How to balance Lean Transformation & Manufacturing Agility with respect of cGMP

L. Terzy (Catalent)
F. Henry (UCB)
D. Fabris (GSK)

Feb 10th 2017
GSK, Wavre
Workshop output
Is there contradiction between OPEX and Quality functions

• There is no direct contradiction, it is more about perception and how OPEX is introduced in the plant. A Cost cutting approach only may create mis-understanding. OPEX and cGmp regulations have the same goal of reducing variability and enforce right first time.

• QA role are well established in a site leadership team, while OPEX are more recent. Some time education is needed as economical reality have changed and reducing the cost base in a smart & compliant manner is becoming even more important.

• All agree on conceptual approach, but friction could appear on how to implement solutions at the shop floor level
How does your QA and Compliance is positioning themselves versus the Operational Excellence deployment

• Most of the case QA is convinced that a stream lined process will help them to achieve their goals. QA population being risk averse and insisting to have fully compliant solution. As a consequence, taking short cut is not an option. A robust diagnostic, and a careful implementation plan are prerequisite to ensure success.
What are the best practices used to manage the situation?

• Share the burning plateform across functions and ensure it is understood why we need to change
• Compose a fully integrated team, with individual having a mix background
• Ensure the right sponsorship is in place
• Ensure that the « what’s in it » for the QA function is delivered for exemple to reduce deviation or authorities risk exposures
• Advocate and educate stakeholders on lean and 6 σ methodology
• Role model by leaders is a strong levers to ensure good relationship
• Conduct risk analysis at the different gate reviews
Next topics and Way forward
Next topics for SIG at Catalent site in May 2017 is:
« How to select continuous improvement projects and ensure strategic alignment? “

<table>
<thead>
<tr>
<th>Proposed topics</th>
<th>Your vote</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 How to select continuous improvement projects and ensure strategic alignment?</td>
<td>9</td>
</tr>
<tr>
<td>2 Could we measure our performance versus industrial standards to boost excellence program (St Gallen university, Mckz,...)?</td>
<td>8</td>
</tr>
<tr>
<td>3 How to involve suppliers and CMO in a Excellence program?</td>
<td>6</td>
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<tr>
<td>4 Does a consistent business process framework exist to assess maturity level of the organization (eg: risk mgt, procurement, scheduling,...)?</td>
<td>5</td>
</tr>
<tr>
<td>5 How pharma embrace its “Patient First“ culture in order to drive Operational Excellence?</td>
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<tr>
<td>6 Cost and benefit analysis, how to translate Lean 6 Sigma in business case to convince a GM?</td>
<td>3</td>
</tr>
<tr>
<td>7 How to deploy in manufacturing sites, support functions and in our own network (R&amp;D / manufacturing ) an Excellence program?</td>
<td>3</td>
</tr>
<tr>
<td>8 How OPEX can help Lead time optimization and Supply Chain throughput?</td>
<td>3</td>
</tr>
<tr>
<td>9 Integrated manufacturing excellence imply big data fully integrated to drive process and decisions. How Real time data mining and 6 sigma approach could help?</td>
<td>3</td>
</tr>
<tr>
<td>10 Performance measurement: how to use trends analysis to re-inforce system capabilities and department output?</td>
<td>2</td>
</tr>
<tr>
<td>11 How to use OPEX to optimize false rejects?</td>
<td>1</td>
</tr>
<tr>
<td>12 How do you de-bottleneck your QC test associated to OPEX deployment?</td>
<td>1</td>
</tr>
<tr>
<td>13 How to use OPEX as a marketing tool to customer?</td>
<td>0</td>
</tr>
<tr>
<td>14 Because exposition to lean and 6σ is very limited for young professional, could ISPE organize an introduction session to the fundamentals?</td>
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<tr>
<td>15 How OPEX can accelerate Tech transfer and access to Market?</td>
<td>0</td>
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<tr>
<td>16 2 sec improvement is huge on a line, how could OPEX help?</td>
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ISPE – SIG OPERATIONAL EXCELLENCE

How to balance Lean Transformation & Manufacturing Agility with respect of cGMP

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GSK, Wavre
Agenda

• 14h30 – 14h35 : Welcome
• 14h35 – 14h45 : ISPE Intro / GSK Intro D. Fabris (GSK)
• 14h45 – 15h00 : Why today’s topic F. Henry (UCB)
• 15h00 – 15h15 : Success and failure sharing L. Terzi (Catalent)
• 15h15 – 16h00 : Breakout sessions – How to resolve the contradiction
• 16h00 – 16h45 : Share experiences
• 16h45 – 17h00 : Next topics and way forward
ISPE delivers technical and operational solutions to support our Members across the global pharmaceutical and biopharmaceutical industry in the manufacture of quality medicines for patients
ISPE Affiliates and Chapters Around the Globe

90 Countries
20,000 Members
ISPE’s Strategic Areas of Focus

- Biotechnology
- Quality and Performance
- Regulatory
- Supply Chain
- Facilities of the Future
- Operational Excellence
- Emerging Markets
ISPE Belgium Affiliate

• Representing ISPE Global at local level, during more than 25 years, managed by the Committee (Board of Directors). All representatives are coming from Life Science professionals community in Belgium, and as volunteers elected by ISPE Belgium Members.

• Non-Profit organization (vzw/asbl) since October 2014

• Act as a local community & bring people together from (Bio)Pharma companies, Contract Manufacturers, Contract Research Organizations, Medical Devices companies, Clinical Laboratories, Suppliers, Service Providers for Pharma and Biotech industry, ...
ISPE Belgium Affiliate Membership – total >300

Business Category

- API / Pharmaceutical Manufacturer: 46%
- Veterinary: 11%
- Contract manufacturer: 8%
- Cosmetics / Nutraceuticals: 22%
- CROs / Clinical Materials: 2%
- Service Provider / Consulting: 1%
- Educational / governmental: 1%
- Engineering / Architecture / Construction: 3%
- Equipment / Material Supplier: 2%
- Others: 4%

Gender

- Male: 83%
- Female: 17%

Top 10 contributors:

- Janssen
- GSK
- UCS
- Baxter
- Siemens
- Eramin
- Alcon
- Zoetis
- Pfizer
- Merck
- QLD NV
## Europe Membership Development

<table>
<thead>
<tr>
<th>Members</th>
<th>Retention</th>
<th>Growth</th>
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</thead>
<tbody>
<tr>
<td>Nov/15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td>306</td>
<td>84%</td>
</tr>
<tr>
<td>France</td>
<td>217</td>
<td>74%</td>
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<tr>
<td>DACH</td>
<td>1036</td>
<td>87%</td>
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<tr>
<td>Ireland</td>
<td>457</td>
<td>78%</td>
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<tr>
<td>Italy</td>
<td>334</td>
<td>83%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>245</td>
<td>81%</td>
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<tr>
<td>Nordic</td>
<td>704</td>
<td>73%</td>
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<tr>
<td>Poland</td>
<td>89</td>
<td>78%</td>
</tr>
<tr>
<td>Spain</td>
<td>195</td>
<td>82%</td>
</tr>
<tr>
<td>Turkey</td>
<td>119</td>
<td>71%</td>
</tr>
<tr>
<td>UK</td>
<td>798</td>
<td>83%</td>
</tr>
</tbody>
</table>

Source: Membership Stats Linda Walls

**Belgium Affiliate - Best in Class with respect to Growth & Retention!**
Join ISPE Belgium Affiliate

http://www.ispe.org/belgium-affiliate

https://www.linkedin.com/groups/2453247
ISPE Communities of Practices (COP) & Special Interest Groups (SIG)

- Connect like-minded professionals through a community on global level (COPs) and on local level (COPs & SIGs).

- “Communities” currently active in Belgium:
  - GAMP COP Benelux
  - SIG Technology Transfer
  - SIG Automation
  - ....

Connecting & Collecting
Connecting members person-to-person
Collecting relevant information to share

People Tools Knowledge
ISPE Belgium Affiliate Event Calendar

- Yearly Networking Event
- Seminars
- Site visits
- COP/SIG Technical Meetings
- “Young Professional” events
- ...

Visit http://www.ispe.org/belgium/affiliate-event-calendar
Welcome to GlaxoSmithKline
Context

- Behind other sectors in terms of quality and efficiency
- Cost pressure from Healthcare systems
- COG represents twice R&D budget
- $90 billions savings estimated
- Generics competition
- Different approach from regulatory bodies (risk based approach, QbD)

- Historical robust profit margin
- Burden revalidating any process change and getting regulatory approval

Pharma industry embracing Operational Excellence programs
Why ?
Compliance Vs. Operational Excellence
What if?

Compliance encouraging continuous improvement and facilitating change
Boost operational efficiency
Improve Quality
While facilitating Compliance

Increase efficiency
Reduce waste
Control inventory
Optimize resources
Ever heard?

« You can have those white boards and KPI’s ... but you remove them in case of audit »
Why is my QA manager not the first person to support Operational Excellence deployment?
Success and failures
Performance Management: OEE Board

BEFORE

AFTER

RESULT

• 4 Month implementation
• 8% OEE improvement
Supply Chain: Samples flow optimisation

**RESULT**

- After 7 Month-workshop
- ....

- 1 week lead time reduction
- Transport reduction
Key Enablers

**Team Work**

*Set a common goal*

Create the Burning Plateform

**Make it Visual**

*visual change*
Breakout session
Explore potential solutions in sub-group and share experiences with all.

**Input**
- Articles
- 3 prompts

**Discussions**
- Sub group generating solutions: 15:15-16:00
- Plenary sessions to share with all: 16:00-16:45

**Prompts:**
1. How do you resolve the contradiction of the article?
2. How does your QA and Compliance is positioning themselves versus the Operational Excellence deployment.
3. What are the tricks you are using to manage the situation?

**Output**
- Cross-fertilized Solutions

**Set up**
- 3 teams
- 1 reporter per team

**Group 1 Facilitator:** Ludovic Terzi
Nicolas Thurin, Michael Denis, Vincent Mancuso, Tom De Rudder, Ann Vermeulen, Fabian Defonseca, Joris Buffels, Marc De Laet, Bert Nyq,

**Group 2 Facilitator:** Frederic Henry
Maria Verykiou, Jess Hayden, Yves Vancleemput, Davy De Block, Jean-Christophe Cerfontaine, Nicolas Catrysse, Gino Lefevere, Stijn Van Uytfanghe

**Group 3 Facilitator:** D.Fabris
Fabrice Gribon, Eric Lechien, Laurent Lhoir, Bruno Flour, Veerle Soetewey, Patrick Bridoux, Niels De Blende, Daniel Marroyen,
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<th>Group 2</th>
<th>Group 3</th>
</tr>
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<tbody>
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<td>Maria Verykiou</td>
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<td>Bert Nyq</td>
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<tr>
<td>Area</td>
<td>Lean</td>
<td>cGMP</td>
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<tr>
<td>-----------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Objectives</td>
<td>Reduce waste Create value</td>
<td>Ensure product effectiveness Prevent harm</td>
</tr>
<tr>
<td>Focus</td>
<td>Value stream</td>
<td>Product development, manufacturing and quality assurance</td>
</tr>
<tr>
<td>Approach to manufacturing</td>
<td>Quality balance with productivity</td>
<td>Quality first</td>
</tr>
<tr>
<td>Improvement</td>
<td>Continuous and simultaneous</td>
<td>Regulated and prudent</td>
</tr>
<tr>
<td>Typical goals</td>
<td>Reduce cost Improve Quality Reduce cycle time Reduce inventory Improve delivery</td>
<td>Follow validated process Prevent deviation</td>
</tr>
<tr>
<td>Typical tools</td>
<td>Value stream mapping Kaizen improvement Error proofing Moving to pull Simple flow Training Quality function deployment</td>
<td>Documentation Personal qualifications and training Cleanliness Validation and qualification Complaints review Audits</td>
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