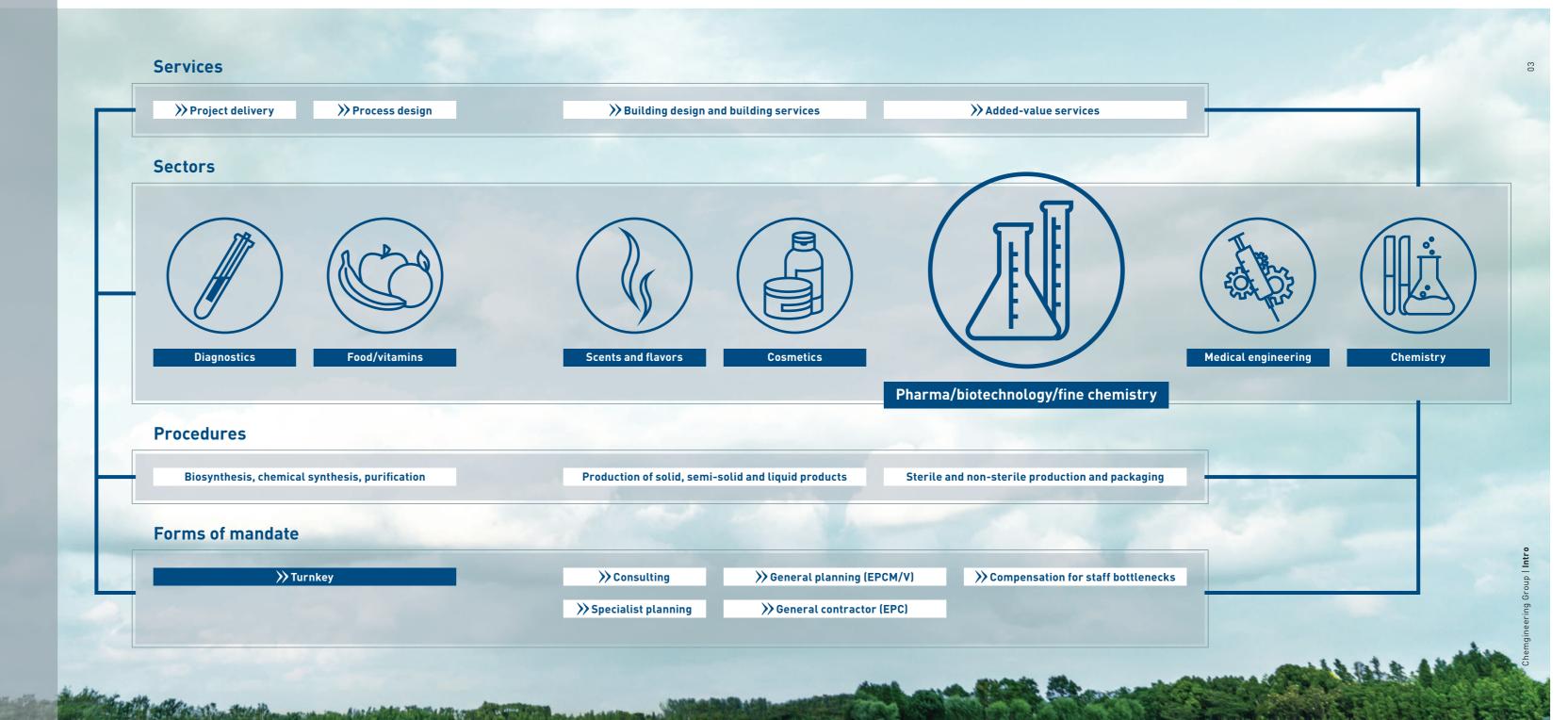


It's possible - with fresh ideas from us.



Getting to grips with investment projects?

It's simple - with our specialists at your side.

your suppliers and subcontractors, and can provide you with



Controlling, purchasing and budget – who is responsible for the various aspects?

We plan your project so precisely that all work packages and responsibilities are clearly defined right from the outset.

>>> Project management

In the kick-off meeting we jointly define the framework conditions for our project together and document them in the project nandbook. To ensure smooth communication from the outset, you will have a central contact person who coordinates closely with you throughout the project and who will be available to assist you until the final presentation of the product.

Scheduling

Work packages, tasks, resources, and milestones We fully integrate all elements by not only documenting the individual planning elements but also illustrating how they relate to each other. This allows us to maintain an overview not only of individual changes, but also their consequences for the entire project.

>> Expediting

We coordinate your suppliers with professional expediting and a structured procurement process. We ensure that all required plant components are delivered to the construction site at the right time, at the stipulated level of quality, and on budget by means of on-site appointments and intensive support from ordering to delivery.

Construction management

We coordinate all trades and check whether the defined performance has been achieved, and that the quality of the work results is appropriate. The entire construction process is documented.

Commissioning

In the Site Acceptance Test (SAT), we check directly at the installation site that your system is working correctly and that the full scope of delivery has been met.

Need to find the right solution quickly?

Our advanced concepts are your go-to option.



From the feasibility study to commissioning:

>> We develop technology solutions individually tailored to your needs, to ensure a GxP-compliant and reliable process.

Process design

Factory planning

Framework conditions in life sciences sectors are undergoing rapid change, in particular mergers and acquisitions, technical innovations, and increasing regulatory requirements. Integrated and effective

factory planning enables you to react flexibly to changes and to ensure efficient production.

Pharmaceutical production including galenic formulation, finishing and packaging

We compile and check all operator information so that we can select the optimum procedure for your plant, and laboratory and pilot plant

tests are also used to ensure that all user criteria are met.

Biotechnological production

for the relevant cell type or microorganism. Our specialist planners work is selected.

Biotechnological production plants must meet the specific requirements—with you and ask the right questions to make sure the right procedure

API synthesis plants

Our interdisciplinary teams devise and implement plans to prepare your plant for the production of Active Pharmaceutical Ingredients (API).

Our specialists' extensive experience means you can be assured that all process-relevant criteria are taken into account and efficiently met.

Process energies and media

The quality, product properties and stability of process energies and media influence the quality of the end product and how your production performs. By making the right selection, we help you ensure efficient and environmentally friendly production.

Process automation

We develop advanced and flexible process automation concepts, meaning that our clients benefit from consistently high quality in their products, while also saving both time and money. These concepts can be easily adapted to new technologies, and feature intuitive operation which re-

duces your processes' susceptibility to errors while also safeguarding patient safety. There is no longer anything standing in the way of completely integrating all work steps - Industry 4.0 is possible.



BIM (Building Information Modeling)

Building Information Modeling enables us to implement integrated digital planning and for all planners to work jointly on a building model. This offers key benefits for

- Better decision-making through the simulation and visualization of variants
- Reliability of costs and scheduling at an earlier stage
- Clear planning
- Complete documentation

Chemaineerina Group | Added-value ser

Do you want to run your daily operations worry-free on a long-term basis?

You've never had so many options.

With our services, we help you operate your business efficiently, safely and progressively over the long term, meaning you can guarantee consistently high quality in your products, deliver on your brand promise, and remain competitive. To support you in this, organization, operational processes, and IT systems are continuously further developed and adapted to changing framework conditions to ensure efficient plants, high-performance organization and audit-proof systems and



For consistent quality and agile management:

Our service solutions create real added value for your investment.



Added-value Services

Management consulting

- Mergers and acquisitions
- Strategy workshops
- Strategic location analyses
- Market environment analyses
- Calculations of the costs of goods sold
- Implementation of key figures
- CIP implementation
- Management information systems
- Efficiency in quality assurance and control
- Work distribution analysis
- Carve-out
- Redesign of the organizational structure
- 360° management evaluation
- OEE improvements
- Process analysis and optimization

Consulting on pharmaceutical compliance

- Lifecycle management for processes and plants
- Concept development
- Quality management: Optimization and implementation
- Risk management
- Quality oversight & KPIs
- Training on all quality-related subjects
- ICH Q3D implementation
- Technology and method transfer
- QC system optimization
- Analytical method validation
- Supplier qualification and third-party audits worldwide
- Preparatory and follow-up work relating to inspections
- Mock audits & GAP analyses
- Reliable track-and-trace concepts
- Person-in-plant and interim management

Medical Device Compliance consulting

- MDD/IVD transition to MDR/
 IVDR
- ISO 13485:2016 certification
- Support in the international approval of medicinal products
- Support in the implementation of audits (MDSAP, preparation for audits by the specified authority, FDA/ANVISA, internal audits, supplier audits)
- Management of the complaints procedure
- Risk management (ISO 14971)
- Compliance advice for combination products

Qualification and validation

- Individual qualification concepts
- Risk analyses
- Standard work instructions
- Plant qualification
- Qualification reviews
- Re-gualification
- Qualification in the context of decommissioning
- Qualification of laboratory equipment
- Process validation
- Cleaning validation
- Sterilization validationTransport validation

Efficient IT

- Validation of non-validated legacy systems in the event of
- Changes in regulatory require-
- Changes in the business model,
 - addition of products or new
 - markets
 Merger/demerger situations
 - Strategic topics:
 - FIT/GAP analyses of existing systems and IT service processes; definition of corrective measures
 - Checking, correcting and setting up the necessary CSV SOPs
- and templates in the IT service
 - Suggestions for improving the validation system (Lean Validation)
 - Audit preparations (e.g. FDA, official or client audits)
 - IT audits for our customers within supplier organizations

- IT/validation project manage-
- In-house training
- Prospective validation consulting and support in the event of software systems being introduced:
- IT-supported business processes, e.g. ERP (SAP, MS-Dynamics, GUS-OS, and others)
- LIMS for laboratory processes and automation/control of laboratory equipment
- MES/SCADA/SPS in production
- Track & Trace solutions
- QM systems
- Document management systems
- Excel spreadsheet validation
- Other solutions: CAPA, EBR, intranet, SPS, Big Data, cloudbased applications
- IT infrastructure
- Revalidation in the event of release changes

Maintenance management

- Maintenance master plans
- Maintenance strategies
- Spare parts strategies
- Analysis of maintenancerelevant data and docu-
- "Bad Actor" and "Waste Producer" analyses
- Cause analyses
- Downtime management
- Equipment assessment
- SOP drafts
- Development of draft specifications for the operational processing of maintenance
- Developing a resource structure
- Spare parts management
- Shutdown coordination



>>> Registered office

Switzerland

Münchenstein (Basel) T +41 61 467 54 00

Sites

Germany

Wiesbaden Stuttgart Heidelberg Hamburg Leipzig

T +49 611 77 88 70

Austria

Vienna Kirchbichl | Tirol Kundl | Tirol Linz

T +43 1 255 74 13 13

Poland Gdansk

T +48 504 028 892

Serbia

Belgrade T +381 11 4003 580

Spain

Sant Cugat del Vallès (Barcelona) Madrid T +34 932 384 990

>> Publishing information

Chemgineering Holding AG

Binningerstrasse 2 4142 Münchenstein | Switzerland

info@chemgineering.com www.chemgineering.com

chemgineering