

# ISPE – SIG OPERATIONAL EXCELLENCE

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

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*D. Fabris (GSK)*

Feb 10th 2017  
GSK, Wavre



# Is there contradiction between OPEX and Quality functions

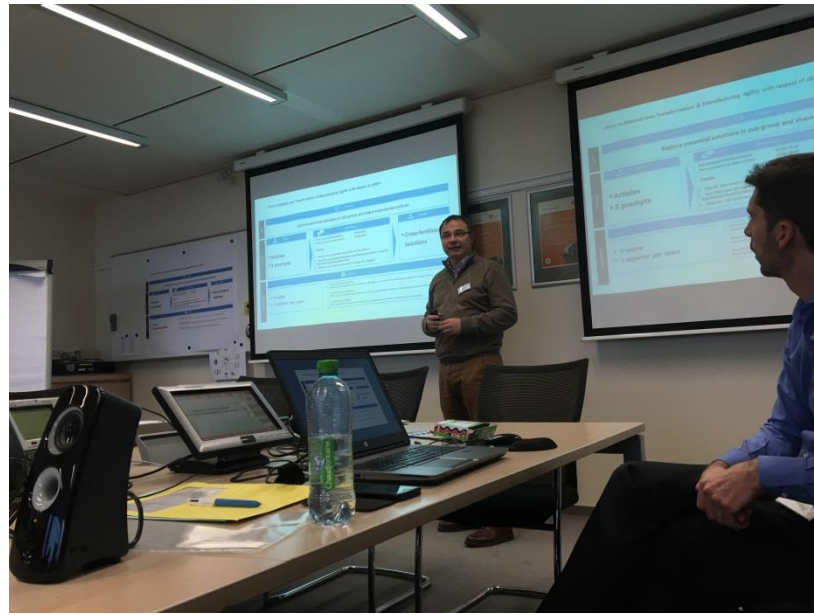
- There is no direct contradiction, it is more about perception and how OPEX is introduced in the plant. A Cost cutting approach only may create mis-understanding. OPEX and cGmp regulations have the same goal of reducing variability and enforce right first time.
- QA role are well established in a site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

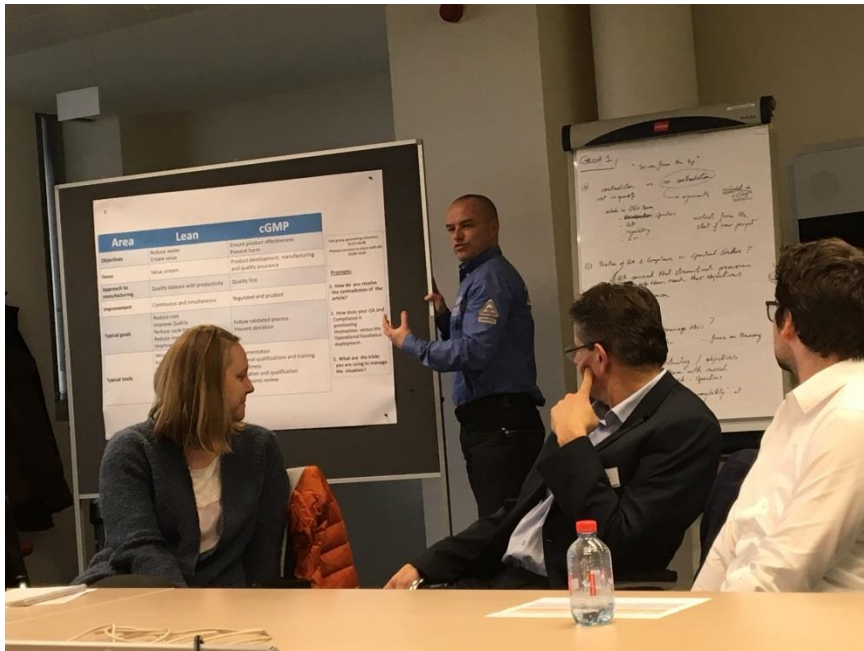
- Most of the case QA is convinced that a stream lined process will help them to achieve their goals. QA population being risk averse and insisting to have fully compliant solution. As a consequence, taking short cut is not an option. A robust diagnostic, and a careful implementation plan are prerequisite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

## What are the best practices used to manage the situation?

- Share the burning platform 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  $\sigma$  methodology
- Role model by leaders is a strong levers to ensure good relationship
- Conduct risk analysis at the different gate reviews















Next topics for SIG at Catalent site in May 2017 is:

« *How to select continuous improvement projects and ensure strategic alignment?* “

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

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# 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





Jean-Jacques Follebouckt  
Treasurer ISPE Belgium  
Head Technology Transfer GSK

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



# ISPE's Strategic Areas of Focus





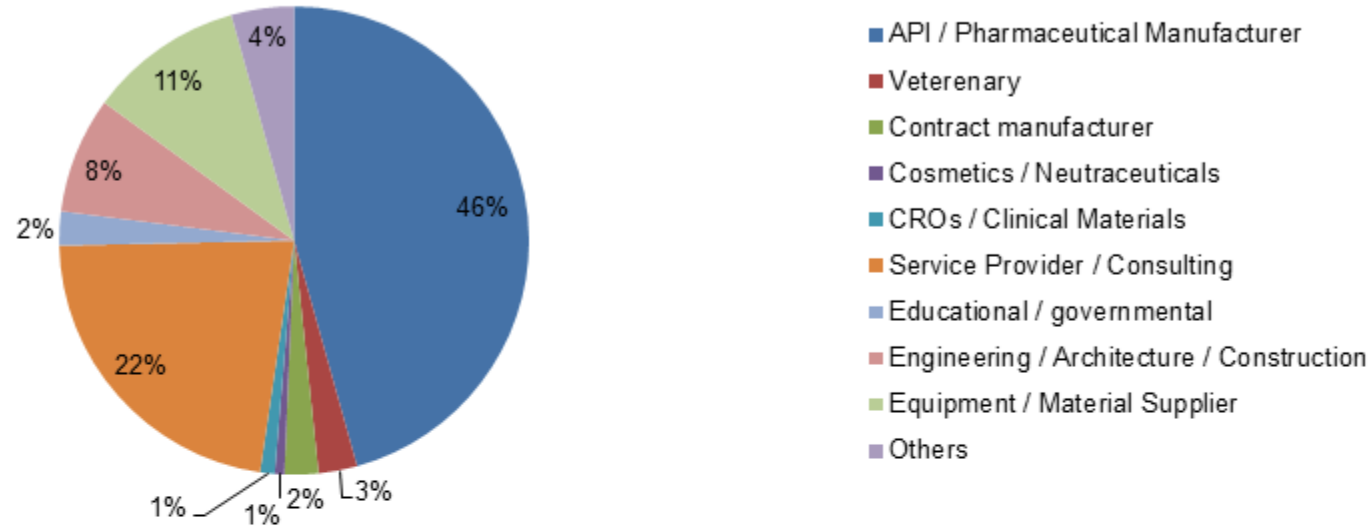
## ISPE Belgium Affiliate



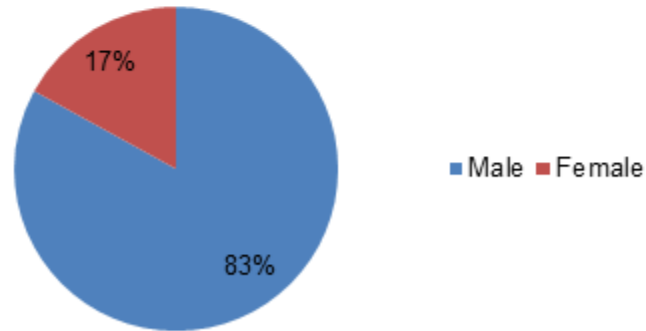
- **Representing ISPE Global at local level**, during **more than 25 years**, managed by the Committee (Board of Directors) . All representatives are coming from Life Science professionals community in Belgium, and as volunteers elected by ISPE Belgium Members.
- **Non-Profit organization (vzw/asbl)**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

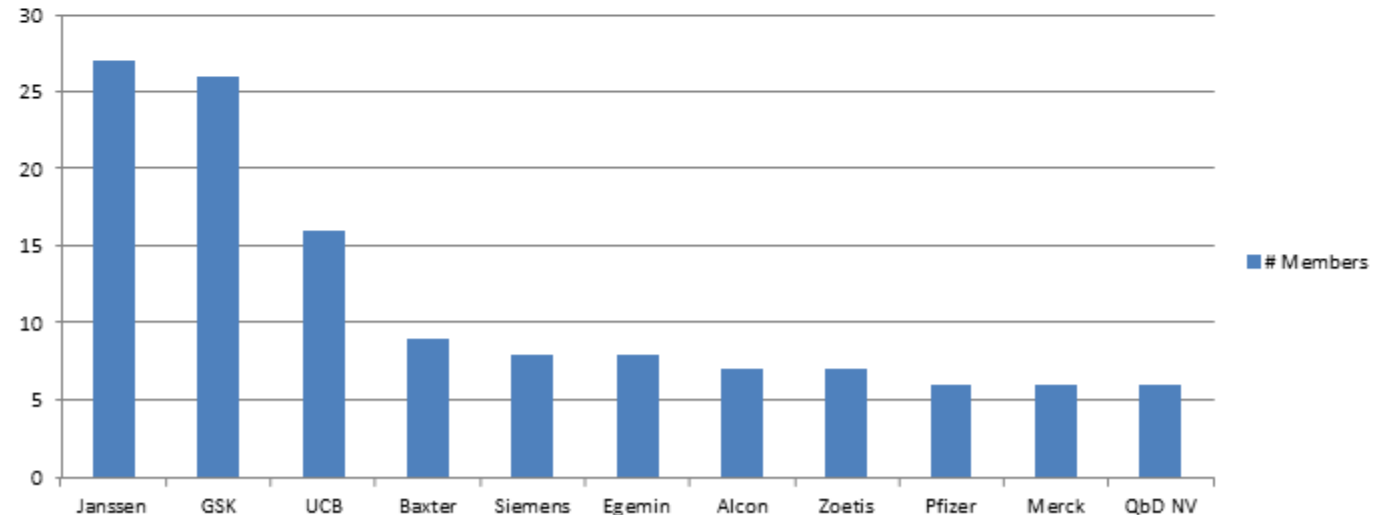
## Business Category



## Gender



## Top 10 contributors



# Europe Membership Development

	members	retention	Growth
	nov/15		
Belgium	306	84%	10,87%
France	217	74%	-8,05%
DACH	1036	87%	9,86%
Ireland	457	78%	4,82%
Italy	334	83%	6,36%
Netherlands	245	81%	1,24%
Nordic	704	73%	-6,38%
Poland	89	78%	8,54%
Spain	195	82%	-2,99%
Turkey	119	71%	7,21%
UK	798	83%	2,31%
source : Membership Stats Linda Walls			

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

# Join ISPE Belgium Affiliate

## Belgium Affiliate



- Affiliate Board
- Communities of Practice
- Affiliate Event Calendar
- Contact Us
- Affiliate Past Events
- Photo Gallery
- Welcome New Members
- Affiliate News and Updates

### About the Belgium Affiliate

For more than 25 years, the ISPE Belgium Affiliate has been active in Belgium offering added value to all active professionals in Life Science Industry.

The ISPE Belgium Affiliate organizes full-day seminars, site visits, workshops, table top exhibitions, etc., which always include the opportunity for networking and sharing experiences with colleagues in the local area. All ISPE Belgium Affiliate news and initiatives are announced via this website, and e-mail communications.

Read more about the Belgium Affiliate

### Join the ISPE Belgium Affiliate

[Join ISPE Belgium](#)

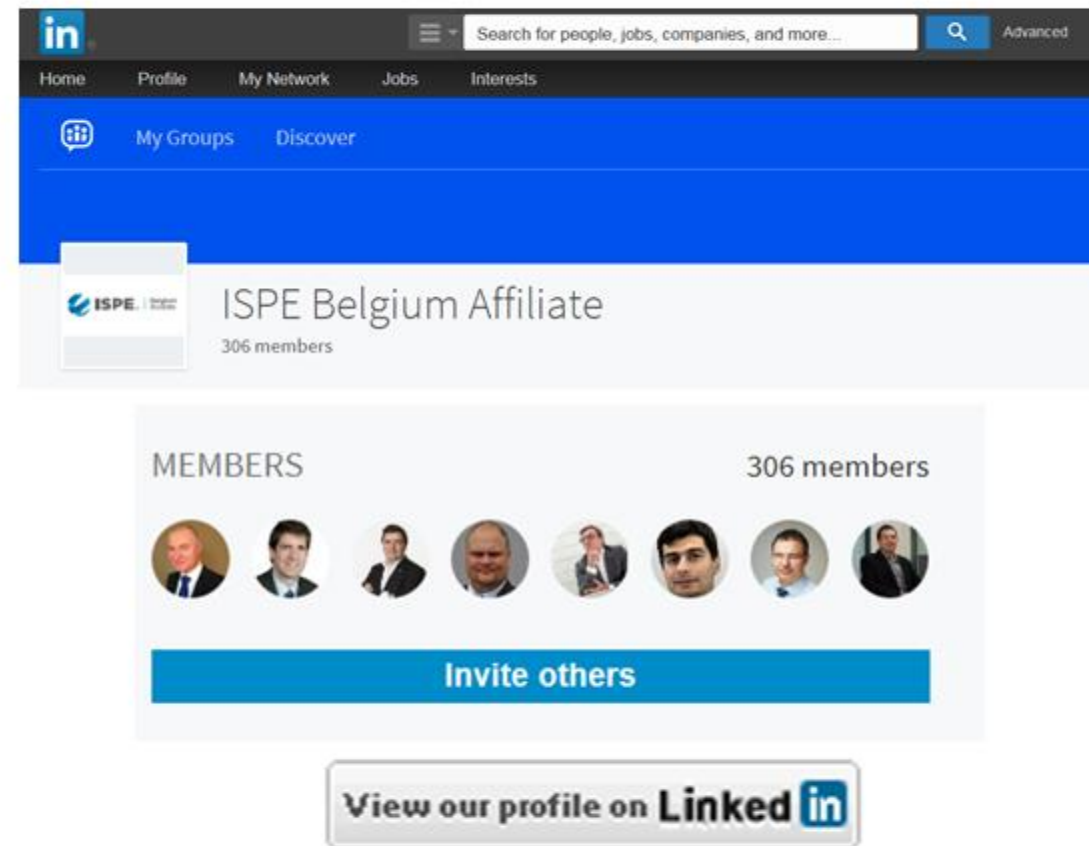
To join the ISPE Belgium Affiliate you must first join ISPE then select the ISPE Belgium Affiliate as your Affiliate during the join process.

### Linkedin Group

Please also join the ISPE Belgium Linkedin group:  [ISPE BELGIUM](#)

### Events

- ISPE Belgium Affiliate Unleashing Innovation (10 Mar 2016 – 10 Mar 2016)
- ISPE Belgium Affiliate SIG Technology Transfer (17 Mar 2016 – 17 Mar 2016)
- 2016 ISPE Continuous Manufacturing (20 Apr 2016 – 21 Apr 2016)
- ISPE Belgium GAMP COP Benelux Mobile Applications (26 Apr 2016 – 26 Apr 2016)
- ISPE Belgium Affiliate Networking Event (18 May 2016 – 18 May 2016)
- 2016 Brussels Training (23 May 2016 – 25 May 2016)
- ISPE Belgium Affiliate Young Professionals Networking Event (02 Jun 2016 – 02 Jun 2016)



The screenshot shows the LinkedIn interface for the ISPE Belgium Affiliate group. At the top, there is a search bar and navigation links for Home, Profile, My Network, Jobs, and Interests. Below the navigation bar, the group name "ISPE Belgium Affiliate" is displayed with a "306 members" count. A "MEMBERS" section shows a row of profile pictures and another "306 members" count. A blue button labeled "Invite others" is visible. At the bottom, there is a button that says "View our profile on LinkedIn" with the LinkedIn logo.

<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



# 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>



The graphic features the ISPE logo and a world map. Below the map is a table of events for 2016. At the bottom, there is a call to action with a globe icon and a calendar icon.

Date	Event	Location	Topic	Organization
10 March	Evening event	Diamond Building, Brussels	Unleashing Innovation - where Pharma meets Technology	Belgium Affiliate + Agoria + Pharma.be
17 March	Technical Meeting (1/2 day)	UCB, Braine-l'Alleud	Technology Transfer Market Access	SIG Tech Transfer
26 April	Technical Meeting (1/2 day)	Actonium, Vugbeek (NL)	Mobile Devices in Life Science Industry	GAMP COP Benelux
10 May	Evening event	Hotel Van der Valk, Brussels	Networking event & General Council 2016	Belgium Affiliate
2 June	Evening event	GSD, Wijk	Networking event Young Professionals	Young Professionals
Sept	Technical Meeting	Gendboux	Containment workshop, incl. company visit Asseptic Technologies	Belgium + DACH Affiliates
11 Oct	Technical Meeting (1/2 day)	Orlina, Mechelen	IT Infrastructure Qualification & Control in Life Science Industry	GAMP COP Benelux
23 Nov	Seminar (full day)	Etal	Seminar Bio Processing, incl. Table Top exhibition and site visit UCB, Braine-l'Alleud	Belgium Affiliate

Visit <http://www.ispe.org/belgium/affiliate-event-calendar>

Opportunities for you to stay connected throughout the year!

Looking forward to see you soon on one of our planned events!

# Welcome to



GlaxoSmithKline

# Context

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



- Behind other sectors in term 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)

➡ Pharma industry embracing Operational Excellence programs







Compliance

Vs.

Operational Excellence

What if ?

Compliance encouraging  
continuous improvement and  
facilitating change



A large stone globe sculpture is the central focus, with a group of bronze figures pushing it from the right using a long wooden lever. The globe is textured and has blue-painted continents. The scene is set in a park-like area with green grass, yellow daisies, and a background of trees.

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 »









Success Ln

Failure Dr

# Performance Management: OEE Board

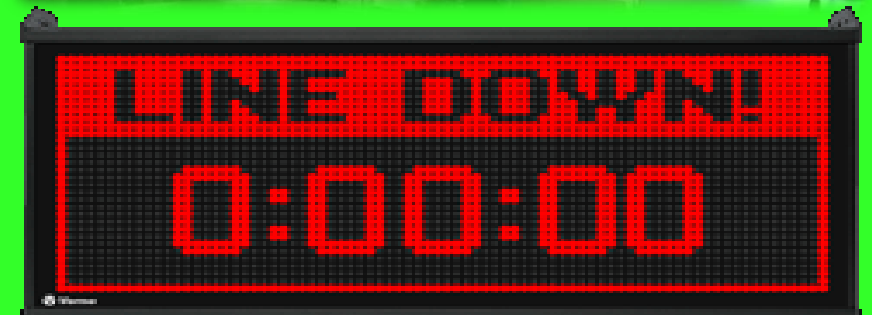
**BEFORE**

TABLEAU DE SUIVI PERFORMANCE

LIGNE 4

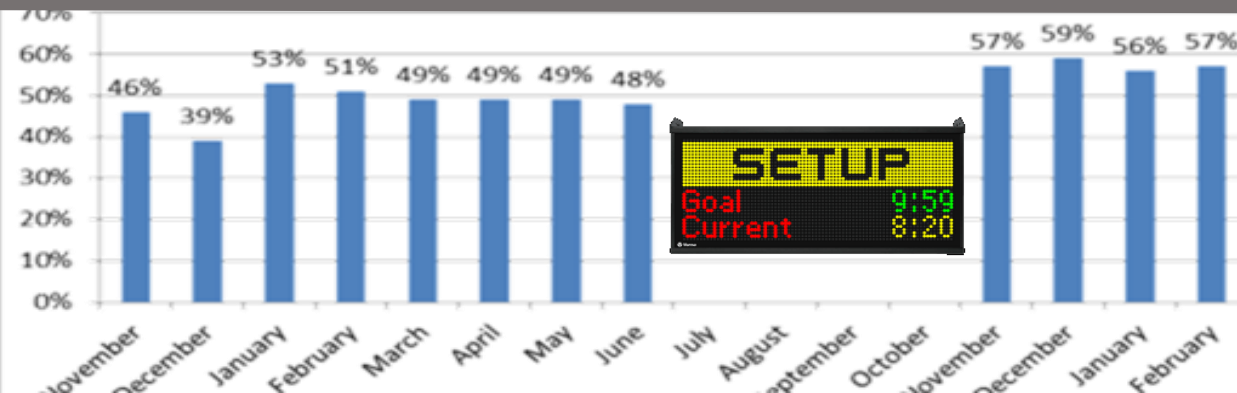
CHIFFRE	REEL	REMARQUE
9500	7891	
9500	11369	
9500	9500	
9500	11624	
3000	3076	
9500	10700	
9500	9600	
9500	10000	
67500	73760	

**AFTER**

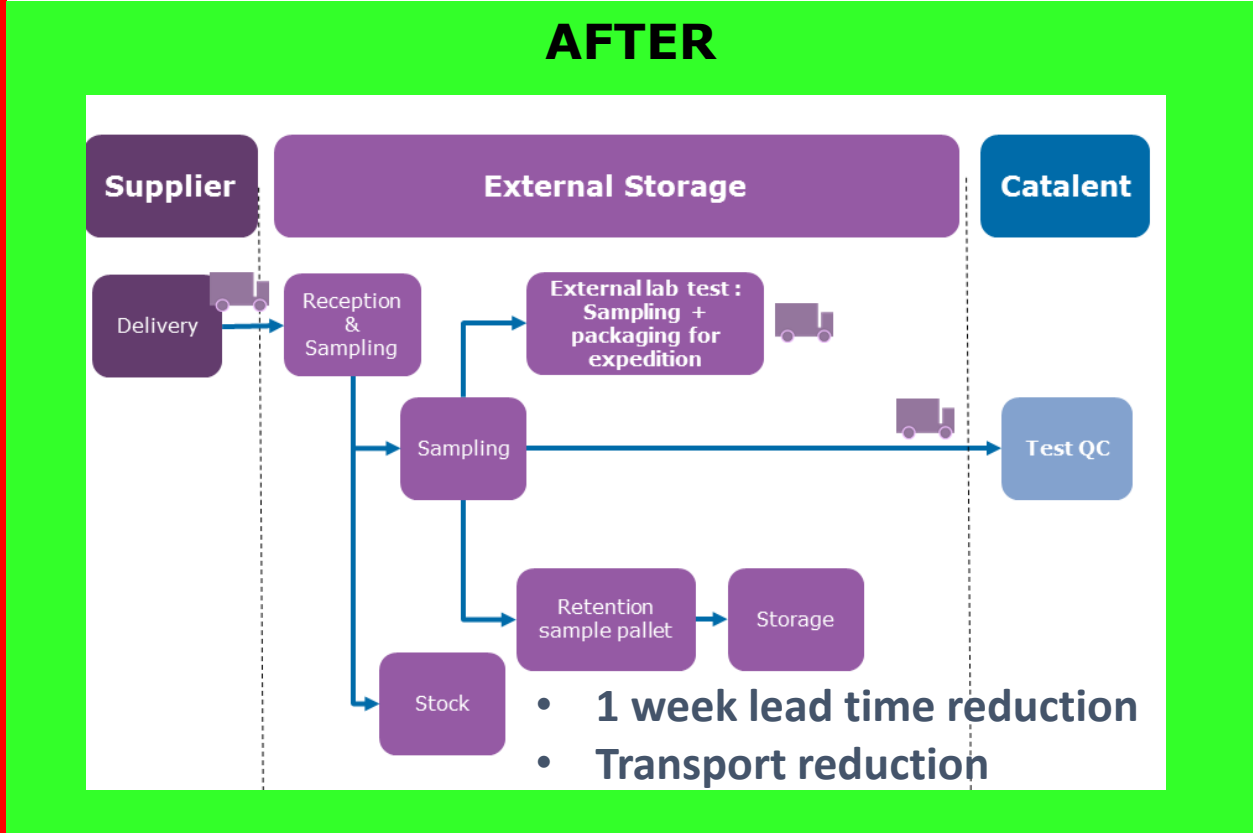
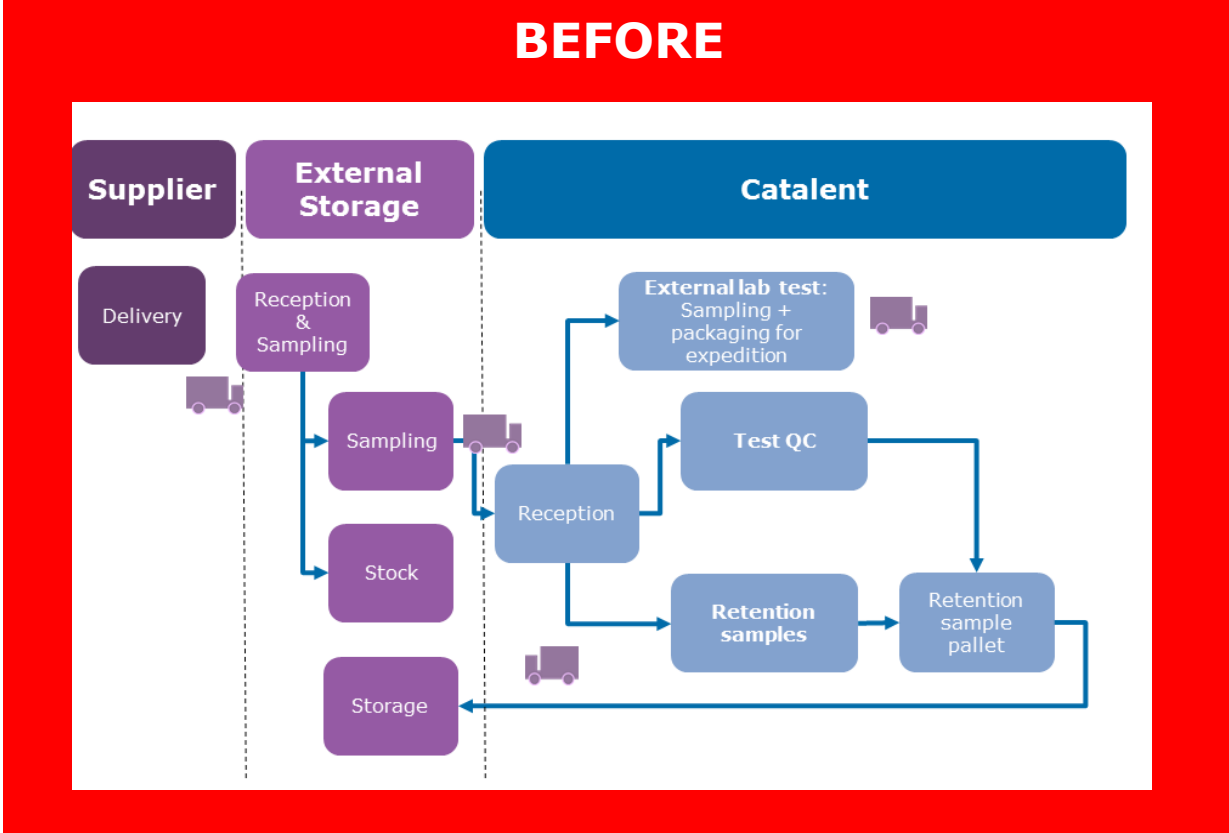


**RESULT**

- 4 Month implementation
- 8% OEE improvement



# Supply Chain: Samples flow optimisation



## RESULT

- After 7 Month-workshop
- ....





# Key Enablers

**Team Work**



**Set a common goal**



**Create the  
Burning Platform**



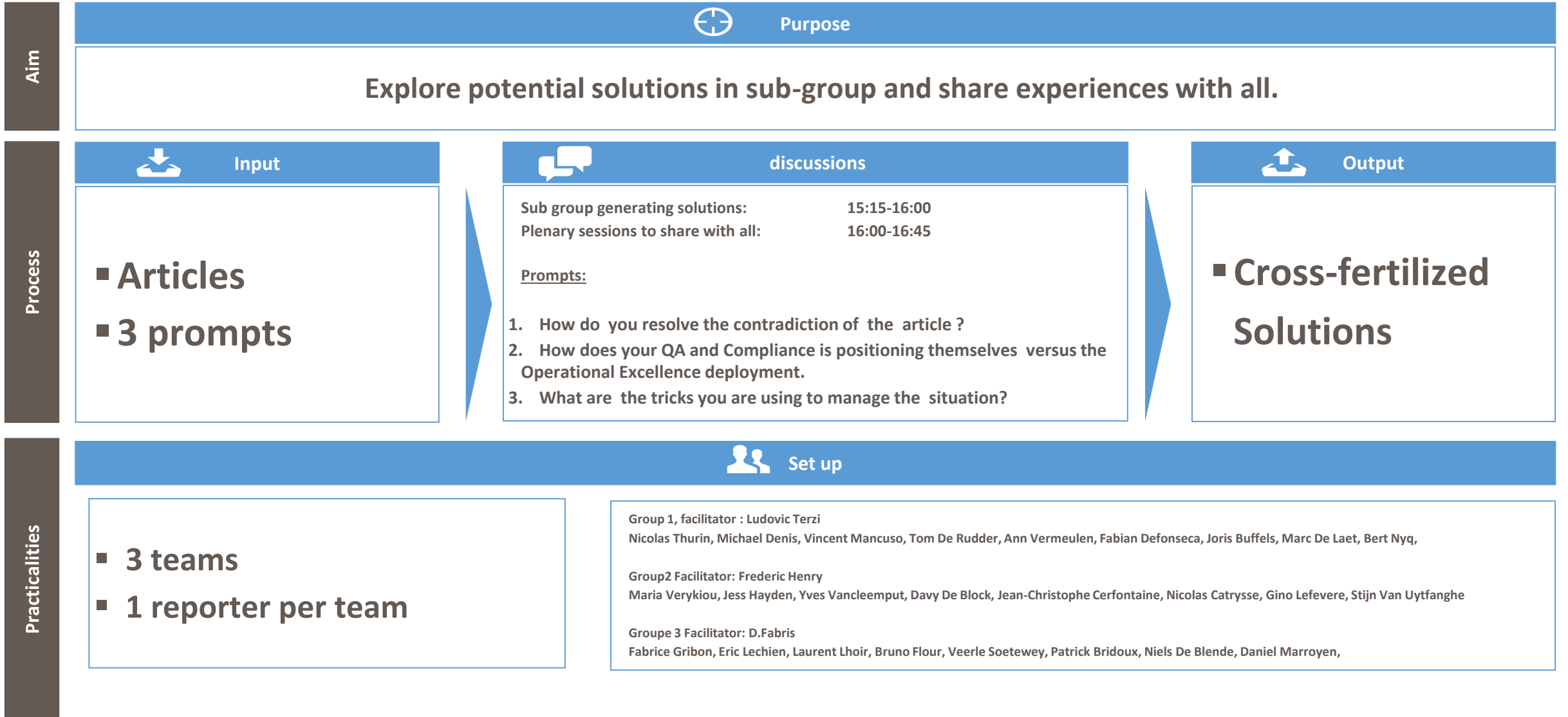
**Make it Visual**





Breakout session

# «How to Balance Lean Transformation & Manufacturing Agility with respect of cGMP»



«How to Balance Lean Transformation & Manufacturing Agility with respect of cGMP»

Group 1	Group 2	Group 3
Nicolas Thurin	Maria Verykiou	Fabrice Gribon
Michael Denis	Jess Hayden	Eric Lechien
Vincent Mancuso	Yves Vancleemput	Laurent Lhoir
Tom De Rudder	Davy De Block	Bruno Flour
Ann Vermeulen	Jean-Christophe Cerfontaine	Veerle Soetewey
Fabian Defonseca	Nicolas Catrysse	Patrick Bridoux
Joris Buffels	Gino Lefevere	Niels De Blende
Marc De Laet	Stijn Van Uytfanghe	Daniel Marroyen
Bert Nyq		

Area	Lean	cGMP
<b>Objectives</b>	Reduce waste Create value	Ensure product effectiveness Prevent harm
<b>Focus</b>	Value stream	Product development, manufacturing and quality assurance
<b>Approach to manufacturing</b>	Quality balance with productivity	Quality first
<b>Improvement</b>	Continuous and simultaneous	Regulated and prudent
<b>Typical goals</b>	Reduce cost Improve Quality Reduce cycle time Reduce inventory Improve delivery	Follow validated process Prevent deviation
<b>Typical tools</b>	Value stream mapping Kaizen improvement Error proofing Moving to pull Simple flow Training Quality function deployment	Documentation Personal qualifications and training Cleanliness Validation and qualification Complaints review Audits

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?**

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