Manufacturing Science & Technology

From process development to commercial production towards a successful product launch

The VTU Manufacturing Science and Technology expert group offers the highest expertise in late stage process development (process characterization), technology transfer, commercial manufacturing including a successful ramp-up, as well as GMP services like validation of cleaning and production processes. We provide up-to-date regulatory, technical and scientific expertise customized to pharmaceutical manufacturers and process owners.

This includes:

> **Conceptual assistance and management of**
- Late stage process development
- Process characterization
- Technology transfer
- Process validation & commercial manufacturing
- Platform and QbD strategies

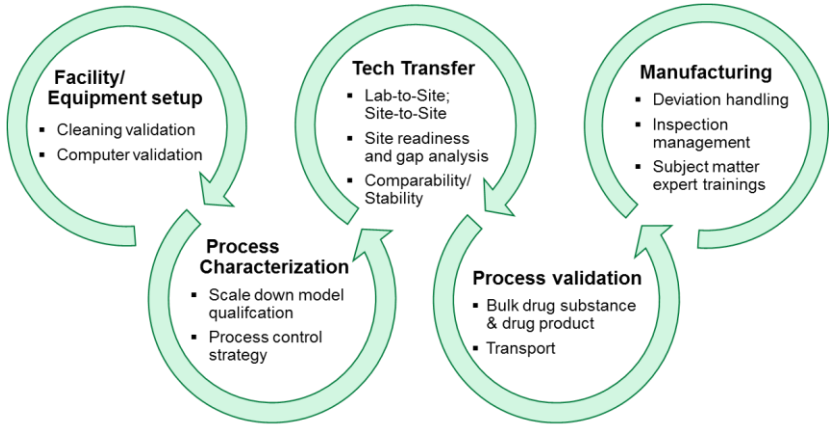
> **Study design and documentation for**
- Process characterization
- Process validation
- Cleaning validation
- Tech transfer
- Computerized systems validation
- Analytical methods validation and transfer
- OPV/CPV

> **Writing of assessments, SOPs, protocols and reports**
- Process control strategy (ICH Q8) / microbial control strategy (Annex 1)
- Process risk assessments
- Cleaning validation assessments
- Elemental impurity / extractables and leachables assessment
- Process characterization / validation studies
- Comparability / stability studies

> **Investigations and CAPA management**

> **Health authority inspection – preparation & management**

Our highly experienced personnel assists in establishing integrated manufacturing processes by introducing sound development and validation strategies. We cover the entire product lifecycle up to aiding in the implementation of OPV/CPV programs, successful deviation handling and inspections. We set up individual quality by design concepts and integrate them into platform strategies, allowing for more flexibility, reduced workload and reduced time to a successful submission.



We have proven experience in the fields of:
- Biotechnology-derived and organic API production (NBE/NCE and biosimilars/generics)
- Vaccine production
- Compounding & fill-finishing processes

We apply the most common tools to perform statistical process evaluations, design of experiments and statistical process monitoring. Powerful simulation tools support the optimization and debottlenecking of processes and systems:
- SAS JMP
- Modde
- Minitab
- Discoverant
- SuperProDesigner

Our work is aligned with current legislation and FDA/EMA requirements. Over the last decade we have contributed to numerous pre- and post-approval GMP inspections, leading to successful product submissions and production continuation.

Your benefits:

> **Proven quality**
- Successful process validation
- Successful submission
- Successful transfer
- Scientifically sound concepts
- Customized solutions
- Smooth interface between CMO and license owner

> **Higher profitability**
- Assistance in peak workload situations/ understaffed divisions

> **On time**
- Submission on time
- Adjustable personnel allocation

VTU engineering

Your person to contact

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