

ZETA  
**BEST**  
PRACTICE



## PHARMACEUTICAL MANUFACTURING

- Multiproduct System for 30+ products
- Dynamic Project Execution
- Fully automated

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FLEXIBILITY AT THE HIGHEST LEVEL

# MULTIPURPOSE PILOT PLANT

Designed for clinical and future routine production  
of new products and pilot production



## CHALLENGES

### The plant design must cover clinical and future routine production of new products in addition to pilot production.

The utmost in flexibility thus needs to be implemented to cover 30 established processes plus any additional new ones that are introduced for products from human blood plasma.

### The highest degree of efficiency means keeping down-times as low as possible, allowing production 24/7 and providing fully automated production processes.

The interdisciplinary ZETA engineering team, comprised of process, mechanical and automation engineers, developed and successfully implemented a multiproduct system meeting all requirements to full extent.

### The highly flexible multiproduct system for running the 30+ production processes

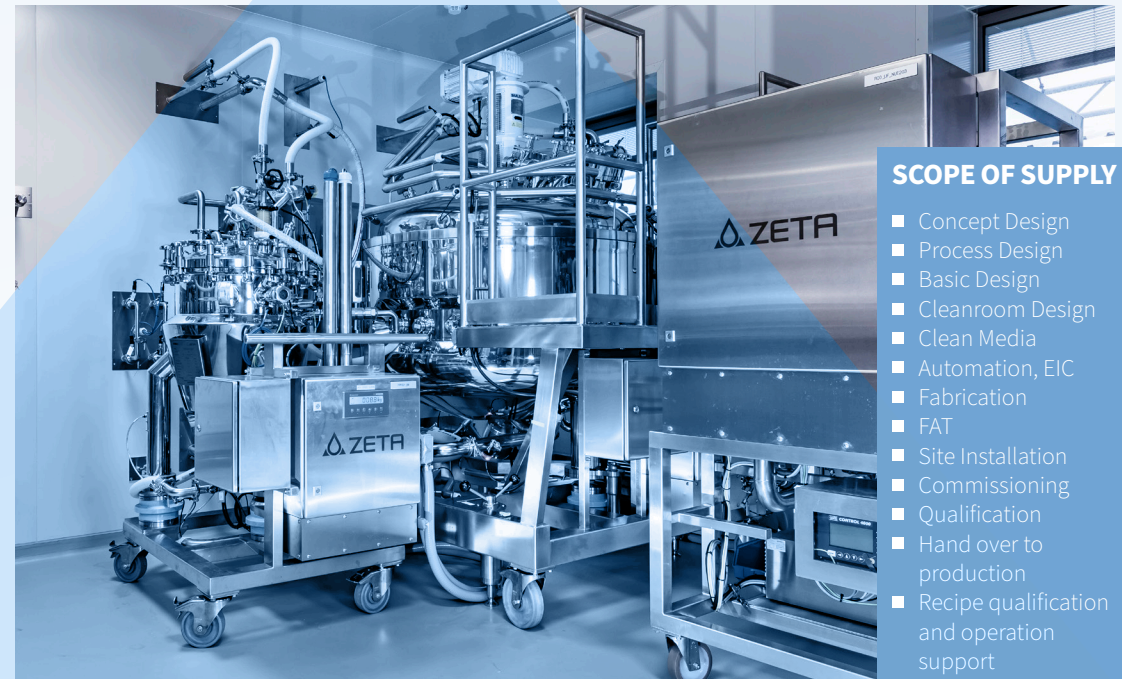
comprises up to 24 mobile vessels connected via 19 docking stations plus a wide range of special equipment such as centrifuges, chromatography systems, ultrafiltration system etc. The system recognizes the vessel automatically and links the vessel-specific data with the respective slot, thereby ensuring flexibility for further tests and production.

### To provide functional completeness despite limited space

all the equipment must be harmonized to deal perfectly with each process defined in terms of size and quality. 7 different types of process vessels - from 1,100l to 10l were designed, with unified connection and operation heights for usability. The design of the components must take them to the absolute edge of their performance limits (volumes). The maximum number and requirements for every docking station were elaborated based on the chart flow for each process.

### To meet the very tight time schedule

the ZETA super-skid concept enabled fast plant construction in parallel to the civil works activities at the customer's site. This complex multiproduct system was implemented in less than 36 months, from detail engineering through to first commissioning.



#### SCOPE OF SUPPLY

- Concept Design
- Process Design
- Basic Design
- Cleanroom Design
- Clean Media
- Automation, EIC
- Fabrication
- FAT
- Site Installation
- Commissioning
- Qualification
- Hand over to production
- Recipe qualification and operation support

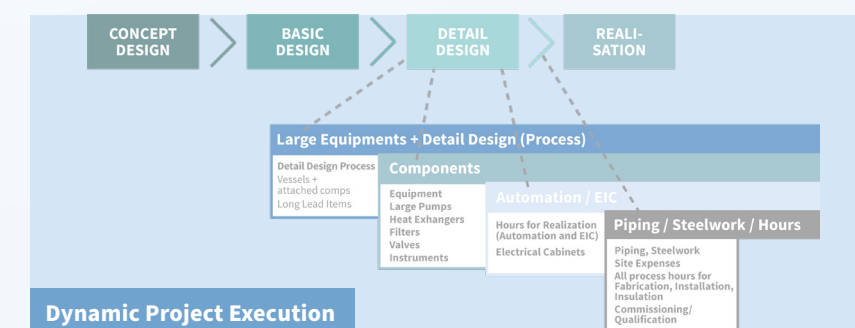
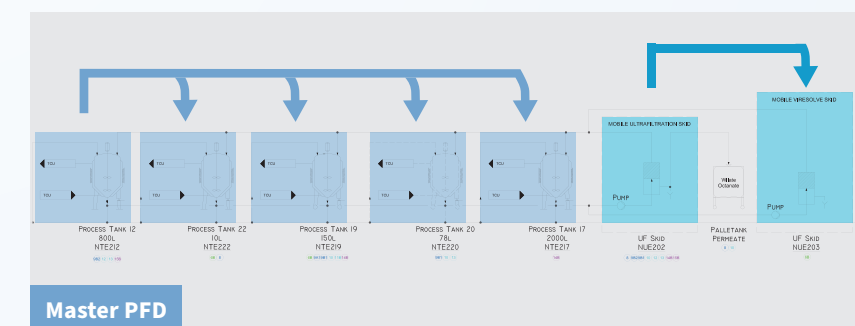
## HIGH-END ENGINEERING WITH FULL SERVICE BY ZETA

Maximum flexibility was the essential starting line for the new production facility to assure perfect cover for all current, hitherto known and potential new products. ZETA covers the entire range of the project requirements by starting early with concept design, progressing to basic and detailed engineering up to commissioning and qualifying new recipes on the production line. ZETA succeeded in setting new benchmarks in the realization of a multipurpose plant by handling this wide range of services.

The success of this project is mainly attributable to ZETA being integrated into planning at a very early stage as the engineering and equipment supplier, thus enabling prioritized planning steps according to research progress. Processes for more than 30 products have been developed, quantified and harmonized in order to merge them all in one master PFD as the basis for the equipment. To achieve connectivity and functionality of the pilot plant 24 mobile vessels have been automated and designed for the utmost flexibility. These are connected via 19 docking stations to the media and CIP system and also to the waste water and exhaust network. ZETA developed a space-saving design to overcome the spatial and architectural limitations. This innovation allows easy maintenance and access during operation despite confined space conditions. The most important target by far is meeting the time-to-market challenge! To do this ZETA has reached out far ahead in its thinking to include all future project activities that will be needed for bringing the plant into operation. The customer took on essential parts of the cleaning validation in parallel to ZETA's dynamic SAT maximizing the time saving.

- Process development and optimization
- Scale up routine & downscales
- Manufacture (pre-) clinical trial batches
- Produce one major product as routine product
- Manufacture commercial batches at pilot scale to bridge large scale production

“ZETA has used the unique plant design with all its challenges as chance to prove its unrivalled engineering expertise in providing full service. This project can be seen as a landmark in project execution that encourages solution development based on trust and highly motivated team spirit”, says Johannes Koch, ZETA Project Manager, and sums up: „Advice provided as needed, flat hierarchies encouraging target-driven decision-making and last but not least full cost transparency based on open book accounting have been the key factors to success and contributed to achieving all the project targets.“



## CHALLENGES

**Dynamic project execution.** On the basis of a new contracting approach providing cost truth at any time, the ZETA project management was empowered to act more flexibly in order to realize customer's demands exactly as wished. Total transparency by maximum control of expenses and handling change orders in real-time is an important step towards true reflection of cost.

**In order to provide a fully automated system,** consistent functional specifications have been developed, based on the process descriptions and P&ID drawn up by ZETA. Since the customer decided for the Simatic PCS7 process control system with Simatic Batch the automation engineers had to develop an application software in accordance with GAMP5 and S88. The installation of a batch management system with formula operation mode and the development of a sustainable reporting system for trend and production reports provide added value for both the user and the management.

**Plant integration was performed within two shutdowns; the essential stride for** doing this was a highly precise planning for moving in two steps within short time intervals for the integration into the existing infrastructure.

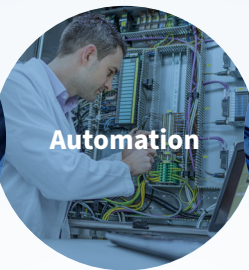
**Ramp Up.** To maximize the plant operation modes, ZETA supports the customer with the implementation of further recipes by preparing the recipe specification, coding, testing and qualifying the recipes. Furthermore, ZETA assists in plant operation to maximize the efficiency of the operator team.

## RELEVANT KEY FIGURES

24 process vessels: 1.100l to 10l  
9 media and secondary vessels  
131 heat exchangers, pumps, filters  
2.848 valves, 1.294 automated  
940 instruments  
7.400 meters piping, 16.300 fittings  
400 meters closed electrical piping  
106 electrical cabinets  
91 process units  
>140.000 working hours

# INNOVATIVE SOLUTIONS FOR OUR CUSTOMERS

## EVOLUTION OF TECHNOLOGY



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### **ZETA Business Activities**

Bioreactors & Fermentation Systems  
Downstream Systems  
Preparation Systems  
CIP/SIP Systems  
Magnetic Agitators  
Freeze & Thaw Systems  
Engineering  
Automation

### **Customer Benefits**

Deep Process Understanding  
GMP FDA Compliance  
Super-Skid Design  
Focus on Sterility  
High Process Reliability  
Scale-up Capabilities  
Experience in Complex Biologics  
Customized Process Systems

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