

cult.tainer



cult.tainer a turnkey concept to overcome ATMP (Advanced Therapy Medicinal Products) production bottlenecks.

cult.tainer®

Valicare, an experienced GMP compliance service supplier with special core competences in supporting ATMP manufacturer and Syntegon, an expert for processing and packaging technology, developed a concept to overcome the production bottleneck for ATMPs.

By using it, customer will get their products in clinical trials and on the market in a short and timely-manner.

Concept

The concept registered under cult.tainer® is modular and standardized to the regular cell manufacturing processes. This means short planning and construction time. Because of the modular basis it is also flexible and can be adapted to customized processes.

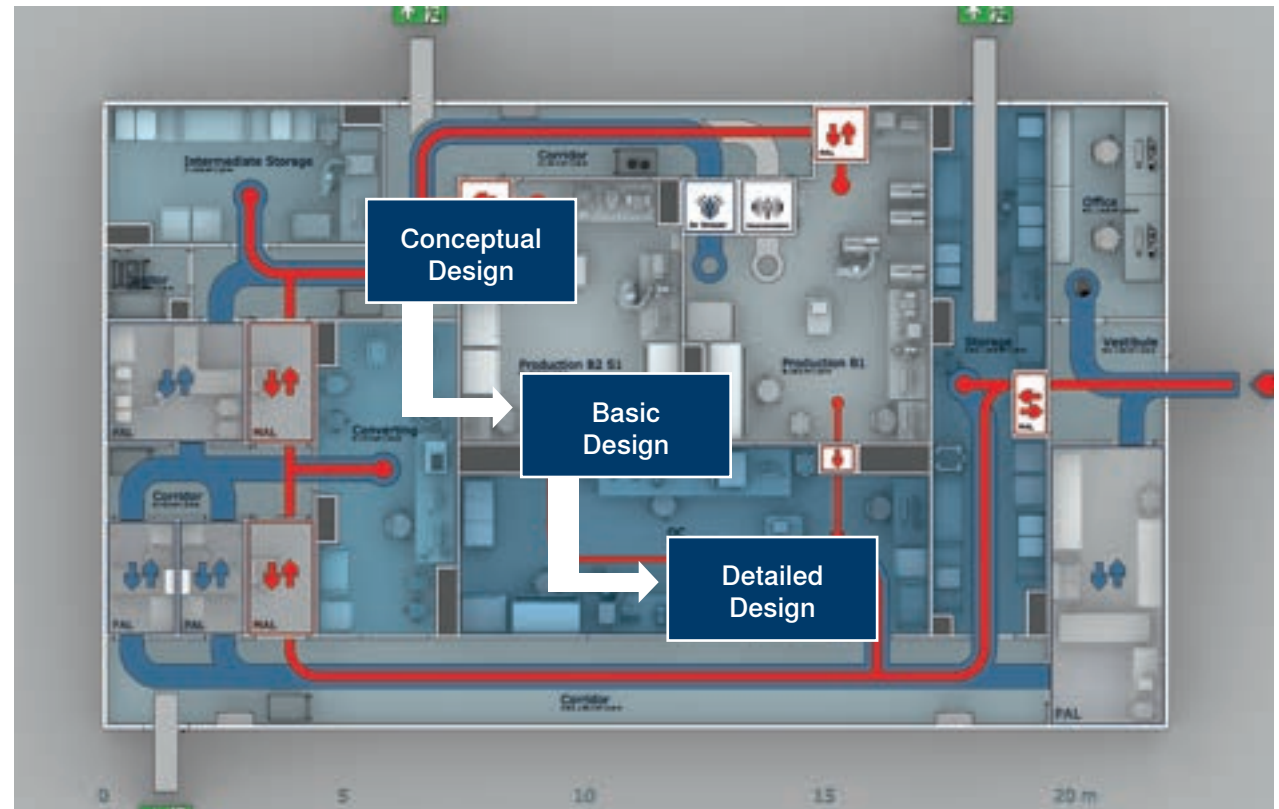
The overall concept includes not only the manufacturing of all the different types of ATMPs (cell and gene therapy not only CAR T-cells) but also biotissue, evaluation of starting and raw materials, vector production, quality control etc. grouped under the registered brand name valicare.tainer®.

Services

Based on the customized manufacturing process, Syntegon and Valicare lead you through the whole design planning of your facility. Optimal flow of process, personnel and goods guaranteed.

Process standardization and implementation is scheduled in parallel by ATMP experts. All services from development to marketing authorization and start of production can be booked in total or on demand.

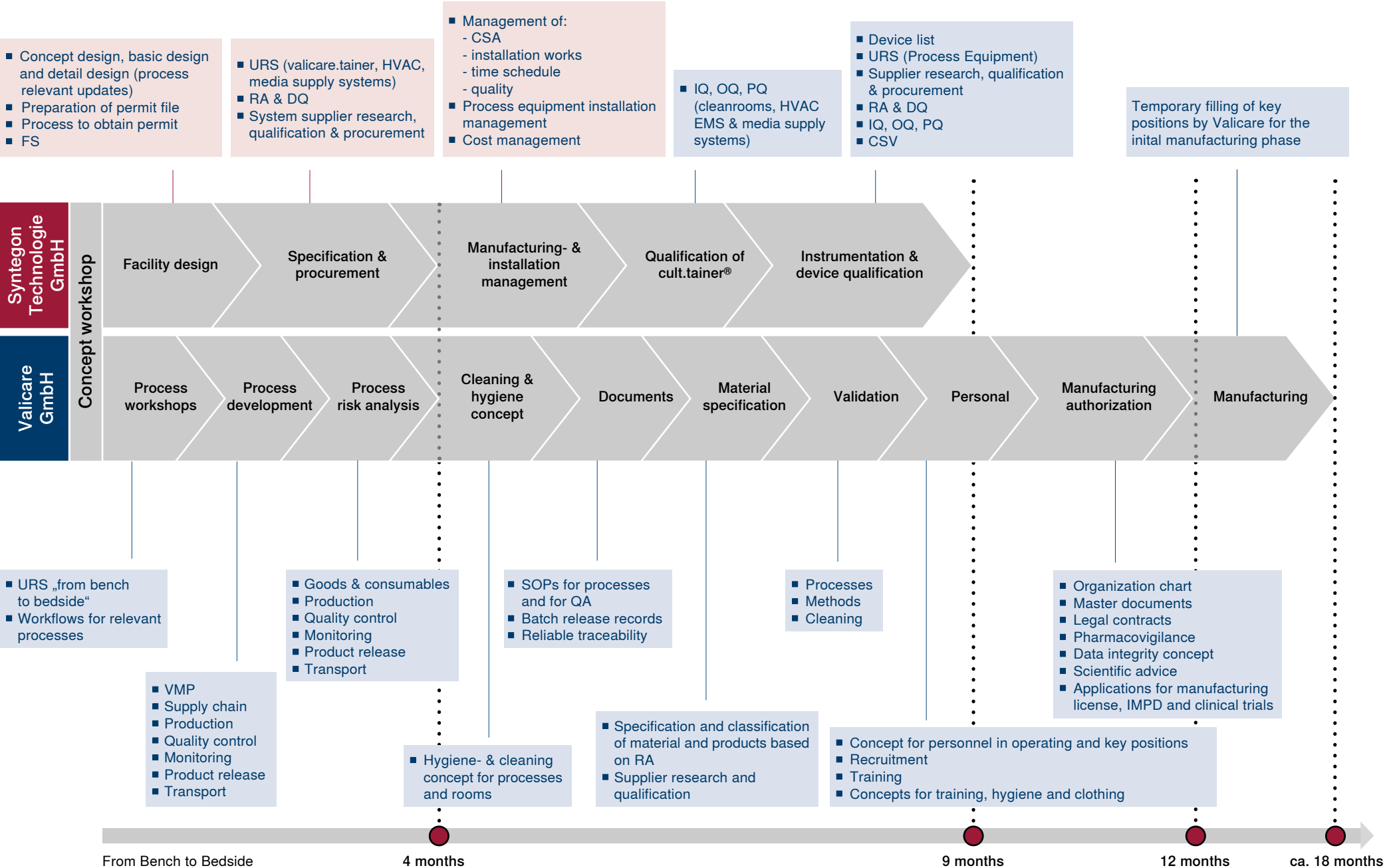
Save your time by getting all services from one source.



Our Competences:

- Experienced in facility design and construction support
- Experts for GMP processes and regulatory requirements specially for ATMPs
- Profound expertise in risk based ATMP manufacturing
- Teams of engineers and natural scientists coworking

Syntegon and Valicare experts support you along the entire value chain.



Service package can be ordered for the whole process or for every single step.

The cleanroom production modules are adapted to different processes and can be combined. Choose the modules you need for your production process from a wide range of variations. We will support you in layout planning, construction support and process implementation.

Manufacturing of GMP-grade input material

Viral vectors

Plasmid DNA

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Cell banks

Producer cell lines

- Plasmid DNA
- DNA vaccines
- RNA vaccines
- Minicircle DNA
- Lentiviral vectors
- Adenoviral vectors
- Adeno-associated vectors
- 3-Plasmid production systems

Manufacturing of ATMP

Cell therapy

Tissue engineering

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Gene therapy

Combined products

- Muscle stem cells
- Mesenchymal stroma cells
- Cartilage tissue
- Skin tissue
- Chimeric antigen receptor T-cells (CAR T-cells)
- Cytokine-induced killer cells (CIK)
- Tumor-infiltrating lymphocytes (TIL)

Pharmaceutical development & automation

Quality control

Filling devices for ATMP

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Automation

Logistics

- Vector filling
- Cell therapy product filling
- Cell culture automation
- Quality control automation
- Upscaling
- ATMP companion diagnostics
- Logistics & distribution
- Material & product testing

Sucessfully in GMP business for over 20 years

Contact us for support

Save time:
Getting all from one source.

Fast in realization:
Generic concept with 3-month planning and 9-month implementation

We support production of your first iATMPs.

Production know-how:
Remains with the customer.

Huge variety:
Coverage and complexity of different product types are given (automation optional).

Your Benefits

Optimize your profit:
Turnkey solution for production site, equipment, personnel, and manufacturing process.

Individual concept:
GMP-compliant modules individually customized to meet your specific needs: design and construction concept included.

Overcome critical steps from bench to bedside:
Fast and flexible solutions for a faster the market entry.

Lean back:
Get all GMP compliance services: documentation, qualification, validation, standardization and transfer.



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