

# *GMP-BERATER Tage 2019*

*24. October 2019*

## ***Construction of a Pharmaceutical Factory – Retrospect and Outlook***

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Sant Cugat del Vallès (Barcelona)

*Maas & Peither*

# *Topics*

- Introduction
- What happened since last year?
- Where are we today?
- Experiences and learnings
- Outlook
- Conclusion

# Boehringer Ingelheim España S.A. Sant Cugat del Vallès (Barcelona)





*The decision was made in July 2016  
to build a new factory in Sant Cugat*

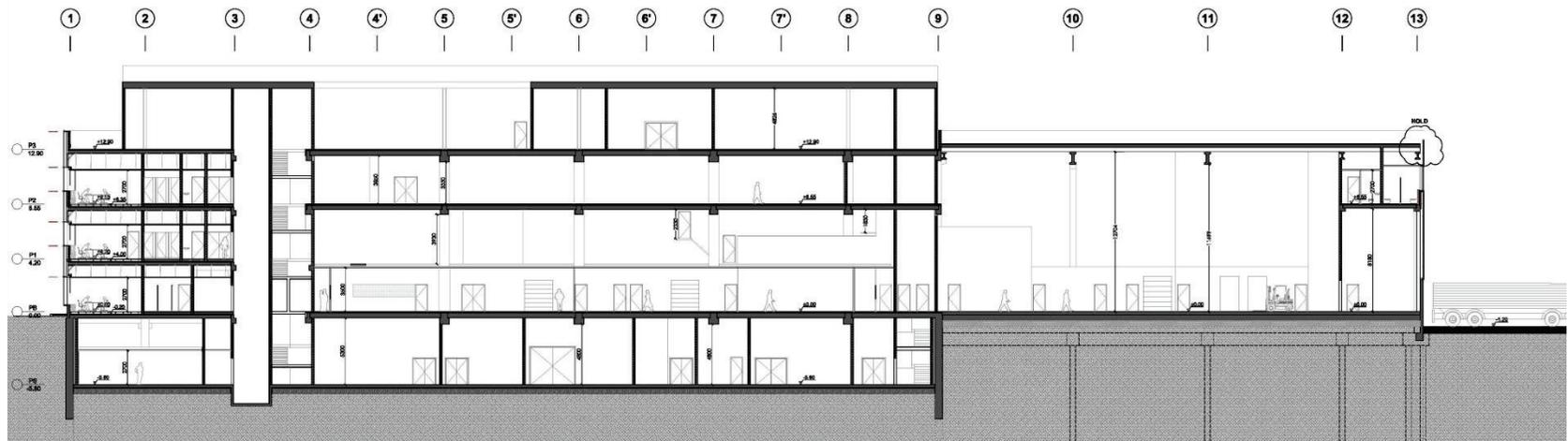


# Blueprint RESPIMAT Factory



- Footprint: 6.000 m<sup>2</sup>; total area: 16.000 m<sup>2</sup>
- Full deployment of independent factory, including labs/offices/staging (“Focused Factory”)
- ca. 200 employees
- Total invest budget: > 100 Mio€

SECOND FLOOR	Chemlab / office	Technical Area	Staging area / TCMA Lab
FIRST FLOOR	Mibi Lab / office	Technical Area	
GROUND FLOOR	Office	Packaging & Filling	Staging area
BASEMENT	Gowning	Utilities & Storage	



# Project Scope

## New Production Plant



## New Products



## New Market



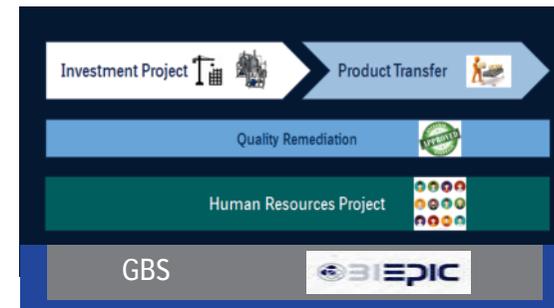
## New Equipment



## New Organization



## Projects & Subprojects



# *Project Timelines*

**FAST TRACK**



## Why "Fast Track"

... in order to support the global launch of a new product:



→ Packaging operations needs to Go Live in October 2019

# What does "Fast Track" mean: building = critical milestone



## August 2017

- Excavation initiated

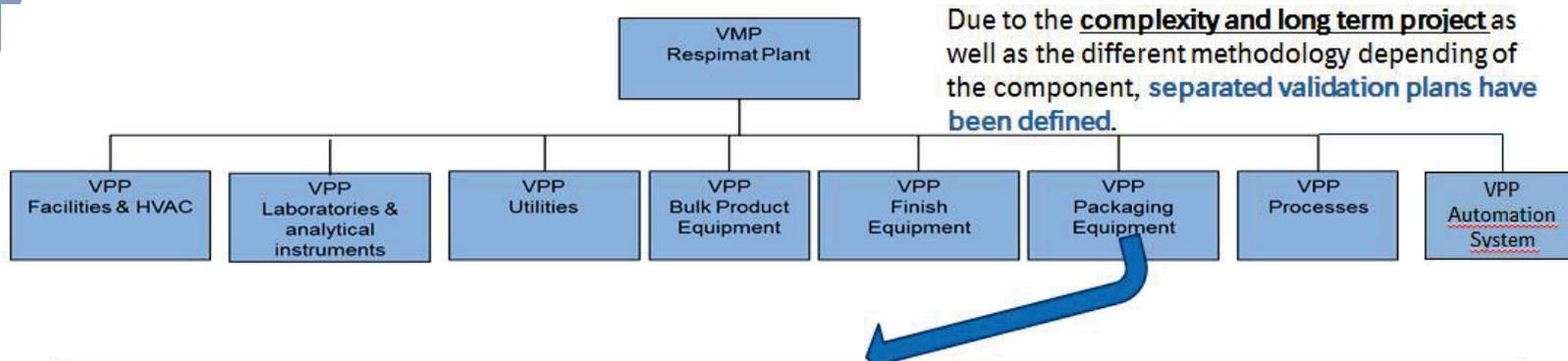


## September 2018

- Building ready for entry of equipment
- Delivery of packaging line: Oct 2018
- Delivery of fill&finish line: Oct 2018

*What does "Fast Track" mean:  
18 m for purchasing & delivering equipment*

# What does "Fast Track" mean – 6 m for equipment qualification



## VALIDATION LIFE CYCLE MANAGEMENT (VLCM): PACKAGING LINE OF RESPIMAT

MODULE	Codigo	SUPPLIER	VMP	URS	21 CFR 11 EVA.	RA	DQ	FAT	IQ	OQ	OQ Linea	PQ	PPQ	VSR
Depalletizer	RPAC01-Y001	Pester		✓	✓	✓	PV RDV	PV RV RDV	PV RV RDV	PV RV RDV				
Device transport system	RPAC02-L020	Uhlmann		✓	✓	✓	PV RDV	PV RV RDV	PV RV RDV	PV RV RDV				
Device labeler	RPAC03-Y002	Uhlmann		✓	✓	✓	PV RDV	PV RV RDV	PV RV RDV	PV RV RDV				
Cartridge Sorter	RPAC05-L005	HH/Cirkon		✓	✓	✓	PV RDV		PV RV RDV	PV RV RDV				
DI Assembling Unit	RPAC06-Y010	HH		✓	✓	✓	PV RDV	PV RV RDV	PV RV RDV	PV RV RDV				
DI sorter	RPAC04-L006	HH/Cirkon		✓	✓	✓	PV RDV		PV RV RDV	PV RV RDV				
Cartridge Labeler	RPAC07-Y003	Bausch & Ströbel		✓	✓	✓	PV RDV	PV RV RDV	✓					
Cartoning machine erector C2155	RPAC10-Y005	Uhlmann	✓ A1	✓	✓	✓	PV RDV	PV RV RDV	PV RV RDV	PV RV RDV				
Cartoning C2206	RPAC11-Y006	Uhlmann		✓	✓	✓	PV RDV	PV RV RDV	PV RV RDV	PV RV RDV				
Single Unit	RPAC12-Y007	Pester		✓	✓	✓	PV RDV	PV RV RDV	PV RV RDV	PV RV RDV				
Top loader (Case packer)	RPAC13-Y008	Pester		✓	✓	✓	PV RDV	PV RV RDV	PV RV RDV	PV RV RDV				
Palletizer	RLOG01-U001	Pester		✓	✓	✓	PV RDV	PV RV RDV	PV RV RDV	PV RV RDV				
Grading machine	RPAC00-Y009	TBD					PV RDV							
Pucks washing machine		TBD					PV RDV							

✓: DOCUMENT    AX: Annexes    PV: PROTOCOL    RV: REPORT    RDV: eRAW DATA

Done    Ongoing on time    Planned    delayed

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# Milestones from the past



Feb '19:  
Mock  
audit

Mar '19:  
FQ



# Milestones from the past



Feb '19:  
Mock  
audit

Mar '19:  
FQ

Apr '19:  
EMPS  
inspection

SAP Go  
live &  
PPQ

first  
routine  
batches

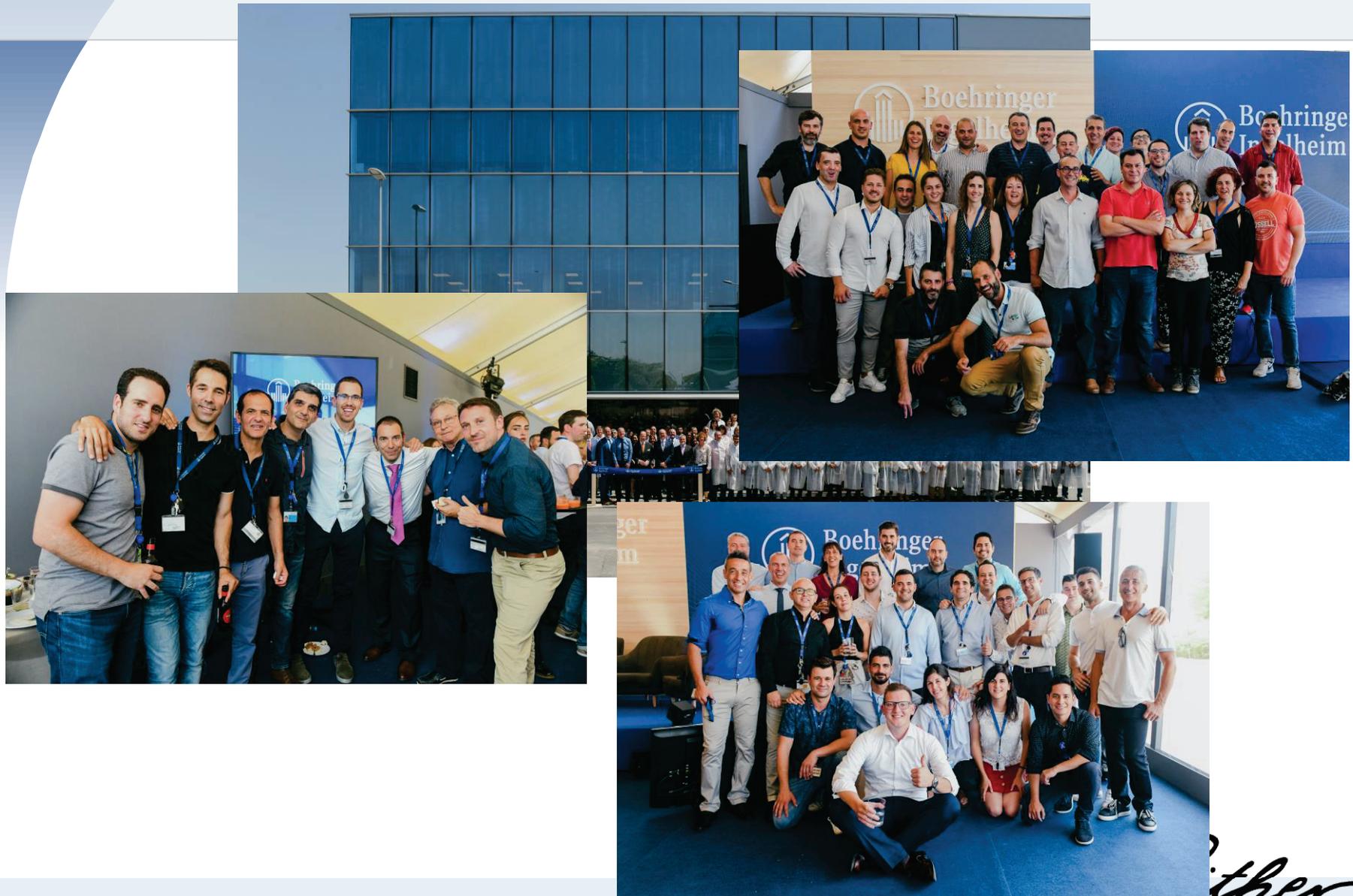
first  
batches  
released



## Milestones from the past



# Opening ceremony (27 June 2019)



*Boehringer Ingelheim*

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# *Virtual Factory tour*

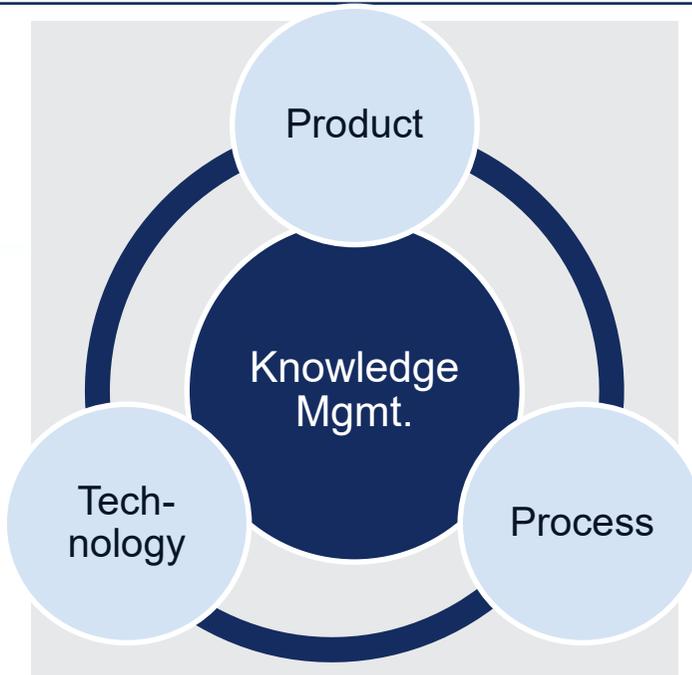


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# Knowledge management

During the project & transfer phase most of the knowledge is being exchanged.



## Our advantaged pupils...

FILL	 Laura Ávalos	Analista-Monitorización CMA	Operaria Filling Respimat
	 Jonatan Merino	Operario Fabricación de Inyectables	Operario Filling Respimat
FINISH	 Alejandro Romagosa	Operario Inspección de Inyectables	Operario Finish Respimat
	 Jaime Morales	Electromecánico Inspección de Inyectables	Electromecánico Finish Respimat
	 Carlos Ramírez	Operario Inspección de Inyectables	Operario Finish Respimat
QA	 Rubén Colomer	Responsable de Equipo Fabricación inyectables	QA Officer Respimat

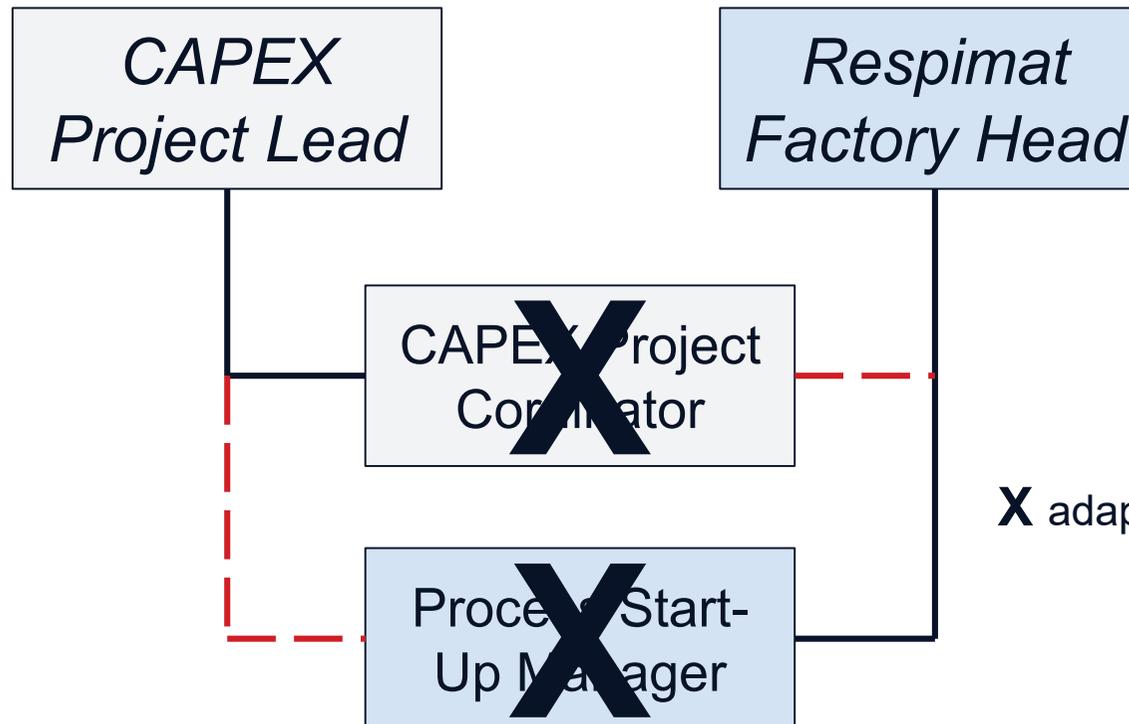
# *Project Management*

- Project Setup
- Project Teams
- Project Governance

# Project Setup

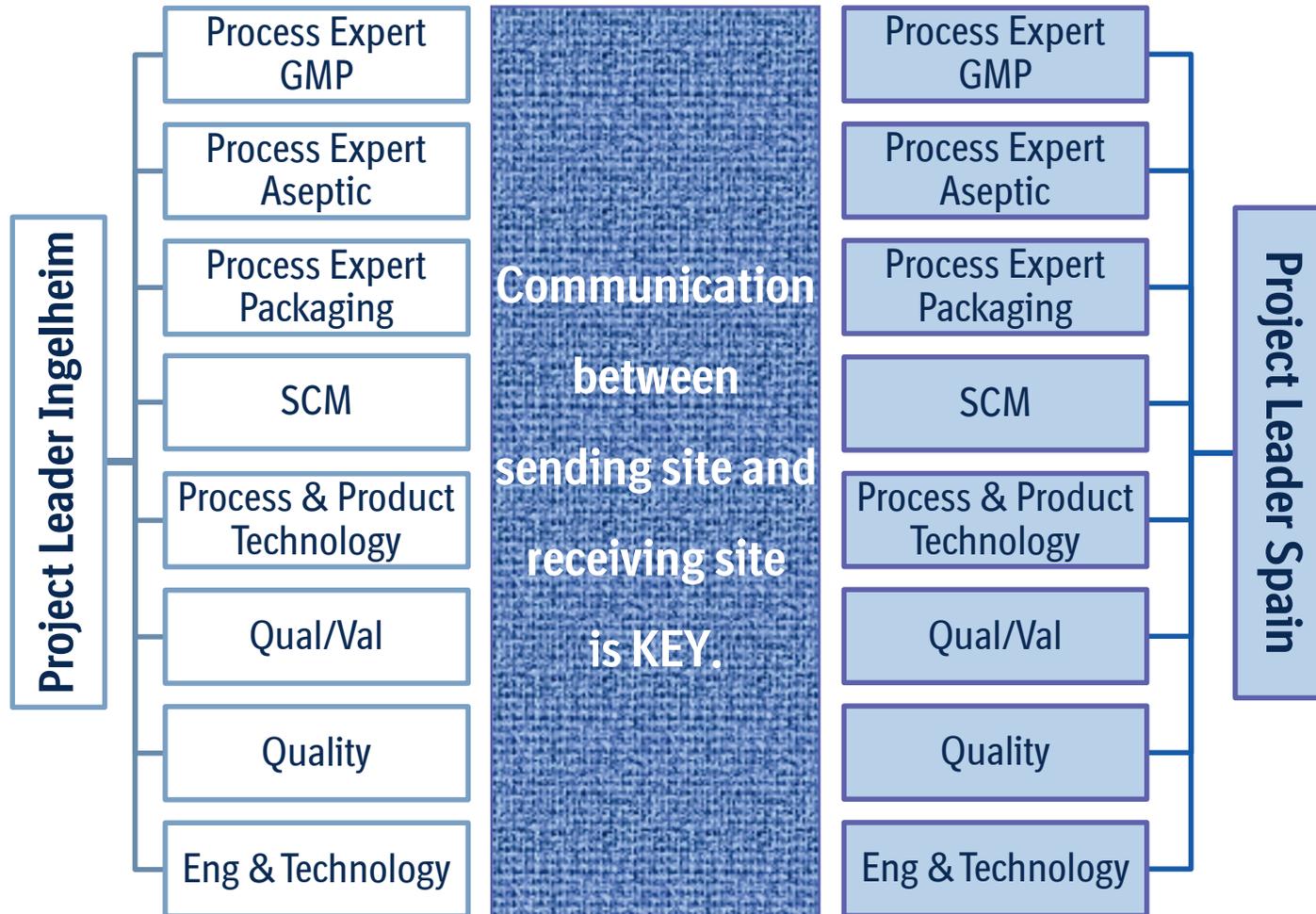


→ Tandem project lead: ENGINEERING + PHARMA



**X** adapted since April 2019

# Project Teams



# Project Steering – Steering Committee blueprint: moving from CapEx to process/product related topics

Targets	Participants
<ul style="list-style-type: none"> <li>Align project scope, project budget, and financial goals.</li> <li>Approach periodic review of progress, timelines, budget and resources.</li> <li>Escalation in case of non-alignment and/or deviations.</li> <li>Approve significant changes.</li> </ul>	<ul style="list-style-type: none"> <li>CapEx Project Leader (Chair)</li> <li>Transfermanager</li> <li>Factory Head Boehringer Ingelheim</li> <li>Factory Head Pharmasant Cugat</li> <li>Global Quality</li> <li>Global IT</li> <li>Global Engineering</li> <li>Legal&amp;Compliance</li> <li>Finance</li> <li>Site Head Manufact. Pharma Sant Cugat</li> </ul>
Meeting prerequisites	Minutes
<ul style="list-style-type: none"> <li>Status report updated by CapEx Project Leader and Controlling.</li> </ul>	<ul style="list-style-type: none"> <li>Distributed by CapEx Project Leader</li> </ul>
Frequency	Time
<ul style="list-style-type: none"> <li>Every 2 months</li> </ul>	<ul style="list-style-type: none"> <li>2 hours</li> </ul>

**Finally 2 more meetings in 2020 planned**

# Success factors

- 
- **The right people in the right place**
  - **Team spirit and team motivation**
  - **Communication (internal/external)**
  - **Project controlling (daily!), one project plan**
  - **Process start-up management**
  - **Knowledge transfer/management**
  - **Timely transition from project to operating mode**

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# Next milestones (upcoming)



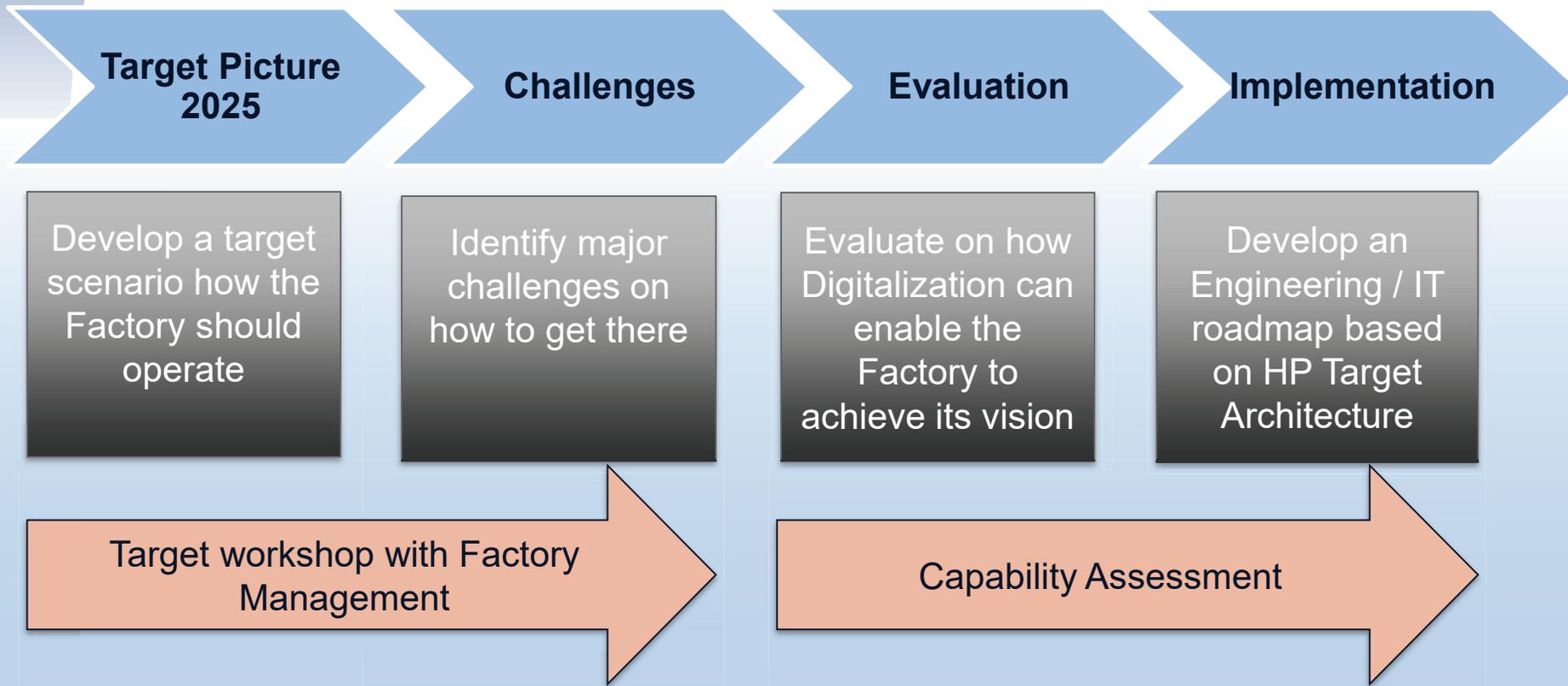
# *Digitilization*

## **What are the benefits of digitalization?**

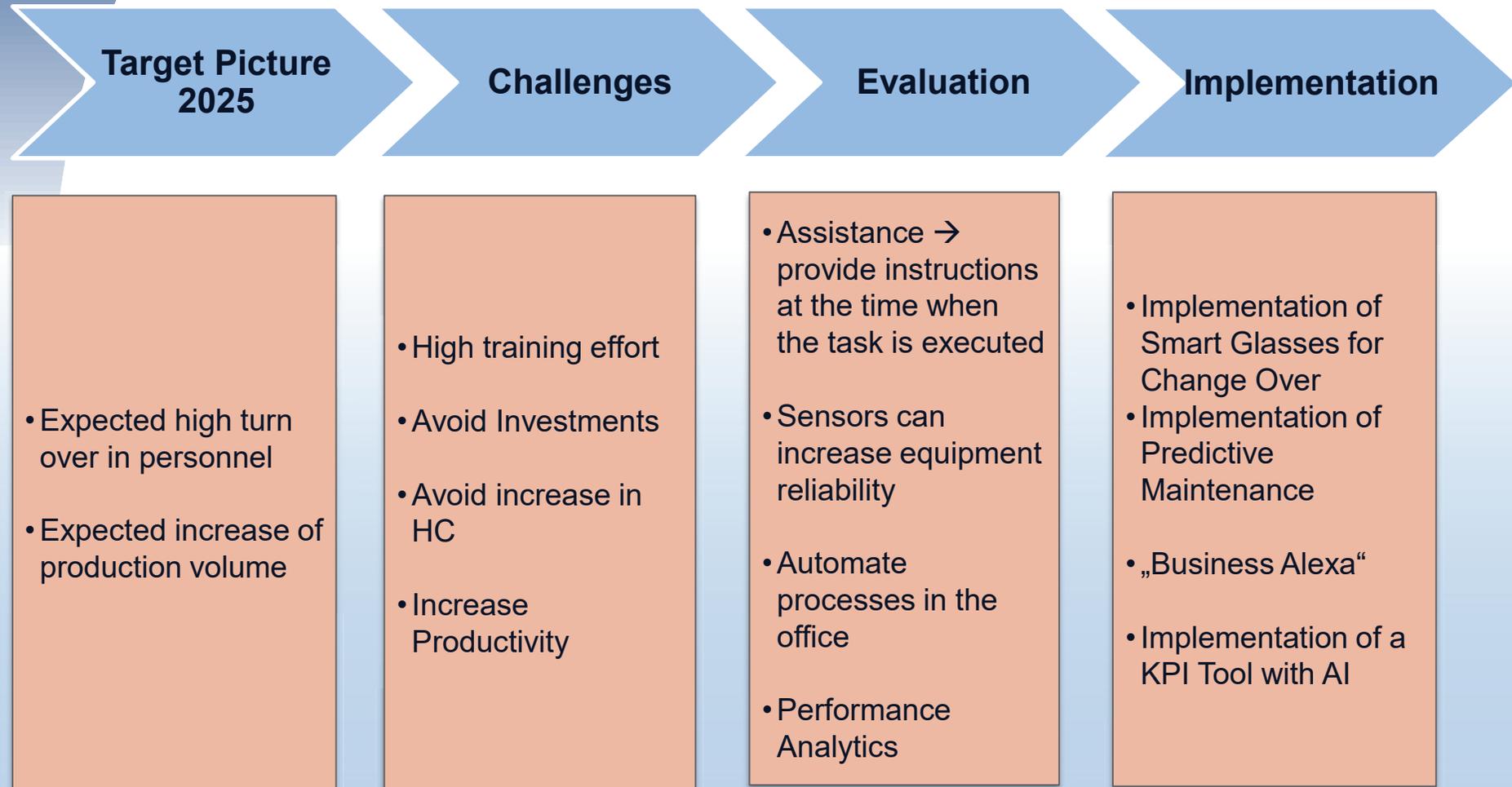
- More information, which allows you to make better decisions.
  - Technological tools to make your work easier.
- Digitalization of business can lead to a significant increase in productivity and can reduce costs.

# How to plan for Digitalization?

**OVERALL TARGET:** Ensure a transparent and need based Automation and IT Strategy for each Factory.



# How to plan for Digitalization? – Example



# *Roadmap for Digitalization?*

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# Fazit



- Be open to CHANGE and INNOVATION.



- Involve PEOPLE.



- COMMUNICATION is KEY.