Case Study: how to use simulation to design air-locks and storage capacity

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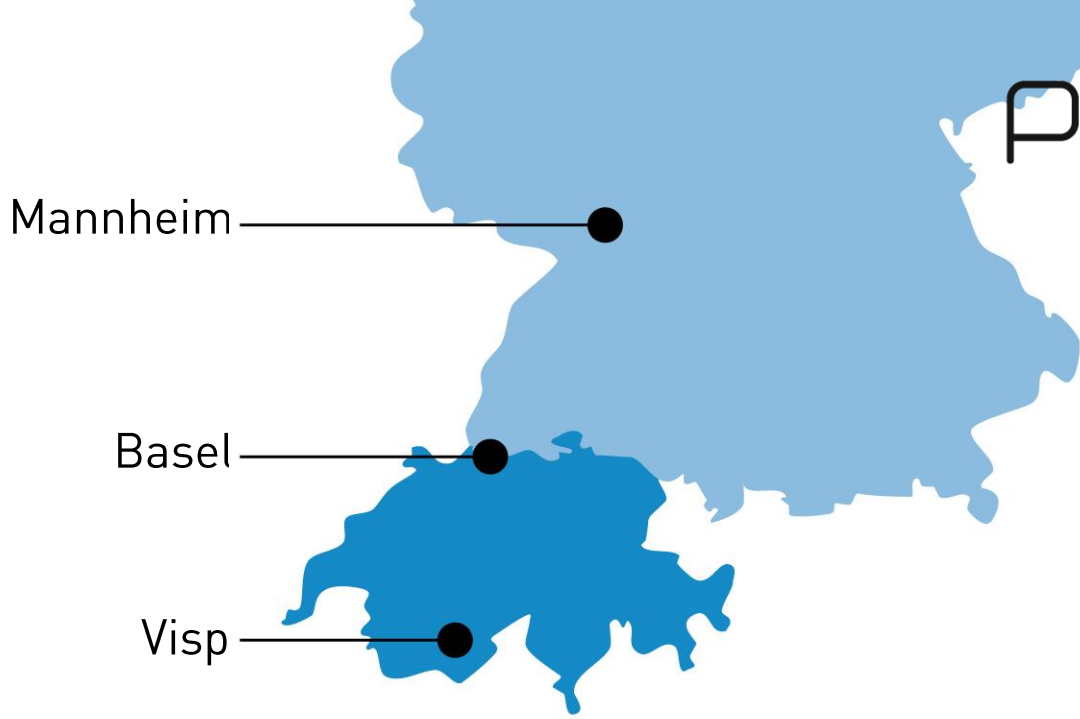
Das Unternehmen:

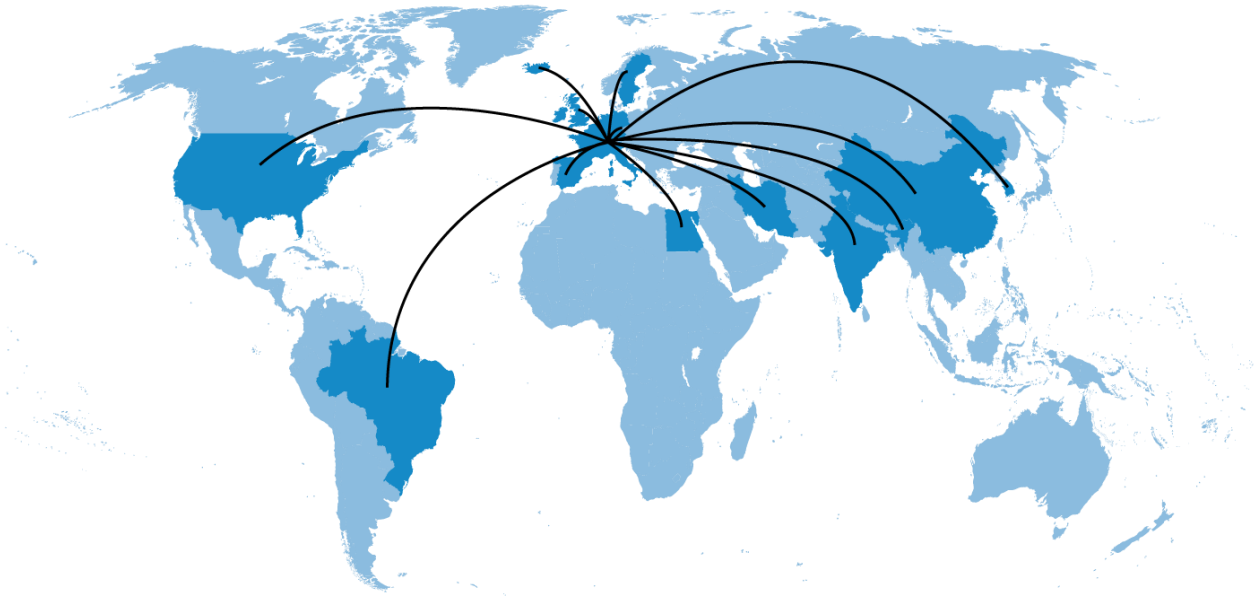
3 Standorte

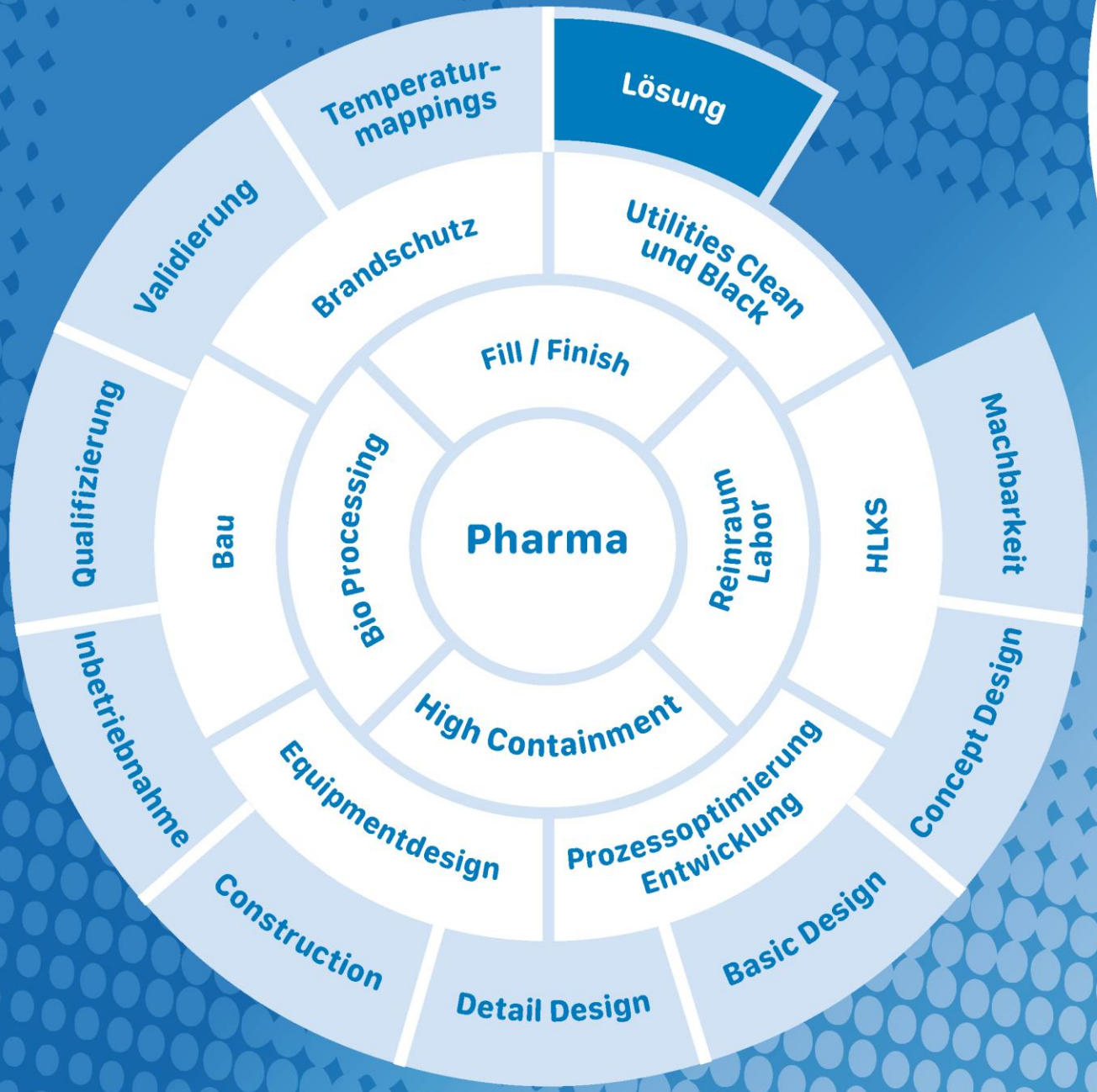
- Visp (Hauptsitz)
- Basel (Zweigstelle)
- Mannheim (Tochtergesellschaft)



75 Mitarbeiter

Projekte in Europa
.... aber auch weltweit





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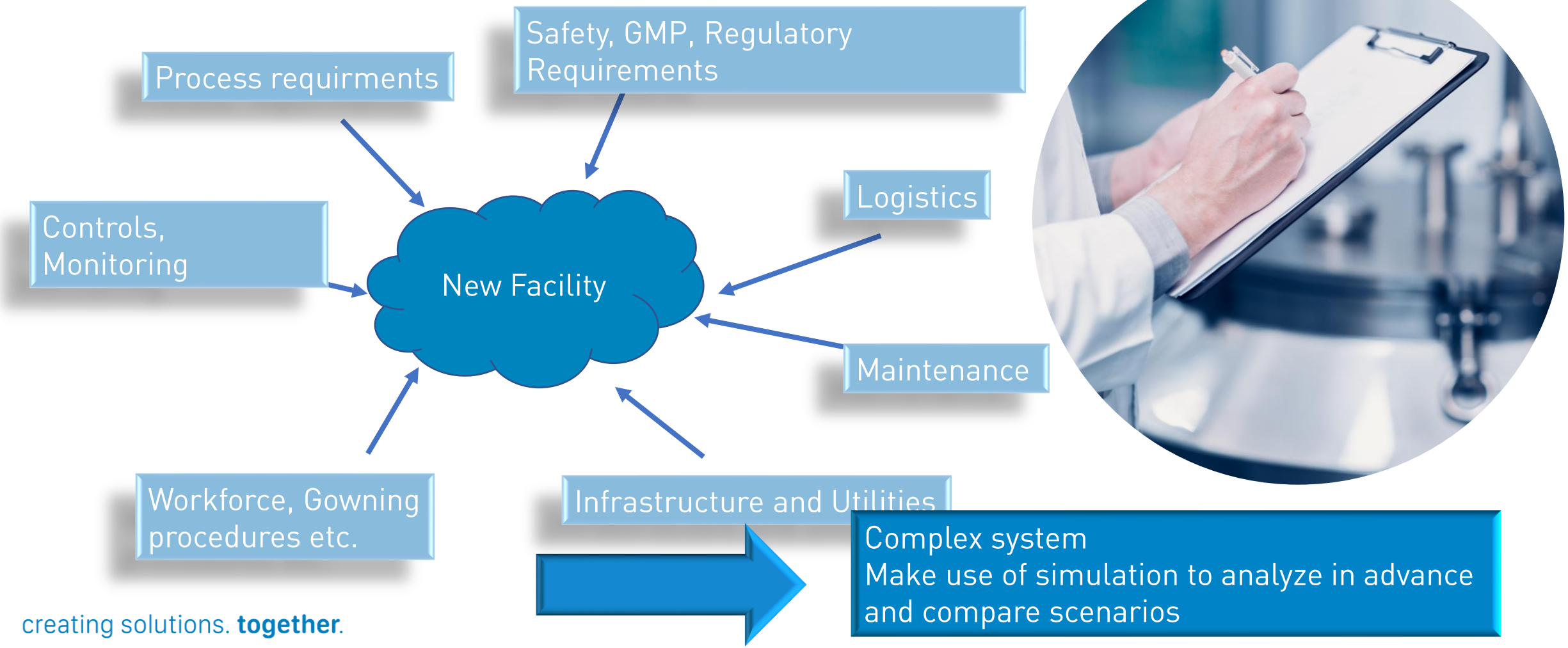
Use of Simulation in Pharma

- Planning of new processes in existing or new plants
- Debottlenecking of mono- or multi-product plants with simulation tools
- Optimisation of occupancy rates (plant, infrastructure, resources)
- Dimensioning + specification of material, equipment, utilities & resources
- Comparison of scenarios (cost, time, feasibility)
- Production planning

Designing the optimal facility



Complex system
Make use of simulation to analyze in advance and compare scenarios

How does it work?

- Quality of input defines quality of output
  - Define goals
  - Define system boundaries
  - Gather structured data

- Set-up process simulation model by our experts
  - Set rooms, process-equipment, operators in model
  - Define parameters per room, process-equipment
  - Linking all entities to build your model

- Simulation
  - Run the model to see, what happens to the entities
  - Make a stress analysis with different scenarios

How does it work?

- Including production plan
  - Introduce different product types with different storage requirements
  - Run large number of consecutive batches/campaigns

- Define parameters for design
  - How many people need to use the air lock at the same time
  - How much gowning material needs to be provided e.g. during one day
  - How much will be the peak storage capacity needed.

- Feedback Loop, reiterate with updated input data

Personnel and Material Air Locks

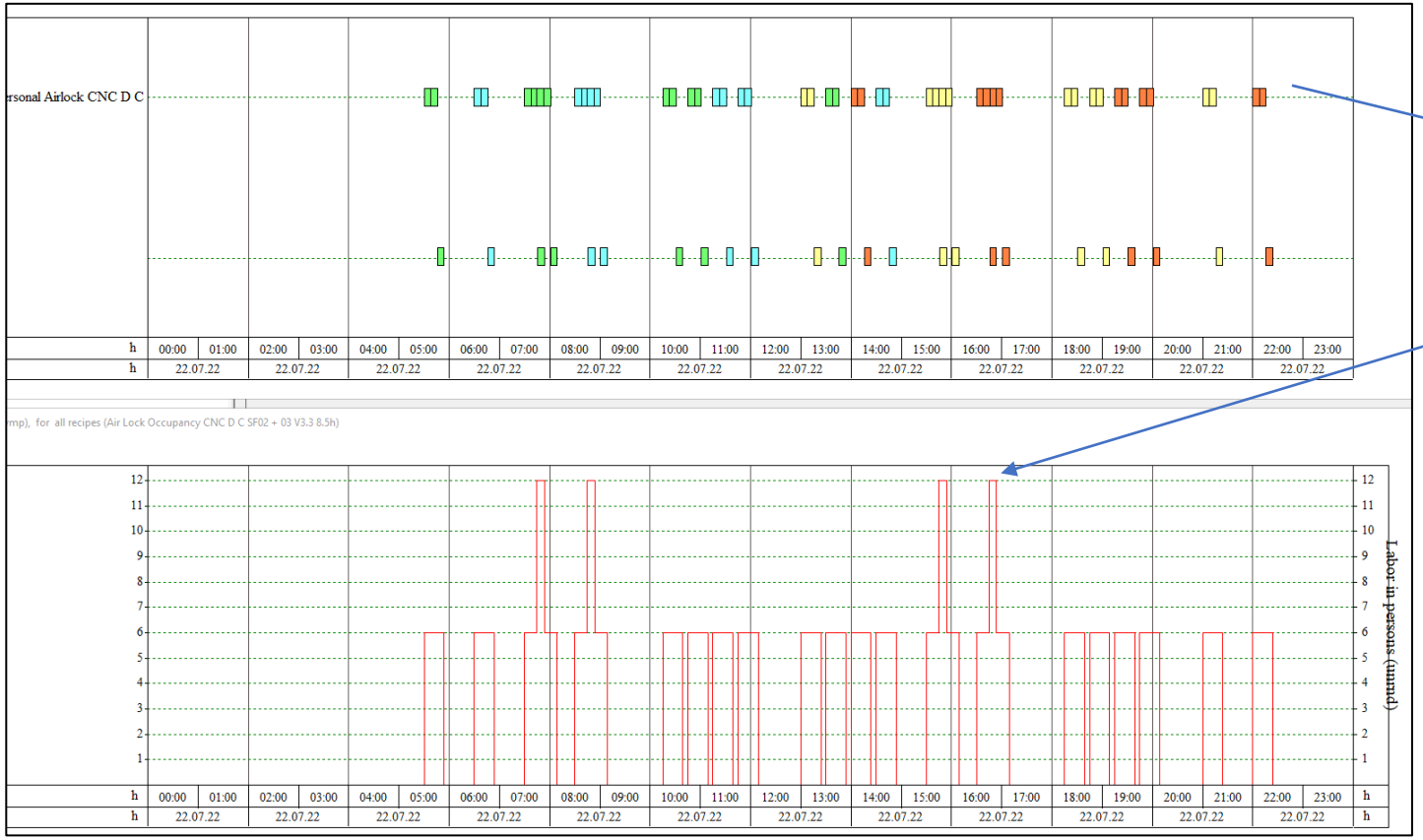
- Transfer of people or material from lower graded zones to higher graded zones is critical for product quality and hygienic conditions.
- Gowning procedures and disinfection and particle reduction are time consuming
- Equipment in the cleanest area will define use of air-locks in the complete system
- It is essential to have the right amount and size of air-locks.

The Capacity or the expected utilization of air-locks can be simulated with a process simulation. This helps to understand potential bottlenecks.

Example #1: Designing your PAL/MAL

An efficient production, requires the appropriate personnel at the right time at the right place

→ Proper size of personnel air lock is crucial



Different Shifts ( ) going in and out at the same time can cause bottlenecks

→ Early analysis of frequencies helps prevent traffic jams and delays

Example #2: Operator Analysis

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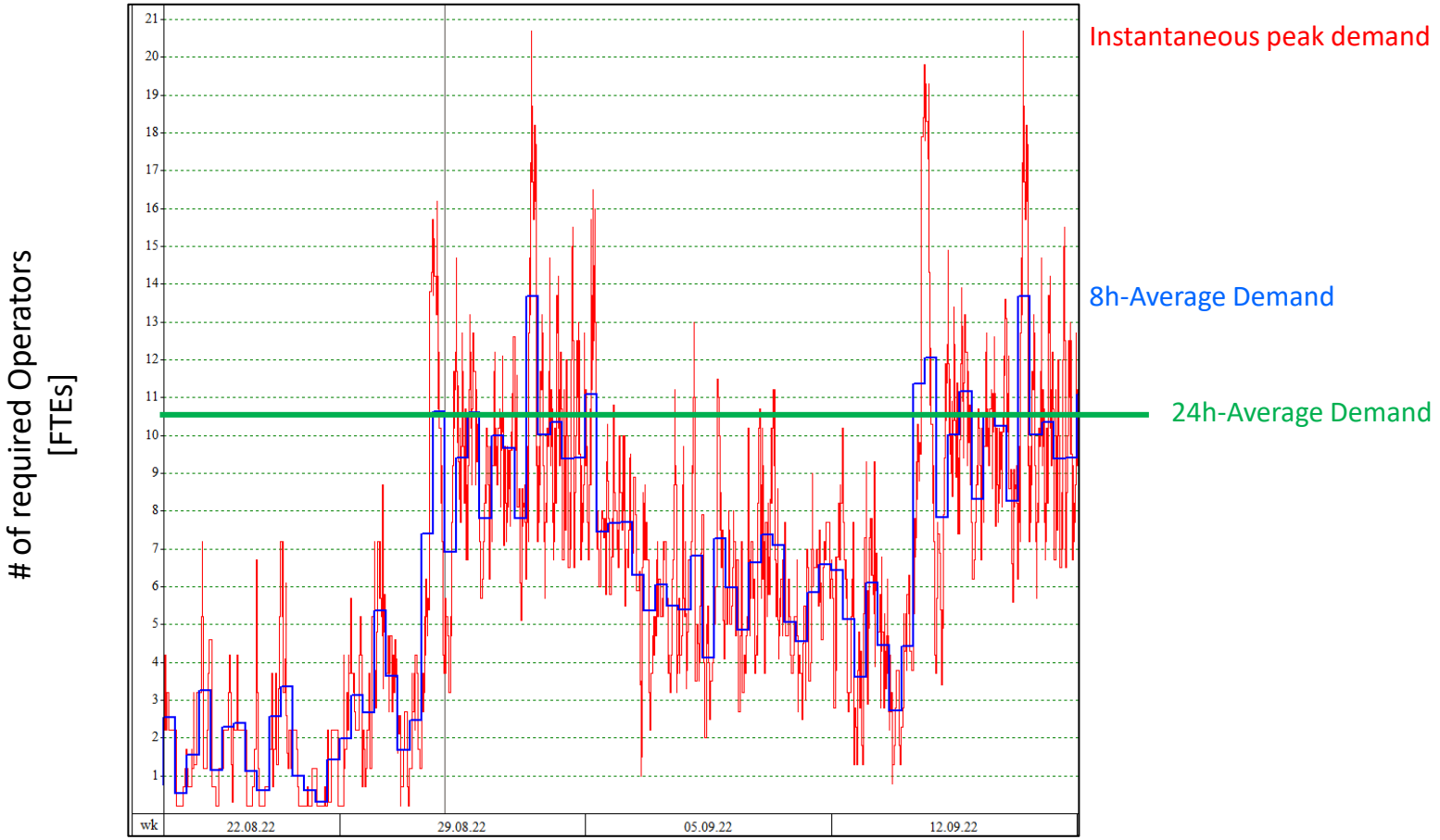
Different Types of Operators are needed for different tasks (e.g., process, media/buffer prep, sampling etc.)

→ Plan your shift size (e.g., 8h-average)

→ Estimate your peaks (red peaks)

→ Plan your daily activities



Storage Capacity

- Storage of the right type is essential for pharmaceutical products
- Special focus is on special storage types or special situations like incoming goods areas, 2 – 8°C, -20°C etc.
- For cold rooms it is essential not to have more space than necessary.

- Storage capacity analysis can help to especially address storage of specific storage types

The Capacity or the expected utilization of air-locks can be simulated with a process simulation. This helps to understand potential bottlenecks.

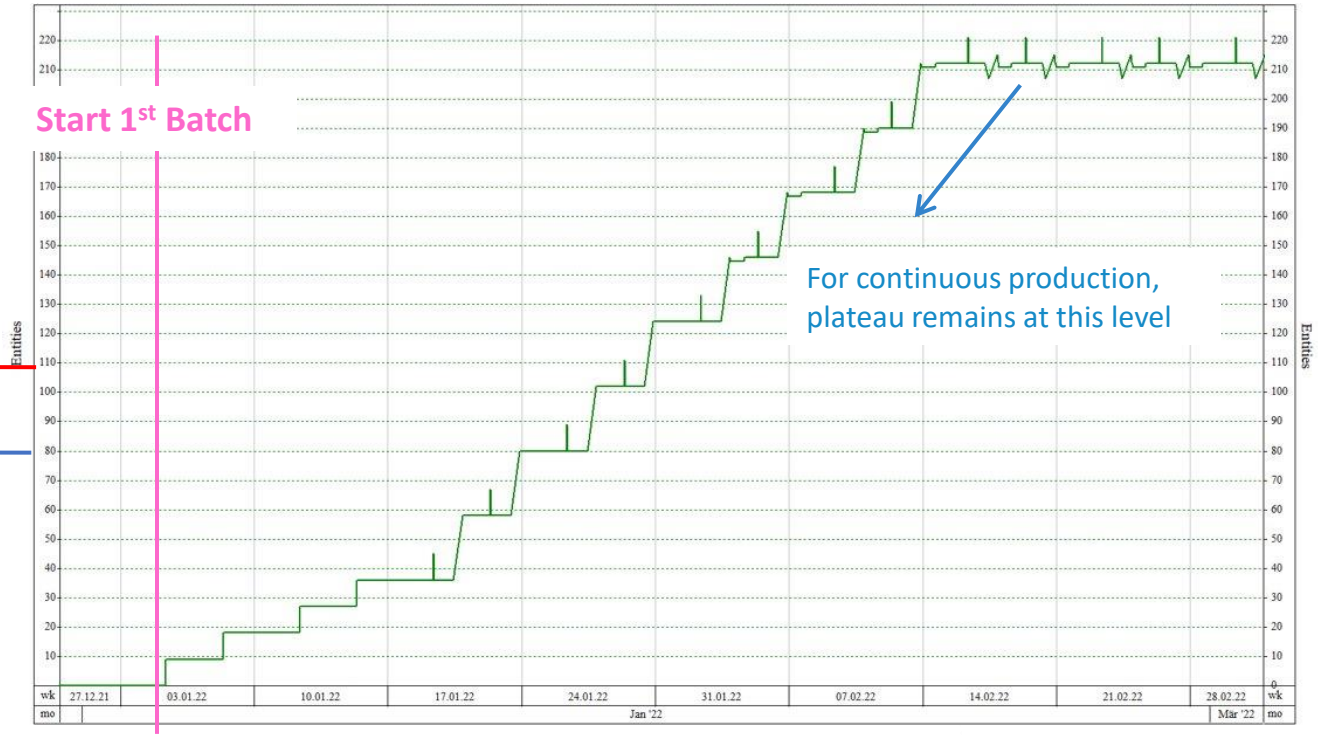
Example #3: 2 – 8 °C

How much cold room capacity is necessary in steady state?

→ Plan your capacity

→ Estimate your peak demand

→ The model can be used to simulate different holding times to see how e.g. faster release of product can influence cold room capacity needs.



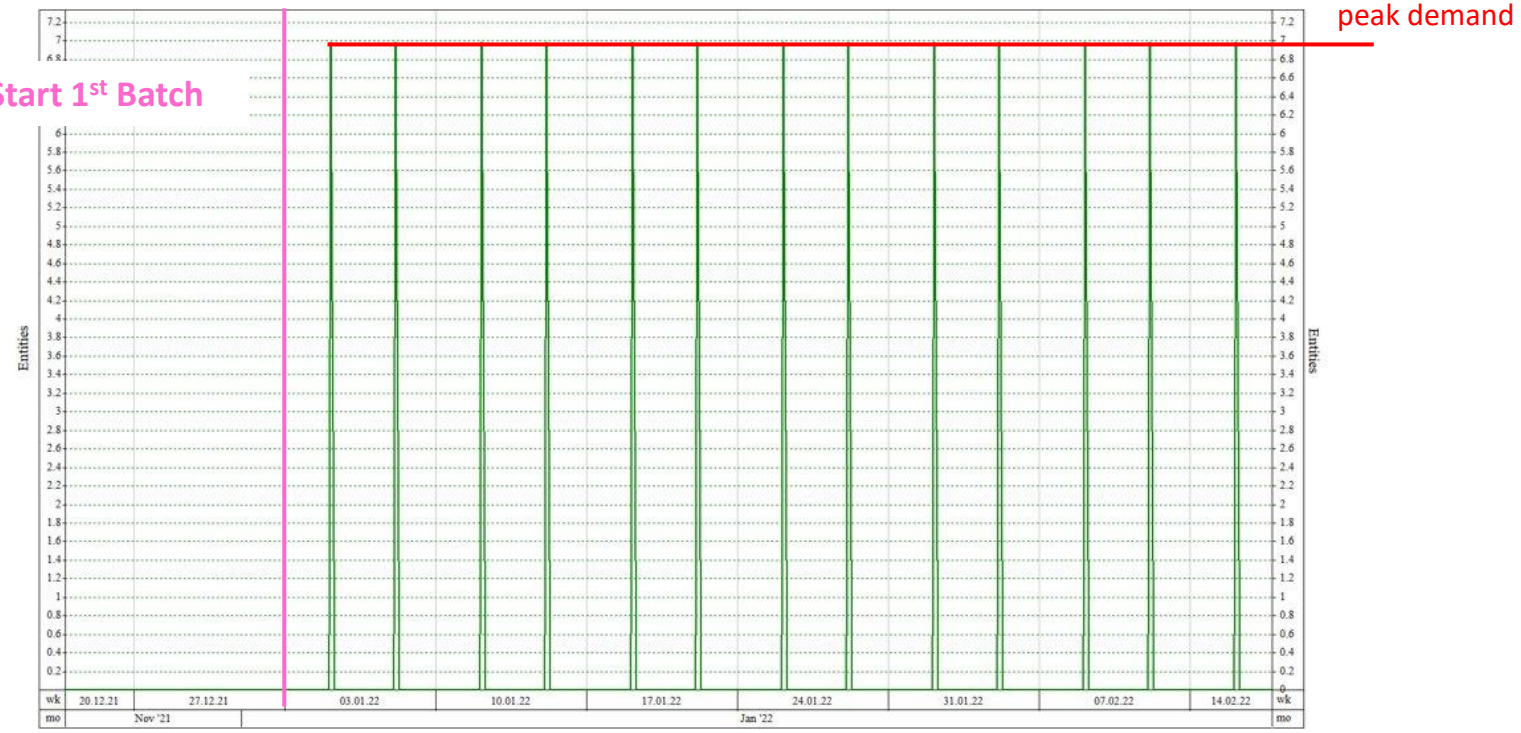
Example #4: staging before process

How much place is necessary to provide for staging

→ Decision to have staging area

→ Right capacity

→ The model can be used to also reflect the operators impact of staging



Summary

- Take care of your input quality and define the goals of the simulation in advance
- Get important output data such as volume, capacity and utilization, time…
- → space demand → layout → building design
- Identify Bottlenecks and challenge debottlenecking solutions
- Optimal sizing of the PAL/MAL or storage according to defined scenarios
- Stress-testing to find out how the systems reacts to changes

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