Boston Scientific's Quality Culture Journey

November 11, 2014
ASQ Executive Roundtable
Earl Brown Heritage Center

Ken Brown
Quality Director, Boston Scientific Maple Grove
Boston Scientific Quality Culture Background:

Boston Scientific has undergone a positive shift in quality performance since receiving a corporate warning letter from FDA in 2006.

- Quality Culture has been the key to the turn around

BSC Maple Grove Plant Experience:

- Examples of the Corporate Quality Culture shift locally in Operations.
- Illustrate how the Manufacturing Plant built off of the Corporate Quality Culture to create a lean culture with a quality focus that was recognized externally.
Quality: Our Journey
Our Quality Journey

**Investment**
- Corporate Warning Letter: 25-Jan-2006
- New Compliant Process Launched: Q3 2006
- Internal Audits: Q1 2007
- FDA Re-Inspections: 2009 - 2010
- CWL Issues Resolved: 11-Aug-2010
- Begin Optimization: Jan-2011
- Begin Harmonization: Aug-2011
- One Quality System: July-2012

**Return on Investment**
- Project Horizon...Built a Quality System with World Class Compliance and Effectiveness: 2009 - 2010
- Efficiency and Continuous Improvement: 2009 - 2010
- We are Here: Q1 2007

**QS Simplification & continuous improvement**
The QSR is the strategic foundation for good business operations.

The “secret sauce” is not just in the strategy but also in the culture, organizational alignment, and disciplined execution required to make it happen.
It starts with Culture

2006: New Quality Policy

• Relevant to every employee
• Stresses continuous improvement
• Results are patient focused
• Quality is everyone’s job

Quality Wall / Quality Day

Supported by Company wide quality Goal's and Objectives linked to individual accountability and reward
We consistently strive to understand and exceed the expectations of our customers. Our commitment to quality and success of our quality objectives builds customer trust and loyalty, which leads to outstanding results for our shareholders. Our objective is to continually improve our ability to provide world-class products and services and enhance customer satisfaction everyday.
CURRENT (POST 2006) QUALITY POLICY

Concise, prudent, easily communicated and understood Quality Policy

Focus on Patient Care

Reviewed during every Quality Management Review meeting, and minimally annually by all BSC employees

Effective in its simplicity and ease of understanding

I improve the Quality of Patient Care and all things Boston Scientific
Project Horizon – Multi year investment in Change

• **Project Horizon Vision** - top-to-bottom **change** that affected our **management philosophy**, our **business processes**, our **systems**, and our **culture**.

• Project Horizon reengineered the way we do business. It took 4 years at a cost of several hundred million dollars and was supported by our 3rd party partner **Quality Hub**.

Some Key Accomplishments:

• **Design Controls & Production / Process Controls** - Revalidated and, where necessary, remediated all product families to meet current reliability requirements. Discontinued hundreds of outdated products.

• **Complaints** - Established rigorous consistent processes for handling complaints

• **CAPA** - Created one global CAPA process with consistent criteria

• **Corrections and Removals** - Put in place a single global Corrections and Removals process

• **Product release** - Established new processes for product release in our distribution centers

• **Supplier Quality** - Changed how we work with suppliers to give us more control over process and quality

• **Training** - Developed new global learning and development infrastructure
The Results

- Over the past 7 years Boston Scientific has successfully conducted a turnaround in quality performance and now demonstrates industry leading quality outcomes.

### Steady decrease in Field Actions Since 2005

### Strong Audit/Inspection Results, e.g., 2013 16 FDA inspections with one 483 observation

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<th>Site</th>
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<tr>
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<td>October</td>
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<tr>
<td>November</td>
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<tr>
<td>December</td>
<td>Quincy, MA</td>
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<tr>
<td>December</td>
<td>Heredia, Costa Rica</td>
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Quality Strategy…Best^4

2007-2009
Re-Engineering

2010-2013
Performance Quality

2014+
Best^4 Competitive Advantage

1. Best Compliance
2. Best Outcomes
3. Best Efficiency
4. Best Agility

2014 Focus Areas
- Truly global, flexible, & agile Quality System
- Value Improvement
- Selling value of quality
- Quality careers

Vision: We all make Quality a competitive advantage for Boston Scientific, always improving and driving high performance.
Boston Scientific Maple Grove Operations
Strategic Evolution (around Culture)
2005 Strategy

TO BE
THE BEST MEDICAL DEVICE
PRODUCER IN THE INDUSTRY

Objective – Meet Customer Requirements
Standard – Defect Free Work
Method – Prevention
Organization – Total Employee Involvement
Attitude – Continuous Improvement

VISION • SUPPORTED BY STRATEGIES • BASED ON FOUNDATIONS
2006 Strategy

"I improve the Quality of Patient Care and all things Boston Scientific"

Objective – Meet Customer Requirements

Standard – Defect Free Work

Method – Prevention

Organization – Total Employee Involvement

Attitude – Continuous Improvement

VISION • SUPPORTED BY STRATEGIES • BASED ON FOUNDATIONS
2007 Strategy

TO BE
THE BEST MEDICAL DEVICE
PRODUCER IN THE WORLD

Meet Customer Requirements
Total Employee Involvement
Defect Prevention

“I improve the Quality of Patient Care and all things Boston Scientific”

VISION • SUPPORTED BY STRATEGIES • BASED ON FOUNDATIONS
2008 Strategy

TO BE
THE BEST MEDICAL DEVICE
PRODUCER IN THE WORLD

Meet Customer Requirements
Total Employee Involvement
Defect Prevention

“I improve the Quality of Patient Care and all things Boston Scientific”

VISION • SUPPORTED BY STRATEGIES • BASED ON FOUNDATIONS
2009 Strategy

TO BE
THE BEST MEDICAL DEVICE
PRODUCER IN THE WORLD

Customer Focus
Quality and Compliance Excellence
Employee Engagement
New Product Excellence

“I improve the Quality of Patient Care and all things Boston Scientific”

VISION • SUPPORTED BY STRATEGIES • BASED ON FOUNDATIONS
2010 Strategy

Vision • Supported by Strategies • Based on Foundations

Customer Focus
Quality and Compliance Excellence
Employee Engagement
New Product Excellence

“I improve the Quality of Patient Care and all things Boston Scientific”
2011 Strategies

TO BE
THE BEST MEDICAL DEVICE PROVIDER IN THE WORLD

Customer Focus
Quality and Compliance Excellence
Employee Engagement
New Product Excellence

“I improve the Quality of Patient Care and all things Boston Scientific”

VISION • SUPPORTED BY STRATEGIES • BASED ON FOUNDATIONS
2012 Strategy

TO BE
THE BEST MEDICAL DEVICE PROVIDER IN THE WORLD

OPERATIONAL EXCELLENCE
(Rates of Improvement)

LEAN CULTURE

CUSTOMER-SERVICE (NPD)

DELIVERING SOLUTIONS

CUSTOMER FOCUS

QUALITY AND COMPLIANCE EXCELLENCE

EMPLOYEE ENGAGEMENT

NEW PRODUCT EXCELLENCE

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VISION • SUPPORTED BY STRATEGIES • BASED ON FOUNDATIONS
2013 Strategy

TO BE
THE BEST MEDICAL DEVICE PROVIDER IN THE WORLD

Customer Focus
Quality and Compliance Excellence
Employee Engagement
New Product Excellence

“I improve the Quality of Patient Care and all things Boston Scientific”

VISION • SUPPORTED BY STRATEGIES • BASED ON FOUNDATIONS
2014 Strategy

To Be The Highest Performing Global Medical Solutions Provider

Operational Excellence (Rates of Improvement)
Lean Culture
Accelerating Growth Through Innovative Solutions
Collaborative Partnerships

Patients and Customers – Caring and providing meaningful innovation
Quality – Always improving and driving high performance
Teamwork – Developing a diverse team with winning spirit
Best Practices – Driving high performance utilizing Essentials
“I improve the Quality of Patient Care and all things Boston Scientific”

VISION • SUPPORTED BY STRATEGIES • BASED ON FOUNDATIONS
2015 Strategy

To Be The Highest Performing Global Medical Solutions Provider

Operational Excellence
Lean Culture
Accelerating Growth
Collaborative Partnerships

Patients and Customers – Caring and providing meaningful innovation
Quality – Always improving and driving high performance
Teamwork – Developing a diverse team with winning spirit
Best Practices – Driving high performance utilizing Essentials

“I improve the Quality of Patient Care and all things Boston Scientific”

VISION • SUPPORTED BY STRATEGIES • BASED ON FOUNDATIONS
Boston Scientific Maple Grove
Operations
Lean Culture
Journey
Our Lean Journey

Lean has been a strategy since our first SQP in 2001

Lean Culture has been our lean strategy since 2010

<table>
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<th>40/20/25/50</th>
<th>10 Essentials</th>
<th>Lean &amp; LBP Essentials</th>
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</thead>
<tbody>
<tr>
<td>Traditional Production</td>
<td>Lean Transformation</td>
<td>Lean</td>
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</table>
What we were experiencing

• Focused on tools and systems

* Courtesy of Jon M Huntsman School of Business: Shingo The Principles of Operational Excellence
Improvements Come and Go
Unless Guiding Principles Drive a Culture

“Know-how" alone isn't enough! You need to "Know-why"!
All too often, people visit other plants only to copy their tools and methods.”

- Shigeo Shingo

• Principles drive increasing rates of improvement
• We asked ourselves “what should our principles be?”
Principles guide our “thinking”, which in turn guides behaviors, which defines our culture.
“Know-how” alone isn’t enough! You need to "Know-why"! All too often, people visit other plants only to copy their tools and methods.”

- Shigeo Shingo
“Don’t get confused. . . .”

Our Guiding Priorities

Patient Care
Quality & Compliance
Customer Service & New Products/Solutions
Cost Reduction

Hitting the "Bulls-Eye" means delivering Quality products to our Customers everyday
Principles of Lean

**BEST**
- Quality
- Cost
- Delivery

RESULT OF WASTE ELIMINATION

**GUIDING PRINCIPLES**
- Flow value
  - Make only what the customer needs, when they need it
  - Flow everywhere you can
  - Pull where you can't yet flow and never push
  - Remove barriers to flow
  - Use takt, level flow, small work increments
- Build in quality
  - Seek Perfection
  - Do not pass defects
  - Make problems visible
  - Stop and fix the root cause of problems
  - Use error proofing

**SUPPORTING PRINCIPLES**
- See the Process and Value Stream
  - Core Disciplines
- Customer Defines Value
  - Ability to see Waste
- Forms of Waste
  - Transportation
  - Inventory
  - Motion
  - Waiting
  - Defects
  - Over-Production
  - Over-Processing

- Teamwork
- Respect
- Empowerment
- Leadership

Continuous Improvement • Standardization • Workplace Organization • Key Partner Involvement • Plan Do Check Adjust • Robustness • Availability • Visual Management
QCD for All Functions

Finance

Production

Quality

Materials

ME
Developed Training Materials

Flyers for Every Principle

Facilitator Guides for Every Principle

Tools and Systems to Support Principles

Continuous Improvement Board

- IDEAS
- TO DO (PLAN)
- DOING
- CHECK & ADJUST
- DONE

Submit Ideas
Focus Ideal Management Challenge
Improvement of the Month
Implemented Ideas
Continuous Improvement System

Continuous Improvement Ideas Per Employee

Reset CI Count Every Year

- 2011: 2651 submitted, 1241 implemented
- 2012: 3492 submitted, 2303 implemented
- 2013: 5116 submitted, 3080 implemented
Shingo Silver Medallion Recipients

Maple Grove was awarded the Shingo Silver Medallion, the second highest form of recognition from the Shingo Institute

Key Strengths:

• Continuous Improvement Culture: Striving to improve everything we do every day
• Strategy Deployment: Our impressive organizational understanding of our strategies and direction defined in our SQP
• New Products: Our focus on increasing the speed and reducing cost of new products
• Daily Management: Daily review of our performance and opportunities to deliver the best possible results

Key Opportunities:

• Continuous Improvement Culture: Consider tracking how many CI’s each person submits to encourage even more participation
• Strategy Deployment: Involve all levels of individuals in feedback on strategic direction
• Product and Material Flow: Implement “Pull” systems where we cannot yet continuously flow product and materials
• Coaching: Continuing to look for opportunities to coach our teams to understand and apply lean principles
Closing Thoughts

**Closing Thoughts:**

- We have found that compliance can be leveraged into business value when combined with:
  - A strong quality culture owned by everyone
  - An effective and efficient quality system
  - A disciplined organization focused on execution and continuous improvement

- Quality is the responsibility of all employees, not just the employees in the Quality functions. Until the culture of quality is instilled in all employees you will never achieve your full potential.

- Having a Quality Culture and a continuous improvement mindset are the keys to make quality a business competitive advantage.