MANUFACTURING SCIENCE AND TECHNOLOGY

Biopharmaceutical and aseptic manufacturing processes of

Tomorrow: Today

VTU

Manufacturing Science and Technology

Process development. Commercial production. Successful product launch

As experts in biopharmaceutical and aseptic manufacturing processes, we provide state-of-the-art technical-scientific as well as regulatory expertise, tailored for the pharmaceutical industry.

Your Benefits:

Many years of experience and numerous successful projects

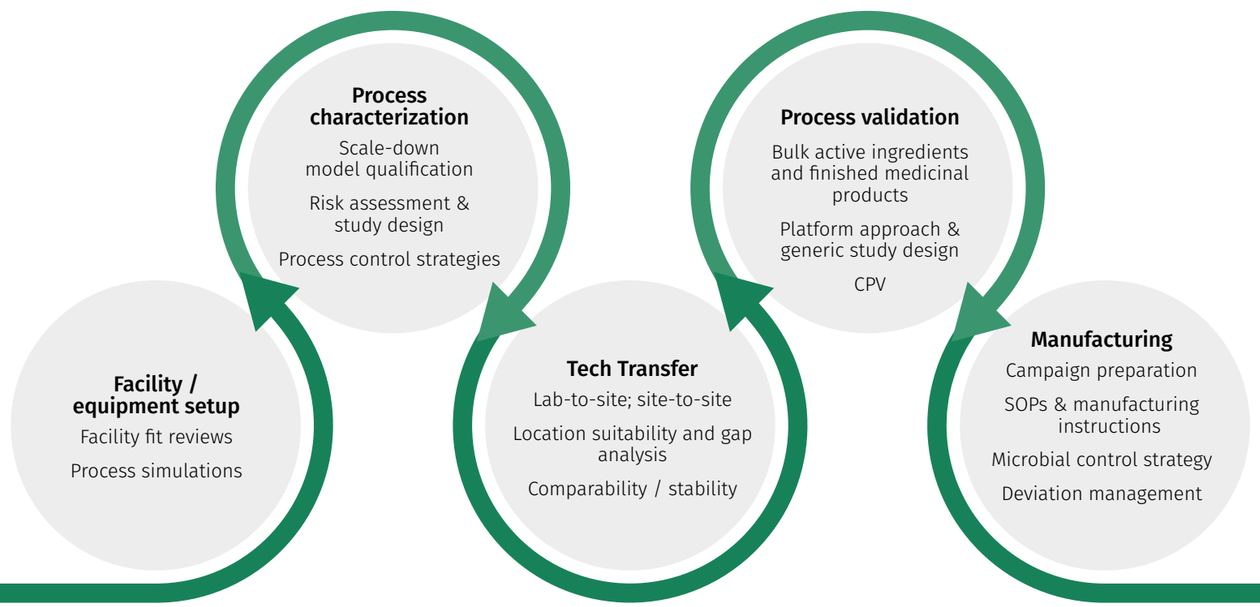
As an experienced partner with a multitude of proven successful projects, we support you during process development and characterization, through to transfer and validation projects and process life cycle. We offer consulting, technical project management as well as the monitoring, data analysis and documentation of necessary studies in order to ensure your success.
We work in accordance with current legislations and FDA/EMA requirements and advise you on the implementation of currently applicable (legislative) requirements.

Increased profitability

We ensure that all project resources - internal and external - are used optimally during the entire project period.
Individual concepts are integrated into platform strategies for higher flexibility, reduced workload and a more promptly achieved, successful submission.

On time

Our customizable staff allocation ensures flexibility even during peak workload periods. Consequently, you can rely on a duly submission at all times.



Our Services:

Conceptual support and management:

- Process development / CMC projects
- Process characterization
- Technology transfer for commercial proucts and from R&D
- Process validation
- Platform and QbD strategies
- OPV / CPV programs
- Process intensification
- Process analytical technology (PAT) and multivariate process control
- Support during regulatory filing and pre-approval inspection

Study design and documentation:

- Process development
- Process characterization
- Process validation
- Cleaning validation
- Technology transfer of manufacturing processes
- Statistical process control (CPV/OPV)
- Process optimization and debottlenecking

Health authority inspections – preparation and management

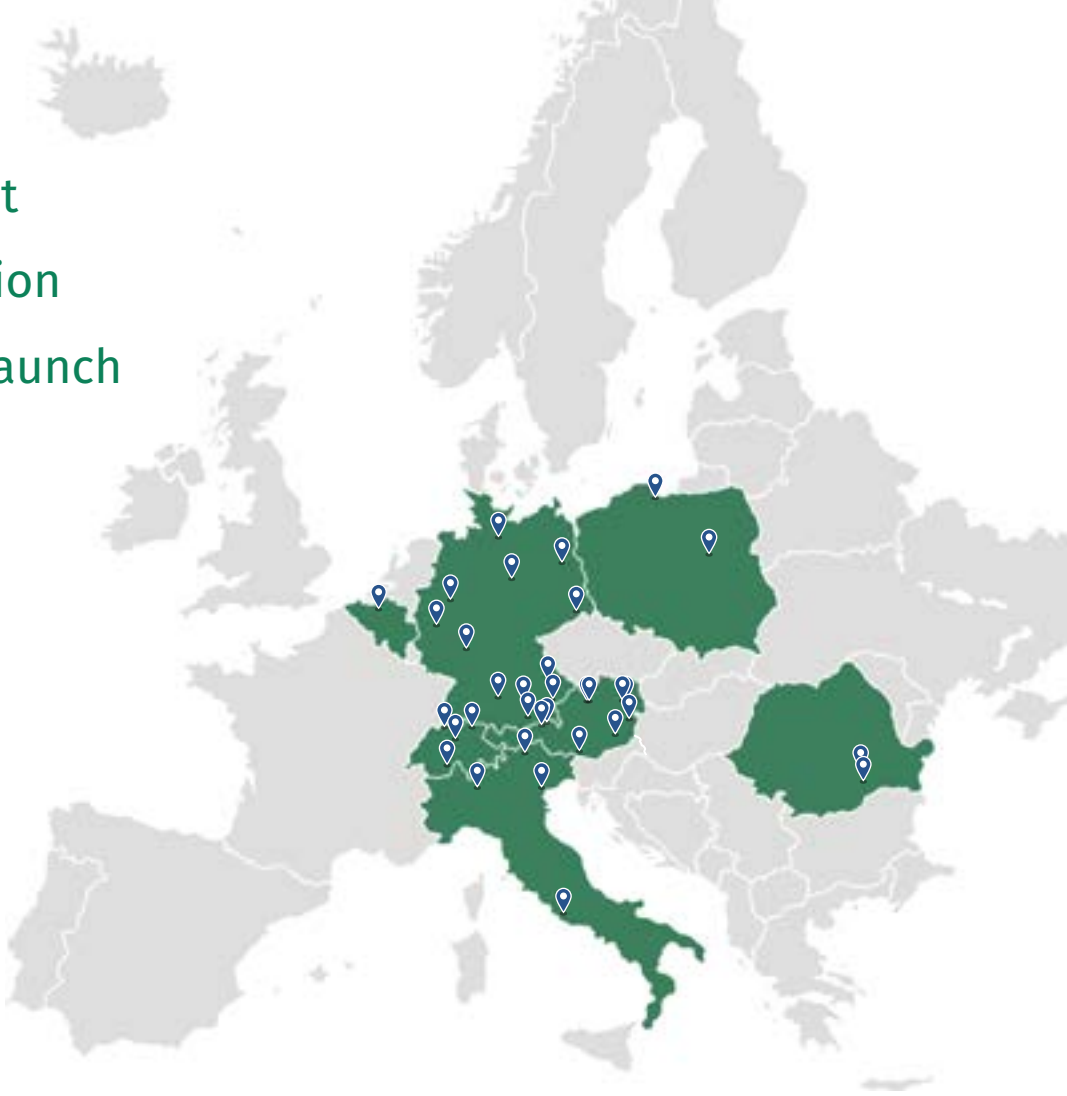
Creation of risk analyses, control strategies, studies:

- Facility fit / tech transfer risk analyses
- Process control strategies (ICH Q8)
- Contamination control strategies (Annex 1)
- Virus control strategies
- Process parameter risk analyses
- Evaluation of cleaning validations
- Assessments and study support on current regulatory topics such as elemental impurities, nitrosamines, extractables & leachables, microbial control
- Study protocols, data analysis and reporting

Process development

Commercial production

Successful product launch



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