

## **Process oriented organization – flexible and efficient at the same time**

Michael Kurdum, Director Production, Wacker Biotech

# Wacker Biotech in a Nutshell



- ▶ We are **THE MICROBIAL CMO** with a solid track record and strong customer focus
- ▶ We are a 100 % subsidiary of Wacker Chemie AG having a high **financial** and **long-term stability**
- ▶ We take your product **from scratch to commercial batch** with two EMA/FDA-inspected GMP facilities (300 L and 1,500 L)
- ▶ We have strong scientific background and offer **innovative, cost-saving *E. coli* technologies**
- ▶ We are **leading** the production of difficult-to-express proteins and antibody fragments

# The Wacker Group – Over 100 Years of Success



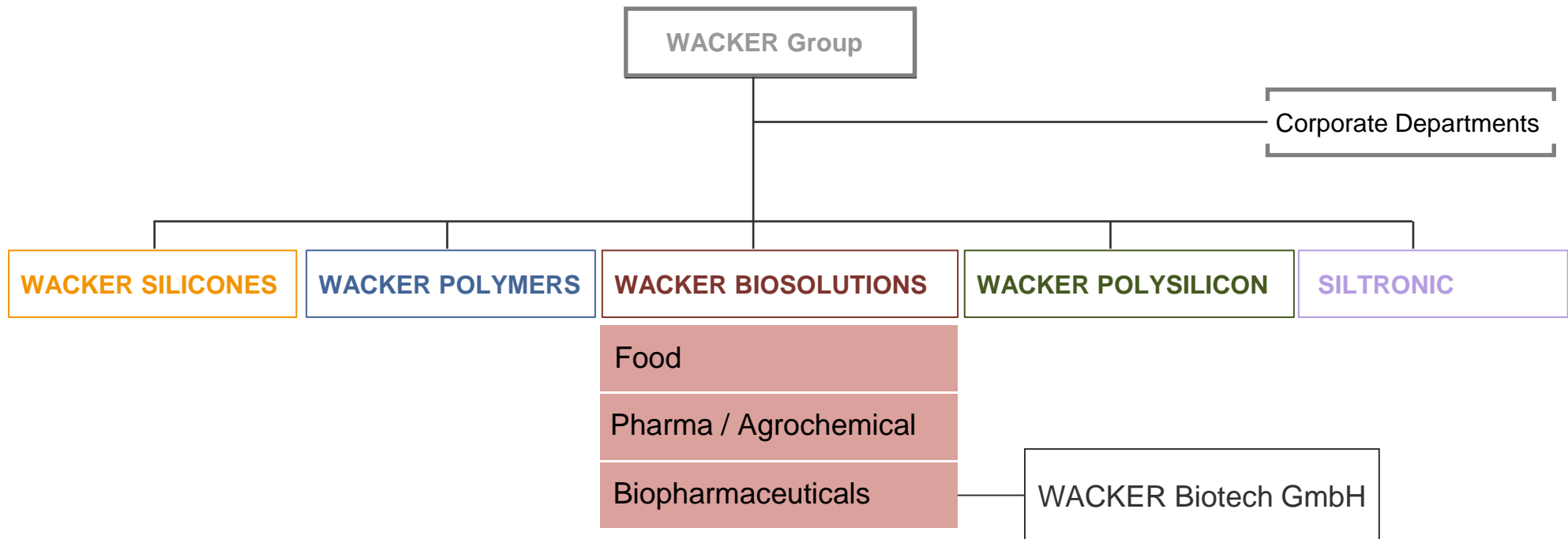
## Wacker Chemie AG

- ▶ Founded in 1914 by Dr. Alexander Wacker
- ▶ Headquartered in Munich

## WACKER Group (2015)

- ▶ Sales: € 5.30 billion
- ▶ EBITDA: € 1.05 billion
- ▶ R&D: € 175 million
- ▶ Investments: € 834 million
- ▶ Employees: 16,972

# Wacker Biotech is Part of Wacker's Life Science Division



# WACKER is a Full Service Provider Covering the Entire Process Chain From the Cell to Commercial Manufacturing

## „From Scratch to Batch“

### Develop



- ▶ Cell line development
- ▶ Process development
- ▶ Analytical development

### Manufacture



- ▶ GMP drug manufacturing
- ▶ GMP cell banking

### Control



- ▶ Release testing
- ▶ Stability testing



# Wacker Biotech Operates 2 State-of-the-art GMP Facilities in Germany



## Jena Site

- ▶ ~90 FTEs
- ▶ 300 L line
- ▶ EMA approved
- ▶ FDA meeting



## Halle Site

- ▶ ~90 FTEs
- ▶ 1,500 L line
- ▶ EMA approved
- ▶ FDA inspected

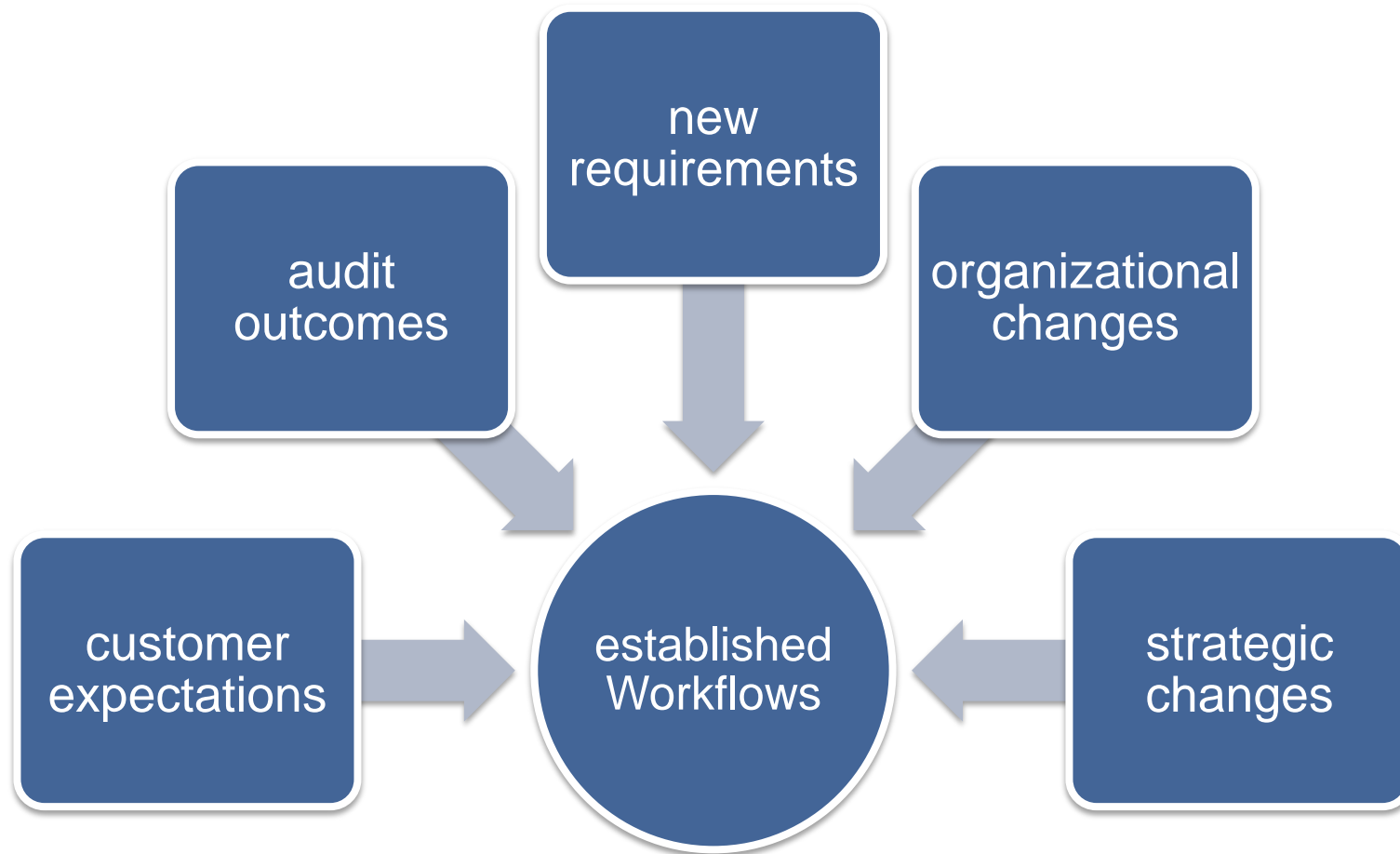


FTE by September 2015

**It is not the strongest of the species that survive, nor the most intelligent, but the one most responsive to change.**

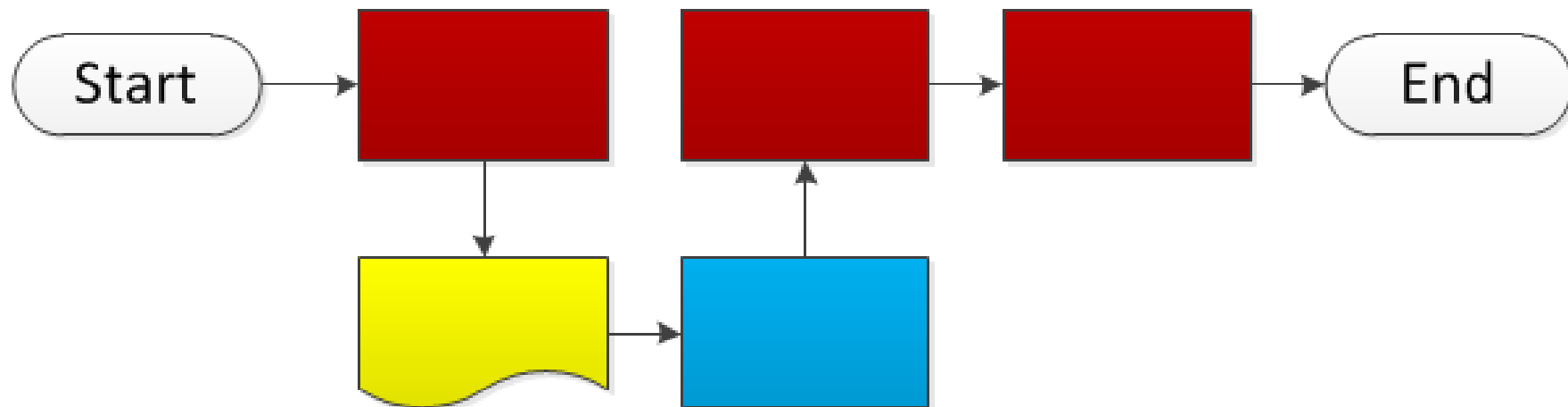
**Charles Darwin**

# Continuous adaption of workflows are required

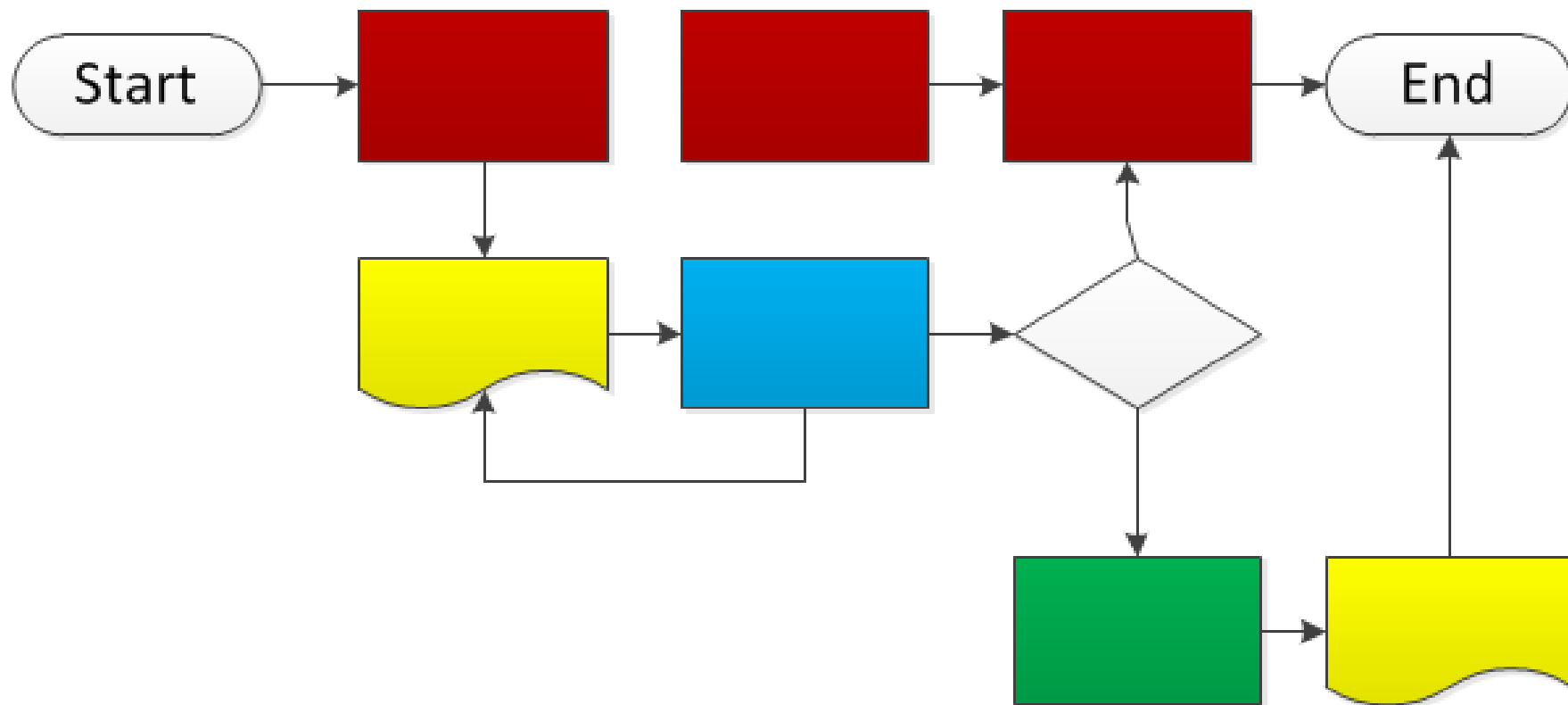




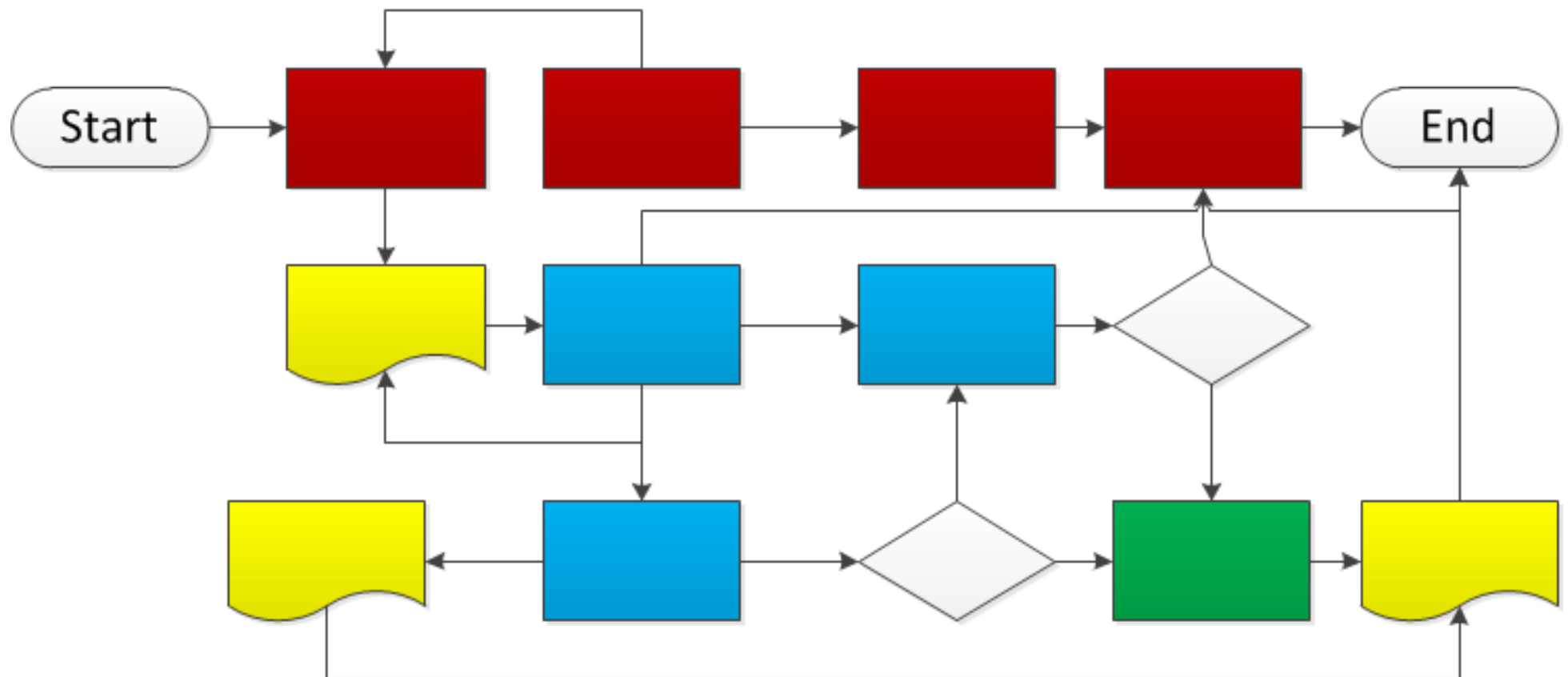
## How it should be...



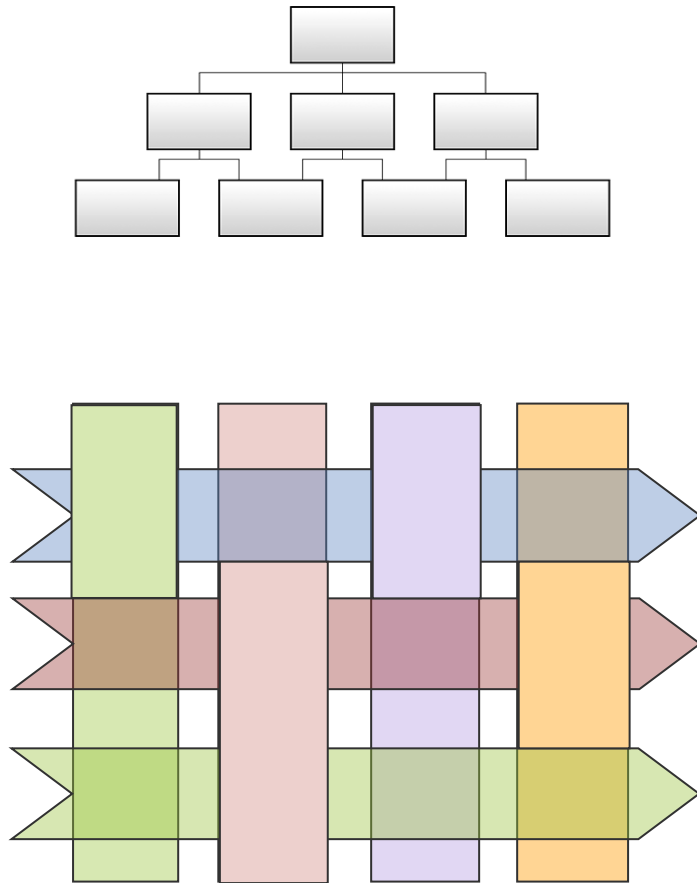
## How do you think it is...



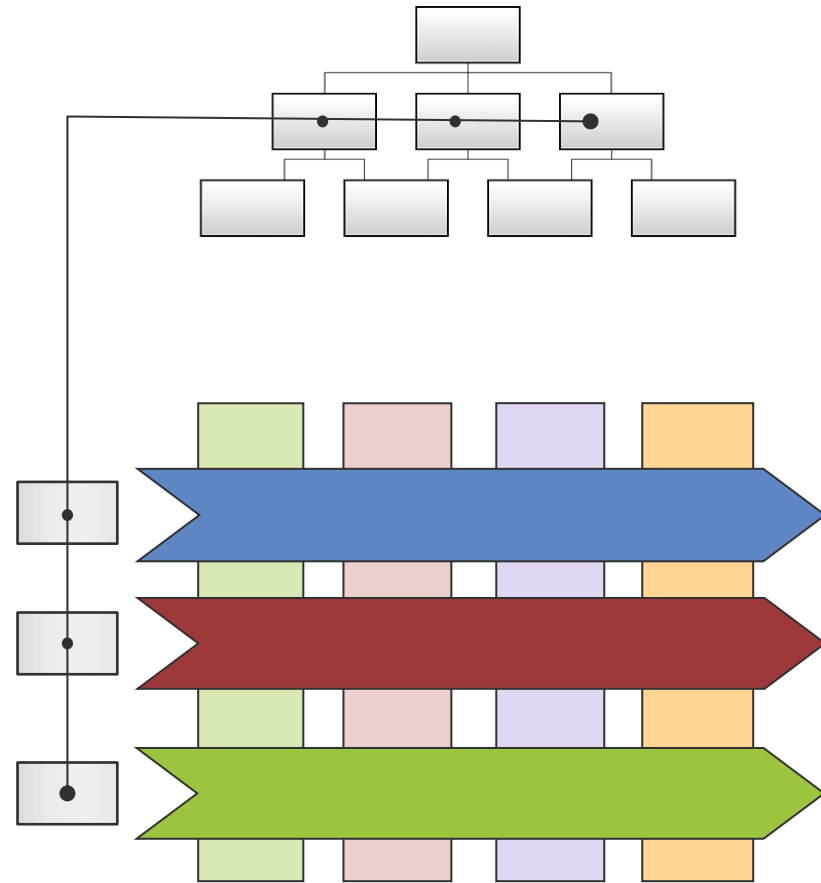
## How it really is...



# Functional – vs process oriented organization



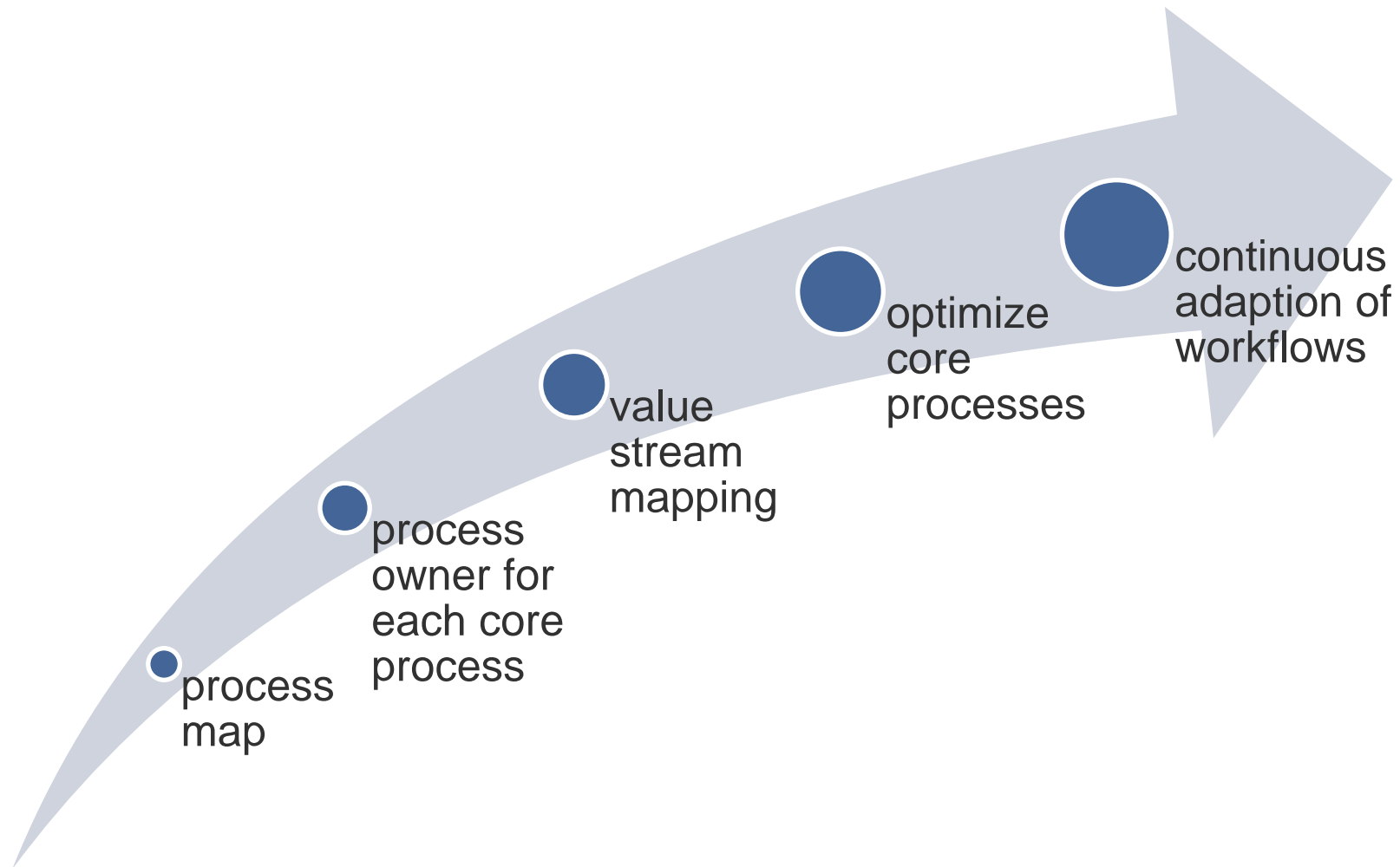
► Functional organization



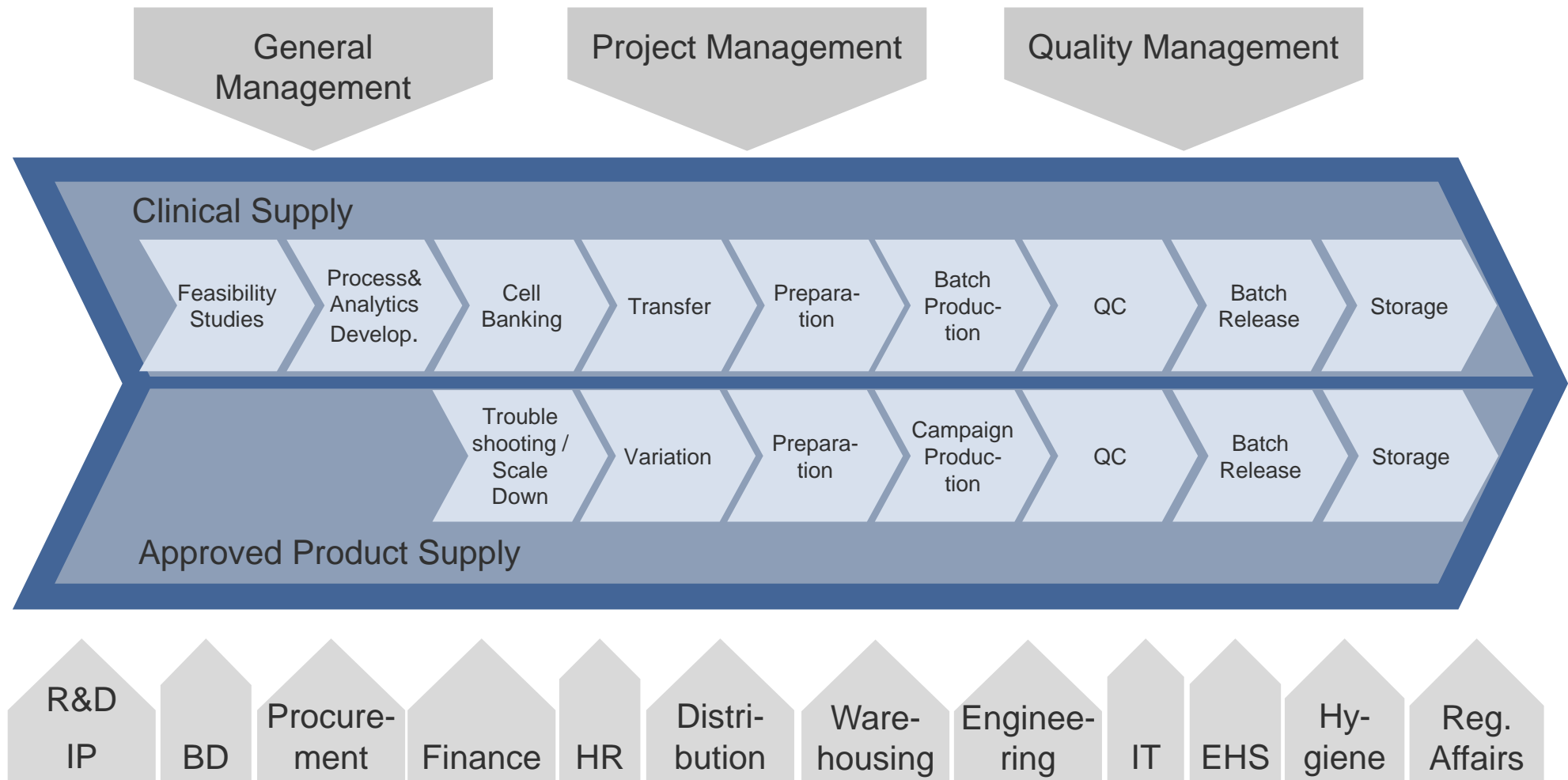
► Process oriented organization

# Steps to a process oriented organization

## ► supported by change management

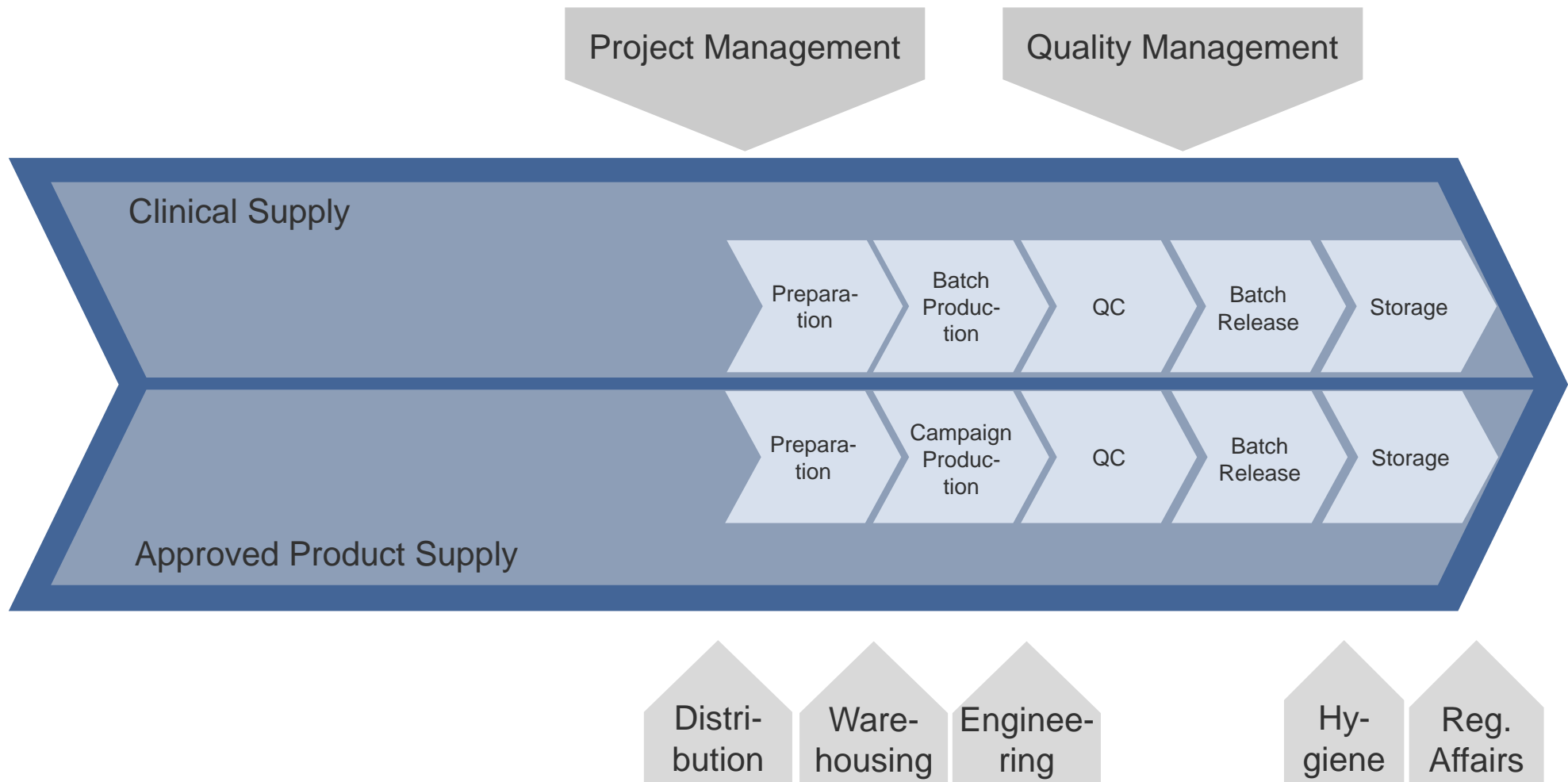


# Process map



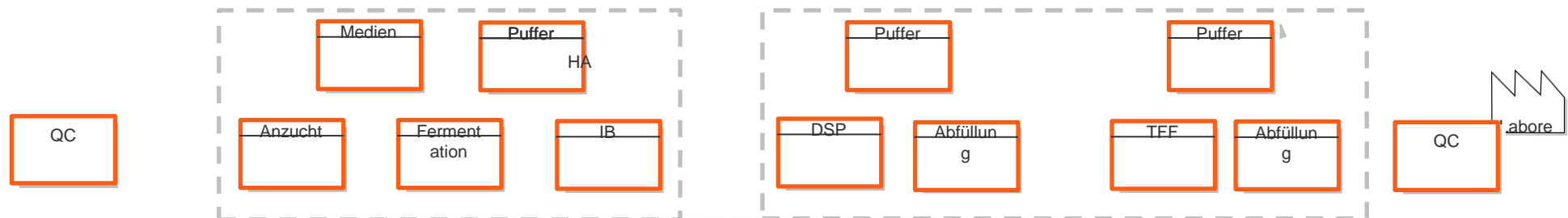


# Value stream mapping of core processes

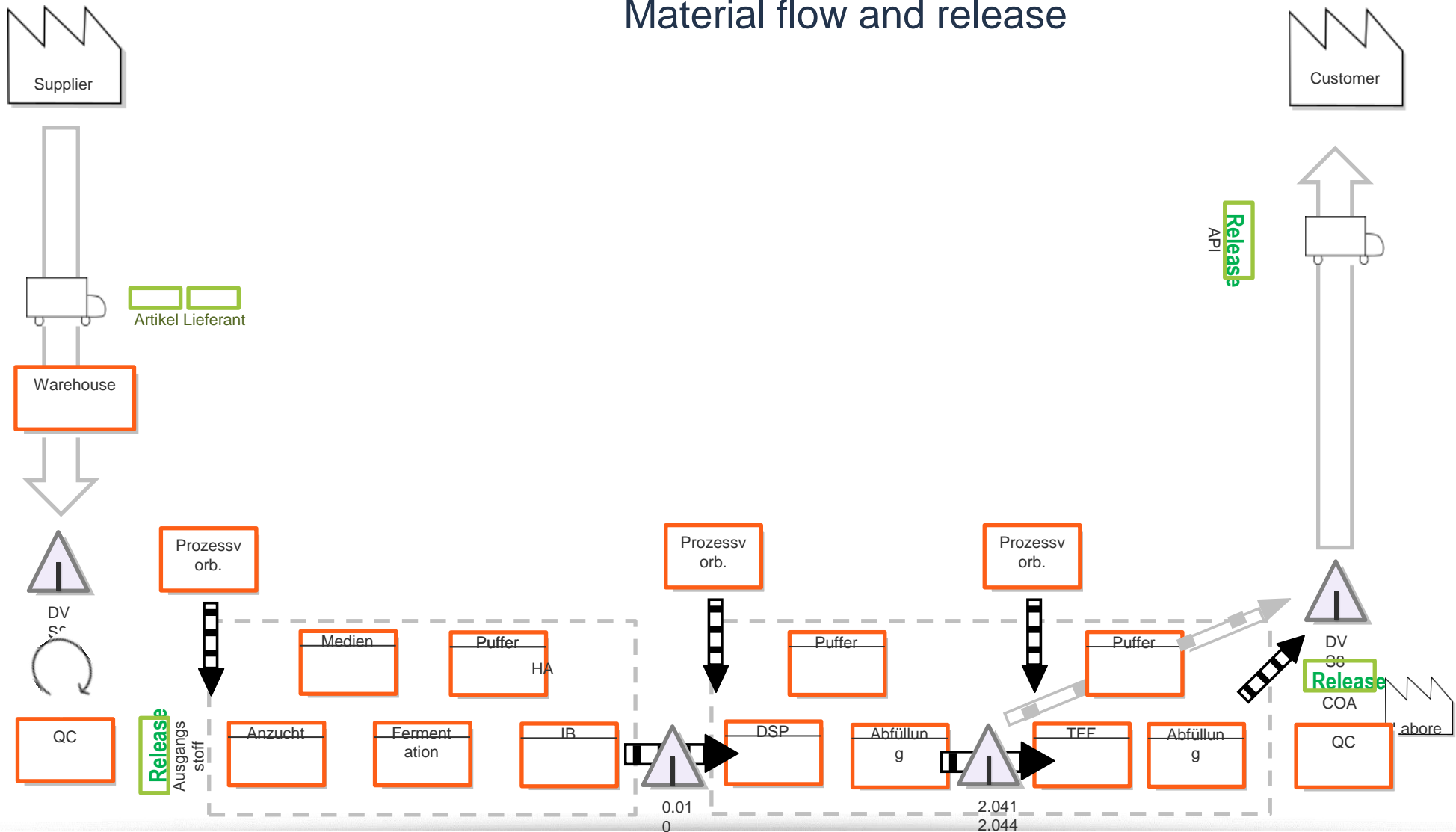




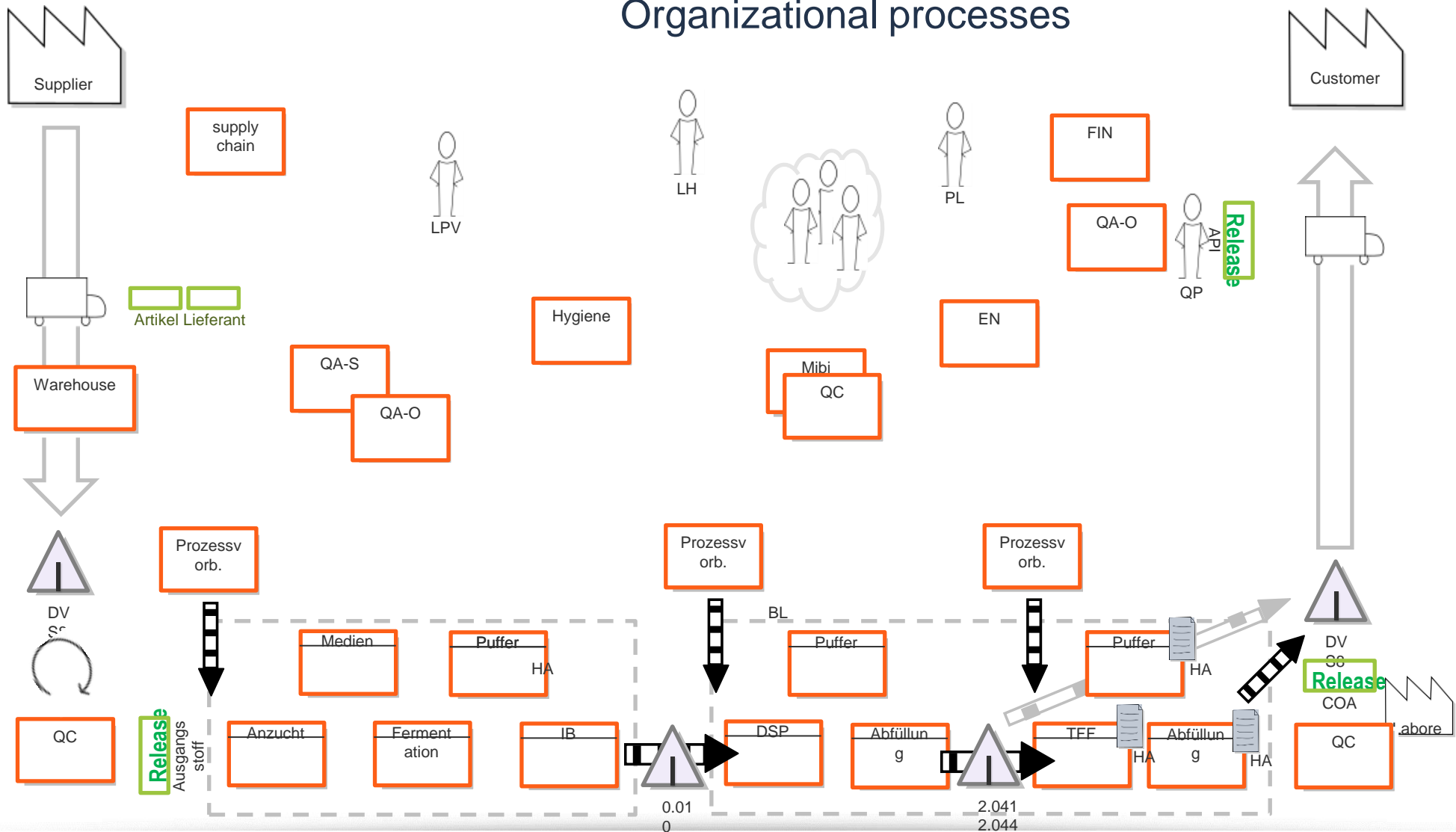
## Production process



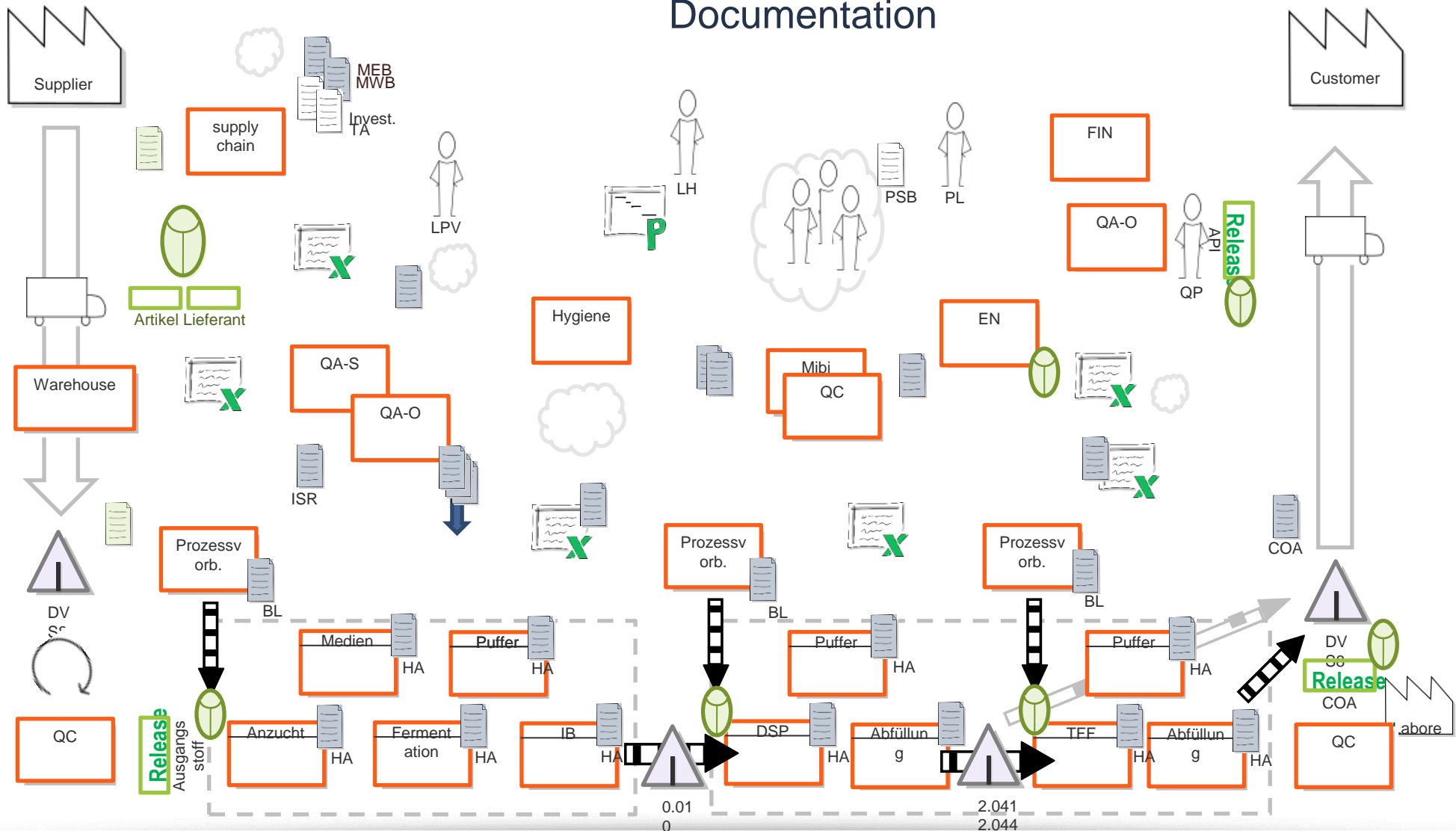
## Material flow and release



# Organizational processes

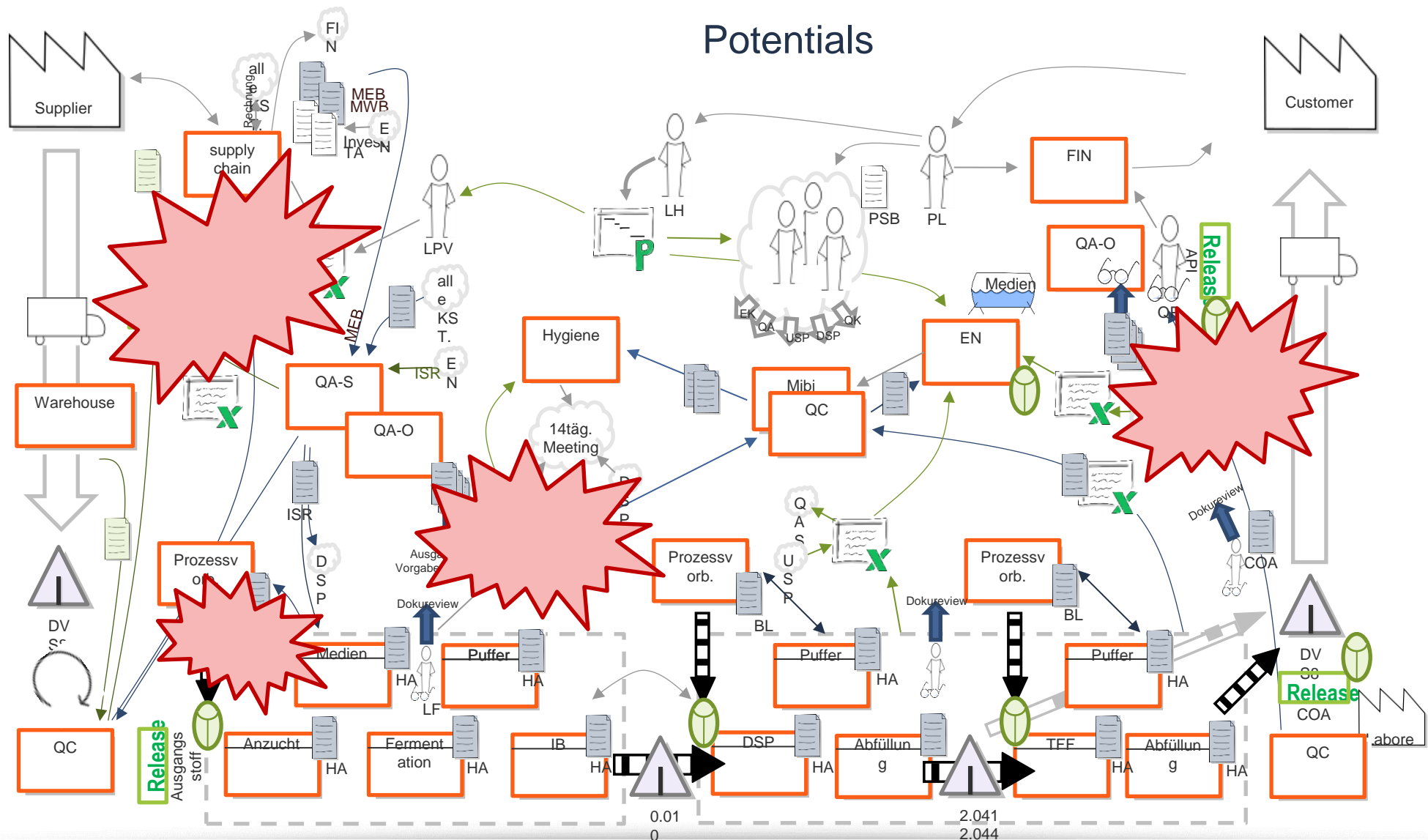


# Documentation









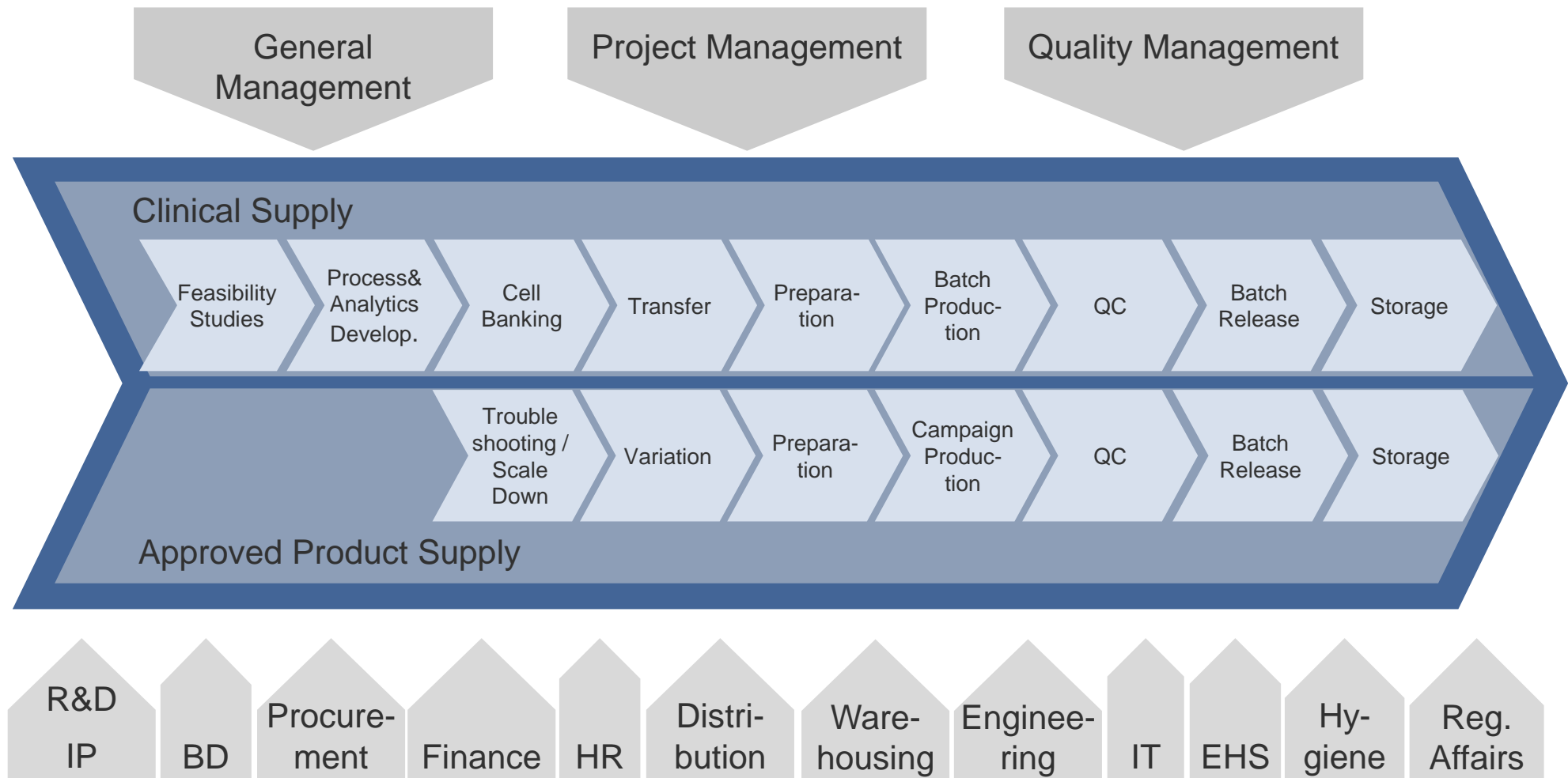
# Results

- ▶ **processes with high potentials were identified – goals can be set more easily**
- ▶ **overview about strengths and weaknesses of the organization**
- ▶ **information about cultural behavior**

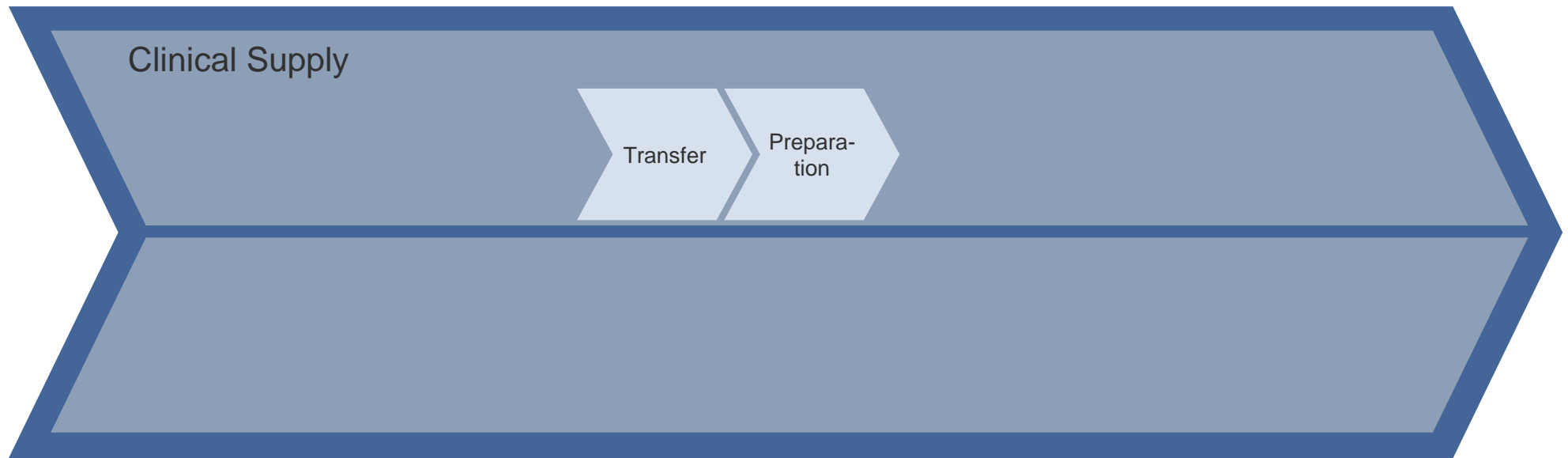


**process owners start optimization projects across departments and sites**

# Optimization of technology transfer



# Optimization of technology transfer



# Optimization of technology transfer - goals

- ▶ **optimization of the whole process across all involved departments and across production sites**

- ▶ **goals:**

offer a efficient and fast technology transfer to our customers of < 15 weeks  
(from start first demonstration run to start first production run)

reduction of working hours of >20%

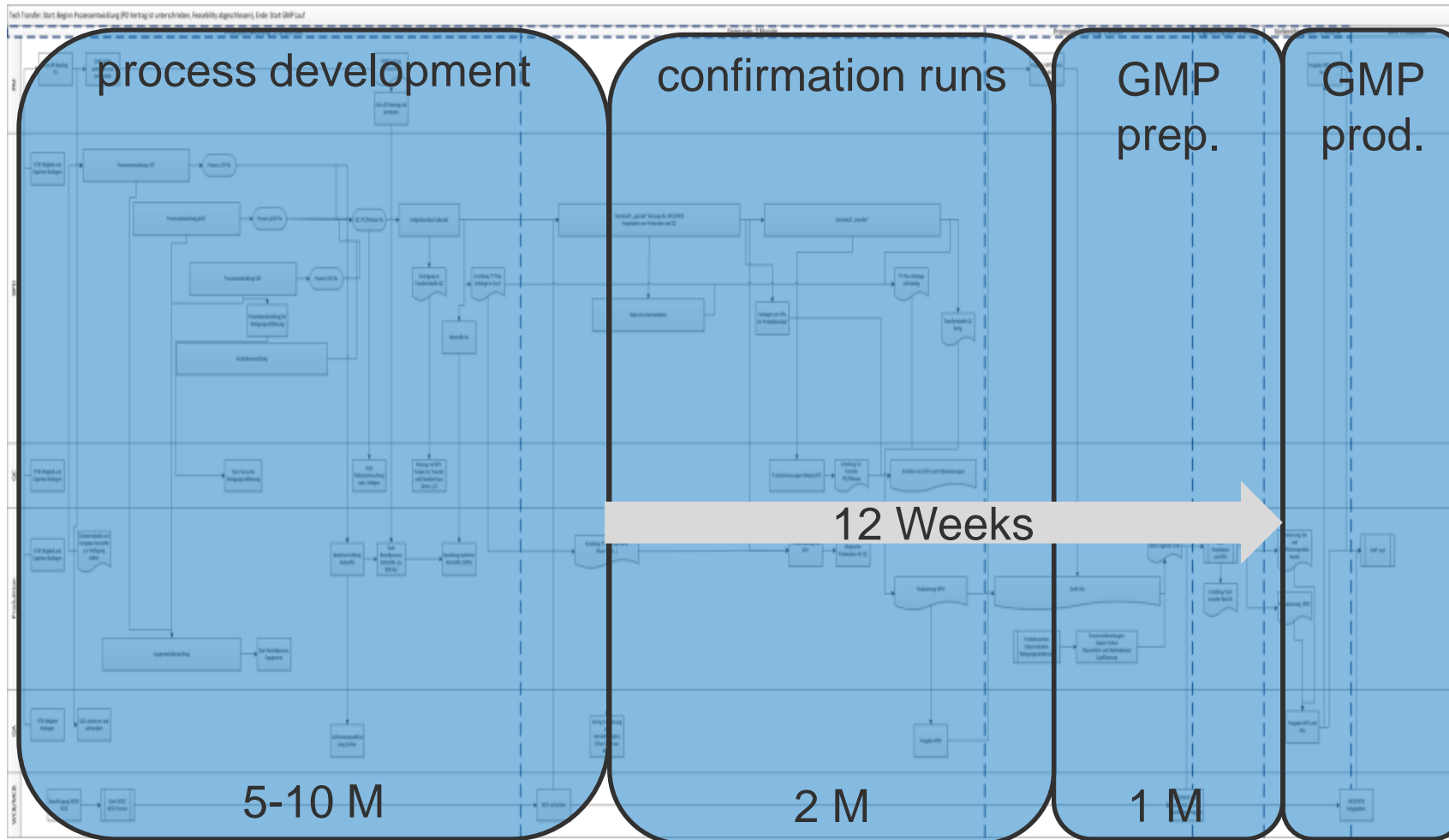
establish one workflow for both production sites

# Workflow before optimization





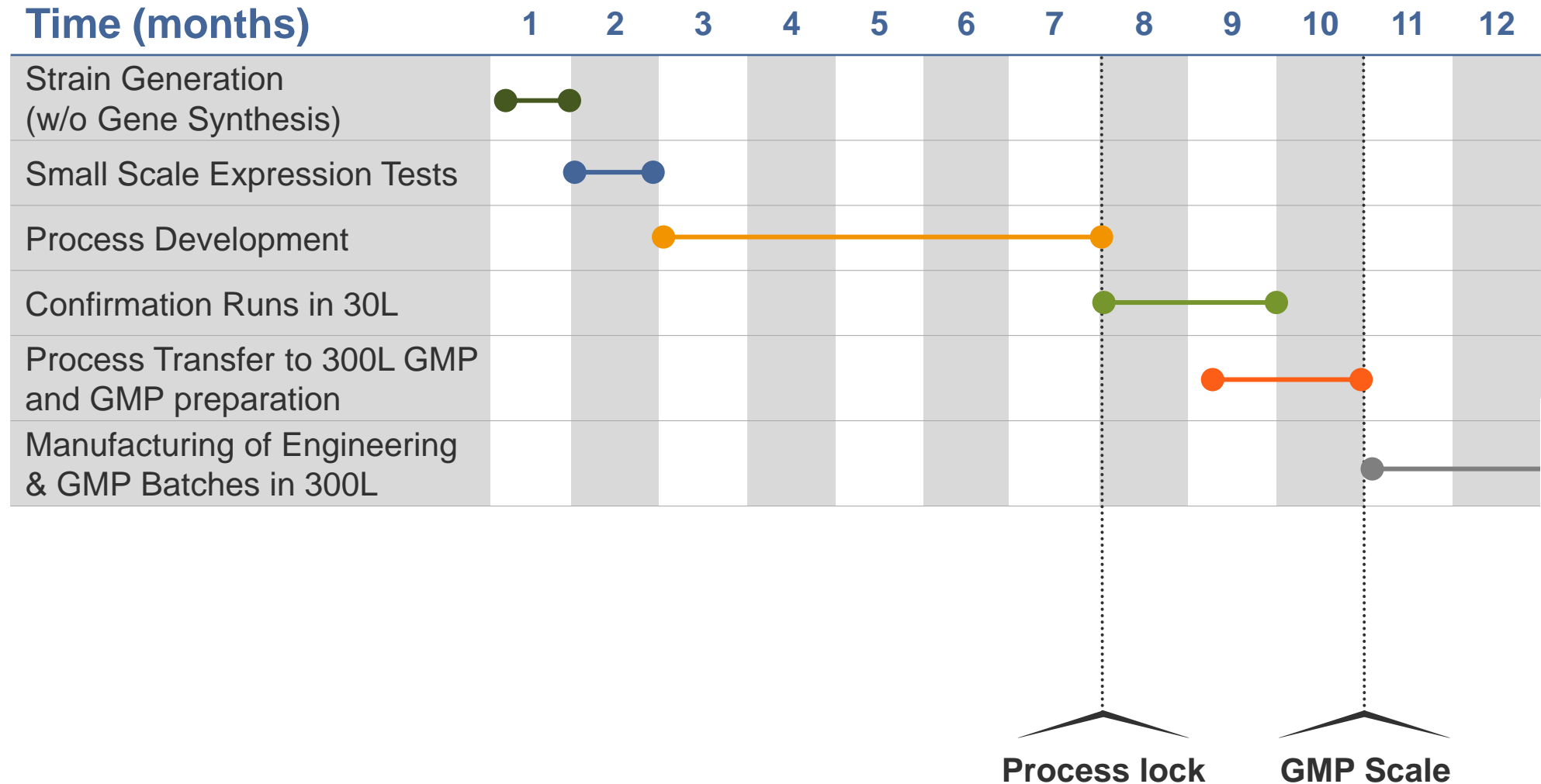
# Workflow after optimization



# Optimization of technology transfer - results

- ▶ reduced working hours of around 20%
- ▶ reduced duration of transfer from 17 weeks to 12 weeks
- ▶ establish one workflow for both production sites
- ▶ people think and act in a more holistic way, increased team thinking
- ▶ people became more creative to find simple solutions
- ▶ less stressed people

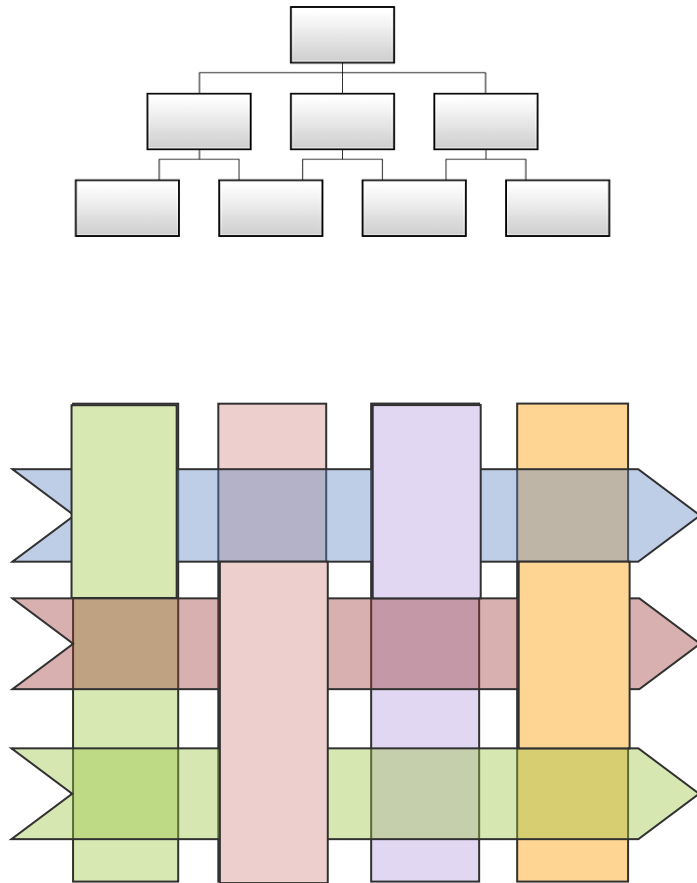
# Case Study – 1<sup>st</sup> Successful Customer Project Completed Based on the Optimized Technology Transfer Process



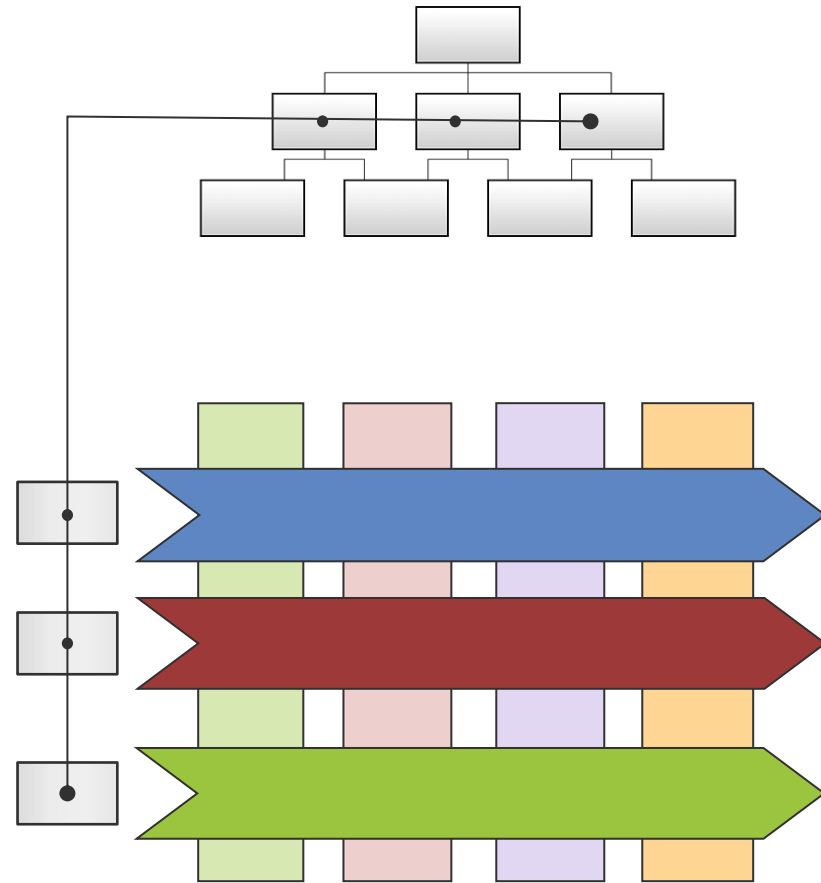
# Conclusion

- ▶ **we can offer efficient processes and sustain flexibility at the same time**
- ▶ **define process owner across departments is a crucial element for success**
- ▶ **employees create the solutions for their workspace – not the department leaders**
- ▶ **to accept continuous changes is a process...**
- ▶ **organization became more responsive to changes**

# Functional – vs process oriented organization



► Functional organization



► Process oriented organization

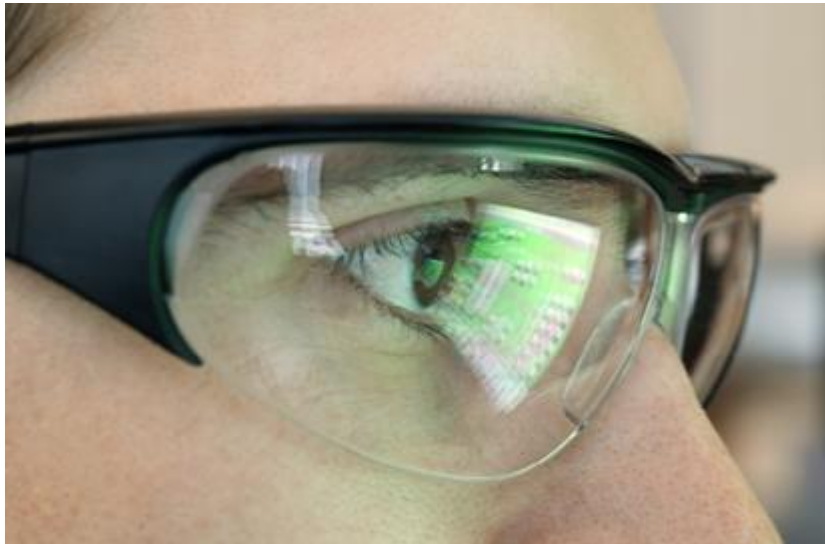
# Functional – vs process oriented organization



► **Functional organization**



► **Process oriented organization**



**THANK YOU FOR YOUR  
ATTENTION**

**Wacker Biotech  
THE MICROBIAL CMO**

*Your partner in  
microbial biologics production*