cult.tainer - a brand of Valicare

Turnkey ATMP production solution

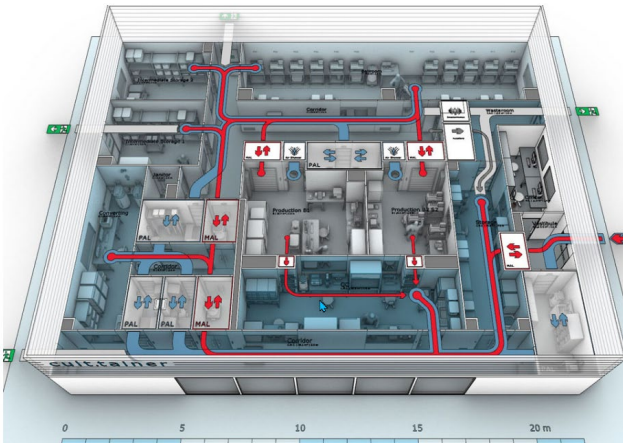
ATMPs must be manufactured aseptically and in accordance with good manufacturing practice (GMP) according to part 4 of EU GMP guideline. Therefore, the requirements in premises are very high and production capacities are scarce.

Valicare offers a unique opportunity:

In cooperation with the engineering and project management department of its parent company Syntegon Technology GmbH, Valicare created a new concept of cleanroom modular buildings (cult.tainer) for GMP-compliant development and manufacturing of starting materials up to iATMPs. These turnkey GMP-compliant cleanroom modules are customized to individual requirements.

Example for a Stand-Alone-Unit

- Required land plot of ~1,000 m^2
- Modular unit of approx. 470 m^2
- 12 – 18 month for facility setup up to manufacturing licence and start of production
- Aseptic manual manufacturing (cells & tissues)



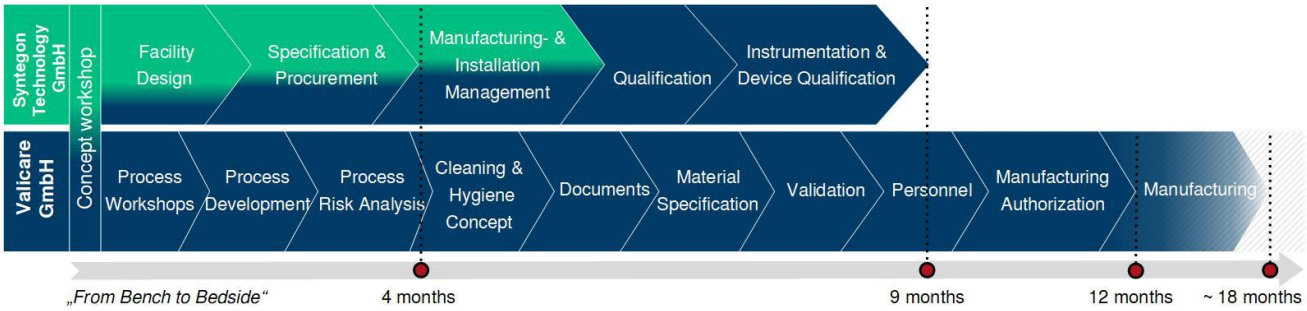
- Automation optional (culture systems, IT, Electronic Batch Record)
- Capacity for up to Phase III clinical study and market supply
- Clean rooms, QC-lab, office, storage including N_2-freezing, waste disposal

Benefits

- Turnkey solution for facility, equipment, personnel and manufacturing process
- Optimized flow of process, personnel and goods
- Quick and flexible manufacturing solutions with fast entry of products into clinical trials and into market
- Faster return of investment costs (profit optimization)
- Production expertise remains at customer

valicare
GMP Compliance Services & Solutions

Valicare and Syntegon support you successively in the planning, construction and set-up of turnkey cleanrooms:



- Concept workshops
- Feasibility studies
- URS for the overall process (“from bench to bedside”)
- Process risk management
- Process transfer & validation
- Supplier selection and qualification
- Personal management
- Pharmaceutical procurement and qualification of equipment for the manufacturing, control and storage of the ATMP
- More information are available on our website under Services ››GMP for ATMPs›› ATMP manufacturing solutions

Contact us if you are planning an ATMP manufacturing project or already started one. We will support you!

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