



Managing Change in Lean Six Sigma Deployments in Highly Regulated Environments

Brian Eden, Mylan

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Agenda



- Welcome
- Introduction of MBB Webcast Series
 - Larry Goldman, MoreSteam.com
- Managing Change in Lean Six Sigma Deployments in Highly Regulated Environments
 - Brian Eden, Mylan
- Open Discussion and Questions



MoreSteam.com – Company Background

- Founded 2000
- Over 300,000 Lean Six Sigma professionals trained
- Serving over 50% of the Fortune 500
- First firm to offer the complete Black Belt curriculum online
- Courses reviewed and approved by ASQ
- Registered education provider of Project Management Institute (PMI)



Today's Presenter



Brian Eden

*Senior Director and Global Head, Operational Excellence,
Mylan*

- 20 years of operations, continuous improvement and leadership experience in a range of industries
- B.S. in Physics from The University of Connecticut; M.S. in Engineering from Purdue University
- Certified Master Black Belt by The General Electric Company

Mylan Forward Looking Statement

This presentation and any subsequent Q&A may contain “forward-looking” statements, including with respect to:

- Mylan’s anticipated earnings;
- Anticipated future financial and operating performance and results; and
- Expectations for our products and plans for growth.

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- Changes in third-party relationships;
- Changes in economic and financial conditions affecting the Company’s business; and
- Unexpected legal or regulatory challenges.

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Please refer to Mylan’s earnings press release, dated Oct. 26, 2011, for a reconciliation of certain non-GAAP financial measures included in this presentation to the most directly comparable financial measure calculated and presented in accordance with GAAP. This press release is available in the Investor Relations section of Mylan’s website. In addition, see the company’s past quarterly earnings releases for additional GAAP to non-GAAP reconciliations, available at www.mylan.com.

Overview

- Continuous improvement deployments can be fragile
- One key to their successful uptake is cultivation of strong sponsorship and proper management of natural resistance to the changes the improvement work will bring
- Resistance to change is natural in all areas of continuous improvement application and highly regulated industries such as Food and Pharmaceuticals have specific considerations in this regard.
- This session will focus on:
 - Methods to assess, cultivate and sustain sponsorship for continuous improvement work
 - Lessons learned from deployment work in Food and Pharmaceutical continuous improvement start ups
 - Questions, answers and sharing from the larger group on what works, what doesn't work, and tips and tricks to manage complex change landscapes

Topics We Will Cover

- A Brief Introduction to Mylan
- Sponsorship
- Slow and steady wins the race
- Regulations: A core aspect of industry culture
- 5 aspects of leadership and the 2 that really work in OE
- Managing negative reactions
- The Humble Approach

Mylan at a Glance

- World's **3rd largest** generics and specialty pharma company
- Products sold in **150+** countries and territories
- A global workforce of **more than 18,000**
- One of industry's **broadest, highest quality** portfolios
- One of industry's most **robust pipelines**
- One of the world's **largest** API manufacturers
- **Dey Pharma**, specialty division

1/26/2012

Our Promise

Helping to provide 7 billion people access to medicine. We do this by producing high quality, affordable medications to be made available everywhere, every day – no exceptions.

Sponsorship

- *Sponsorship*: support from the person(s) with
 - Authority to make changes legitimate
 - Ability to apply consequences (“carrot *and* stick”) to help manage change
- Lack of sponsorship is a leading cause of failure for OE deployments
- Chicken and Egg reality: Great sponsorship helps to drive change, but successful demonstrated change is often needed to secure sponsorship!!
- Don’t assume that you have perfect sponsorship . . . It doesn’t exist
- Reflect often on the real sponsorship picture you have to deal with
- Formulate incremental strategies to continue to shore up support

Slow and Steady Wins the Race

- Most of us are trained to “hit the ground running”
- In clean sheet OE deployment, the Company needs to get used to you
 - YOU need to earn the Company’s trust
 - The Company needs to have time to learn about OE (formally and informally)
 - The organizational structure needs to adapt to your new and different group
 - You can damage relationships and give your effort bad branding by pushing an agenda
- Some suggestions
 - Make a list of everything you could possibly do to deploy OE . . . And pick **3 things only** to start
 - Keep focused on successful, small scale projects to build a track record
 - Use “pull” (we know about that, right?) and overall practice what you preach
 - Keep a watchful eye for signs of resistance and limit the number of issues you take “head on”

Regulations are Core to Industry Culture

- You can unknowingly offend by pushing too hard
 - The regulatory environment is a powerful aspect of pharmaceutical company culture
 - Some areas of production, R&D and Quality are very sensitive with respect to change
 - Good news: It *is* possible to affect change in the above areas *and* many other processes are not as highly regulated
- Some Suggestions
 - Non-Value Add (“NVA”) is not a diplomatic choice of wording
 - Remember: A variety of regulations and regulatory bodies may be applicable
 - A group’s relationship with its *particular* inspection team is a critical factor to be understood
 - Read up (Various CFR codes, ICH Q9, 10 and 11, internal SOP’s, Laboratory Methods, etc.)
 - “Interpretation” goes hand-in-hand with regulation
 - Coordinate changes with Regulatory Affairs and Quality departments

Leading Change in OE

- The Standard Leadership Techniques

- The Carrot
- The Stick
- Appeal to Hierarchy



- Traditional
- Work sometimes
- Do not work well in OE

- The Other Techniques

- Inspire people with a true path
- Teach people, help people



- Work well always
- Work particularly well in OE

An Accurate Gage of Your Leadership: Is anyone following you?

Managing Negative Reactions

- Why would someone not welcome you right in?
 - Established leaders can feel threatened by outsiders
 - People have “seen these things before” and are wary to extend trust
 - Processes needing change were likely designed by the people you meet
 - All new people and departments go through a “proving time” and OE is no different
- How should you manage these reactions?
 - Take negativity, don’t react, smile, take notes . . .
 - Give people benefit of the doubt
 - Follow up 1 on 1
 - Above all, resist the temptation to react hastily!!

The Humble Approach

- How good are we at what we do?
 - Many OE movements fail, just as many other business initiatives do
 - We are as good at OE as other folks are at their jobs
- What should we do, then?
 - Practice self-deprecating humor
 - Let it be someone else's idea
 - Don't refer to "your last company" or "your last department"
 - Practice full and early ownership of anything that **doesn't** go well
 - Practice complete self-sacrifice of credit for anything that goes well

Questions



Thank you!



Master Black Belt Program

- Offered in partnership with Fisher College of Business at The Ohio State University
- Employs a **Blended Learning model** with world-class instruction delivered in both the classroom and online
- Covers the **MBB Body of Knowledge**, topics ranging from advanced *DOE* to *Leading Change* to *Finance for MBBs*



Resource Links and Contacts

Questions? Comments? We'd love to hear from you.

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Additional Resources

Archived presentation, slides and other materials:

<http://www.moresteam.com/presentations/>

Master Black Belt Program: <http://www.moresteam.com/master-black-belt.cfm>

Mylan Careers: <https://www.mylancareers.com/>