#### **Design & Implementation of a new flexible Vaccine Drug Substance production facility**

Case Study by Dr. Minör (IDT Biologika) and D.Steinhäuser (Glatt Engineering) - Pharmakongress 2022





IDT Biologika Glatt Ingenieurtechnik GmbH

# Case Study new Bio Drug Substance Facility Agenda

- 1. Introduction of IDT Biologika
- 2. Objectives for new bio Drug Substance facility and specific Requirements
- Overview on project 205: Multipurpose Drug Substance Manufacturing facility
- 4. Engineering phase and Fast track implementation
- 5. Commissioning and Qualification
- 6. Go live Challenges and solutions
- 7. Lessons learnt







# IDT Biologika in the Early Days

#### 1921

IDT originated in the Bakteriologisches Institut der Anhaltischen Kreise based in Dessau. In 1925 the first commercial production of erysipelas serum started.

#### 1930

Foundation of the **Anhaltisches Serum Institut Dessau** (ASID) for the industrial manufacture of serum for passive immunization in humans and animals.

#### 1945

Vaccine and diagnostic material production at the vaccine research institute **Forschungsinstitut Dessau** for fighting infectious diseases.

#### Introduction





# IDT Biologika Today

#### 1993

Entrepreneur Hartmut Klocke privatizes the company under the new name Impfstoff-werk Dessau-Tornau GmbH.

#### 2015

IDT acquires a **production location in Rockville, MD, USA** for the process development and production **I.** of vaccines in clinical phases I and II.

#### 2016

IDT expands process development capacities for human viral vaccines in Magdeburg, Germany.

#### Today

Contract development and manufacturing of human viral vaccines, gene and immune therapeutics and fill & finish of biologics.

#### Introduction





# **IDT Biologika Investments**



Setting up safety devices and autoinjector assembly lines



2016

Expanding storage capacities at - 80°C and for stability and retention samples, GMP upgrade of pharma production facility. Setting up pilot filling line and Schubert Multipacker packaging line



2019

Expanding Drug Substance Manufacturing capacities by set-up of a new building

2015

Expanding visual inspection capacities, Setting up large scale filling line

Expanding large scale filling capacities with a new state-of-the-art filling line



#### 2023

Investments:

- Large scale filling capacities with a new state-of-the-art filling line
- Additional capacities in **Drug Substance** production with a new building
- Visual Inspection

Introduction







2017

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## Company Sites in Germany and the US

**BSL2** production facilities I FDA, EMA, ANVISA



#### IDT Biologika in Dessau-Rosslau



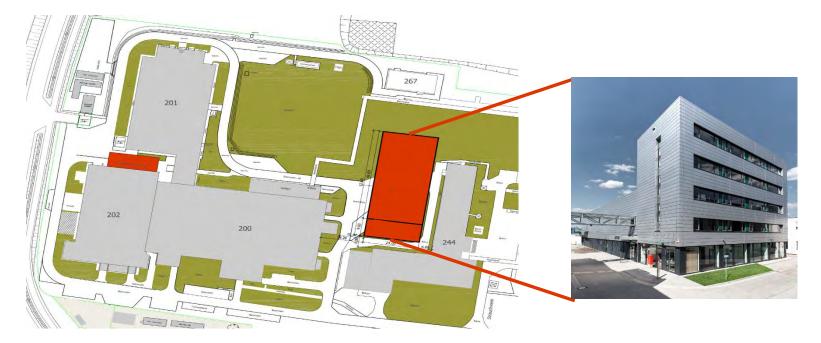


#### Case Study: a new DS Facility at IDT Biologika in Dessau





#### Part of Task: Integration into existing environment





## Situation at IDT Biologika and Requirements

- Increased demand for virus vaccines
- DS and DP capacities are well used for commercial products
- New technologies How to transfer to large scale manufacturing ?
- Construction of new facilities takes > 4 years (at least)

(until Manufacturing permit)

→ Can design, implementation and qualification be speeded up?



# Objectives IDT Biologika for the new Bio project

#### Multipurpose manufacturing facility for the production of:

- Live recombinant viral vaccines
- Gene Therapy Medicinal Products (GTMP)

Key elements:

- High quality clean rooms
- Containment for environmental safety and prevention of cross contamination
- Waste control and inactivation
- Cleaning and room decontamination



### Objectives and Requirements for the new Bio project

Flexibility and scalability

Key elements:

- Tentative process flow scheme / design / volume flow
- Preparation for open aseptic operations (grade B environment for grade A operations)
- Large size clean rooms
- Major focus on disposable technologies
- Fast track change over systems



### Objectives and Requirements for the new Bio project

Fast track and successful start of manufacturing

Key elements:

- Experienced management
- Knowledgeable engineering team
- Knowledgeable and well trained operators
- Experienced quality support



"People who have done that before"



#### Project 205 at a Glance

- New biologicals drug substance manufacturing plant for human vaccines (BSL 2)
- Time of Construction and Commissioning 20 months
- Production building with approx. 900 sqm clean rooms class B and C for multi product use; plus additional office building and social area
- Contract manufacturing for external customers
- Mainly single-use technologies in Upstream / Downstream Processing
- Facility planed for possible extension







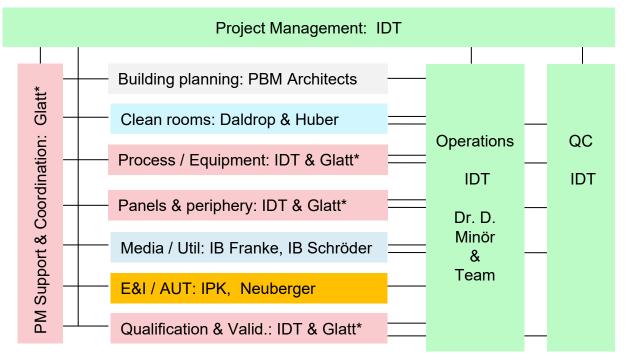
Project at a Glance 14

# Key Facts IDT Biologika Project 205

| Area parameters   | Building footprint: 1150 m <sup>2</sup><br>Clean room area: 900 m <sup>2</sup>                     |                                      |  |
|-------------------|--|--------------------------------------|--|
| Investment volume | 23 million €   |                                      |  |
| Time schedule     | Start Planning (Basic Design & Permit doc.s)<br>Start of construction<br>Topping out ("Richtfest") | Dec. 2017<br>April 2018<br>Sep. 2018 |  |
|                   | Installation, Commissioning + Qualification +<br>Validation → Permission for GMP Manufacturing     | Dec. 2019                            |  |
|                   | Time Construction and Commissioning<br>Total Time duration   | 20 months<br>24 months               |  |
| Main partners     | Architecture/ Building: PBM Architects Gmb-<br>Process Engineering: Glatt Ingenieurtechnik         |                                      |  |
|                   |  |                                      |  |



# Project structure and further partners



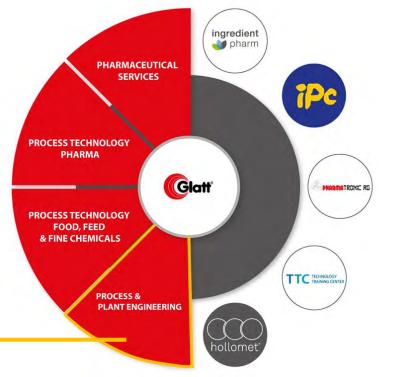
\* Glatt = Glatt Engineering, i.e. Glatt Ingenieurtechnik GmbH



Project structure 16







Glatt Ingenieurtechnik GmbH HQ in Weimar, Germany

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Glatt GIT 17

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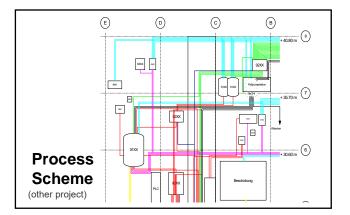


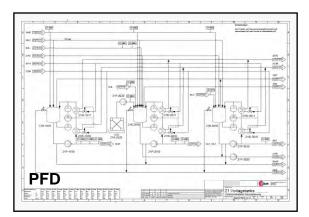
- Engineering services for process equipment, periphery and support equipment, utilities
- Equipment arrangement and Layout planning
- Specification for process equipment, coordination with vendors / suppliers, FAT / SAT
- Technical coordination and PM support, scheduling and resource planning, controlling support
- Qualification: participation in preparation and implementation of DQ, IQ, OQ, PQ,
- Coordination of calibration





# Glatt Overview on Case Study project 205 **Process Engineering**





#### **Generation of Process Fundamentals**

- Process strategy / schemes  $\succ$
- Process Flow Diagrams (PFD's)



Main equipment data ->  $\geq$ Equipment list (type and number), main parameters and dimensions

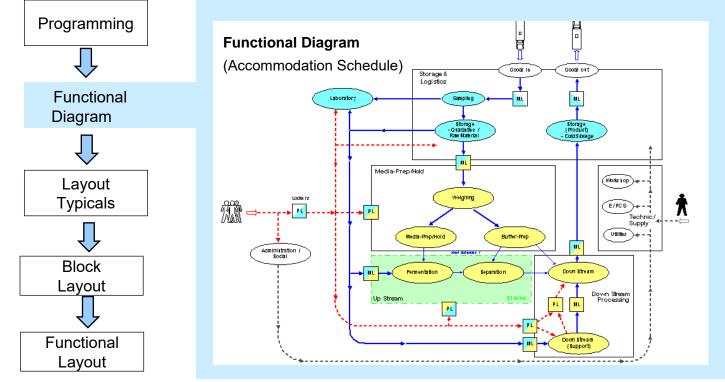
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| Angahi     Angahi     Angahi     Angahi     Angabon für 1     Angabon für 1     Pigebent     Angabon für 1     Pigebent     Aggegstorsten     Angabon für 1     Pigebent     Aggegstorsten     Angabon für 1     Pigebent     Ingebent     Ingebent   | Betrieb<br>Peserve<br>Bruckgeri<br>Bruckgeri<br>Auslegun<br>S)<br>in Temperan<br>bedingung<br>erau   | Stick<br>Re<br>by US<br>RESS<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Str  | Vantilisung<br>Batoli<br>Hitro penieroso<br>Behaker<br>- 4<br>- 0<br>(*) 1*) | 20144638EU<br>20144638EU<br>1<br>FRissigund<br>(1)<br>(1)<br>(1)<br>(1)<br>(1)<br>(1)<br>(1)<br>(1)<br>(1)<br>(1)  | z Sonoffisgereim, Hrunnu<br>AD2000<br>gasförmig<br>X<br>Xishdasperkrami  |   |
| Anachi     Anachi     Anachi     Anachi     Betriebsisterval     Betriebsisterval     Betriebsisterval     Betriebsisterval     Angabasin für     Angabasin     Angabasin | Betrieb<br>Peserve<br>Bruckgeri<br>Bruckgeri<br>Auslegun<br>S)<br>in Temperan<br>bedingung<br>erau   | Stick<br>Re<br>by US<br>RESS<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Str  | Vantilisung<br>Batoli<br>Hitro penieroso<br>Behaker<br>- 4<br>- 0<br>(*) 1*) | 2014463EU<br>1<br>Flissigund<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1  | z Sonoffisgereim, Hrunnu<br>AD2000<br>gasförmig<br>X<br>Xishdasperkrami  |   |
| Analysis      | Betrieb<br>Peserve<br>Bruckgeri<br>Bruckgeri<br>Auslegun<br>S)<br>in Temperan<br>bedingung<br>erau   | Stick<br>Re<br>by US<br>RESS<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Strick<br>Str  | Vantilisung<br>Batoli<br>Hitro penieroso<br>Behaker<br>- 4<br>- 0<br>(*) 1*) | 2014463EU<br>1<br>Flissigund<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1<br>1  | z Sonoffisgereim, Hrunnu<br>AD2000<br>gasförmig<br>X<br>Xishdasperkrami  |   |
| 5<br>6<br>6<br>6<br>6<br>6<br>7<br>7<br>7<br>7<br>7<br>7<br>7<br>7<br>7<br>7<br>7<br>7<br>7   | Betrieb<br>Peserve<br>Bruckgers<br>e Austegun<br>23<br>in Tempesto<br>bedingung<br>erstur<br>niedstlasse   | Stick<br>ate<br>mgsdaren<br>brifij<br>wTS C<br>brifij<br>pen<br>C  | Vantilisung<br>Batoli<br>Hitro penieroso<br>Behaker<br>- 4<br>- 0<br>(*) 1*) | 20144634EU<br>1<br>Flissigund<br>1<br>Maess<br>8<br>10<br>10<br>10<br>11<br>Maess<br>5<br>10<br>10<br>11<br>11<br>11<br>12<br>12<br>12<br>12<br>12<br>12<br>12<br>12<br>12<br>12 | z Sonoffisgereim, Hrunnu<br>AD2000<br>gasförmig<br>X<br>Xishdasperkrami  |   |
| Anabi     Anabi     Anabi     Anabi     Anabi     Berindenervia     Anabi     Berindenerv     Anabishn für     Anabishn     Anabishn   | Betrieb<br>Reserve<br>Druckgeri<br>e Auslegun<br>PS)<br>in Tempestr<br>bedingung<br>erstor<br>miniskliesse   | Stick<br>ate<br>ngsdaren.<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift<br>Strift  | Vantilisung<br>Batoli<br>Hitro penieroso<br>Behaker<br>- 4<br>- 0<br>(*) 1*) | 2014463EU<br>2014463EU<br>1<br>Flicssig and<br>0<br>0<br>Marcs<br>8<br>5<br>5<br>5<br>5<br>5<br>5<br>5<br>5<br>5<br>5<br>5<br>5<br>5<br>5<br>5<br>5<br>5<br>5                    | z Sonoffisgereim, Hrunnu<br>AD2000<br>gasförmig<br>X<br>Xishdasperkrami  |   |
| Image: state              | Betrieb<br>Reserve<br>Druckgeri<br>e Auslegun<br>PS)<br>in Tempestr<br>bedingung<br>erstor<br>miniskliesse   | 9tijsk<br>ate<br>ngsdaten<br>w(TS) 0-(1)<br>bar(1)<br>bar(1)<br>c<br>c<br>c<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>(1)<br>c<br>()<br>c<br>( | Vantilisung<br>Batoli<br>Hitro penieroso<br>Behaker<br>- 4<br>- 0<br>(*) 1*) | 2014463EU<br>2014463EU<br>1 Flissigund,<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10  | z Sonoffisgereim, Hrunnu<br>AD2000<br>gasförmig<br>X<br>Xishdasperkrami  |   |
| Anabi     Anabi     Anabi     Anabi     Benistaiverval     Benistaiverval     Anabi     Benistaiverval     Anabi     Anabi     Anabi     Anabi     Payatent     Angergatassan     Moda     Machanischut     Modanischut     Modanischut   | Betrieb<br>Reserve<br>Druckger2<br>e Ausbegun<br>S3<br>in: Temperato<br>bedingung<br>eratur<br>niekskiesse<br>eratur<br>niekskiesse                  | 0004           Be           ngsdaren           wr(73)         0xr(0)           wr(73)         C           swr(0)         0xr(0)           pon         0x           (%)         0x           (%)         0x           (%)         0x  | Vantilisung<br>Batoli<br>Hitro penieroso<br>Behaker<br>- 4<br>- 0<br>(*) 1*) | 2014469EU<br>11<br>Filissig and<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10  | ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>ACCOM<br>AC |   |
| Image: Second                    | Betrieb<br>Peserve<br>Druckgier/<br>e Austegun<br>%]<br>in. Temperati<br>bedingung<br>eraur<br>niekskiesse   | 0004           Be           ngsdaren           wr(73)         0xr(0)           wr(73)         C           swr(0)         0xr(0)           pon         0x           (%)         0x           (%)         0x           (%)         0x  | Vartilisong<br>Batoli<br>Howeleneoss<br>Calabi<br>Behalter<br>Cor<br>Cor     | 2014469EU<br>11<br>Filissig and<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10<br>10  | z Sonoffisgereim, Hrunnu<br>AD2000<br>gasförmig<br>X<br>Xishdasperkrami  |   |
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# Approach for Case Study project Design Principles and Layout Concept

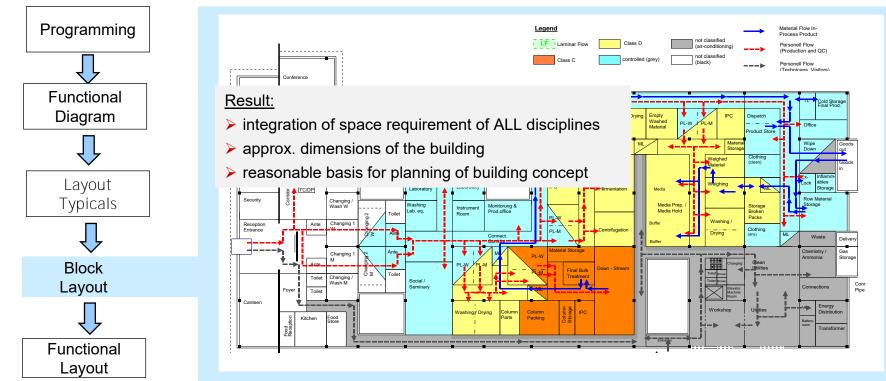


Method bases on:

- ISPE Baseline Guides for
  - a) Biopharmaceuticals &
  - b) Sterile Manufacturing Facilities chapter 4.3.2.
- relating GMP cleanliness classification to functions
- optimized structuring of GMP zoning concept, personnel and material flow



# Approach for Case Study project Design Principles and Layout Concept





# Overview on Case Study project 205 Flexibility by prepared compartments



Class B, AER 40 / h



production compartments



## Overview on Case Study project 205 Flexibility by "House-in-house" concept





# Overview on Case Study project 205 Layout Concept and Equipment arrangement



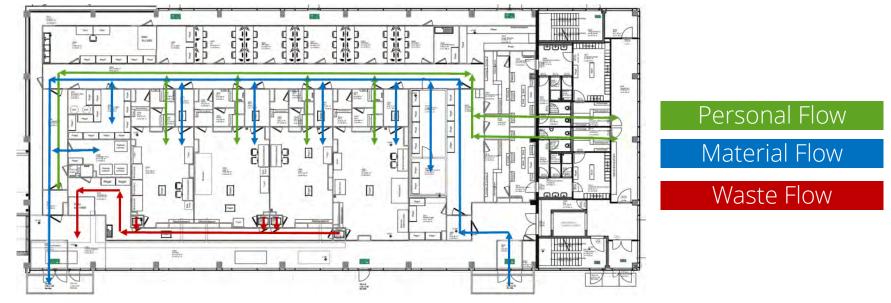
Layout concept (image from other example)



Arrangement of Single Use equipment in 3D CAD conceptual model using typicals from supplier



## Overview on Case Study project 205 Layout Concept and Flows







### Multipurpose Drug Substance Plant 205 Fast track building construction

Fast track building construction with prefabricated concrete elements









### Multipurpose Drug Substance Plant 205 Fast track building construction





Combined building construction: concrete and steel

Fast track building construction with prefabricated concrete elements



### Multipurpose Drug Substance Plant 205 Fast track building construction



Elements fitted

Floor prep work

Civil 29





## Multipurpose Drug Substance Plant 205 Internal finishing and cleanroom construction



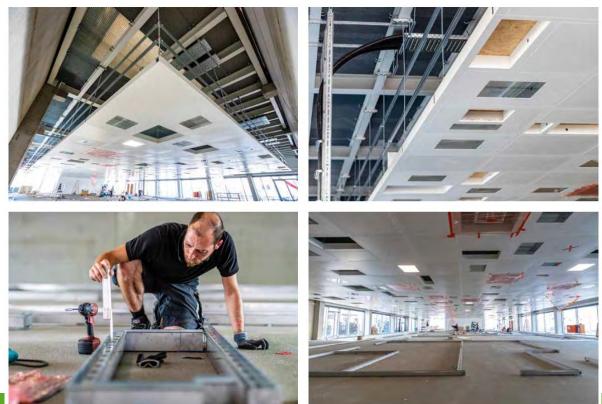


Cleanroom floor installation work

Interiors 30



## Multipurpose Drug Substance Plant 205 Internal finishing and cleanroom construction



Cleanroom ceiling installation work

Cleanroom floor installation work

Interiors 31





# Case Study IDT Biologika Project 205 Overview on periphery and systems







Technical level

Clean room ceiling, walkable



# Case Study IDT Biologika Project 205 Overview on support and service systems



WFI use point / Media panel



Connect panel from cleanroom ceiling (keeps flexibility on floor)

Clean steam sampling and media panel



Decontamination autoclave





## Case Study IDT Biologika Project 205 Impressions



Production area (during installation / IQ)



Clean corridor for service





### Multipurpose Drug Substance Plant 205 Commissioning and Qualification

#### C & Q of the Clean rooms





C&Q 35

# Case Study new Bio Drug Substance Facility Agenda

- 1. Introduction of IDT Biologika
- 2. Objectives for new bio Drug Substance facility and specific Requirements
- Overview on project 205: Multipurpose Drug Substance Manufacturing facility
- 4. Engineering phase and Fast track implementation
- 5. Commissioning and Qualification
- 6. Go live Challenges and solutions
- 7. Lessons learnt







### Multipurpose Drug Substance Plant 205 Commissioning and Qualification

### C & Q Strategy

- …integrated…
- ...parallel....

Qualification of Equipment & Systems (Planning and Execution)

- Risk analysis (FMEA)
- DQ/IQ/OQ/PQ Qualification plans / reports
- Test protocols
- TRM (Traceability Matrix)
- CSV (Computer Software Validation) according to GAMP 5 / 21 CFR Part11





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## Fast Track implementation

Fast track implementation of new facility

### Expectations

- Minimum of process implementation time
- Flexible processes
- Short Change over times

### Key Elements

- Process equipment available
- Single use materials
- Effective room decontamination
- Well trained & experienced personal





# Case Study IDT Biologika Project 205 Overview on equipment and systems

### Equipment

- Autoclaves (sterile /decontamin.)
- CO<sub>2</sub> Incubators
- Block thermostates
- Safety workbenches
- Roller racks
- Moebius mixing systems
- Pallet tanks
- Tangential Flow Filtration (TFF)
- Chromatography systems (Äkta Ready)
- LN2 storage tanks / system

### Small units

- Bio sealer, Bio welder
- Fridges and freezer cabinets
- Filter integrity measurement
- Peristaltic pump skids
- Scales / balances
- etc.

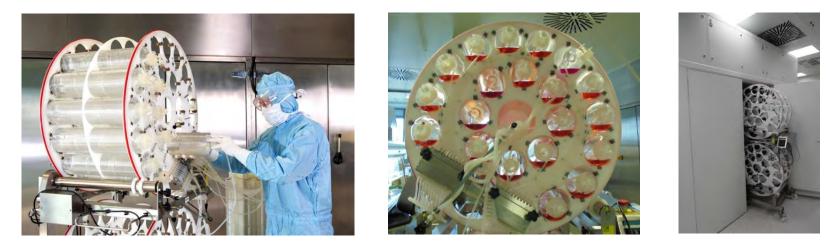
### Further systems

- HVAC units (AHUs and special systems)
- Clean rooms / Air locks (grade D, C, B)
- WFI distribution / loops / use points
- Clean steam distribution / use points
- Cold stores, cooling capacity
- Incubation rooms
- H<sub>2</sub>O<sub>2</sub> room decontamination systems
- Wastewater inactivation plant (thermal)
- Mixed gas supply
- Clean gases supply (N<sub>2</sub>, CO<sub>2</sub>, O2)
- Media panels





### Case Study IDT Biologika Project 205 Impression Upstream Bioprocessing area



Roller racks RC 40 with single-use bottles for cell cultivation





### Case Study IDT Biologika Project 205 Impression Upstream Bioprocessing area





#### Cell stack manipulator

Mobile rack of cell factories



## Case Study IDT Biologika Project 205 Impressions Downstream Bioprocessing area

- Flow through centrifugesTFF
- Filtration
- Sonication
- Chromatography







## Case Study IDT Biologika Project 205 Process flexibility via single use systems







## Case Study IDT Biologika Project 205 Pros and Cons of single use equipment

### Pros Single Use Equipment



- Short supply time (less engineering effort, shorter manufacturing / delivery time)
- Lower cost of investment
- No CIP/SIP and no cleaning validation
- Sterile (gamma irradiation)
- Mobile availability (not fixed to specific processes or locations)
- Moderate qualification effort (DQ,IQ,OQ)
- In summary short process until use





## Case Study IDT Biologika Project 205 Pros and Cons of single use equipment

### Cons Single Use Equipment





- Higher manual effort due to less automation (intense training)
- Complex disposal
- Comparable high operating costs (procurement, incoming goods inspection, documentation and logistic)
- Risk of confusion / necessity of clear identification (Leachables & Extractables)
- Higher space requirement due to manual handling
- Potentially open processes caused by tube connections
- Complex supply chain
- Sensitive plastic materials (difficult detection of leakages)

# Case Study new Bio Drug Substance Facility Agenda

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### Multipurpose Drug Substance Plant 205 Lessons learnt

- Mechanical defects (defect weld on bags, defect connectors)
   check at delivery / before use, apply scrutiny
- Handling errors (f.e. connecting of wrong tubes, filigree sterile connectors)
   train, implement checking routine, document
- In time material supply
   → long lead times, order on stock
- Air bubbles in tube systems, esp. critical for chromatography systems
  - → check, if prone to occur: implement bubble trap







### Case Study IDT Biologika Project 205 Conclusions

Recommendation of single use application:

- Small scale to medium batch size
- Frequently change over
- Fast track implementation / time to market
- Difficult cleaning validation





#### **Design & Implementation of a new flexible Vaccine Drug Substance production facility**

Case Study by Dr. Minör (IDT Biologika) and D.Steinhäuser (Glatt Engineering) - Pharmakongress 2022







Thank you ! **Time for your Questions** 

**IDT** Biologika Glatt Ingenieurtechnik GmbH