

MUNI
PHARM

BioPharma Hub

GMP Pilot Plant MUNI Pharm

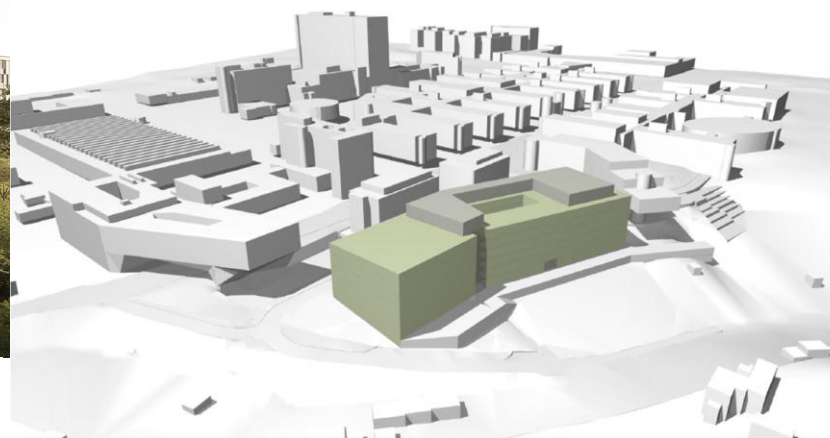
Jan Gajdziok



MUNI
PHARM

GMP PILOT PLANT

MUNI BioPharma Hub



Funded by
the European Union
NextGenerationEU



- 5+3 floors/>33 000 m²/finished VI-2026
- high-tech building within the University Campus in Brno - Bohunice
- unique infrastructure for synergy of modern education and state-of-the-art research
- strategic step in the biomedical research

MUNI
PHARM

New site - New challenge - New philosophy

- Safe pharmaceutical market
- New situation in EU
- Independent final drug and API production
- Human resources needed

Educated people = key to successful pharmaceutical industry



Fusion of modern education & research



- Preclinical Center
- Center for Molecular Medicine
- GMP Pilot plant

GLP + GMP + GCP (University Hospital)



Industrial cooperation centre



- new element in MUNI and MUNI Pharm
- reaction to industry needs

- **Pharmaceutical Quality System knowledge**
- **Practical GMP knowledge**
- **Risk analysis skills**
- **Practical operations**
 - production, warehouse, distribution
- **Quality control aspect**
- **Product releasing**
- **Qualified person function**

Focus to practical & applied approach



GMP Pilot Plant - Intro & Motivation

GMP Pilot Plant

- part of R&D of innovative and generic drugs
- small-batch manufacturing site operated under **Good Manufacturing Practice (GMP)**, serving to develop drug formulations and **produce small-scale (clinical) batches of drugs (1-10 kg)**
- help **researchers and companies** with limited possibilities in **manufacturing small batches of drugs under GMP conditions**



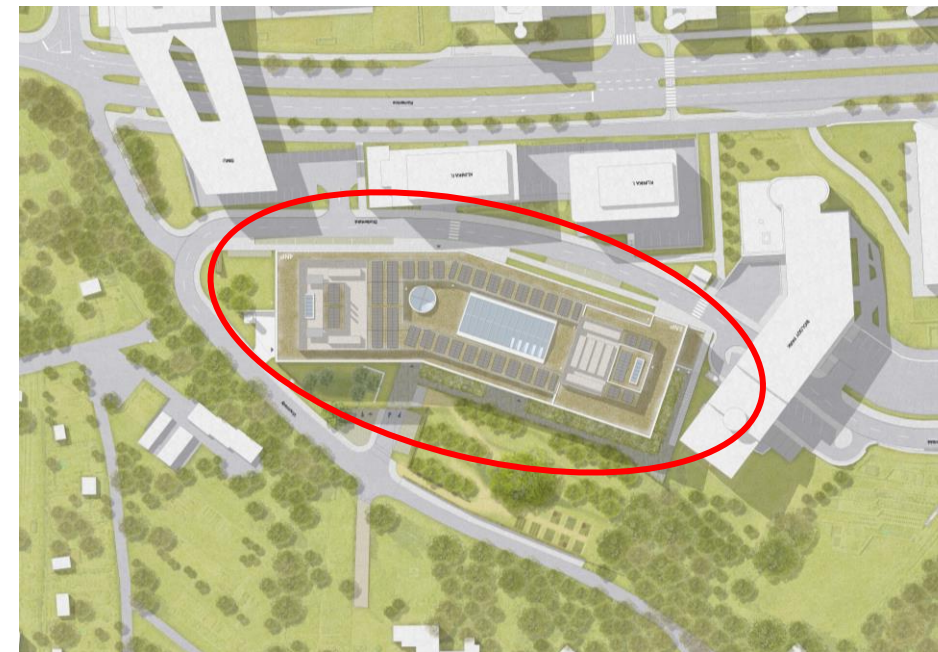
Intention

- to build **GMP facility to develop and manufacture drug forms and evaluate their quality**
- GMP Pilot Plant - part of **BioPharmaHub**
- the manufacturing site occupies ~ 350 m² + 200 m² (QC with MB)

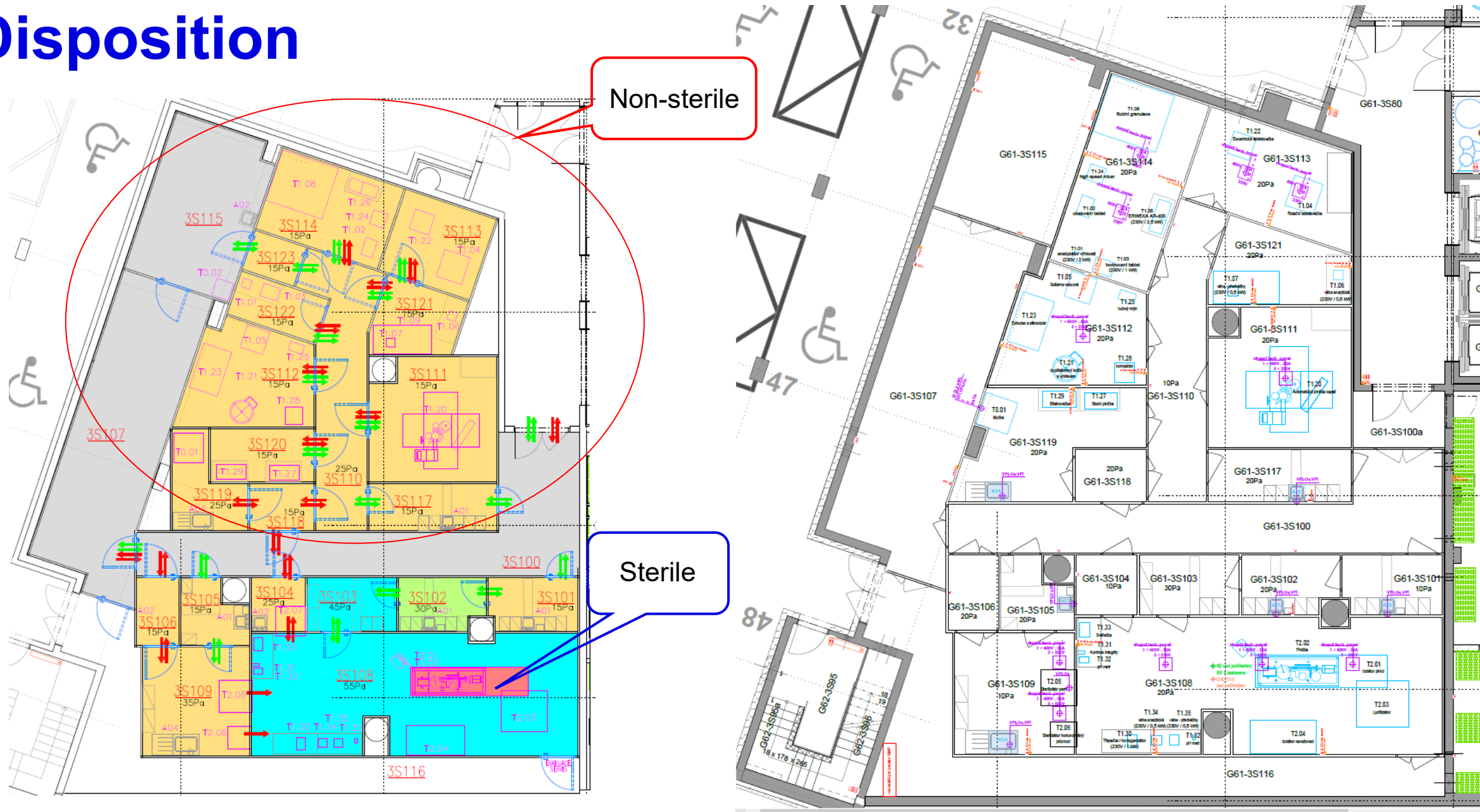
- **PQS**
- part for **Solid, semi-solid, and liquid drug forms** (class D)
- class B area with isolator/RABS (A) for **Sterile preparation of liquid and lyophilized drug forms**
- dedicated **Quality Control (QC) laboratories** with the possibility of pharmacopoeial and in-house testing of prepared drugs, **stability testing & Microbiological testing (MB)**
- pharmaceutical **Warehouse, Packaging**
- utilities and engineering systems (GEP)

Location

MUNI BioPharma Hub



Disposition



Non-sterile

Sterile

PQS as "roof" of GMP Facility

- Responsible management
- Marketing authorization responsibility
- Risk management
- Documentation system
- Qualification and Validation methodology
- Product Quality Review
- CAPA system
- External and Internal audits
- Staff training and Education
- Contract manufacturing and Control



Non-sterile – solid DF (Semi-Solids and Liquids)

– batch 1-10 kg; production area Clean room Class D (ISO 8); 180 m²

Operations

- Sieving
- Dry & wet milling
- Granulation – wet & dry
- Fluid bed processes
- Encapsulation
- Tableting
- Coating of solid drug forms
- Packaging
- IPC

Equipment

- Cabinet dryer
- Jaw & oscillation mill
- High-shear mixer
- Roller compactor
- Multi-purpose ERWEKA device
- Rotary/excentric tablet press
- Fluid bed equipment - granulation, drying, and coating (Wurster)
- Tablet/capsule coating device
- Automatic capsule filler
- Tabletop container filler/tablet counter
- Blistering machine



Sterile Forms - liquid and lyophilized

- Aseptically sterile product formulation and filling; batch up to 10L
- Clean rooms Class A/B for production (60 m²) + Class D for sterilization and cleaning (25 m²)
- Standard personal and material lock

Operations

- Dissolving & Wet mixing
- Lyophilization
- Filling
- Hot air sterilization
- Steam sterilization

Equipment

- Hot air pass-through sterilizer
- Isolator/RABS
- Lyophilization device
- Steam sterilizer
- Filling device
- Tabletop bottle capper by crimping
- Sterile packaging welder



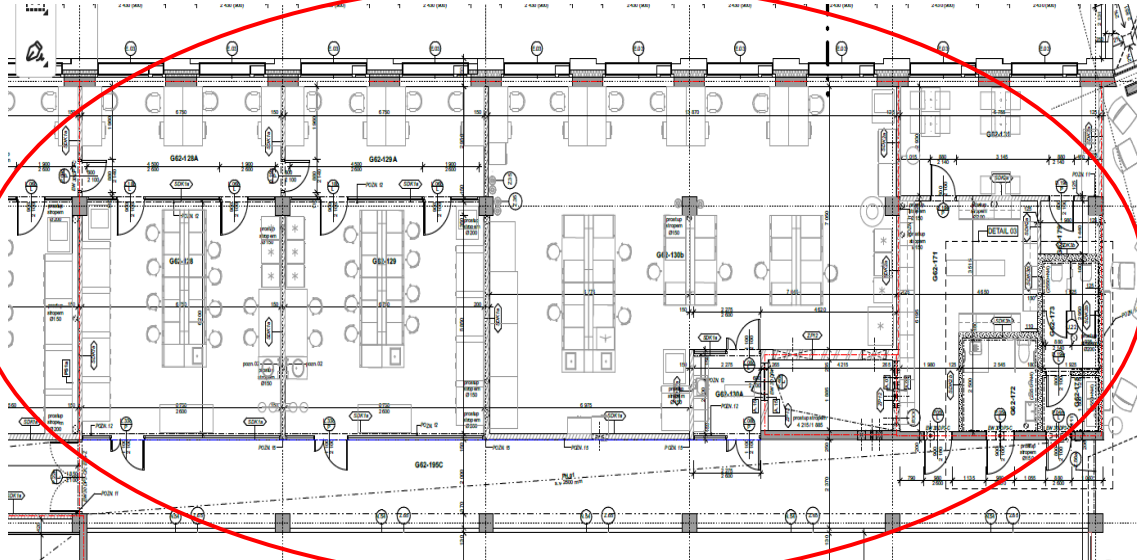
QC Labs

Operations

- Pharmacopoeial methods (F-CH)
- “In-house” methods development (F-CH)
- Microbiological testing
- Stability testing

Equipment

- Dissolution apparatus USP I/II/IV
- Helium pycnometer
- HPLC/UHPLC with UV/VIS (DAD) and MS
- IR spectrometer
- Conductometer
- Laser diffraction (wet and dry measurement)
- X-ray powder diffraction
- Stability boxes - 25 °C/60 %RH; 30 °C/65 %RH; 40 °C/75 %RH
- Thermal analysis
- Raman microscopy
- Karl-Fischer



Warehouse & Utility + Engineering systems

Pharmaceutical warehouse (40 m²)

- Standard warehouse with manual operation
- Temperature and Relative Humidity control
- FIFO or FEFO system
- Validate software and barcode for control
- Sampling units
- Dedicated storage places for recall, OOS products

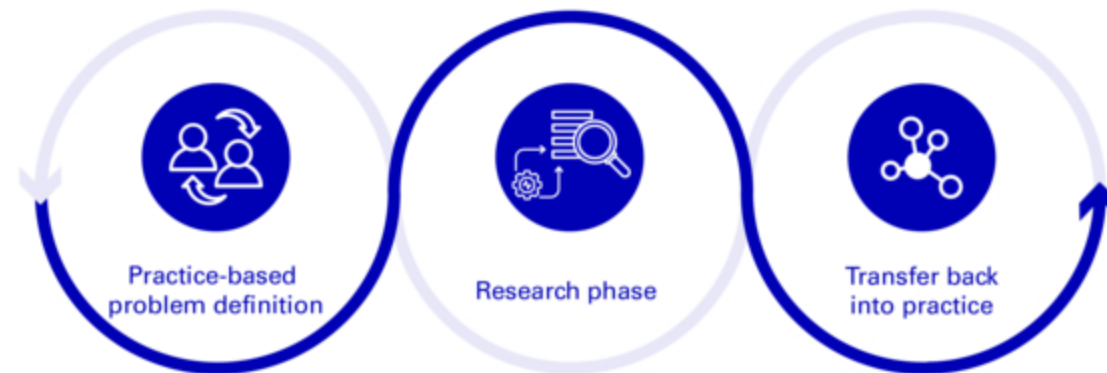
Utility and Engineering systems

- HVAC as part of Clean rooms
- Local PW and WI units
- Compressed Oil free Air
- Compressed Nitrogen form Storage tank of liquid N₂
- IT network
- Back up Diesel generator
- Danger waste material collection and discarding

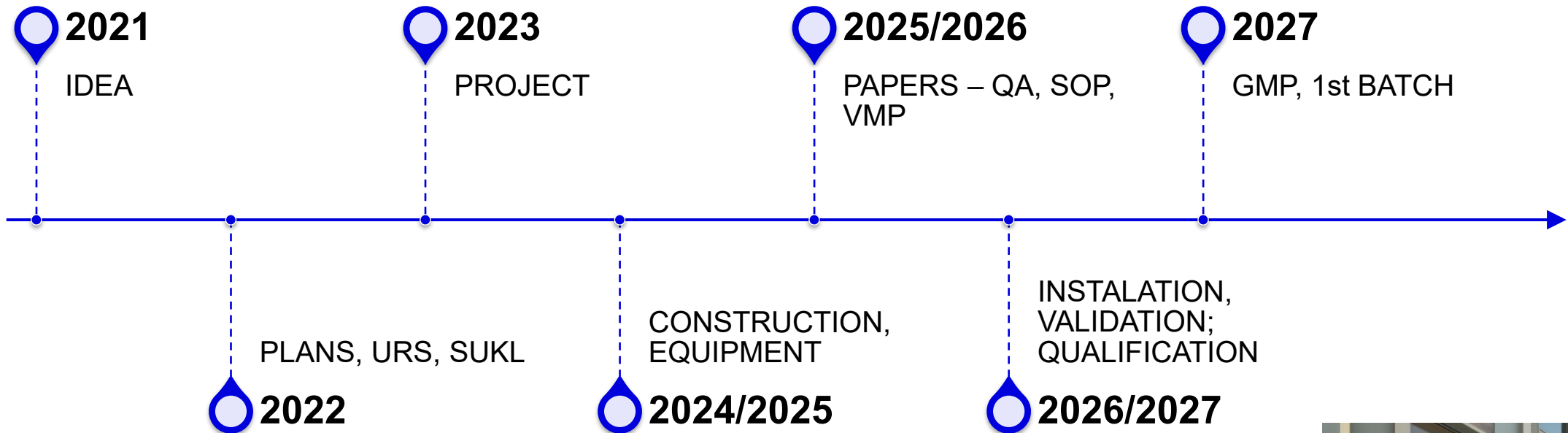


GMP PP - Mission

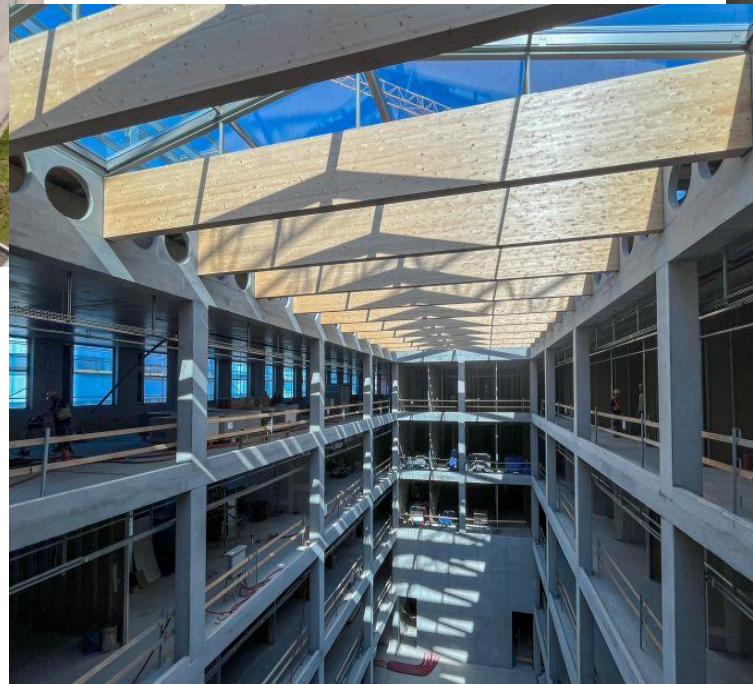
- connection of R&D with the industrial sphere
- modern GMP facility will have a significant scientific-research contribution
- **transferring excellent research results into practice**
- the facility will supplement large-capacity manufacturers



GMP PP - Timeline



BPH - now



Cooperations - non GMP

Services and cooperation in R&D of application/dosage forms in non-GMP mode:

- research, development, and evaluation of modern solid, semi-solid, and liquid dosage forms
- areas of pharmacy, cosmetics, medical devices, veterinary medicine, food industry
- consulting activities, formulation proposals, solving formulation problems
- evaluation of dosage forms, stability studies, analytics
- cooperation in projects as the university partner
- Ph.D. study or internship on a specific project

Current partners and projects

- Addicoo – modern veterinary application forms
- Oritest – toxic substance detection tubes
- Oncomed – parenteral lyophilized drugs
- Promed – formulation of innovative solid preparation
- Hartmann – medical devices



Formulation of tablets, capsules, fluid processes

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<https://biopharmahub.muni.cz/en>

<https://www.pharm.muni.cz/en/science-and-research/research-activities>

