

ISPE – SIG OPERATIONAL EXCELLENCE

How to select continuous improvement projects and ensure strategic alignment?

June 16th 2017
Catalent, Brussels



Introduction

Shared Interested Group

GMP Shared Interests Group



What is driving **Operational Excellence (OpEx)** in the pharmaceutical industry?

- How is **Catalent** embracing its "Patient First" culture?
- What tools are used in **UCB** manufacturing sites to deploy OpEx?
- How is **GSK** transforming based on a 12-week Project Life Cycle?

Join Ludovic, Frederic and Denis in the newly created *Shared Interests Group* on a discussion on

«How to Balance Lean Transformation & Manufacturing Agility with respect of cGMP, data integrity, and CFR part 21»

When: Friday 10th February, 9h00 – 16h00
Where: GSK, Wavre, Salle Bang

Contact us now to reserve your place (max. 20): ispebelgium@ispe.org.

This is the first of quarterly meetings which will rotate among the various ISPE members' sites. We are looking forward to meeting you!



Frédéric Henry
 UCB
 Operational Excellence Director – Internal Manufacturing



Ludovic Terzi
 Catalent
 CI & Technology Leader



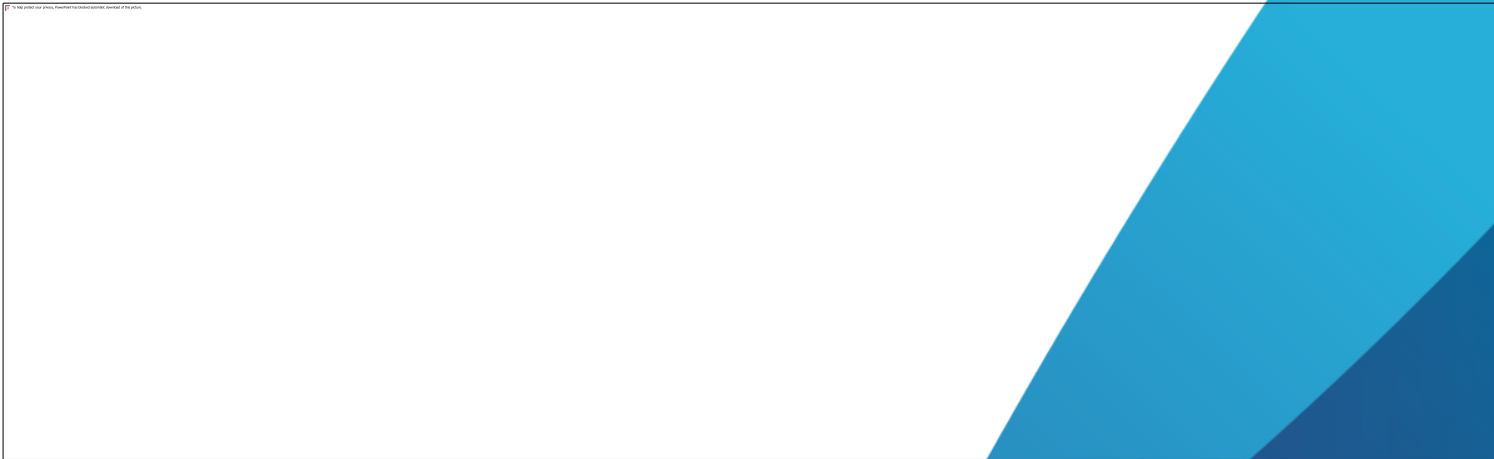
Denis Fabris
 GSK
 Operational Excellence Director





Agenda

- 13h00 – 13h10 : Welcome
- 13h10 – 13h15 : ISPE SIG, Operational Introduction
- 13h15 – 13h45 : Catalent presentation
- 13h45 – 14h00 : Hoshin Kanri
- 14h00 – 15h00 : Catalent site tour, inspection and packaging of prefilled syringes
- 15h15 – 16h45 : **How to select continuous improvement projects and ensure strategic alignment?**
- GSK: Overall Roadmap & Gate review 10mn
 - UCB: Project selection, go no go decisions
 - Catalent: Operation Excellence Vision linked to VSM
 - Breakout sessions: “ **From... To...** ” exercise
 - Share experiences, feedback session, discussion
- 16h45 – 17h00 : Next topics and way forward
- 17h00 – 18h00 : Networking drink



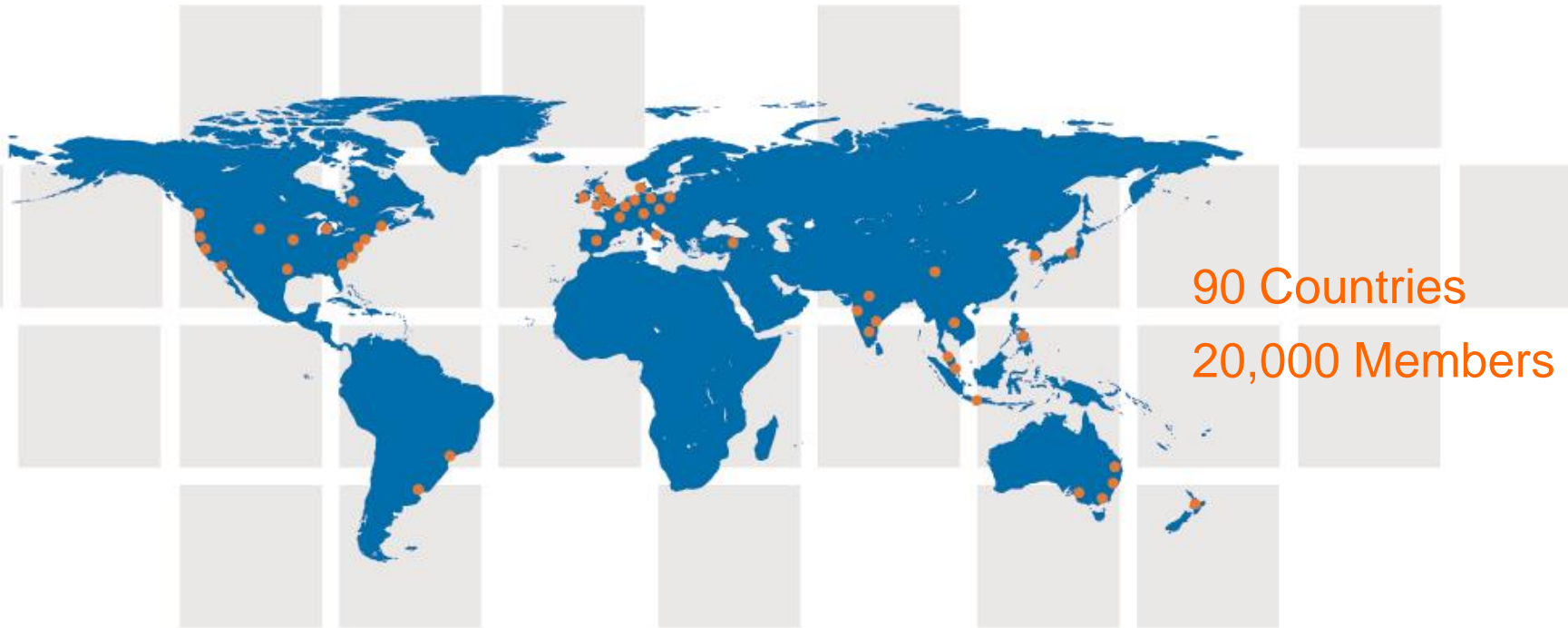
D. Fabris

Director Operational Excellence
(Primary-International)

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



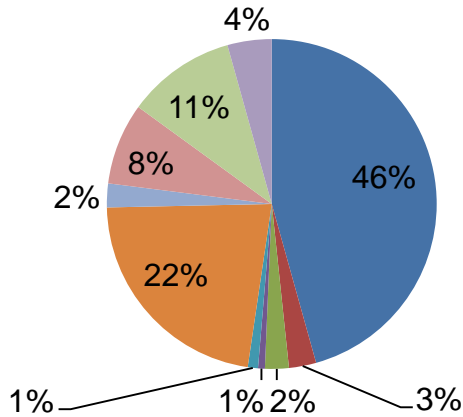
- **Representing ISPE Global at local level**, during **more than 25 years**, managed by the Committee (Board of Directors) . All representatives are coming from Life Science professionals community in Belgium, and as volunteers elected by ISPE Belgium Members.
- **Non-Profit organization (vzw/asbl)**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

Global ISPE membership includes automatically Local Affiliate membership.



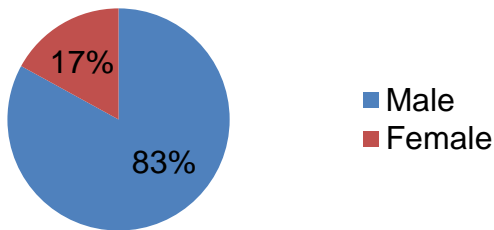
ISPE Belgium Affiliate Membership – total >300

Business Category

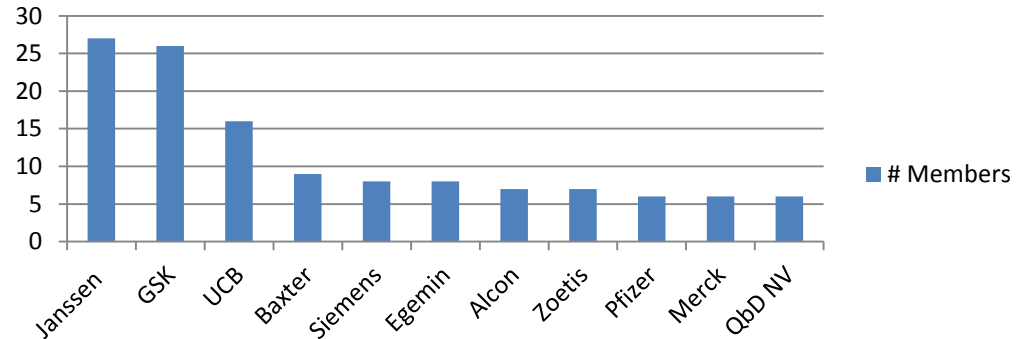


- API / Pharmaceutical Manufacturer
- Veterenary
- Contract manufacturer
- Cosmetics / Neutraceuticals
- CROs / Clinical Materials
- Service Provider / Consulting
- Educational / governmental
- Engineering / Architecture / Construction
- Equipment / Material Supplier
- Others

Gender



Top 10 contributors



Europe Membership Development


	members now/15	retention	Growth
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

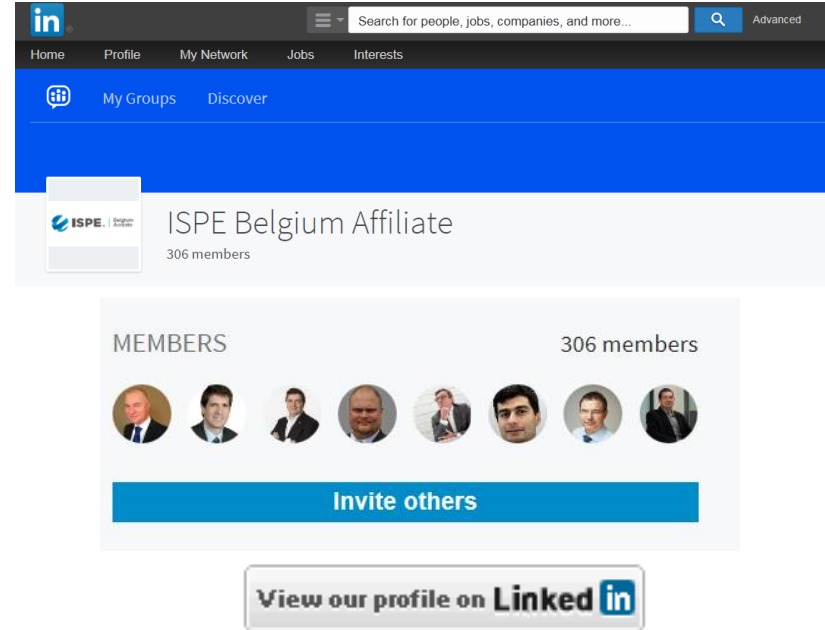


Affiliate Board	About the Belgium Affiliate	Events
Communities of Practice	For more than 25 years, the ISPE Belgium Affiliate has been active in Belgium offering <i>added value</i> to all active professionals in Life Science Industry.	<ul style="list-style-type: none">• ISPE Belgium Affiliate Unleashing 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)
Affiliate Event Calendar	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.	
Contact Us	Read more about the Belgium Affiliate	
Affiliate Past Events		
Photo Gallery		
Welcome New Members	Join the ISPE Belgium Affiliate	
Affiliate News and Updates	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



The screenshot shows the LinkedIn profile for the ISPE Belgium Affiliate. The profile name is "ISPE Belgium Affiliate" with 306 members. Below the name, there is a "MEMBERS" section displaying 10 member avatars and a "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".

<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
 -

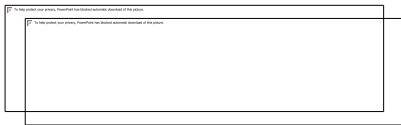
Connecting & Collecting

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](http://www.ispe.org/belgium/affiliate-event-calendar)



www.ispe.org

What face-to-face will exchanges, attend events and make a difference in your geographic region

ISPE Affiliates and Chapters Around The World

ISPE Belgium Affiliate Event Calendar 2016

Date	Event	Location	Topic	Organization
10 March	Evening event	Dierckx Building, Brussels	Unleashing Innovation : where Pharma meets Technology	Belgium Affiliate + Agencia + 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)	Actovium, Veghel	Mobile Devices in Life Science Industry	GAMP COP Benelux
18 May	Evening event	Hotel Van der Valk, Brussels	Networking event & General Council 2016	Belgium Affiliate
2 June	Evening event	QBD, Wilrijk	Networking event Young Professionals	Young Professionals
Sept	Technical Meeting	Gemblooux	Containment workshop, incl. company visit Aseptec Technologies	Belgium + DNCH Affiliates
11 Oct	Technical Meeting (1/2 day)	Ordina, Mechelen	IT Infrastructure Qualification & Control in Life Science Industry	GAMP COP Benelux
23 Nov	Seminar (full day)	tdx	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>

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

Catalent®



Introduction to Catalent Pharma Solutions

BRUSSELS, 4 July 2017



DEVELOPMENT



DELIVERY



SUPPLY

more products. better treatments. reliably supplied.™

Catalent®



our capabilities CORPORATE OVERVIEW



DEVELOPMENT



DELIVERY



SUPPLY

more products. better treatments. reliably supplied.™

Catalent is the **#1 ADVANCED DELIVERY PARTNER** in helping pharmaceutical, biotech and consumer health innovators **DEVELOP** and **SUPPLY** superior products that improve people's lives.

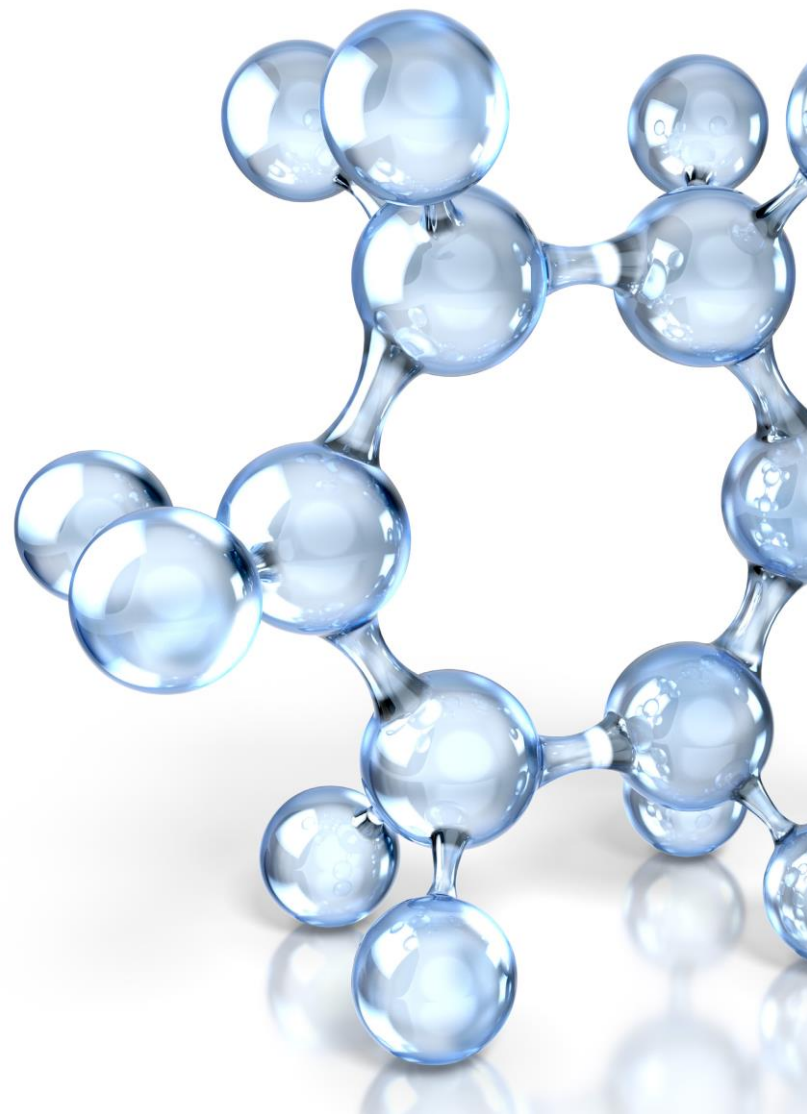


YOUR PRODUCT HAS SO MUCH POTENTIAL. WE SHARE YOUR PASSION TO UNLOCK IT.

From early development through manufacturing we will help accelerate your product to market.

With the deepest expertise and broadest set of **SUPERIOR TECHNOLOGIES**, we've helped develop and launch thousands of oral, inhaled and sterile products.

Whether you seek a single **TAILORED SOLUTION** or an **INTEGRATED PARTNERSHIP**, we look forward to putting our passion to work on your products.



OUR PROMISE

more products. better treatments. reliably supplied.™



DEVELOPMENT

more products to clinic and market faster
with our expert development solutions



DELIVERY

better treatments with our optimal
drug delivery technologies



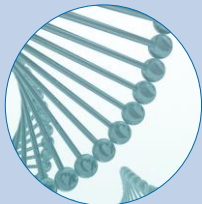
SUPPLY

reliably supplied with our flexible global
network and integrated supply solutions

**EXPERTISE, TECHNOLOGIES & SCALE TO TRANSFORM
YOUR MOLECULES INTO SUCCESSFUL TREATMENTS**

EVERY MOLECULE HAS A CHALLENGE. WE HAVE A SOLUTION.

BIOLOGICS,
BIOSIMILARS
& ADCS



COMPREHENSIVE
DEVELOPMENT &
BIOAVAILABILITY
SOLUTIONS



FAST & OPTIMAL
DOSE FORM
DEVELOPMENT



ANALYTICAL
LAB SERVICES



DEVELOPMENT SOLUTIONS

RP SCHERER
SOFTGEL
TECHNOLOGIES



FAST DISSOLVE
TECHNOLOGY



IMMEDIATE,
CONTROLLED &
COMPLEX RELEASE



INJECTABLES,
INHALATION &
BLOW/FILL/SEAL



DELIVERY TECHNOLOGIES

CLINICAL TRIAL
SUPPLY



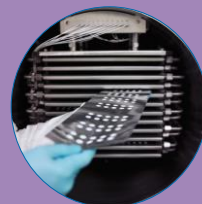
FLEXIBLE
MANUFACTURING
& PACKAGING
SOLUTIONS



POTENT
HANDLING &
CONTROLLED
SUBSTANCE
HANDLING



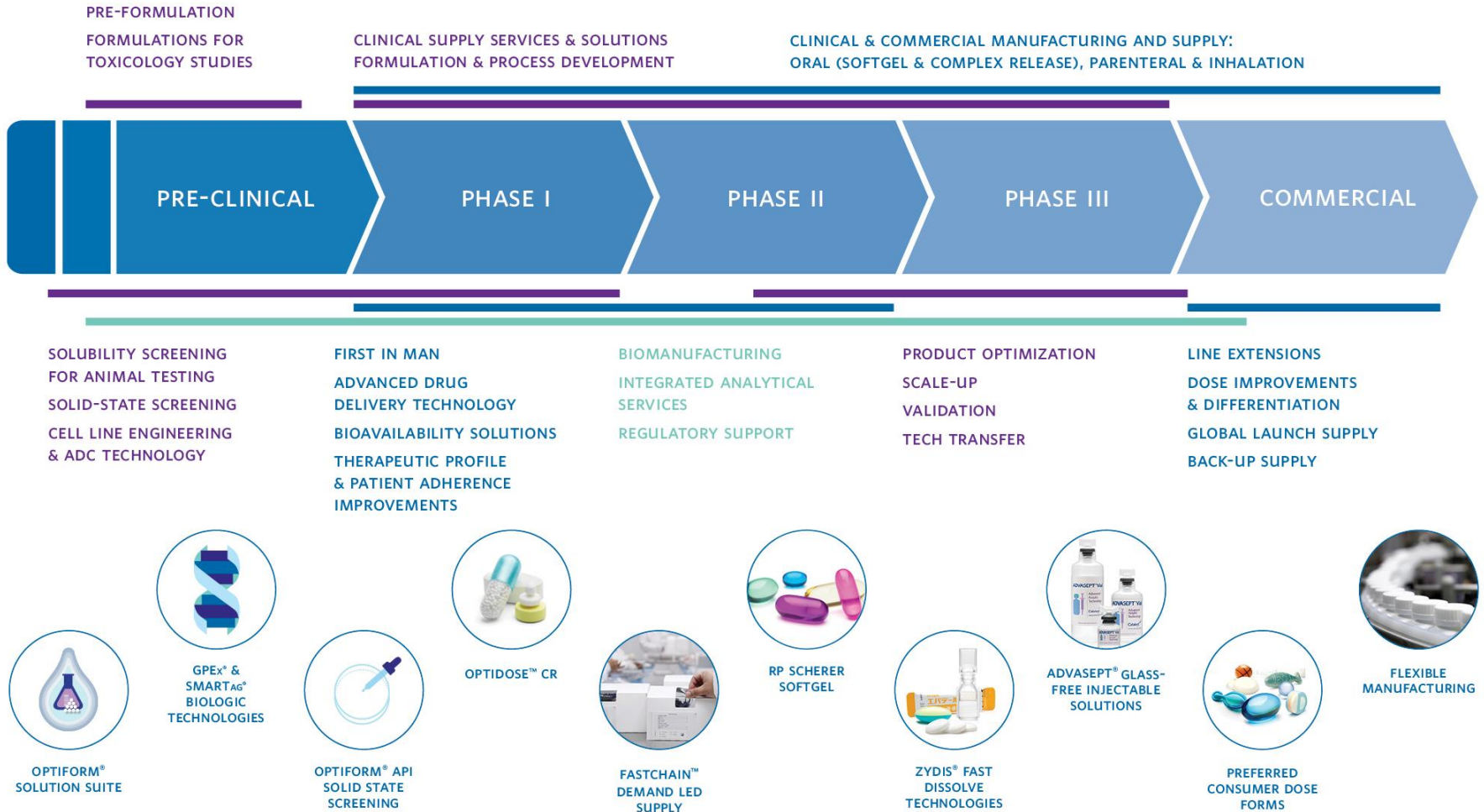
GLOBAL
COMMERCIAL
SUPPLY



RELIABLE SUPPLY

WE CAN IMPROVE THE VALUE OF YOUR TREATMENTS AT EVERY STAGE

Pharmaceutical, Biologics, Consumer & Animal Health



SOLUBILITY SCREENING FOR ANIMAL TESTING
SOLID-STATE SCREENING
CELL LINE ENGINEERING & ADC TECHNOLOGY

FIRST IN MAN
ADVANCED DRUG DELIVERY TECHNOLOGY
BIOAVAILABILITY SOLUTIONS
THERAPEUTIC PROFILE & PATIENT ADHERENCE IMPROVEMENTS

BIOMANUFACTURING
INTEGRATED ANALYTICAL SERVICES
REGULATORY SUPPORT

PRODUCT OPTIMIZATION
SCALE-UP
VALIDATION
TECH TRANSFER

LINE EXTENSIONS
DOSE IMPROVEMENTS & DIFFERENTIATION
GLOBAL LAUNCH SUPPLY
BACK-UP SUPPLY



OPTIFORM® SOLUTION SUITE



GPEX® & SMARTAG® BIOLOGIC TECHNOLOGIES



OPTIFORM® API SOLID STATE SCREENING



OPTIDOSE™ CR



FASTCHAIN™ DEMAND LED SUPPLY



RP SCHERER SOFTGEL



ZYDIS® FAST DISSOLVE TECHNOLOGIES



ADVASEPT® GLASS-FREE INJECTABLE SOLUTIONS



PREFERRED CONSUMER DOSE FORMS



FLEXIBLE MANUFACTURING

A GLOBAL NETWORK SPANNING FIVE CONTINENTS

+30 SITES SUPPLYING +70B DOSES OF +7000 PRODUCTS TO +1000 CUSTOMERS



BIOLOGICS

INHALATION

INTEGRATED PACKAGING

PARTICLE SIZE SCIENCES

STERILE TECHNOLOGIES

CLINICAL SUPPLY SERVICES

DEVELOPMENT & ANALYTICAL SERVICES

ORAL SOLID SOLUTIONS

SOFTGEL TECHNOLOGIES

SALES & MANAGEMENT OFFICE

GLOBAL RELIABLE SUPPLY: DISCIPLINE, RIGOR & RHYTHM EVERY SHIFT. EVERY DAY. EVERY SITE.

Unrivaled supply performance

Long-standing partnerships and transparent scorecards with top innovators for 80+ years

Uncompromising quality systems

One global QMS, extensive supplier assurance and world-class inspection readiness

World-class manufacturing and supply network

Rigorous cGMP, EHS, security and operational controls across entire network

Unsurpassed global scale

70 billion doses and 240,000 shipments annually to 80+ countries

Industry-leading regulatory expertise

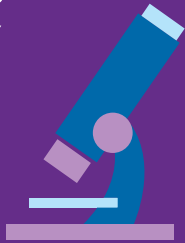
Accredited by 35+ global agencies and 100% success on PAI outcomes

\$1B invested in new capacity &
capabilities in the last 5 years



180⁺

PRODUCTS
LAUNCHED
ANNUALLY



WHY CATALENT?

Unrivaled experience, expertise, and track record of market successes on a global scale.

550⁺

BIOLOGICS
DEVELOPMENT
PROGRAMS COMPLETED

600⁺

NEW PRODUCT LAUNCH
PROJECTS AT ANY TIME



20⁺

R&D TEAMS, 1,400 SCIENTISTS
& 1,100 PATENTS ON
SUPERIOR TECHNOLOGIES



TOUCHED NEARLY 50%
OF FDA APPROVALS IN LAST 10 YEARS

PARTNERSHIPS



24 OF TOP 25 BIOTECHS

22 OF TOP 25 GENERICS

21 OF TOP 25 CONSUMER HEALTH

GLOBAL CLINICAL SUPPLY

5,000⁺
CLINICAL TRIALS

150,000⁺
SHIPMENTS A YEAR
TO 80+ COUNTRIES

99%
ON-TIME DELIVERY

Catalent[®]

Catalyst + Talent.
Our name combines
these ideas.

www.catalent.com

solutions@catalent.com

+ 1 888 SOLUTION (765-8846)

+ 800 88 55 6178 EUROPE

CATALENT BRUSSELS

Our Mission, Vision and Values

Our Mission

Our MISSION is to develop, manufacture, and supply products that help people live better and healthier lives.

Our Vision

Our VISION is to be the world's most trusted, reliable and innovative drug development and delivery partner by upholding the highest industry standards and exceeding customer expectations while driving strong, sustained growth for the company

Our Values

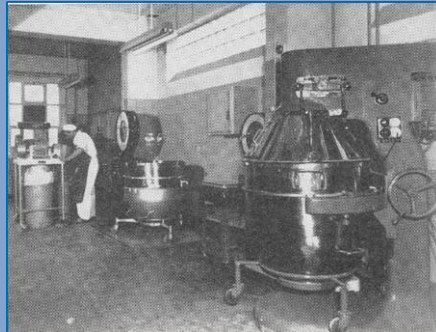
Patient First - Customer Dedication - People
Innovation – Integrity - Excellence

Catalent Brussels Site

Capabilities Overview



Brussels Facility History



1920

The first facility was located in the centre of Brussels city



2006

New facility located in Neder-Over-Hembeek



Total Site	26.000m ²
Building Surface	15.000m ²
Sterile Area	2.600m ²
Packaging Area	2.300m ²
Warehouse	2.400m ²
Laboratories	750m ²
Offices	1.800m ²

Specializing in the manufacturing of sterile fill/finish of prefilled syringes

Customer

Primary & secondary
components
Manufacturer



Catalent®



Customer



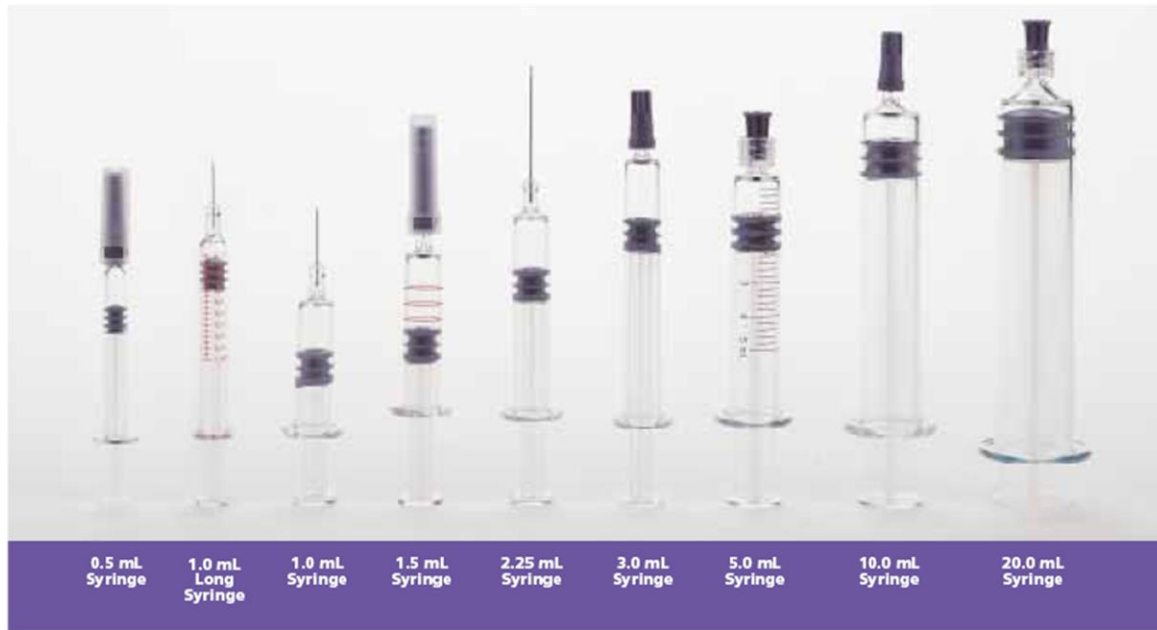
Formulation
Filling
Sterilization
Visual Inspection
Labelling
AI assembly
Packaging
Testing



Analytical development & transfer

Catalent Brussels Site Capabilities

- ❑ Extensive range of pre-filled syringes sizes (0.5mL to 20mL)
- ❑ Syringe top: luer, luer lock or with needle
- ❑ Glass and plastic
- ❑ Aseptic/terminal sterilization of filled syringes
- ❑ Inspection, labeling, blistering and cartoning of syringes



Capacity

175 million PFS
(1mL format)

Applications

- Small molecules
- Biologics
- Vaccines (inactivated)
- Diluents
- Contrast media

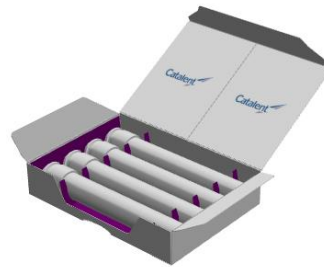
Innovation at Catalent Brussels

Full automated auto injector assembly line

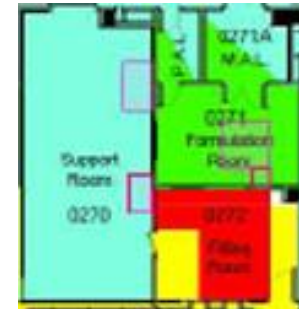


FAT - May 2017
Installation - June 2017
Operational ready - 2017

Evaluation on full carton packaging line for Auto injectors



Biologics filling line in idle suite



- ✓ Peristaltic and rotary piston filling mechanisms
- ✓ Insertion tube and vacuum stoppering
- ✓ Disposable system design
- ✓ Automated IPC
- ✓ Temperature controlled
- ✓ Flexible vial and cartridge



<https://www.youtube.com/watch?v=7v9yHL8thIU>

« Hoshin Kanri »

Denis Fabris
Head of Operational excellence ,
Primary operations international



How to select continuous improvement projects and ensure strategic alignment

Hoshin Kanri

Description of a governance method for project selection

2017

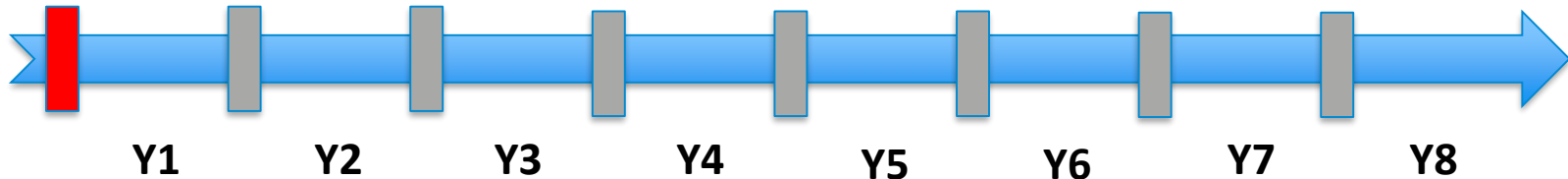
Félix Duparc – Life Sciences Projects Director

Stéphane Jullien – Life Sciences OE Consultant

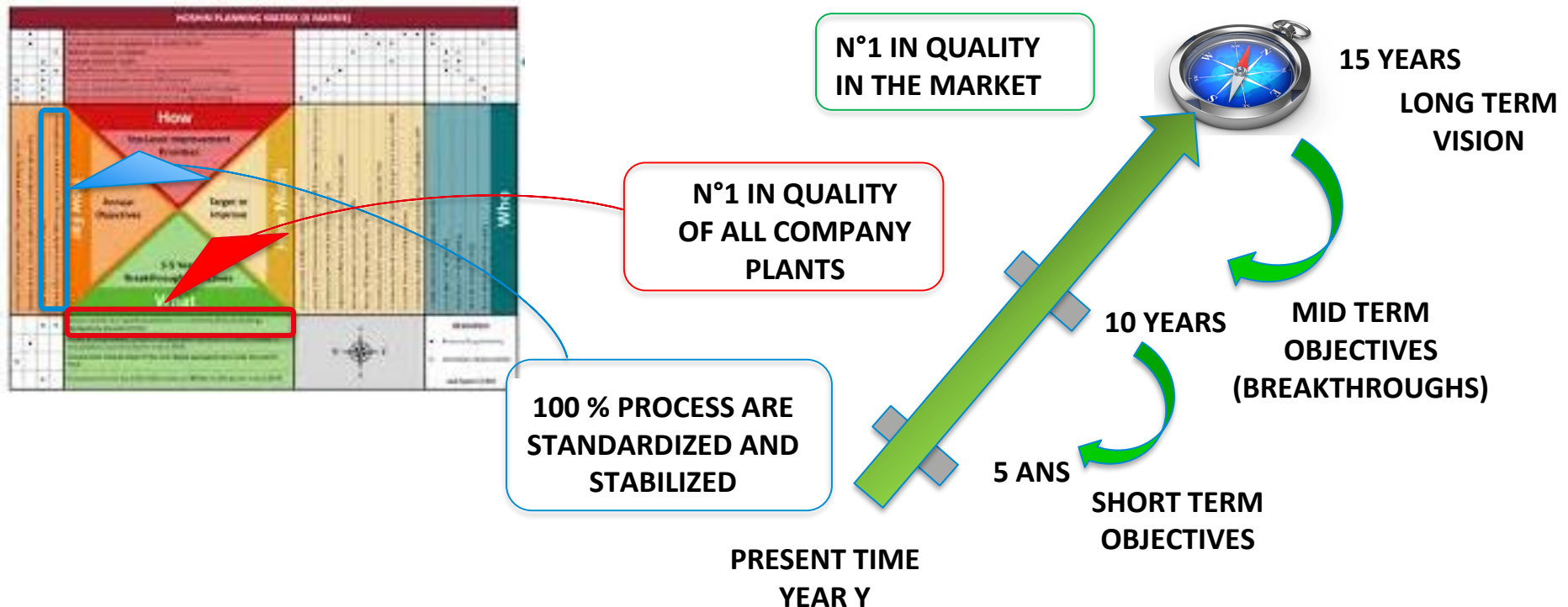


Example of Hoshin application
in the
agricultural technology industry

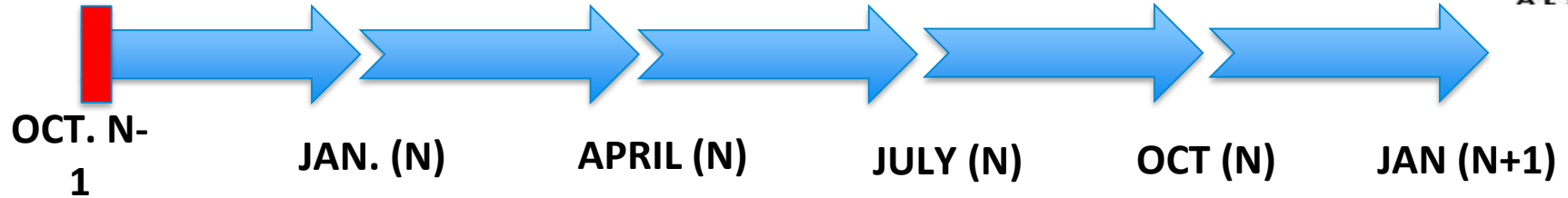
Example of Hoshin Application



DEFINITION OF LONG TERM VISION AND BREAKTHROUGHS



Example of Hoshin Application



EVERY YEAR, STEP #1 : ROUND TABLES (1/2 Day)

6 tables, for each one:

- 6 participants
Middle Management Transversal
- 1 post-it color
- 1 board

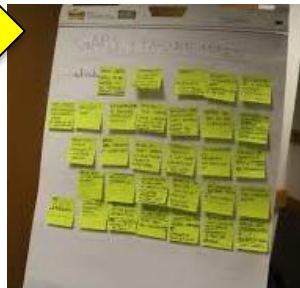


Brainstorming in each table

On post-its, participants write:

- 1 Idea of improvement per post-it

Group post-its by thematics:
(Equipments, Safety, ...)

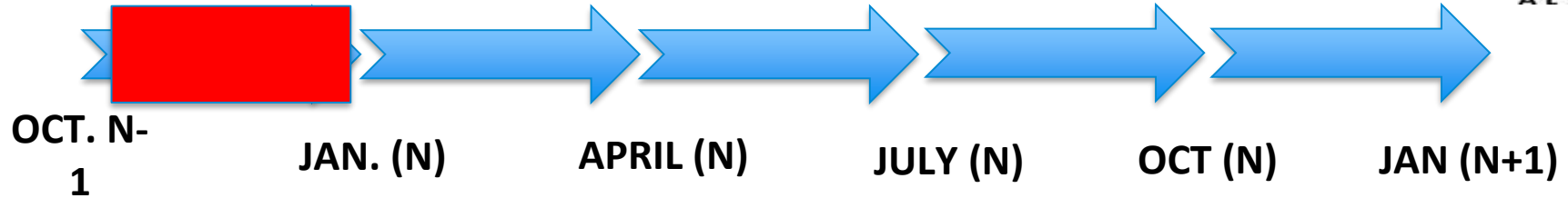


Each Table introduces their ideas to the Top management

Global grouping of all post-it by thematics



Example of Hoshin Application



STEP #2 : PROJECT DEFINITION BY THE TOP MANAGEMENT (3 months)

THINK GLOBAL, ACT LOCAL

Selection of improvement topics

Criteria:

- Number of post-it by topic
- Match with breakthrough objectives



Definition of 5 – 6 major topics:

- By topic:
 - 1 sponsor among Top mngt
 - 3 projects (+ Project Leaders)

Examples of major topics:

- *Work Conditions*
- *Standardized and Stabilized Process*
- *Employee development*
- ...

Example of Hoshin Application



MAJOR TOPIC: « STANDARDIZED AND STABILIZED PROCESS »

PROJECT #1: Write and Improve Assembling Work Instructions (WI)

1 year

OBJ #1.1 : Finalize WI writing

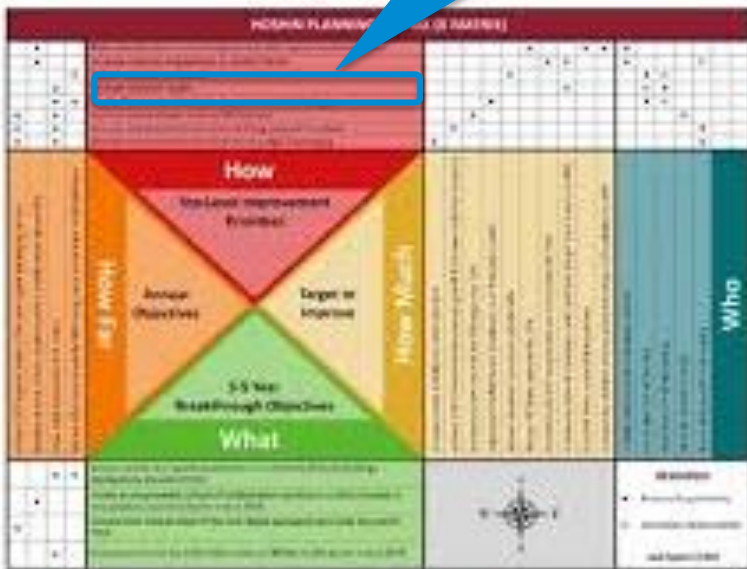
OBJ #1.2 : Develop Software for copying from ERP to WI

PROJET #2: Implement Automatic Painting process (Painting Robot)

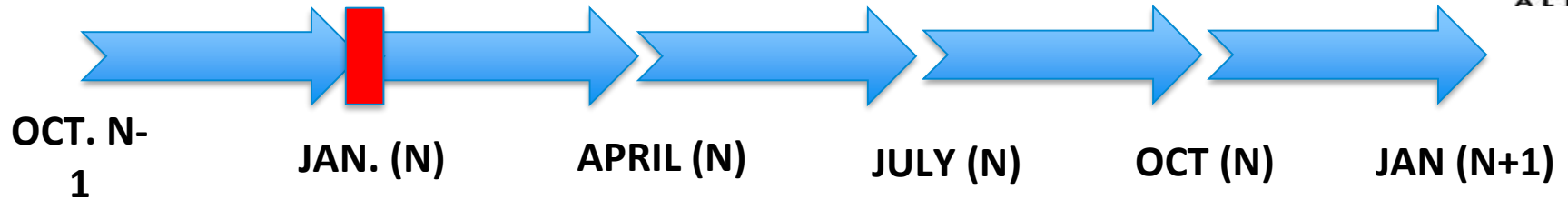
1 year

PROJET #3: Launch WI in Supply chain

1 year



Example of Hoshin Application



STEP #3 : PROJECT INTRODUCTION TO THE MID MANAGEMENT

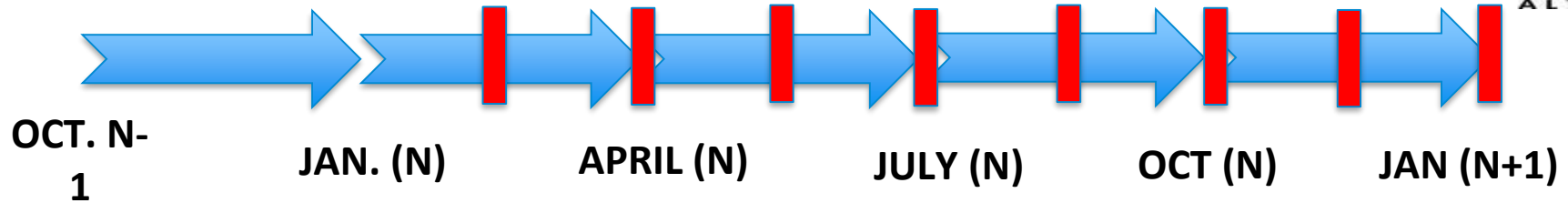
Top Management introduces to the Mid Management:

- A Reminder of Hoshin Vision and Breakthrough objectives
- Major topics and projects

+ Statement of Year N-1 Hoshin Project (by Project leaders)
Global Hoshin (by Top Management)



Example of Hoshin Application



STEP #4 : PROJECT FOLLOW UP

Project Leader To the Top Management

- 2-3 X / quarter for each project
- The 3 projects of a topic are introduced successively
- In a designated room,
- using a A3 poster



Project Leader To the Middle Management

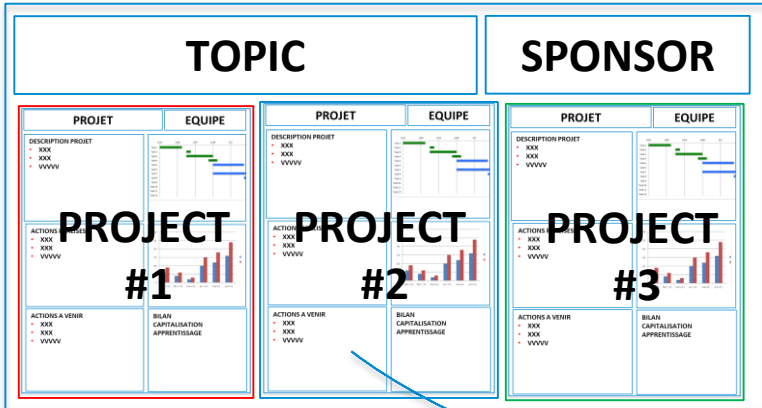
- 1 X / quarter
- In amphitheater



Example of Hoshin Application



ALLEN

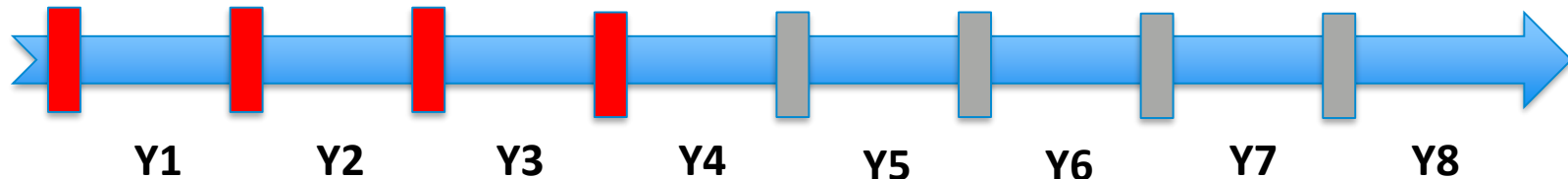


STEP #4 : PROJECT FOLLOW UP

EXAMPLE OF PROJECT A3 POSTER



Example of Hoshin Application



HOSHIN PROCESS IMPROVEMENT

Every Year,

Top Management brings one improvement to the Hoshin Process :

- Increase the number of participant at the roundtables: 20, 30, 40, ...
- Communicate Hoshin projects and results to a larger audience

Questions ?



Plant Tour: Packaging Zone

- Visual inspection
 - Manual
 - Semi Automatic
 - Automatic
- Blister line
- Manual Packaging Line
- Performance management: OEE Board
- Problem Solving Board



**« GSK ways to align and cascade a
portfolio
of programs across several factories »**

Denis Fabris
Head of Operational excellence ,
Primary operations international

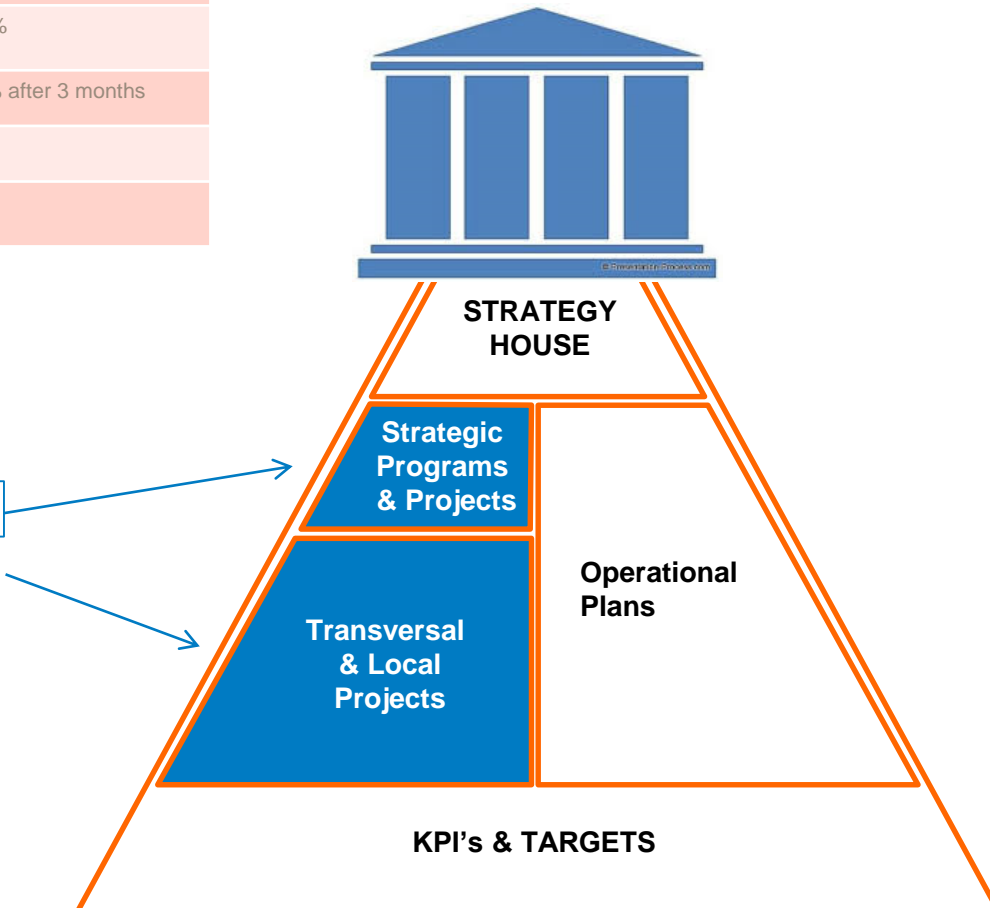
Industrial Operations and Quality Strategic Alignment



Your long term vision is the start point!

	2013	2014
Approval process (Days)	426 (6 moths late)	276
Known status of projects in portfolio	53%	100%
On time delivery	Baseline	+ 7% after 3 months
Project team satisfaction	Baseline	+5%
Resources allocation	50% project staffed as asked	80%

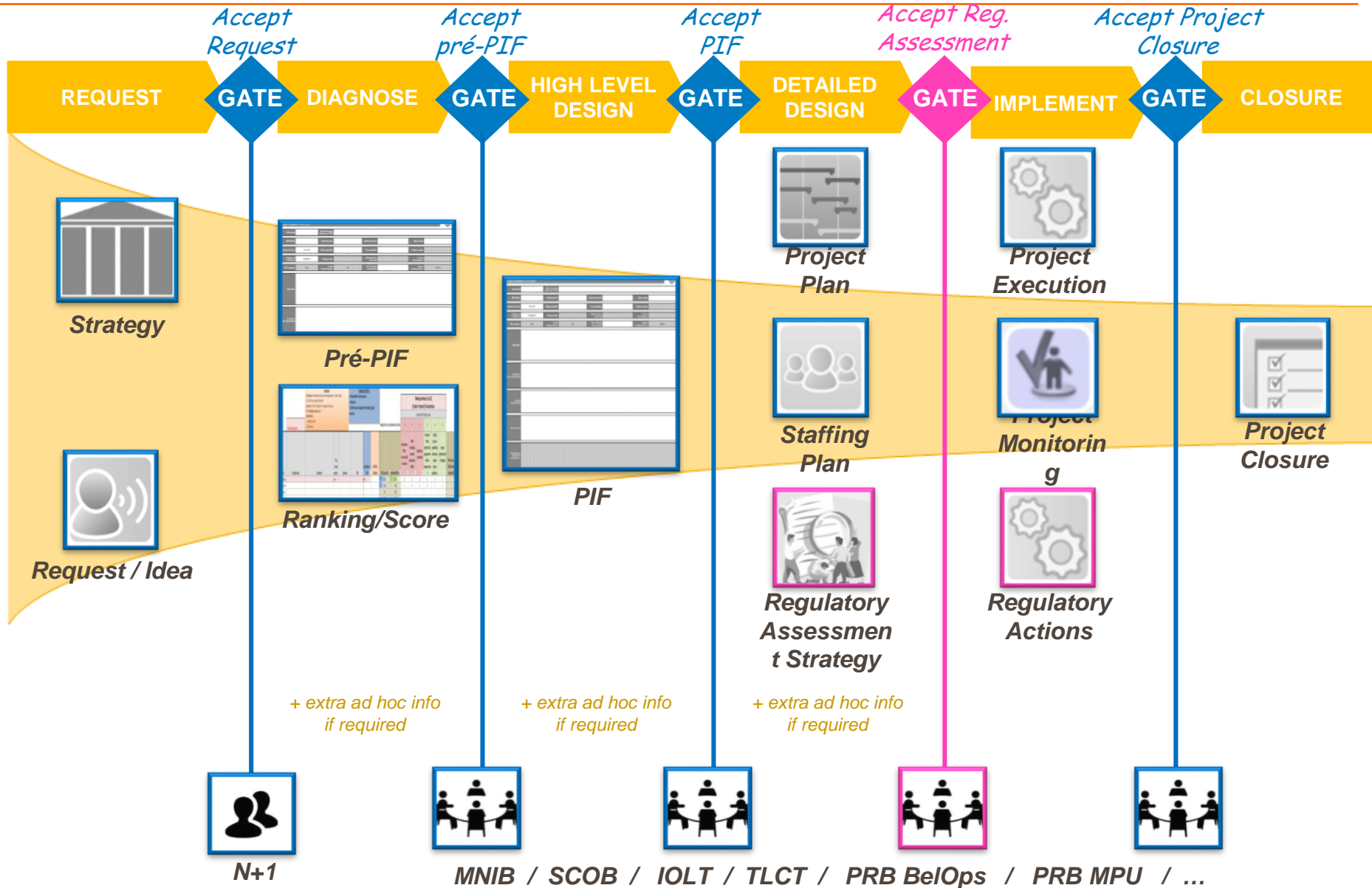
Focus of this



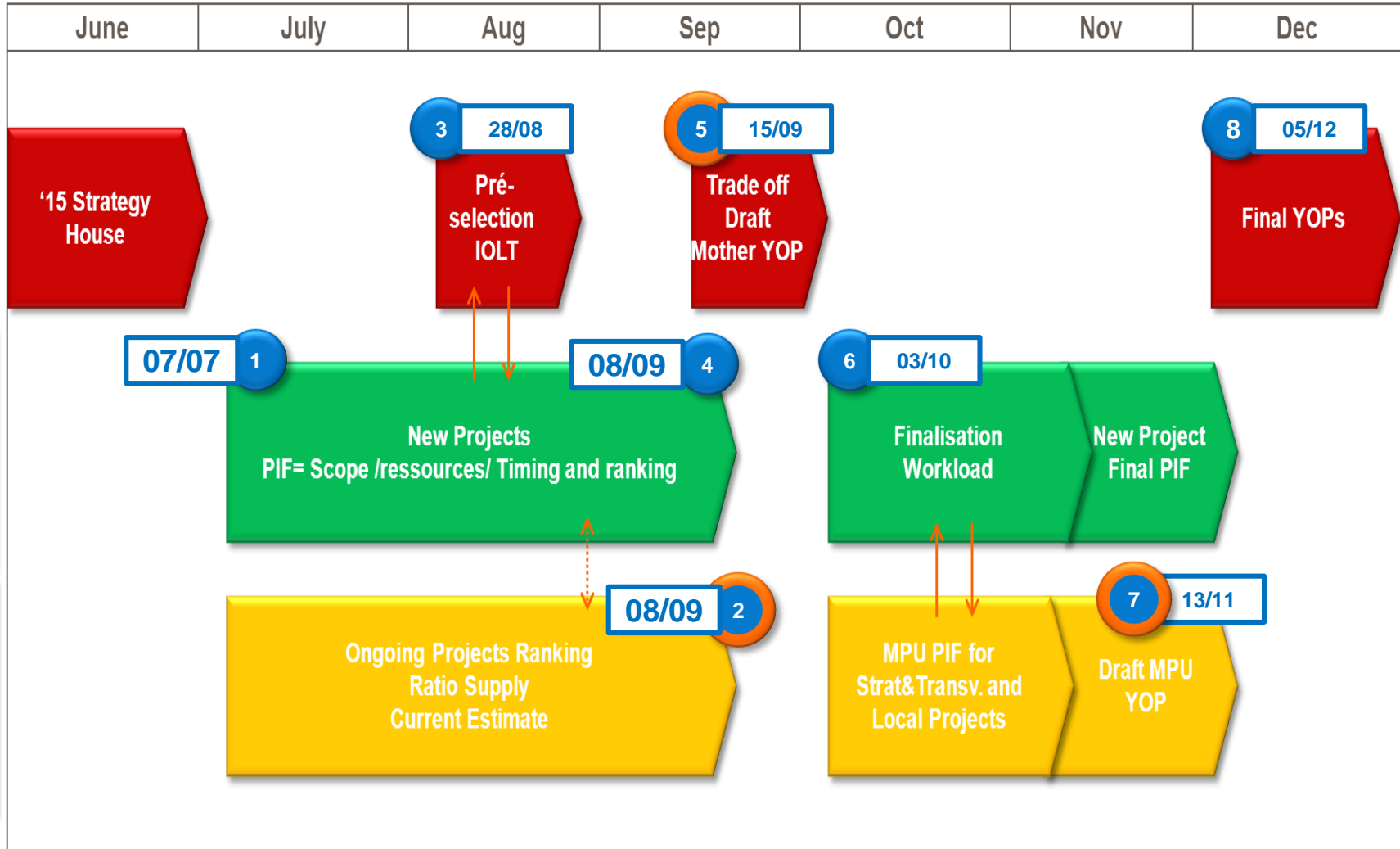


Importance of Gates reviews

Phases, Gates and Deliverables



Formal calendar shared across all factories (>20)

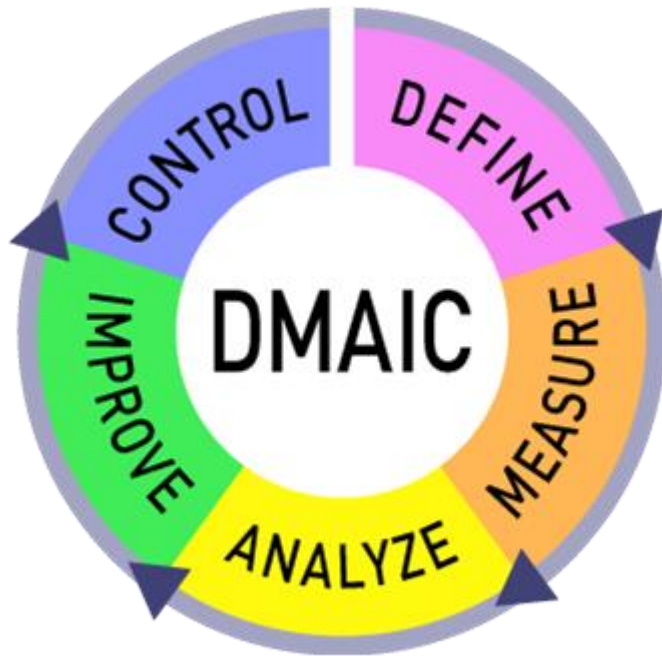


3 Key take away?



« GSK ways to align and cascade a portfolio of programs across several factories »

1. Start with the long term vision
 2. Gate reviews and formal « Portfolio Review Board » will enable you to manage pro-actively your portfolio
 3. Formal calendar process aligned from Senior executives until department's Heads to enable trade off.
-



Continuous Improvement Projects Selection

Theory vs. Practice

A real life example

What have we done ?

- Reminded the leadership team that picking the right projects is a key responsibility of organizational leadership.
- “Post It” session with leadership team to list the reasons why we ended up in such a situation.
- List the projects and link them again with latest strategic objectives.
- Abandon the ones that were not matching.
- Moving from a portfolio of 20 projects to 5-7 projects.
- Decide that we need to work on strategic planning tools and process (increase maturity within the organization)

What do we want to do next ?

Create positive experiences by :

- Develop leaders in strategic planning tools
- Encourage executives to use more structured methodology/proposed tools for next strategic planning cycle

What have we done ?

The details

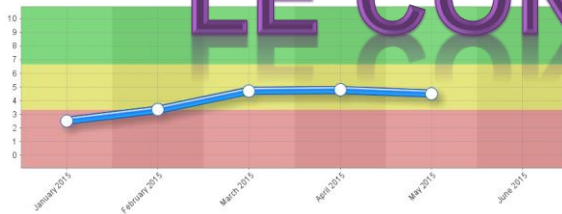
Projets Green Belt

CONSTAT

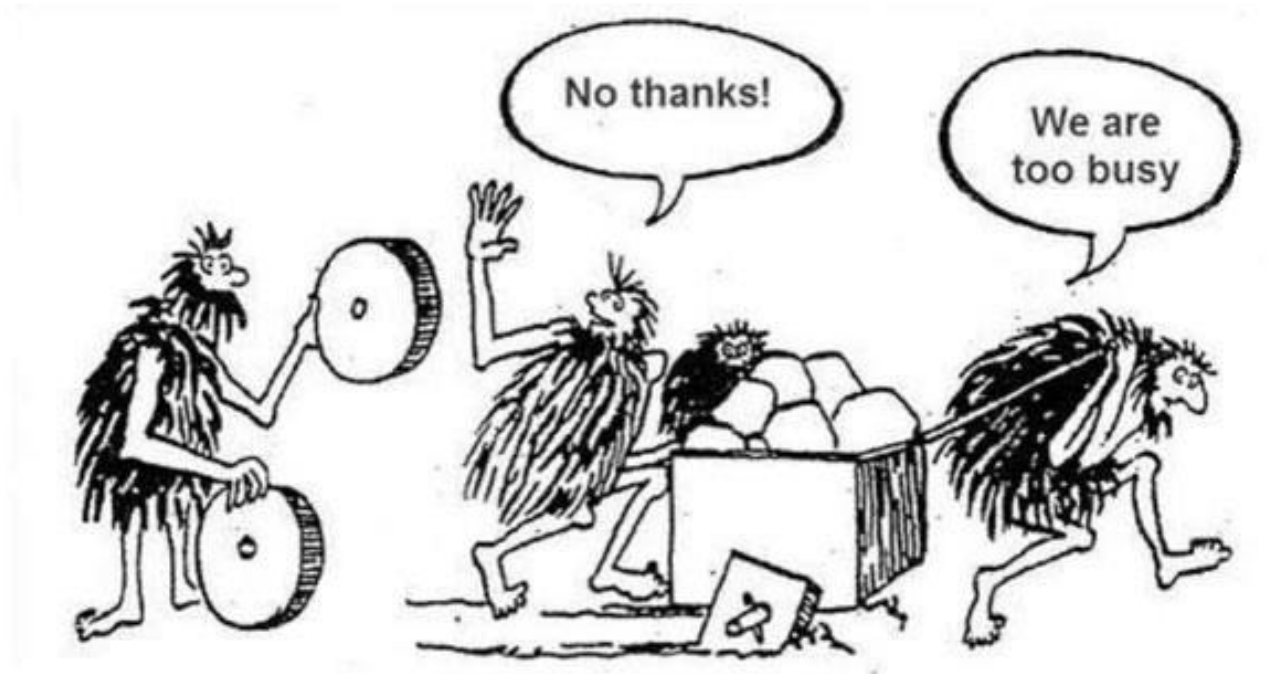
Nos projets sont abandonnés ou prennent du retard par rapport au planning initial

- Sur 20 projets Green Belt :
 - 7 Projets abandonnés (2) ou mis on hold (5)
 - 4 Projets dans le rouge au niveau planning

Balanced Scorecard : KPI Projets green belt pas à l'objectif



CONSEQUENCES



Projets Green Belt

Brainstorming sur les CAUSES

PERFORMANCE = SAVOIR X POUVOIR X VOULOIR
PERFORMANCE = KNOW X ENABLE X WANT



Les Causes

Résultat du brainstorming

Vouloir :

- Alignement avec les axes stratégiques
- Priorité pour le Management/ pour le Sponsor
- Processus de sélection des projets
- Priorité pour l'équipe projet

Pouvoir :

- Ressources – Projet Leader
- Ressources – L'équipe
- Choix/Sélection du project leader
- Choix/Sélection du Sponsor

Savoir :

- Culture et support du Sponsor
- Connaissances Project Leader
- Culture lean



Les Recommandations

CAUSES



RECOMMANDATIONS

Vouloir :

- Alignement avec les axes stratégiques
- Priorité pour le Management/ pour le Sponsor
- Processus de sélection des projets
- Priorité pour l'équipe projet

Pouvoir :

- Ressources – Projet Leader
- Ressources – L'équipe
- Choix/Sélection du project leader
- Choix/Sélection du Sponsor

Savoir :

- Culture et support du Sponsor
- Connaissances Project Leader
- Culture lean

Vouloir :

- Lier les projets Green Belt à la stratégie
- Lister les projets non CAPEX venant du top et des autres dpt afin d'avoir la vue complète sur le portefeuille
- Finaliser le brainstorming des idées projet
- Outil de sélection du projet : challenger l'input reçu de façon plus importante

Pouvoir :

- Arrêter de le faire « en plus », considérer le project leader comme à 0.6 FTE pour le dpt

Savoir :

- S'assurer que tout les sponsors soient familiés avec la culture lean et y adhèrent

Plan d'action

RECOMMANDATIONS



Plan d'action

Vouloir :

- Lier les projets Green Belt à la stratégie
- Lister les projets non CAPEX venant du top and des autres dpt afin d'avoir la vue complète sur le portefeuille
- Finaliser le brainstorming des idées projet
- Outil de sélection du projet : challenger l'input reçu de façon plus importante

Pouvoir :

- Arrêter de faire « en plus », considérer le project leader comme à 0.6 FTE pour le dpt

Savoir :

- S'assurer que tout les sponsors soient familiés avec la culture lean et y adhèrent

2 actions provenant des recommandations sélectionnées dans un premier temps

1. Lier formellement les idées de projets Green Belt aux axes stratégiques de BTO (lien avec LRP)
2. Finaliser le brainstorming des idées de projets et avoir une liste partagée

What do we want to do next ?

The details

Where do we want to improve ?

Step 1 : Project ideation

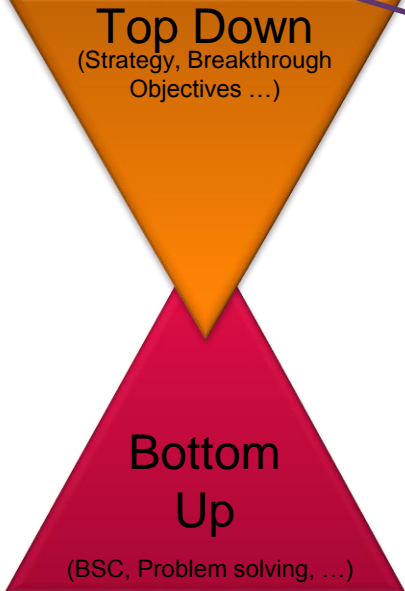
Step 2 : DMAIC Project scoring and selection

Step 3 : Get endorsement from Project Committee according to applicable governance

Step 4 : Follow up of Definition, Execution, Closure as per standard project governance

Work on the upstream part of the process:

By using Hoshin Kanri Starting from Value Stream Map



Objectif	Indicateur	Responsable	Statut
Augmenter le chiffre d'affaires de 10%	Chiffre d'affaires	Direction Générale	En cours
Améliorer la satisfaction client	Score de satisfaction	Service Client	En cours
Optimiser les coûts de production	Marge brute	Production	En cours
Augmenter la productivité	Productivité	R&D	En cours
Améliorer la qualité	Taux de défaut	Production	En cours
Améliorer la sécurité	Nombre d'accidents	Production	En cours
Améliorer l'environnement	Émissions CO2	Production	En cours
Améliorer la flexibilité	Temps de livraison	Production	En cours
Améliorer la fidélité	Taux de rétention	Marketing	En cours
Améliorer la réactivité	Temps de réponse	Service Client	En cours
Améliorer la visibilité	Précision des prévisions	Finance	En cours
Améliorer la résilience	Capacité d'adaptation	Direction Générale	En cours
Améliorer la performance	Performance globale	Direction Générale	En cours



Value Stream Mapping

June 16th 2017



DEVELOPMENT



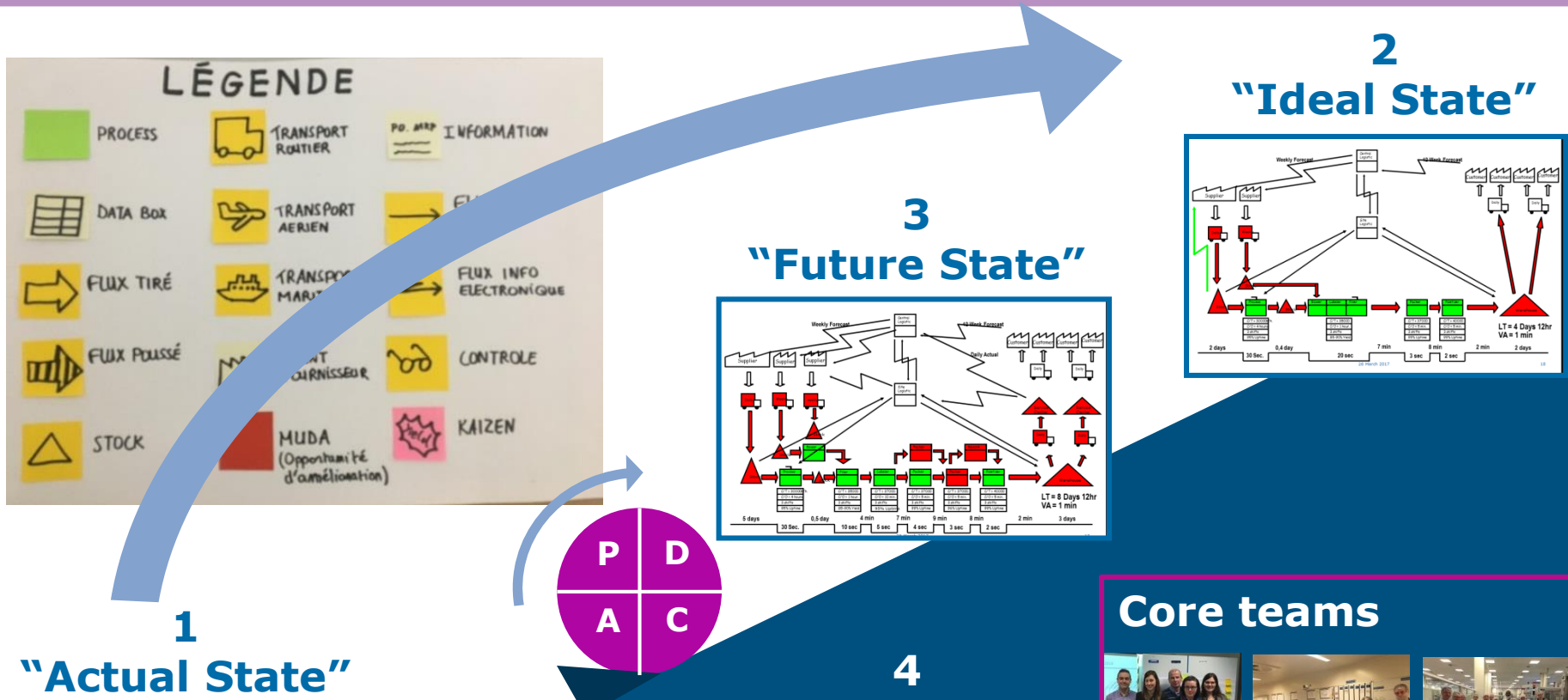
DELIVERY



SUPPLY

more products. better treatments. reliably supplied.™

OpEx Vision: Value Stream Map

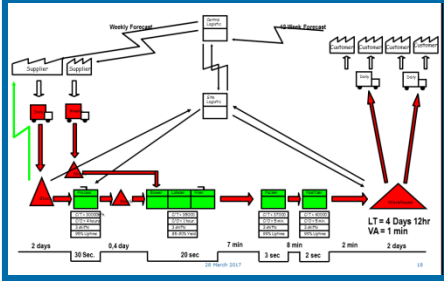
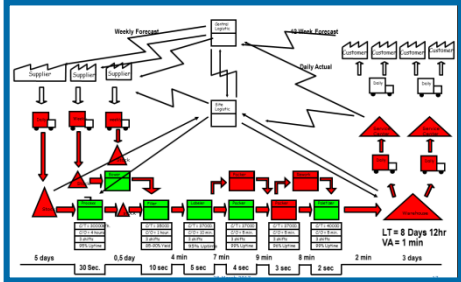


Project List

- Components Quality
- Samples flow
- Batch size
- Additional tank
- ...

Core teams

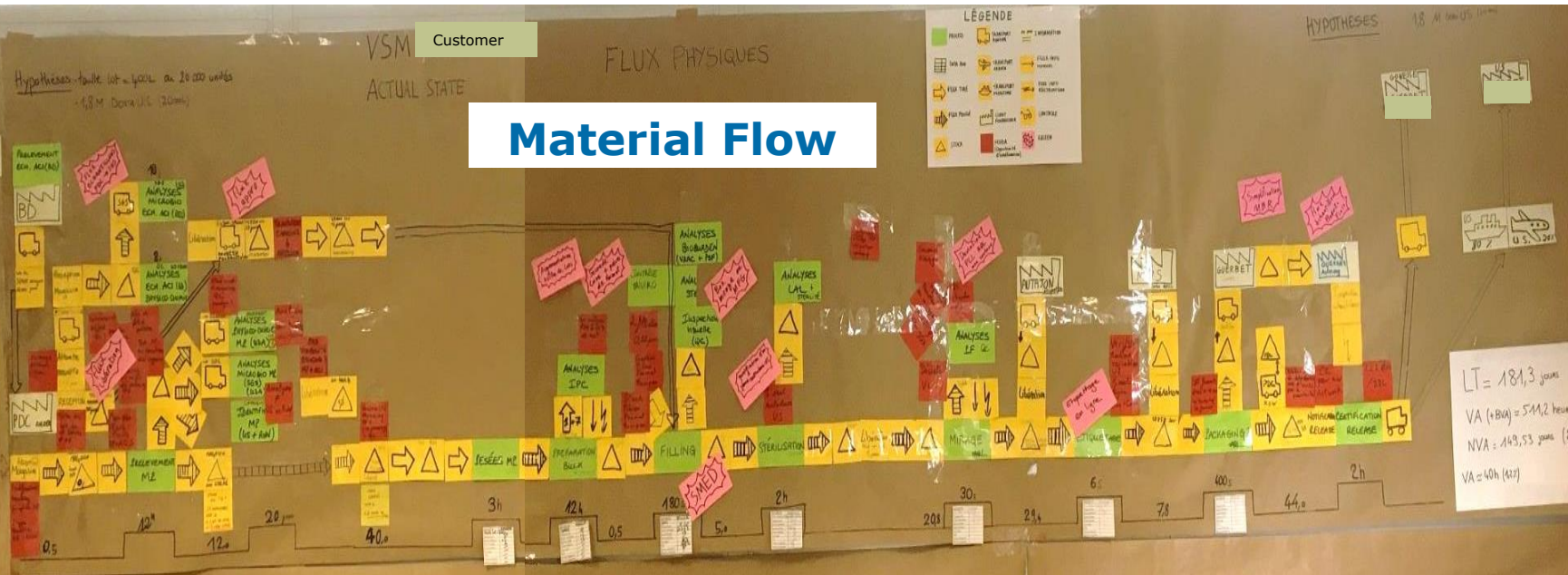
Milestone



Actual State

Material Flow

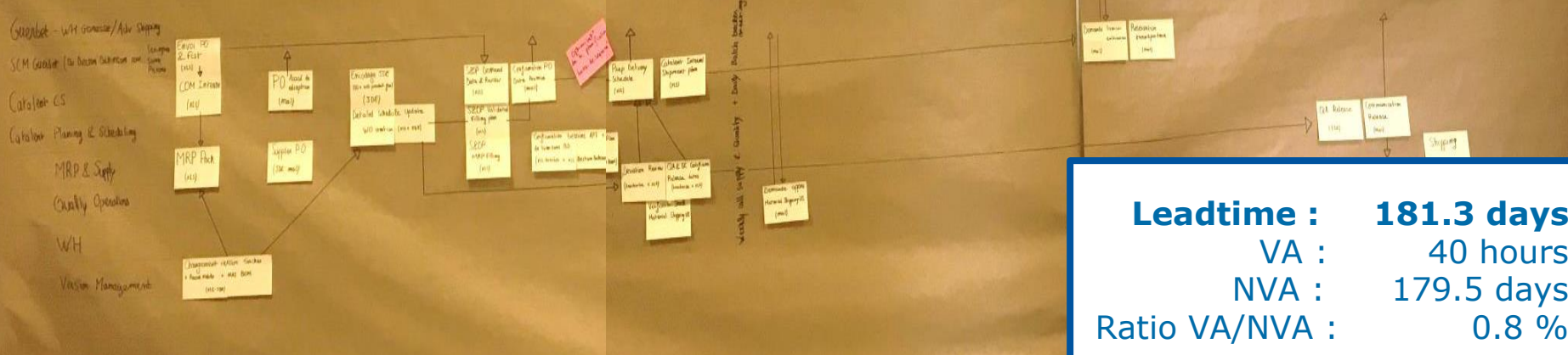
VSM Customer
ACTUAL STATE



LT = 181,3 jours
VA (+BQ) = 5M2 heures
NVA = 143,53 jours (87,5%)
VA = 40h (21%)

Information Flow

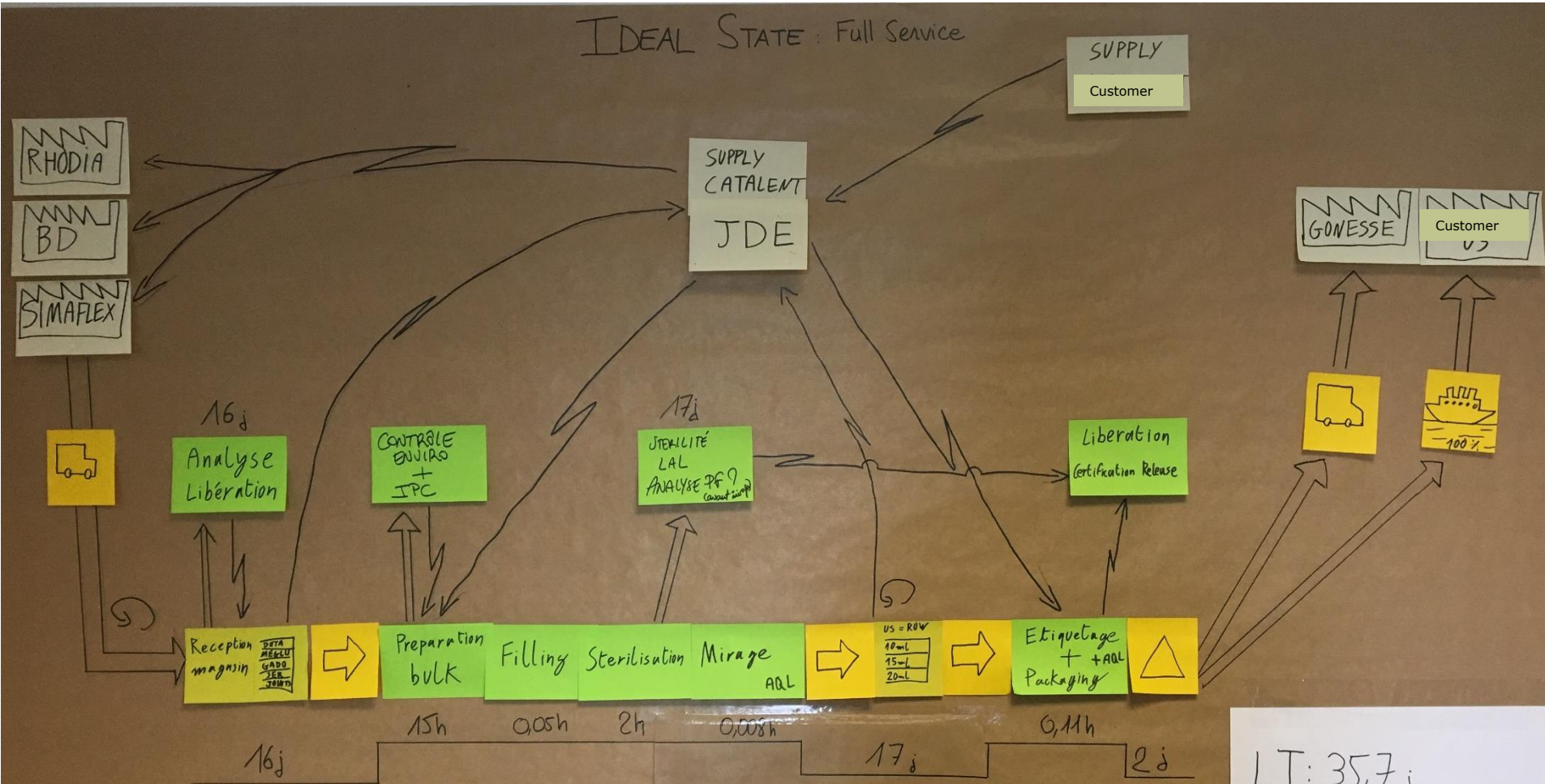
FLUX D'INFORMATIONS



Leadtime :	181.3 days
VA :	40 hours
NVA :	179.5 days
Ratio VA/NVA :	0.8 %

Ideal State

IDEAL STATE: Full Service



LT: 35,7 j

VA: 0,7 j

NVA: 35 j

Breakout Session: “ From.... To..... ” exercise

Split in 4 Groups and look for tools to go,

How to select continuous improvement projects and ensure strategic alignment?

1. *“**From** short term projects **To** sustainable long term vision”*
2. *“**From** few advocate **To** full sponsorship”*
3. *“**From** low project team engagement **To** high committed team”*
4. *“**From** pet project **to** breakthrough impact full initiative supporting the strategic plan”*



Share experiences, feedback session, discussion



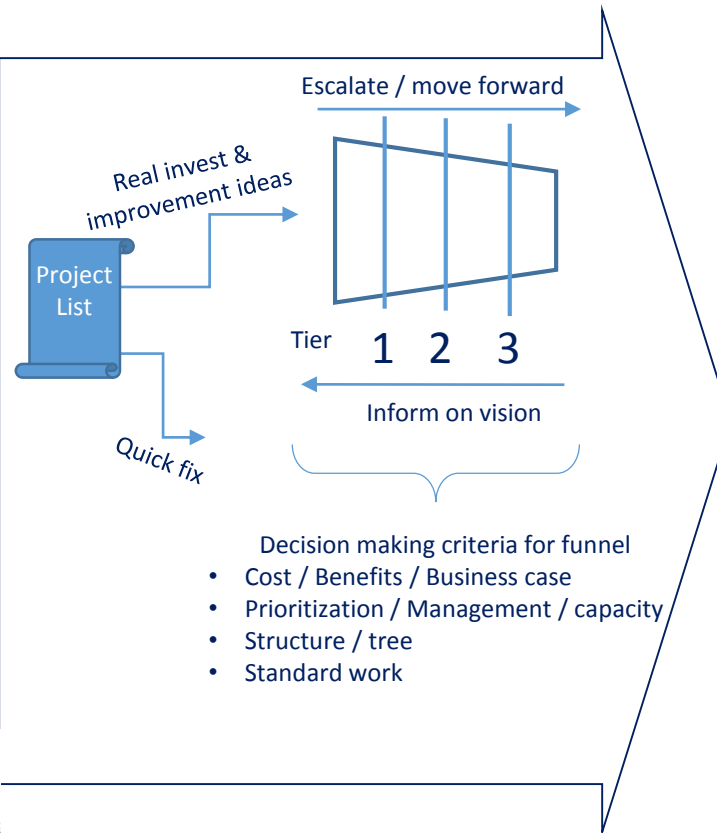
How to select continuous improvement projects and ensure strategic alignment?

From...

Key topics for change

To...

1. Short term projects



1. Sustainable long term vision

How to select continuous improvement projects and ensure strategic alignment?

From...

Key topics for change

To...

**2. Few
advocate**

1. Define a stakeholder Management Strategy and link it to the communication strategy / Ensure role modeling of key opinions' leaders
2. Have the results / advancement visible for all
3. Explain the why of the project (benefits) and the link with the strategy
4. Formalize it into everyone's objectives.
5. Make sure every one is concerned by the project and potential personal opportunities
6. Acknowledge shopfloor results
7. Let the team shopfloor decide how
8. Limit the number of projects (SMART targets)

**2. Full
sponsorship**

How to select continuous improvement projects and ensure strategic alignment?

From...

3. Low project team engagement

Key topics for change

Engagement Cycle

1. UNDERSTAND:
 - Business case
 - Yellow Belt Training
2. ACCEPTABLE
 - Make the project feet with the employee Value
 - Sustainability of the company, Safety Ergonomic
3. INVITED TO PARTICIPATE
 - Not “Forced to”, → “Due to your specific skills
4. RECOGNITION
 - Team members presenting the project
5. MAKE THE STRONG RESULTS VISIBLE
 - Measure and communicate results
6. CELEBRATING SUCCESS
 - Event , Team Building

To...

3. High committed Team

How to select continuous improvement projects and ensure strategic alignment?

From...

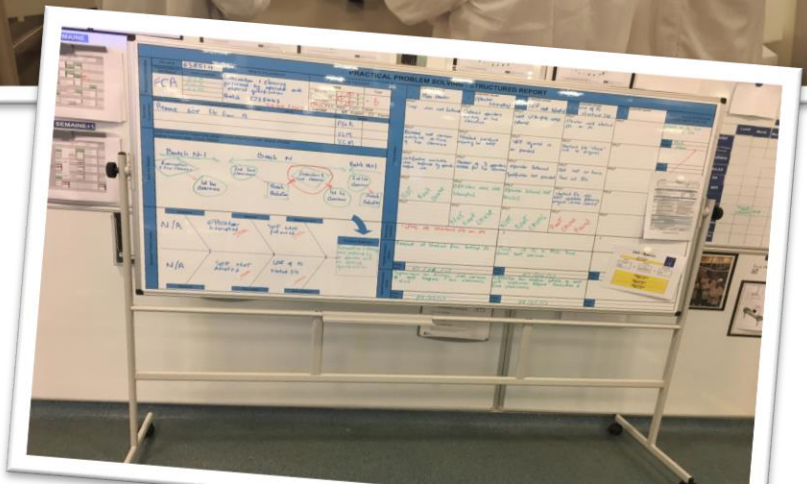
4. Pet project

Key topics for change

- 
1. Clustering Tree
 2. Governance around ideation
 - Scoring
 - Business case
 - ROI
 - Heat map / Piloting
 3. White Board
 - Communication and Visibility
 4. Sell and convince
 5. Diagnostic Phase
 - External
 - Reviewed
 6. Leadership

To...

4. Breakthrough impact full initiative supporting the strategic plan



The team



Participants

First Name:	Last Name:	Company:	Email Address:	Job Title:
Dierik	Rotsaert	A.C.i.	info@tqm.be	Director
Stephane	Jullien	ALTEN BELGIUM	sjullien@alten.be	Life Sciences Consultant
Nicolas	Thurin	Catalent Pharma Solutions	nicolas.thurin@catalent.com	APD Manager / QC-Chemistry Manager
Yves	Vancleemput	Janssen	yvancee@its.jnj.com	Operations Director
Nicolas	Catrysse	Siemens	nicolas.catrysse@siemens.com	Account Manager Pharma industry
Frédéric	Henry	UCB	Frederic.Henry@ucb.com	Director Operational Excellence
Bruno	Flour	Ajinomoto OmniChem	bruno_flour@omnichem.be	Director Business Systems, IT and OE
Herve	Huens	ASSAR ARCHITECTS	hhu@assar.com	Associate Partner
Richard	Horvath	DPS engineering	richard.horvath@dpsgroupglobal.com	Business development
Laurent	Lhoir	Janssen Pharmaceutica	llhoir@its.jnj.com	Engineering Site Lead
Gino	Lefevere	Stexcon	gle@stexcon.be	Project Manager
Matthias	Ringel	Mc Kinsey	matthias_ringel@mckinsey.com	Expert Associate Partner
Sabine	Gillet	Ajinomoto OmniChem	sabine_gillet@omnichem.be	Head of Operational Excellence
Ludovic	Terzi	Catalent Pharma Solutions	ludovic.terzi@gmail.com	CI & Technology Leader
Mario	Habets	Gemu Valves	mario.habets@gemue.be	Account manager
Bruno	Gadeyne	Medgenix	bruno.gadeyne@perrigo.com	Project & Innovation Engineer
Yvan	Gouttebelle	The Biotech Quality Group	ygo@tbqgroup.com	Director
Ann	Vermeulen	Pfizer	ann.vermeulen@pfizer.com	Director Operational Excellence
Felix	Duparc	ALTEN BELGIUM	f.duparc@alten.be	Life Sciences Technical Director
Oluwatobi	Onabule	Catalent Pharma Solutions	oluwatobi.onabule@catalent.com	Deviation Management
Denis	Fabris	GSK	denis.fabris@gskbio.com	Director Operational Excellence
Niels	De Blende	Pi	niels.de.blende@gmail.com	Junior Associate
Pierre	Patenere	The Biotech Quality Group	pierrepatenere@gmail.com	Apollo Practitioner
Bjorn	Mertens	Pfizer	bjorn.mertens@pfizer.com	Operations Excellence