

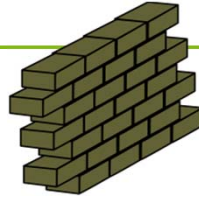
Lean Manufacturing in Pharma – new mindset for operational excellence

Dr. Ing. Frank Ellerkmann – Production Logistics



Status Quo: Guiding principles in the pharmaceutical production

- Protected market
- Independent of business cycle
- Taking advantage of economies of scale
- Campaign building
- Multi-Purpose-operation



Fixed structures

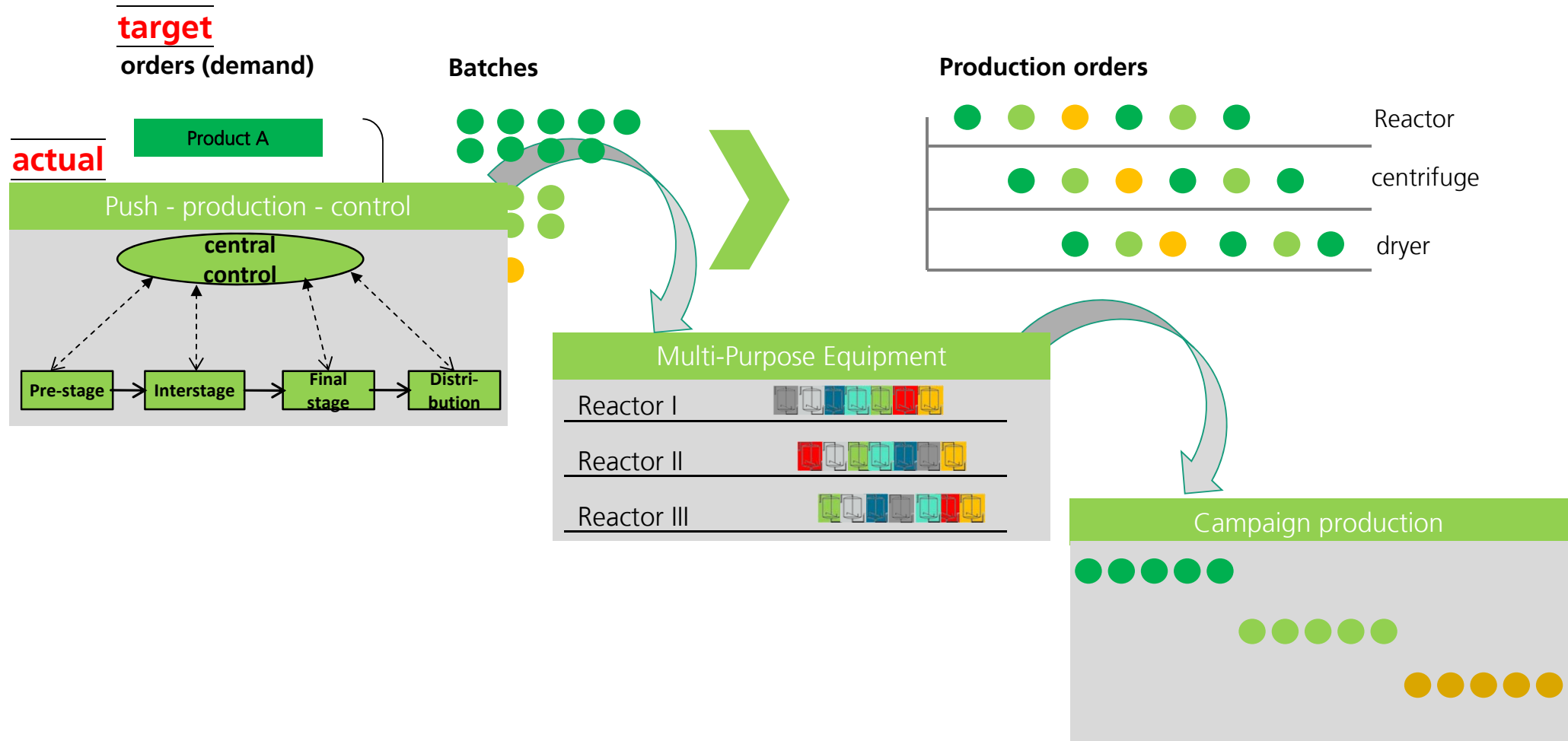
Batch & Queue production



- Large stocks throughout the whole supply chain
 - Long throughput times
 - Supply availability dearly bought through large stocks
- no solutions for future challenges**

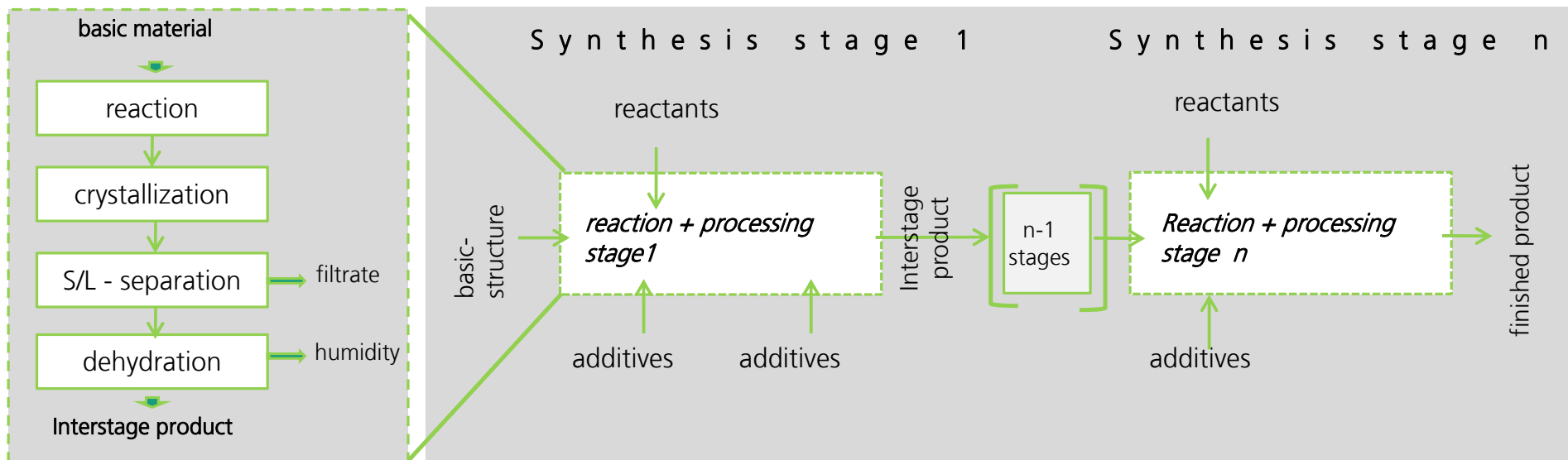


Production Planning in the production of active ingredients

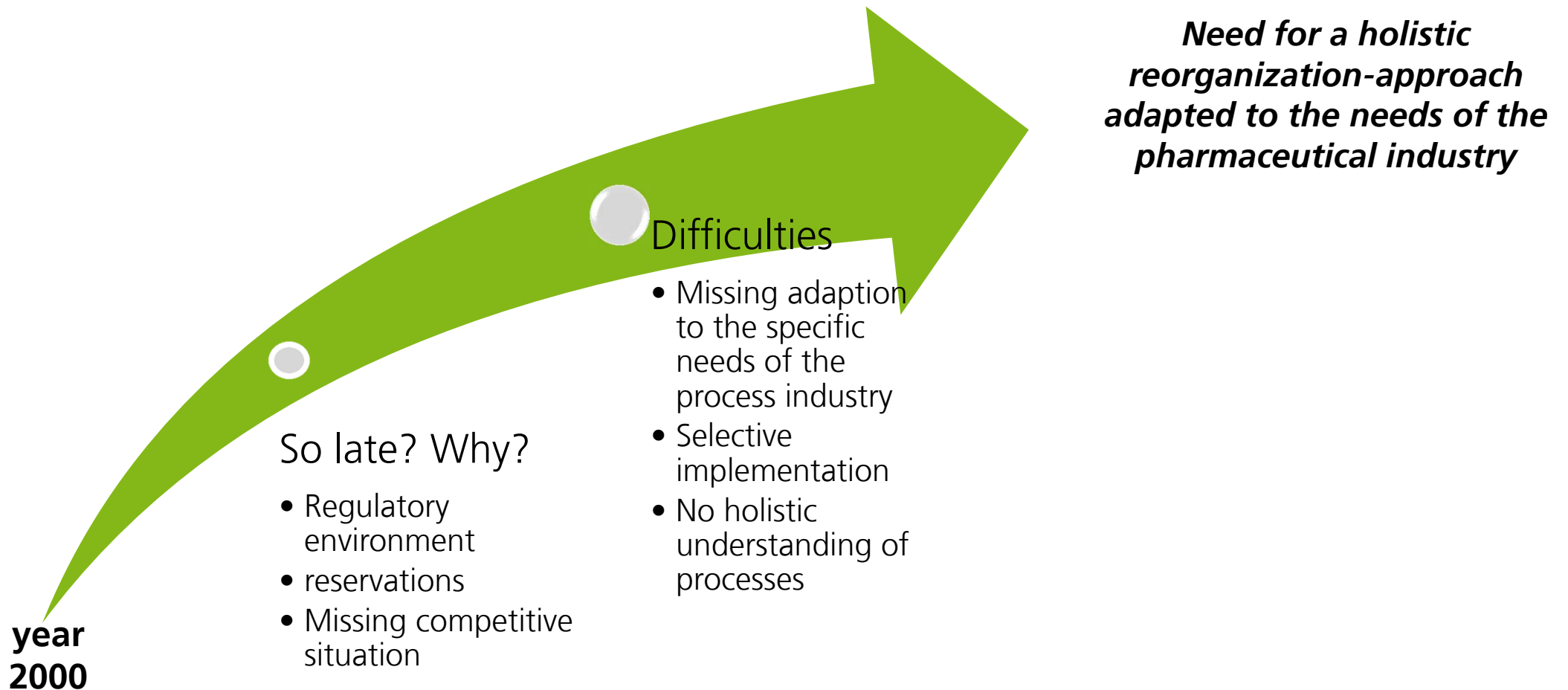


Procedure of active ingredients production

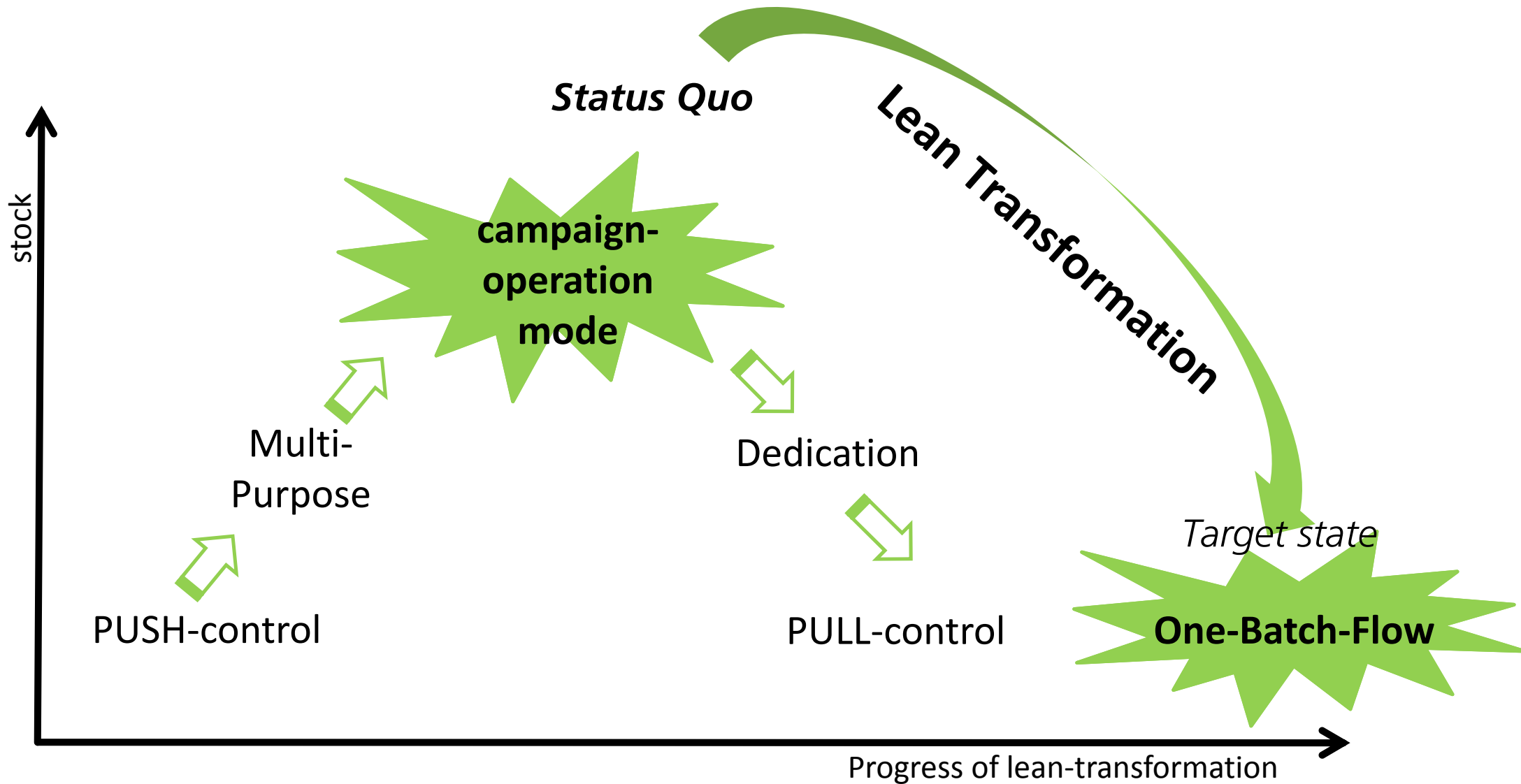
- Multi-stage syntheses following the batch-process
- Non-discrete production units
- Chemical reactions and procedural processing
- Divergent value streams
- Specific boundary conditions (GMP, HSE)



State of the technology: Lean Pharma



Operational Excellence through decomposition of existing structures



Overview: Lean Transformation in the production of active ingredients

Design

- Management Commitment („architect“)
- Optimized flow model
→ **Blueprint**

Standardization

- Standardization, process-orientation & lean thinking as the basis for improvement
→ **Basement**

Stabilization

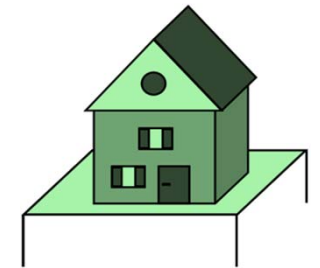
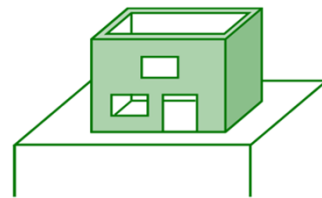
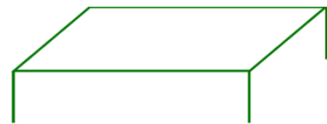
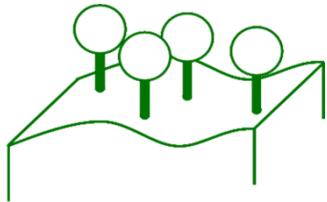
- Robust & efficient processes/facilities – developed in improvement cycles
→ **Walls**

Flow

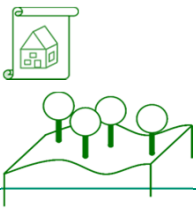
- Synchronized processes & optimal flow enabled by stable frame conditions
→ **Roof**

Perfection

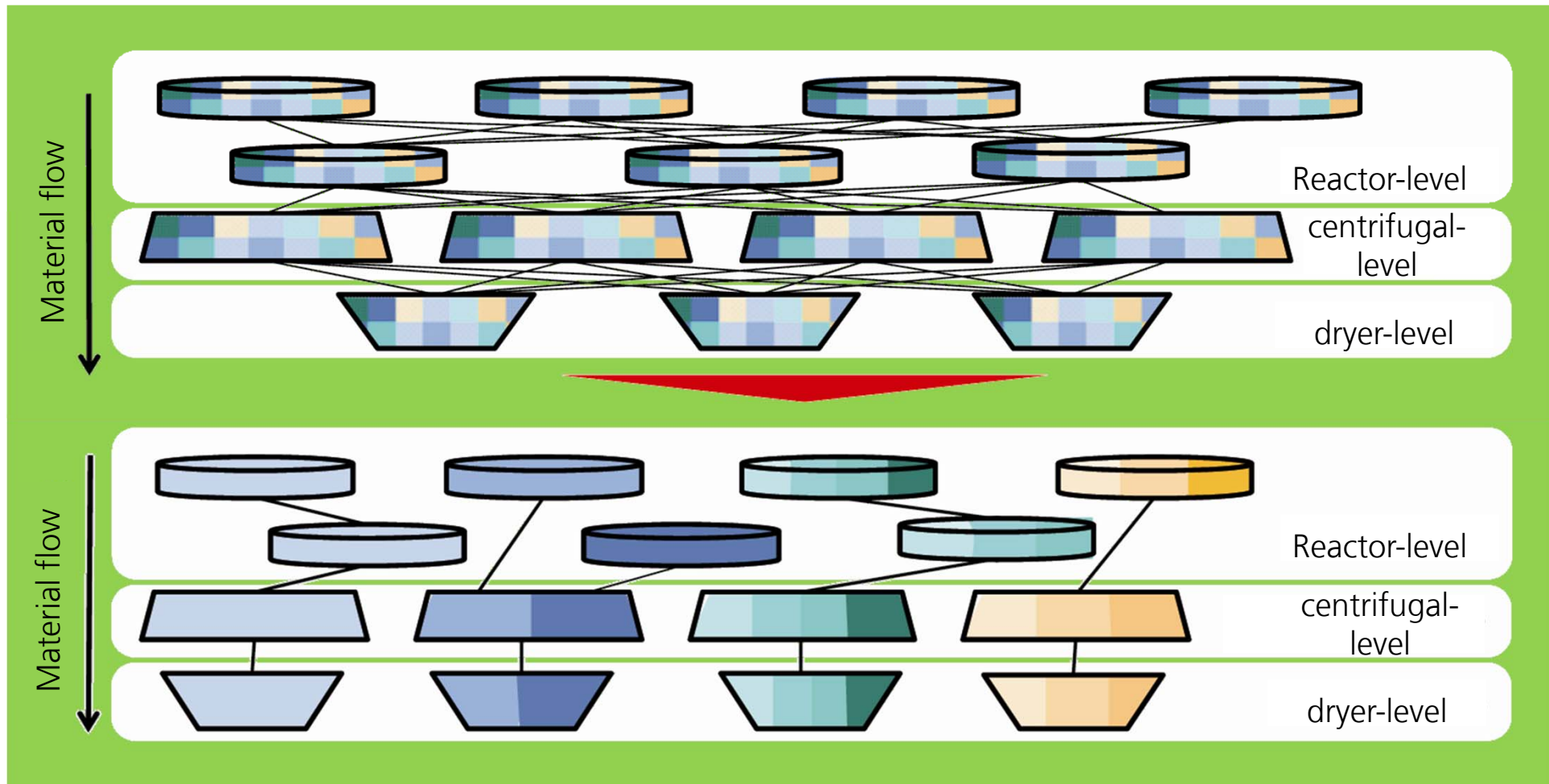
- A learning organization, aspiring towards perfection
→ **Facade**



Monitoring / Change Management / Training

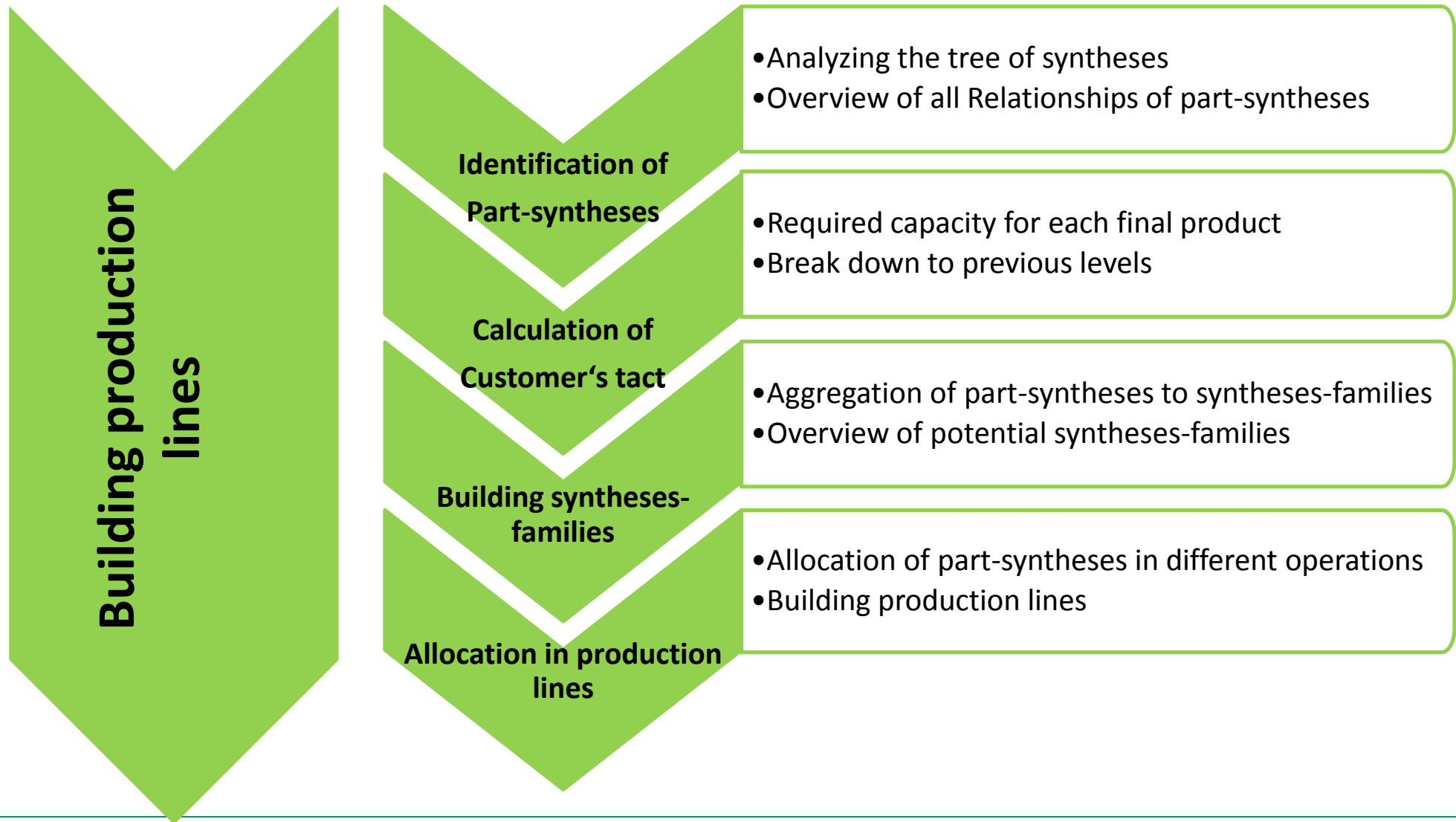


Lean material flow model: Basis Dedication



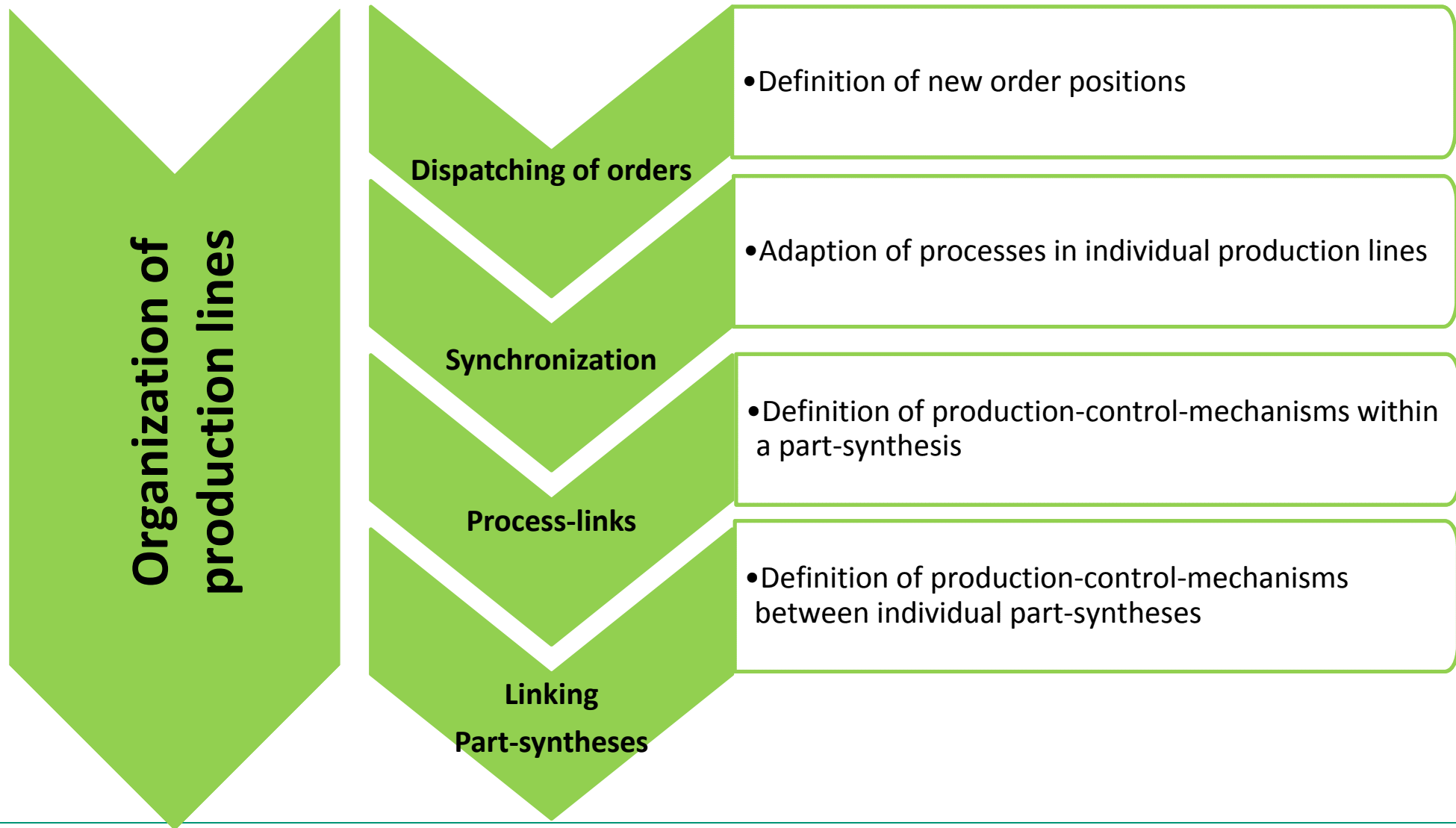


Lean material flow model: Building production lines





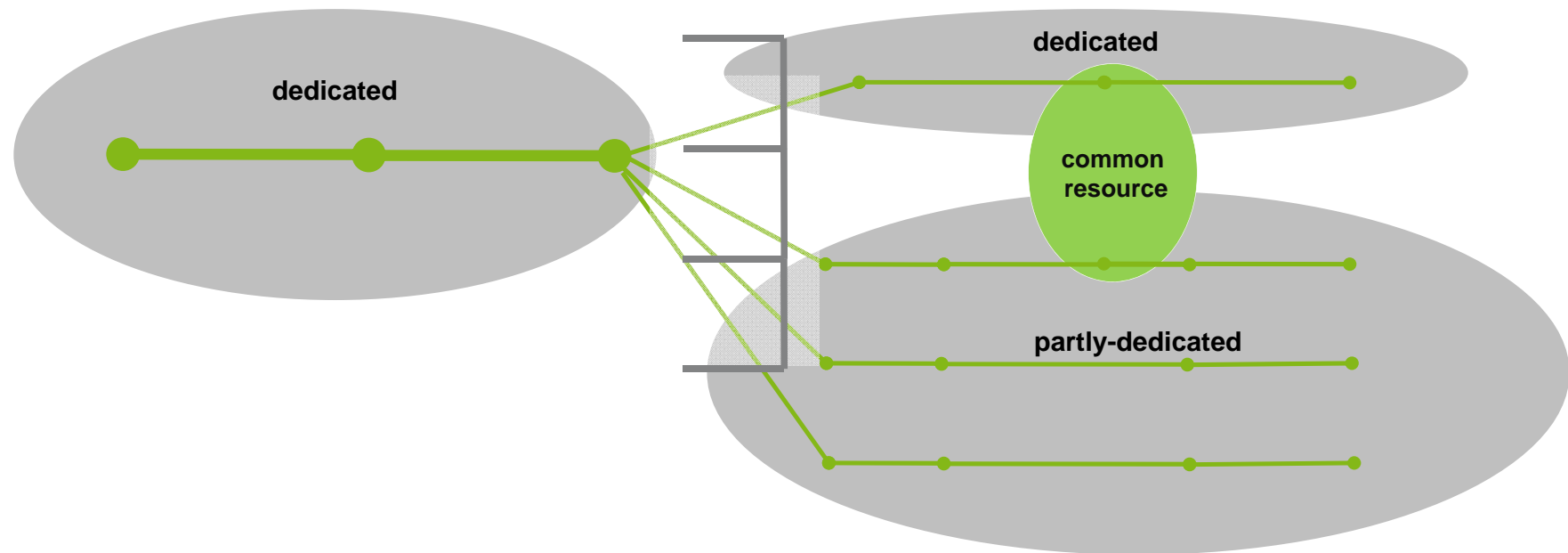
Lean material flow model: Organization of production lines





Lean material flow model: production lines

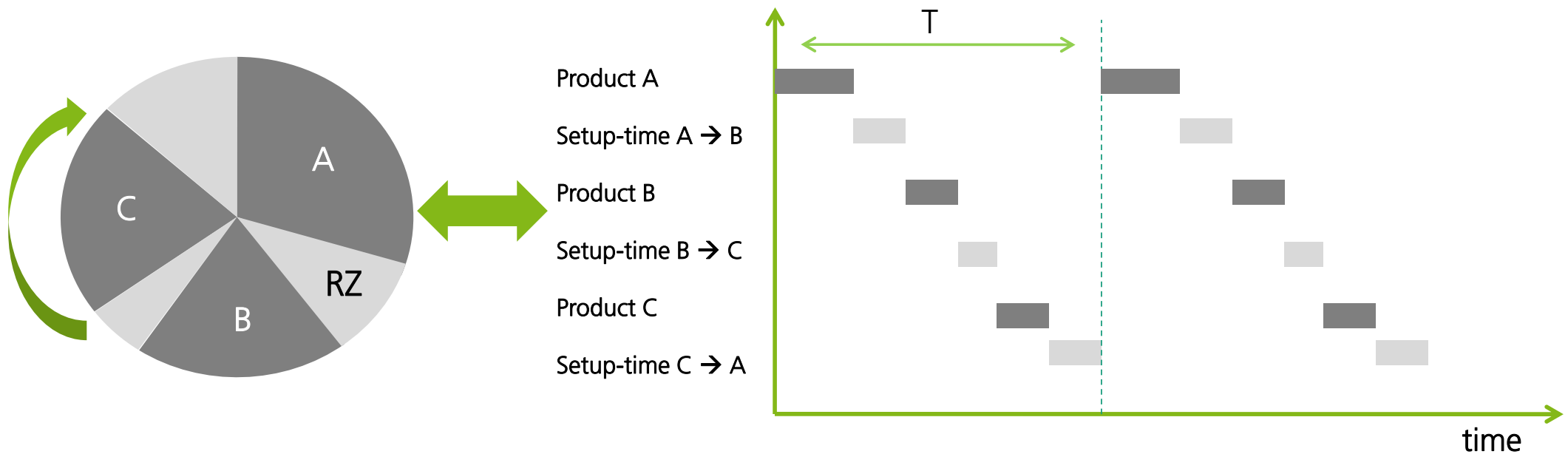
- Production lines originate by assigning all (main-) processes to one of three categories:
 - dedicated line
 - Partly-dedicated line
 - Common resources





Lean material flow model: Design element production-wheel

- Production-wheel includes the time-based capacity of a setup-time-optimized sequence in a production line
- Basic principle: fixed sequence with variable timeframe
- Advantages: reproducibility & transparency

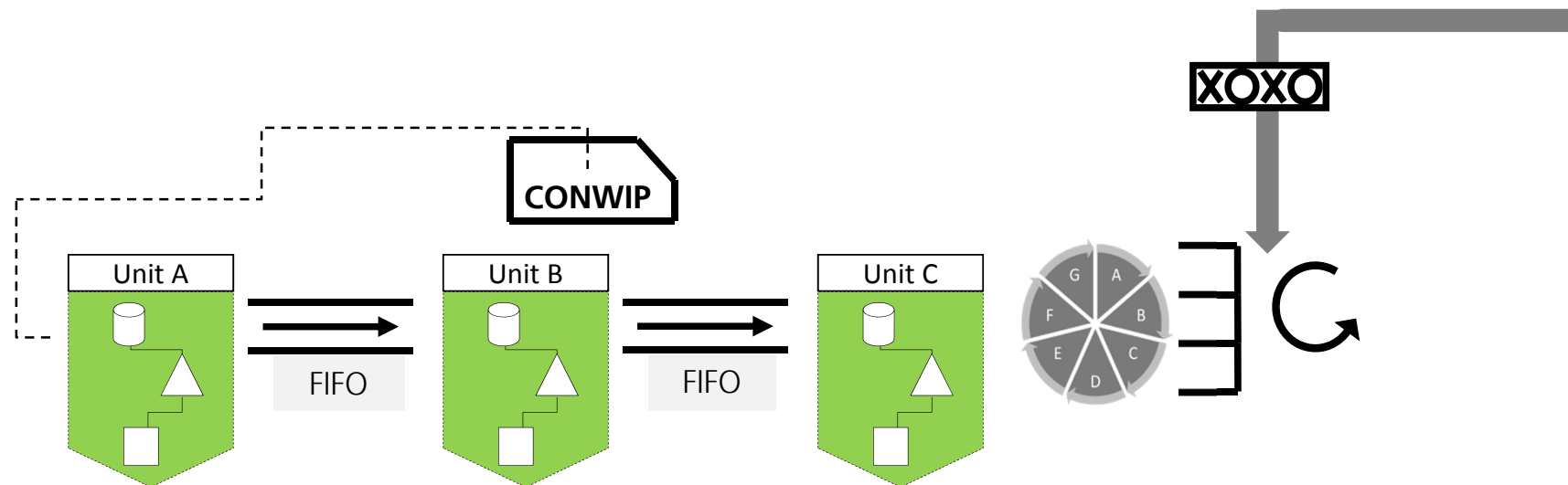




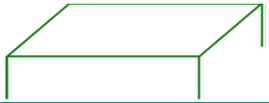
Lean material flow model: Characteristics of production lines

Advantages of a tacted production line

- Decentralized control of all processes (→ minimized controlling efforts)
- Limited inventory buffers (→ avoidance of overproduction)
- Setup-time-optimized sequence(→ stability as the basis of improvements)

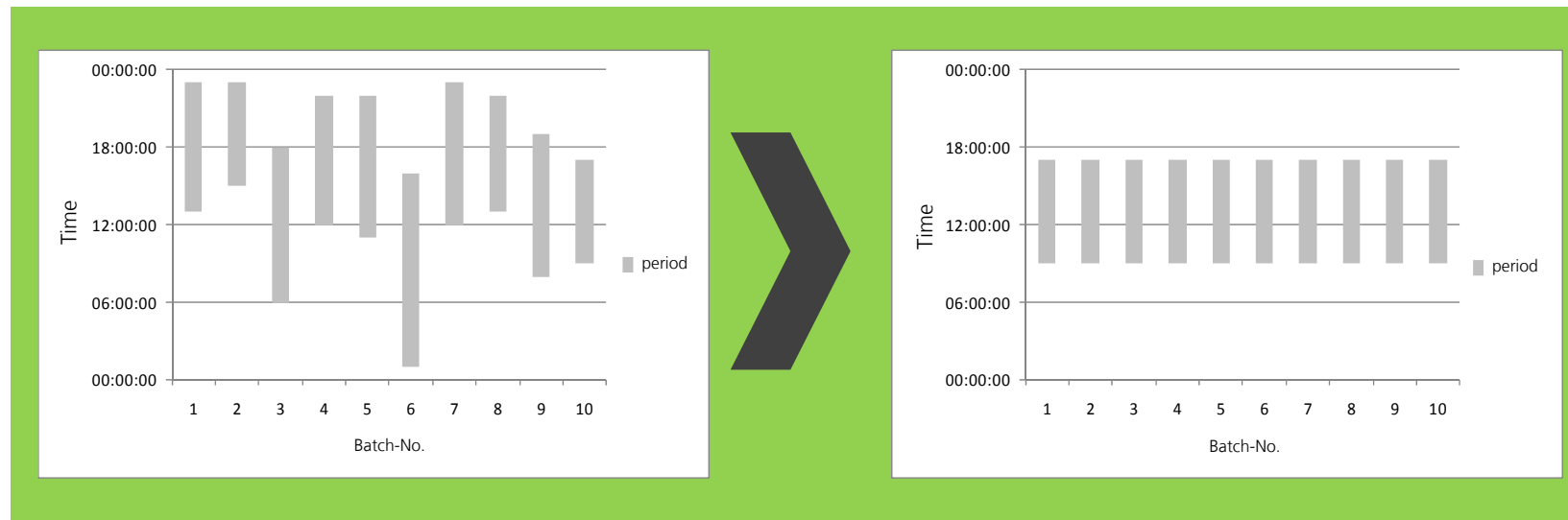


Standardization based on production lines



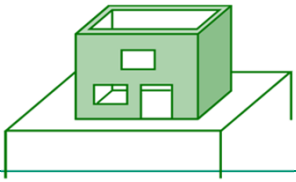
Standardized material supply

Standard work schedules



5S

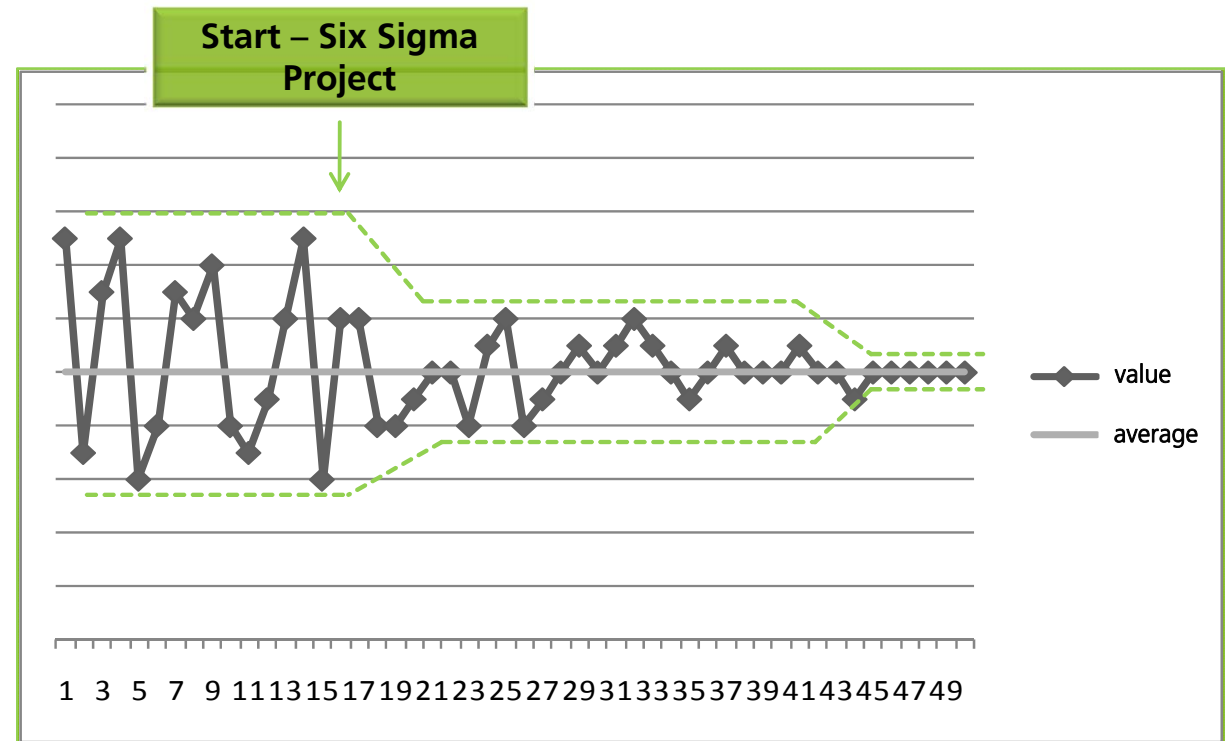
Visual Management



Stabilization based on production lines

Six Sigma as a method of lean transformation

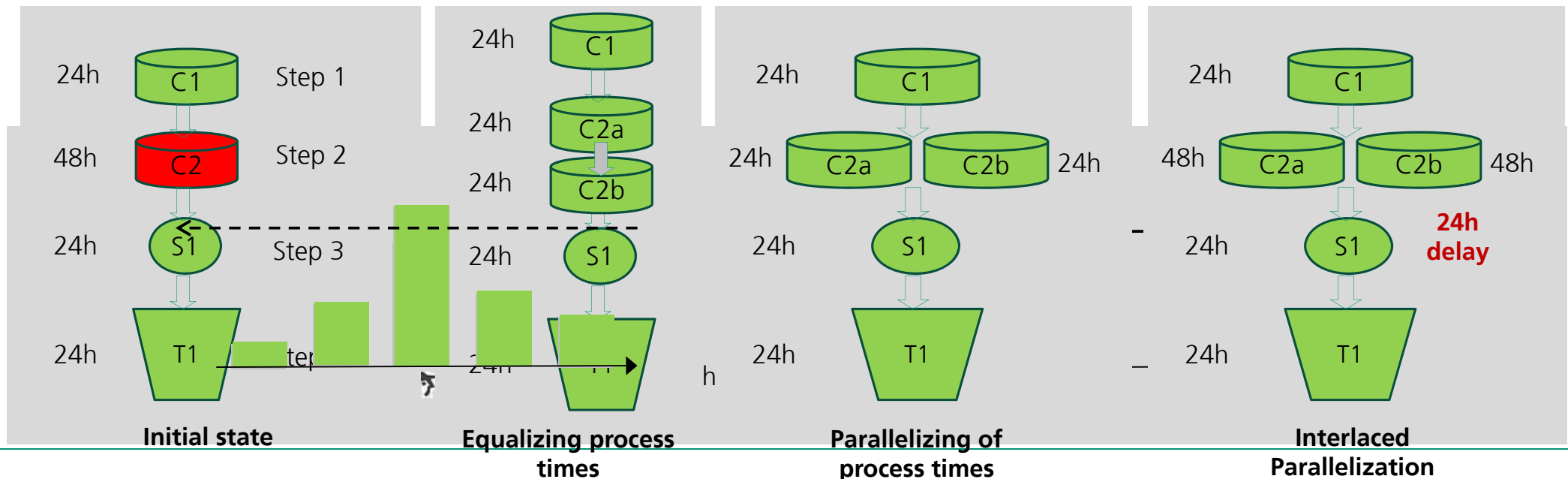
- Examples for objects of investigation
 - Active ingredient concentration within a batch
 - Weight of batch after drying
 - Process-duration
 - Percentage of Contamination
 - ...





Compensation of different cycle times in production lines

- conventional compensation of different cycle times (shifting of work contents) is hindered by:
 - No direct connection between employees and cycle time
 - Validated process
 - Reaction kinetics in close process-borders
- **consequently: development of pharmaceutical-specific solutions**

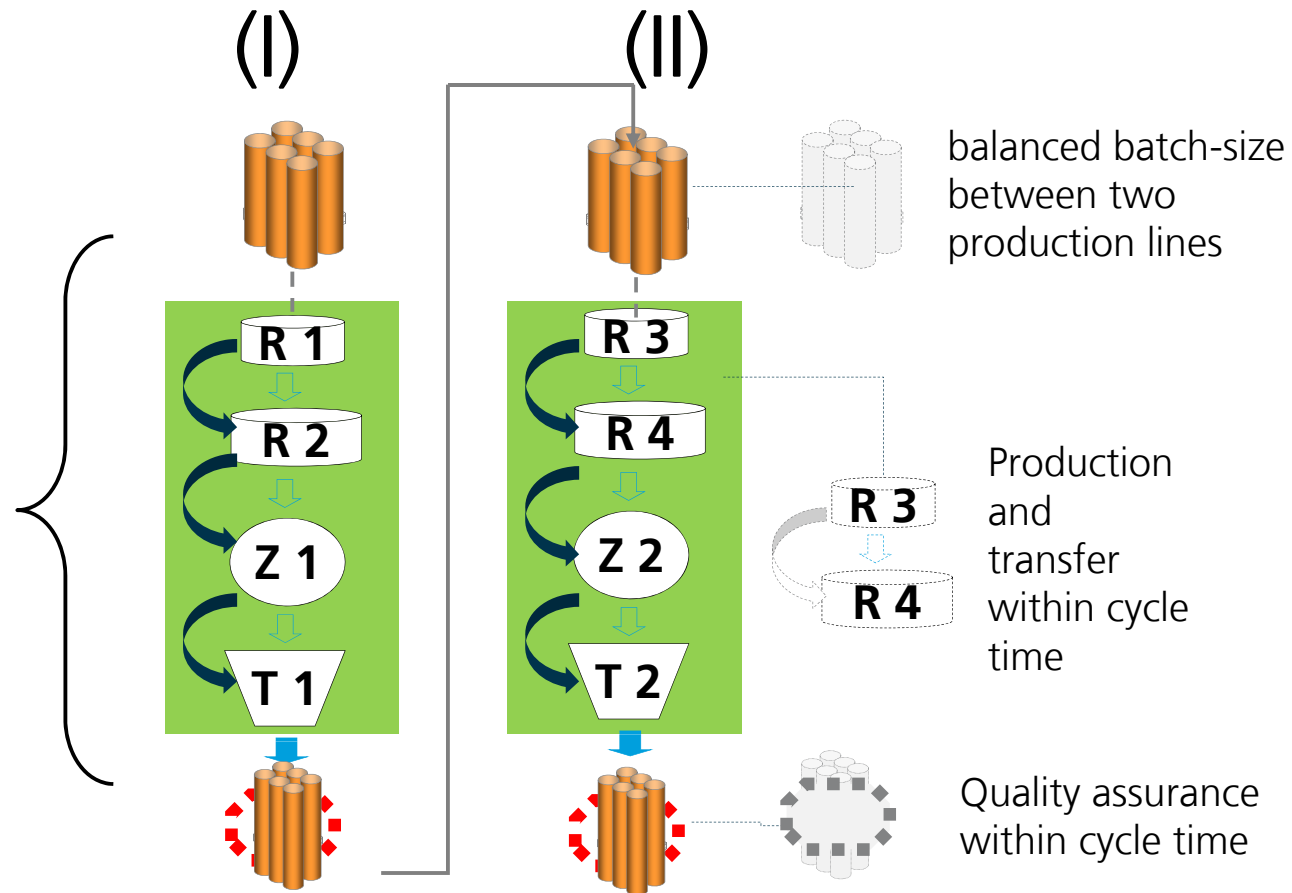


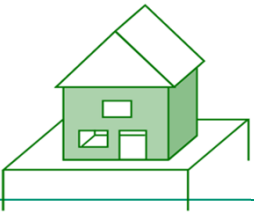


Flow in production lines

Production lines

Equipment

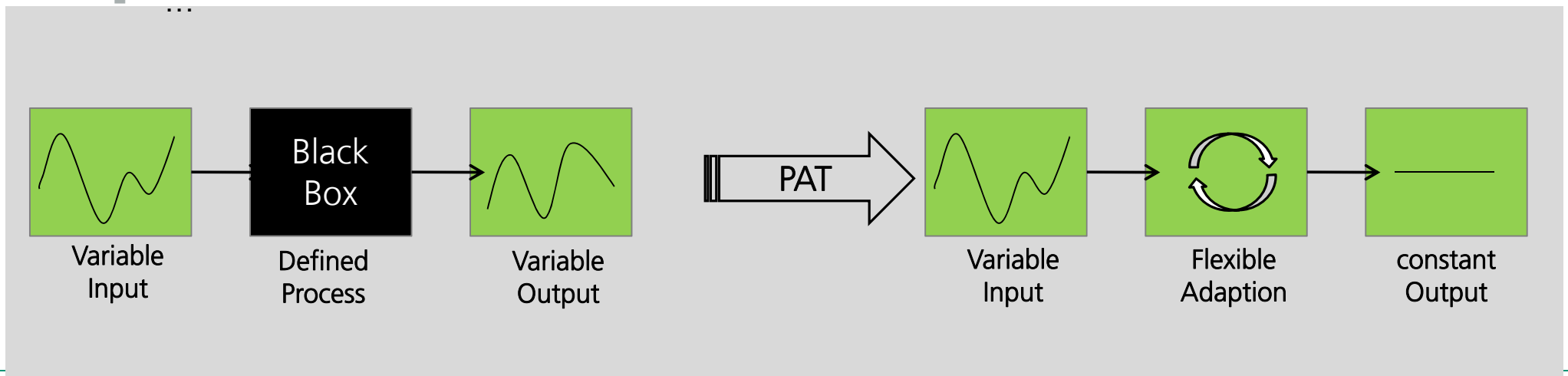


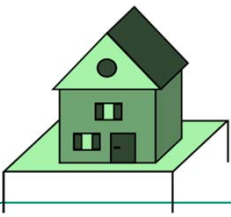


Quality Assurance within flow

■ Measures of the Process Analytical Technology (PAT)

- Quality control throughout the process
- No interruption of value creation through OFFLINE-analytics
- Active process controls
- Parameter of control
 - Degree of transformation
 - Moisture content
 - pH value
 - ...

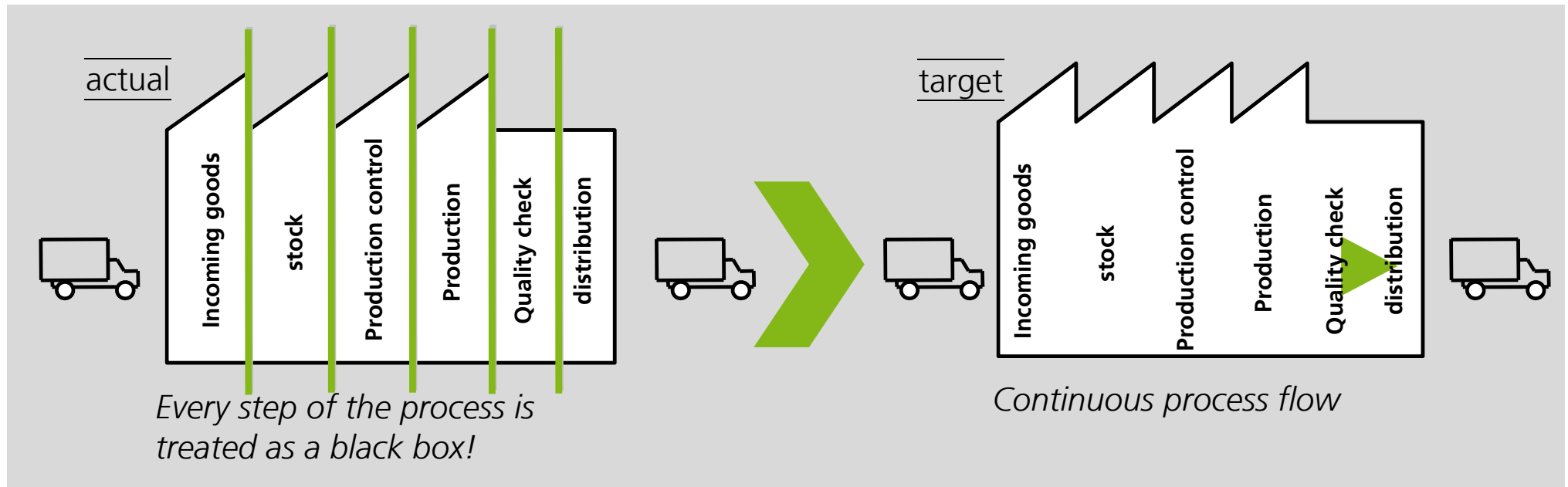




Perfection stage

■ Lean Thinking

- No more thinking in terms of departments
- Corporate aspiring towards a global optimum instead of single solutions
- Process orientation beyond the boundaries of departments





Improving the responsiveness using lean manufacturing



Setting

- Overall cycle times over one year in the production of active pharmaceutical ingredients result in the inability to react to the fluctuating customer demand

Approach

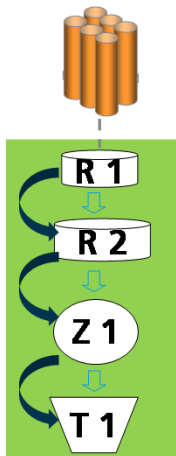
- Reorganization of the material flow
- Revision of the product portfolio
- Dedication of certain production lines to a limited number of products
- Implementation of certain lean methods

Result

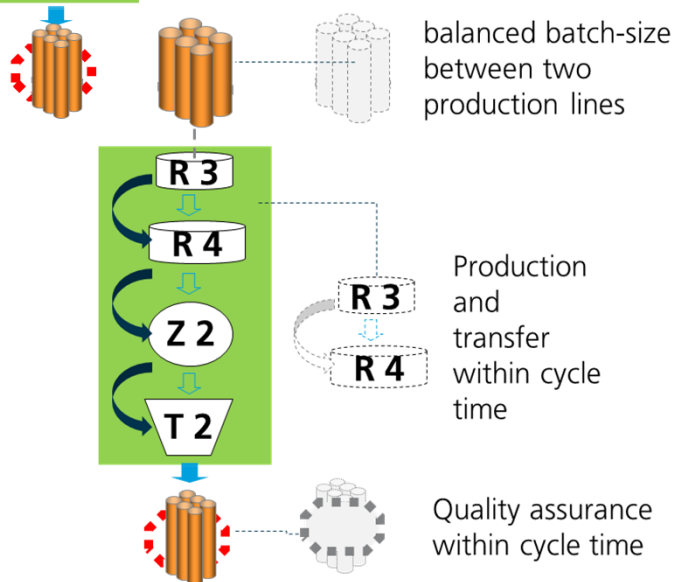
- Decrease of the overall cycle times up to 80%

Goal: Reduction of leadtimes from 350 days to < 50 days

(I)



(II)

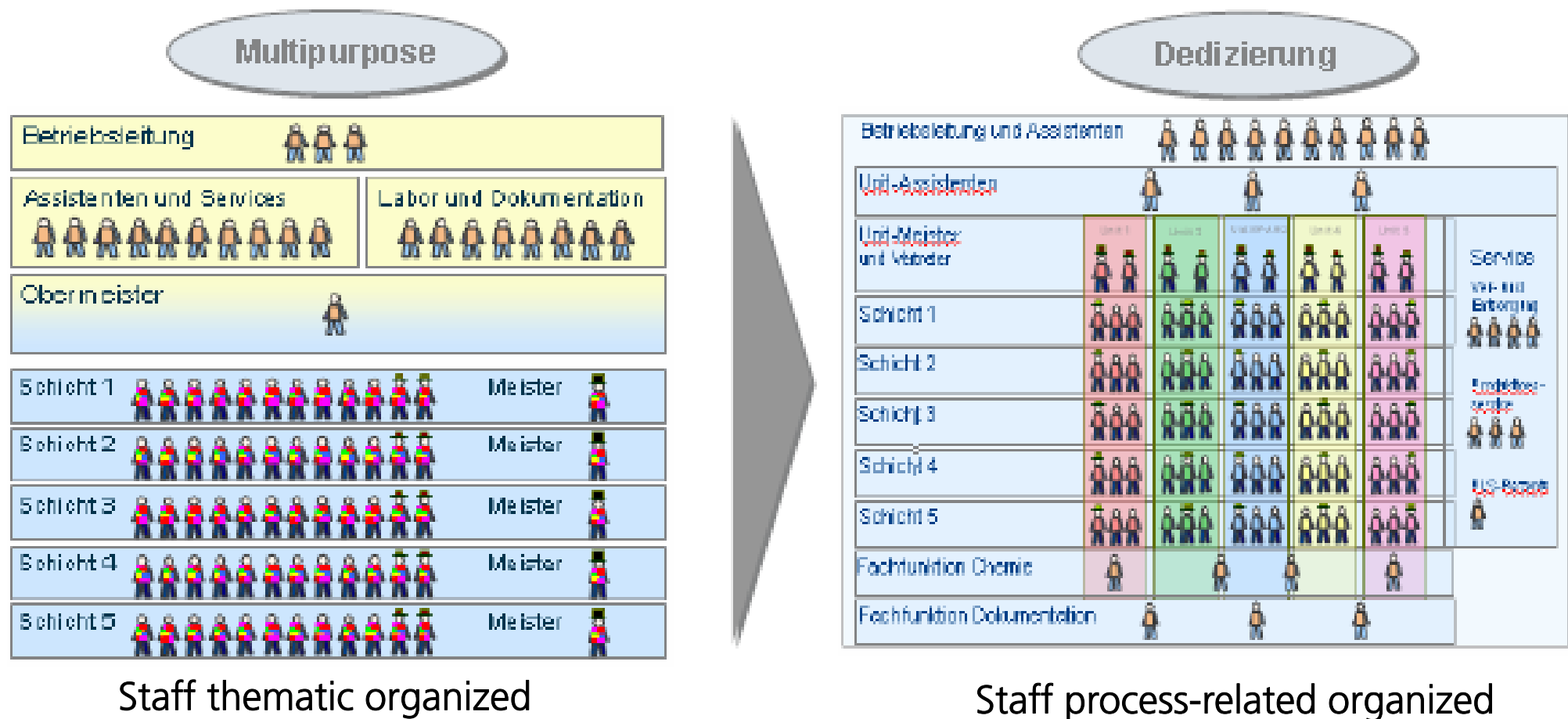


Elements out of the Lean-toolbox

- Changing from multi purpose to dedicated facilities in fixed units
- Valuestreams for the whole process and also for the single steps have been analysed
- Adjustment of the chemical engineering and the staff requirements to the dedicated facilities
- ALL operations on the shop floor have been adjusted on the dedicated facilities. All the additional works are defined.
- Demand driven allocation of equipment
- Units are operated by fixed teams (3-4 employees), specialists with defined responsibilities
- Production in takt-time with defined starting time and finishing time

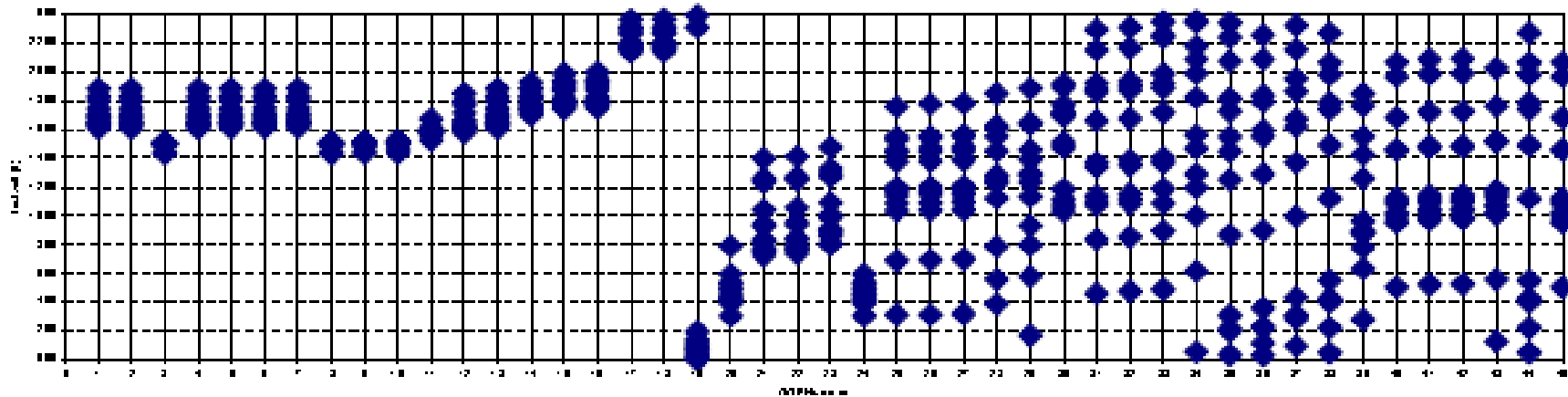
Organisational impacts of Lean

The Change from the former multi purpose production to a dedicated operation mode requires a new plant organisation

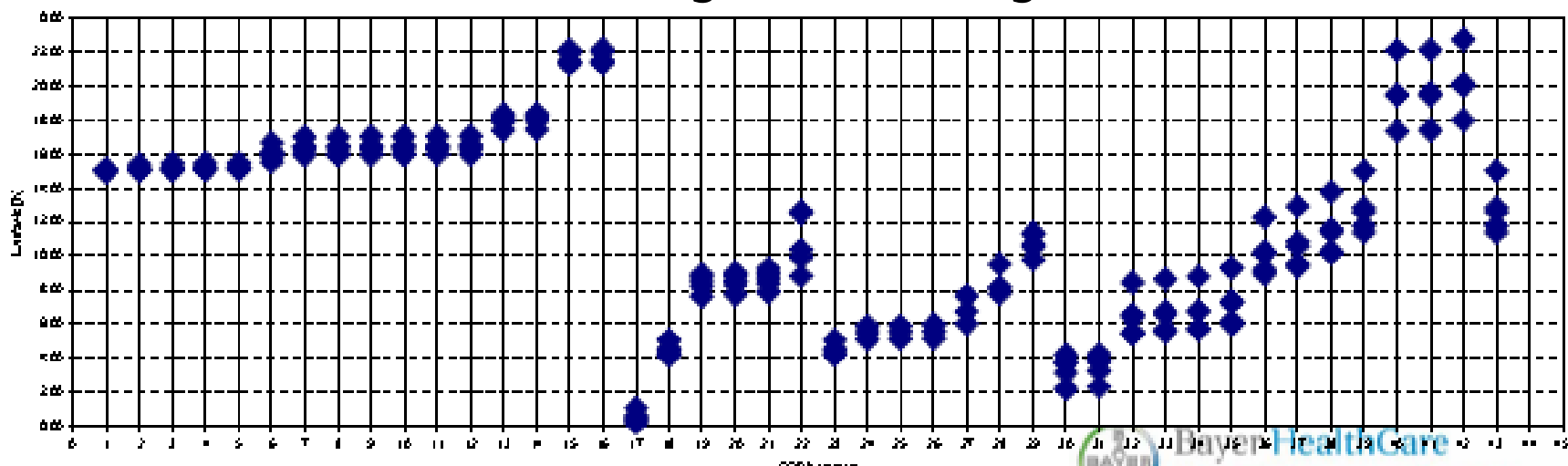


Consequent standardization – Starting times of single operations

Free starting and finishing times



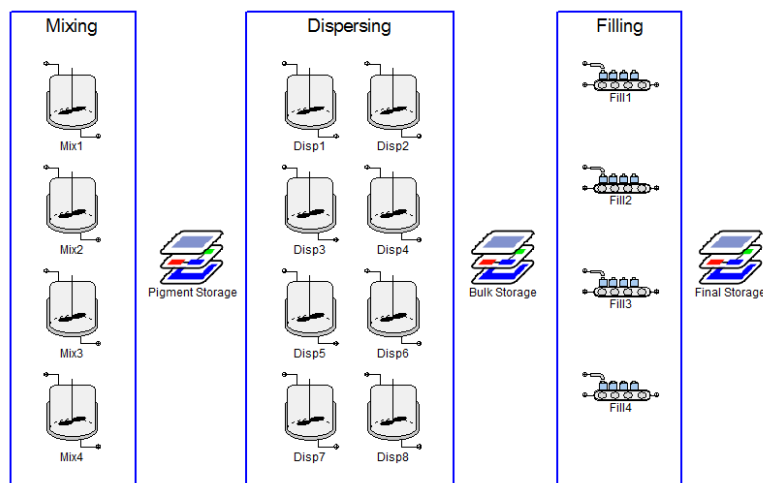
Fixed starting and finishing times



Lean trainings for the process industry



- Management game 1:
Basic principles of Lean Manufacturing
 - Introduction in the principles and methods of a lean production
 - Interactive workouts and experiences of the improvements
- Transferring the methods to the process industry
- Management game 2: Reorganisation of a multi purpose batch production of painting colors via simulation
 - Testing lean principles for the process industry
 - First experiences how to combine and to configure different lean tools



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