labeling issues and I need systems.”
   - BSC President / CEO, Fall 2004

3. **OUS Revenue Risk: Dramatic Increase in Labeling Localization Requirements**
   - Medical Device Directive (MDD) allows EU countries to introduce requirements for native language labeling.
   - In May 04, the European Union added 10 countries. With it’s increase in size and stature, new countries are demanding native translations → “loose leaf / paper” DFU”
As a result of a lack of brand recognition, numerous field actions, new requirements and a rapidly changing global regulatory environment, the company direction was to...

Move to a centralized, global systems solution which would then be executed by the divisions and manufacturing sites

But how?
Solution... Two separate but interdependent Initiatives

Program:  
- Global Labeling Controls
- Lean – Labeling Localization Initiative

Targeted area within Value Chain:  
- Manufacturing
- Distribution

Impact:  
- Infrastructure / Core
- Delivery System

Addresses:  
- Brand Recognition
- Labeling Issues - Field Actions
- Revenue Risk due to Localized Labeling non-compliance
Global Labeling Controls (GLC)

Global Labeling Controls is much more than just a “branding” initiative. It is an integrated labeling system whose processes bring all labeling into compliance with both internal and external requirements and generates and verifies product labeling on one validated labeling platform – Global Labeling System.

At the heart of the system are labeling templates that have been pre-built from standardized design rules, requirements, symbology, sizes and materials. These then populated with product specific content that is reviewed and approved through a set of standardized systems and processes.

In essence, it creates an environment in which “Same” really is “Same” across all sites and divisions.
Packaging and Labeling Design & Review Process
Pre-Printed Labeling

Used to design and review all labeling materials other than those printed in-house

- Pouches
- Lids
- Label stock
- Cartons
- DFUs
- Corrugated Shippers

Carton Artwork

Carton Mechanical Drawing
Key Features:

- Standardized labeling software package - GLS
- Integrated with PDM
- Validated, global networked system with a common database that includes manufacturing, vendor and distribution sites
- Features barcode-based verification using SAP to ensure correct packaging components are used on every product we build
- Supported by two key processes for the design and review of in-house printed labels:
  - GLS Labeling Design (GLD) Process
  - GLS Labeling Review (GLR) Process
Global Labeling Controls (GLC) Continued

Key “Localized Language” Output includes:

- Product Label – 18 Languages
- PoD – 11 Languages Staged

Global Booklet
7- Languages (Staples)

- Std. Structure / Headings
- Formatted to In Design
- Bar code verification
- Std. Size – A3/A4
- 18 Languages Translated
- Std. Fonts / Symbols

Product Label – 18 Languages
Localization – What is it?

The product labeling of the manufacturers’ *Finish Good* meets the general regulatory requirements of the *US and/or OUS* markets. Localization is needed when there is a regional or local regulatory and/or customer requirement that must be satisfied in order to distribute and sell the product in a specific country.

Labeling Localization adapts/augments the finished good product to meet these pre-determined requirements.
Although Distribution Centers have the ability to perform limited “labeling” rework, this rework is based on manufacturing rework processes and would not be suited for Labeling Localization as:

- BSC Lean Manufacturing processes are designed for large lot sizes - the bigger the lot size the greater the efficiency. Labeling Localization activities can contain lots contain as few as one product.
- Process tends to be labor intensive due to required SAP transactions
- The high number of SAP transactions to units produces overhead
- Complexity of transactions increases operational risk.

19 Steps
18 SAP transactions / 29 screens
8 Operators
12.53 Minutes (lot of 1) = $ 3.01
Lean LLI is a postponement process that applies localized labeling requirements at the
point of shipment from our European DC. It is an extension of the product, localized for a
given market.

System is integrated with SAP and PDM. The pick list acts as
the BOM and once the order has been fulfilled, the completed
pick list serves as the DHR.

The localization DHR supplements the manufacturing DHR to form
the complete record for the device.

Although the system is used to apply DFUs and GS1 bar codes at
our European DC, the system is scalable to handle other
components and is expandable to other DC’s that have access to
SAP and PDM.
Lean - Labeling Localization Initiative (LLI)
Quality and Business Gains

- Process achieves the same level of control as the past “mfg. rework” process but with a significant reduction in overhead.

- Increased quality from 0.30% issues to <0.10% recorded at final inspection.

- Significant reduction is SAP transactions: 18 → 3

- Increase productivity from 10.5 to 31.0 lines per worked hour (3X).

- VIP annualized saving of $962k (FTE's).

- Reduced paperwork by 60%.

- 100% RF scanning (manual SAP data entry eliminated).

- Process now exists for post production packaging and labeling activities.

- Process is scaleable across Tier 1 DC’s!
Recap of Past Issues and Results

1. **Lack of brand recognition…**

   Results: With the implementation of the Master Brand Initiative, product packaging and labeling across the corporation now has a distinct and recognizable look.

2. **Field Actions - in 2004, 34% of all field actions were labeling related.**

   Results: Since the go-live of Master Brand at the end of Q2, 2007, labeling related field actions have dropped to zero.

3. **Labeling Localization Requirements: Risk of OUS revenue loss**

   Results: With the go-live of Lean LLI in early 2008, BSC is 100% compliant with all products across 18 languages. Plans in place to migrate to 25 languages.
Currently developing “Next Generation” postponement system which will expand capabilities to address:

1. Inbound Localization at Tier 2 DCs
2. Supports all Localized Parts
3. Centralized BOM infrastructure

The strategy of project GLOBE is to build on the success of the existing centralized labeling (GLS) and postponement (Lean LLI) systems that are currently utilized to support Legacy BSC manufacturing and localization processes.
Long term strategic “postponement” possibilities include…

- Hubbing for local relabeling activities
- Quasi – manufacturing within key countries → Reimbursement rates
- Final packaging within some DC’s → Reduces E&O inventory (high value)
- Expiration date for short-shelf life → Japan
- RFID tags → Growing interest from Health Care Providers
- Registration labels
Lessons Learned / Key Advice

- On being global – don’t say it, do it!
- Understand your customer and their requirements
- Don’t box yourself in with you’re solution – build in flexibility
- Labeling is dynamic – it will continue to change and you need to change with it
- It’s not a one-time fix, it’s an on-going journey
Thank You