

## From the basic evaluation to turnkey delivery:

**We provide all levels of performance through to commissioning for all specialized systems :**

*New building, retrofitting, renovation, expansion, modernisation*

*Pharmaceutical, biotechnology, cosmetics, manufacturer of active pharmaceutical ingredients, food, textile industry, logistics projects*

Feasibility studies - conceptual design  
Basic engineering - design documentation  
Detail engineering – implementation planning  
Preparation and participation in the awarding of contracts  
Site supervision - construction management  
Project supervision and documentation  
Project co-ordination, management  
Quality assurance - qualification  
Cleanroom and hygiene monitoring

## Our range of services in detail:

### **1. Operation analysis**

*Pharmaceutical, cosmetics, food, manufacturer of active pharmaceutical ingredients (API), biotechnology, textile industry, logistics projects*

Assessment of actual data in terms of products, processes, machinery, personnel, rooms, material flow , warehouse, costs,  
Analysis of critical points, risk assessment, Evaluation of GMP /FDA compliance  
Cost analysis  
Recommendations concerning potential improvements

### **2. Product reengineering**

*Pharmaceutical, cosmetics, food industry*

Optimisation of the product portfolio  
Optimisation of in-house-production - external production

### **3. Process reengineering**

*Pharmaceutical, cosmetics, food, textile industry*

Optimisation of formulations and production processes  
Optimisation of batch sizes and campaigns  
Planning and execution of tests and analyses for the introduction of new technologies through to detailed process development  
Classification of new machinery and equipment

- 4. Capacity planning**  
*Pharmaceutical, cosmetics,  
food, textile industry*  
*logistics projects*
- Identification of the areas required for machinery, equipment, personnel, logistical facilities, energy and media such as electricity, process water, clean water, compressed air, clean air, gases, information, control and communication systems, etc.
- 5. Area design and spatial planning**  
*Pharmaceutical, cosmetics,  
food, manufacturer of active  
pharmaceutical ingredients APIs,  
textile industry*  
*logistics projects*
- Definition of the cleanroom and ancillary areas  
Definition of the storage areas and material flow ranges  
Zoning of all areas in accordance with GMP/FDA  
Determination of space requirements and ceiling height in each area
- 6. System and layout design**
- 6.1 Pharmaceutical**
- Material storage and supply
  - Weighing, large and small quantities
  - Solids production and packaging
  - Liquid production and packaging
  - Semisolid production and packaging
  - Injectable production and packaging
  - Production and packaging of special-purpose products, e.g. antibiotics, hormones, etc.
  - Quality control, research and development
  - Social and ancillary areas
- System and layout design**
- 6.2 Biotechnology**
- Material storage and supply
  - Weighing, large and small quantities
  - Development of process data flows (pdf) and P&I diagrams (process and instrumentation diagrams)
  - Development of 3D models
  - Compilation of auxiliary equipment, test points and special part lists
  - Preparation of project pipe classes, special parts specifications and descriptions
  - Preparation of isometric drawings
  - Draw up layout and facility plans

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<b>System and layout design</b>	<ul style="list-style-type: none"><li>• Material storage and supply</li><li>• Weighing, large and small quantities</li><li>• Production and packaging for beauty and health care cosmetic products</li><li>• Quality control, development</li><li>• Social and ancillary areas</li></ul>
6.3. <i>Cosmetics</i>	
<b>System and layout design</b>	<ul style="list-style-type: none"><li>• Weighing, large and small quantities</li><li>• Manufacturing and packaging</li><li>• Quality control, development</li><li>• Social areas</li><li>• Ancillary areas</li></ul>
6.4. <i>Food Industry</i>	
<b>System and layout design</b>	Definition of the materials handling system technology
6.5. <i>In-house and external logistics, storage, materials flow</i>	Definition of the storage systems technology
	Designing areas
	* Incoming goods, sample taking
	* Raw and packaging material storage
	* Finished products storage
	* Tank farms
	* Storage of hazardous materials
	* Cold storage facilities
	* Order picking, shipping
	* Material flow areas
	* Information flow systems

- 7. Preparation and participation in the allocation of machinery, equipment, building services and logistic facilities**
- Pharmaceutical, biotechnology, cosmetics, food, active pharmaceutical ingredients,, textile industry*
- logistics projects*
- Provide technical specifications, functional specifications for tenders, detailed contract specifications
- Examination and evaluation of the quotations using a decision matrix
- Negotiations with bidders
- Instrumental in placing of orders
- Carrying out inspections
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- 8. Utility and Water treatment systems**
- Pharmaceuticals, biotechnology, cosmetics, food, active pharmaceutical ingredients,, textile industry*
- Planning of water treatment and distribution systems for GMP-/FDA compliant manufacturing and distribution of clean water in accordance with USP and water for injection (WFI), as well as pure and ultra pure steam
- Planning/configuration management (CM) of GMP /FDA compliant ventilation and air conditioning systems
- Cleanroom monitoring according to EN ISO DIN 14644 and VDI 2083; particle measurement, differential pressure measurement, cleanroom classification, inspection report
- Industry independent for all air conditioning plants**
- Hygiene inspections of air conditioning plants in accordance with VDI 6022, Cat. A, initial and subsequent inspections
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- 9. Quality assurance systems**
- According to FDA**
- According to cGMP**
- According to GxP**
- Qualification/validation**
- Quality assurance**
- Quality control**
- Pharmaceuticals, biotechnology, cosmetics, food, active pharmaceutical ingredients, textile industry*
- Analysis of the test specifications and testing equipment
- Definition of new test specifications and testing equipment according to GMP/FDA aspects
- Preparation of User Requirement Specifications/URS
- Examination of functional specifications
- Risk analysis according to FMEA, HACCP or HAZOP
- Implementation of all calibration and qualification measures: DQ, IQ, OQ, PQ for machinery and equipment, computer and computer systems, buildings including service facilities and systems, equipment, etc.

	<p>Validation of cleaning procedures Hygienic design evaluation Developing of Site master files Developing of SOPs</p>
<p><b>10. Project management (PM) Construction management (CM)</b></p> <p><i>Pharmaceutical, biotechnology, cosmetics, food, active pharmaceutical ingredients, textile industry, logistics projects</i></p>	<p>Compilation of a/participation in a PM/CM team in accordance with project requirements</p> <p>Create the project execution plan and the project manual</p> <p>Development and management of project and detailed schedules and expediting all components</p> <p>Preparation or examination of tenders, tender documents and contract specifications</p> <p>Participation in procurement of all technical teams</p> <p>TQS implementation of policies, preparation of test plans</p> <p>Design and supervision of building site facilities</p> <p>Pro-active management, co-ordination and supervision of individual technical teams</p> <p>Monitoring of deadlines, project progress, quality and budget compliance</p> <p>Claim and change management</p> <p>Reporting and benchmarking</p>
<p><b>11. Industrial safety and operational hygiene</b></p> <p><i>Pharmaceutical, cosmetics, food, active pharmaceutical ingredients, biotechnology, textile industry, logistics</i></p>	<p>Audit, plant inspections</p> <p>Safety analyses</p> <p>HAZOP/PAAG - studies</p> <p>Safety programs and regulations</p> <p>Measures to implement legal requirements</p> <p>Noise and hazardous materials measurements</p>