cult.tainer

valicare
GMP Compliance Services & Solutions

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

Sucessfully in GMP business for over 20 years

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.

Contact us for support

Dr. C. Papewalis
Head of ATMP Team
Telefon +49 69 153 293 710
Mobil +49 162 295 5876
Claudia.Papewalis@valicare.com

Dr. E. Sons-Brinkmann
Business Development & Marketing
Telefon +49 69 153 293 709
Mobil +49 172 413 0603
Ellen.Sons-Brinkmann@valicare.com

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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.
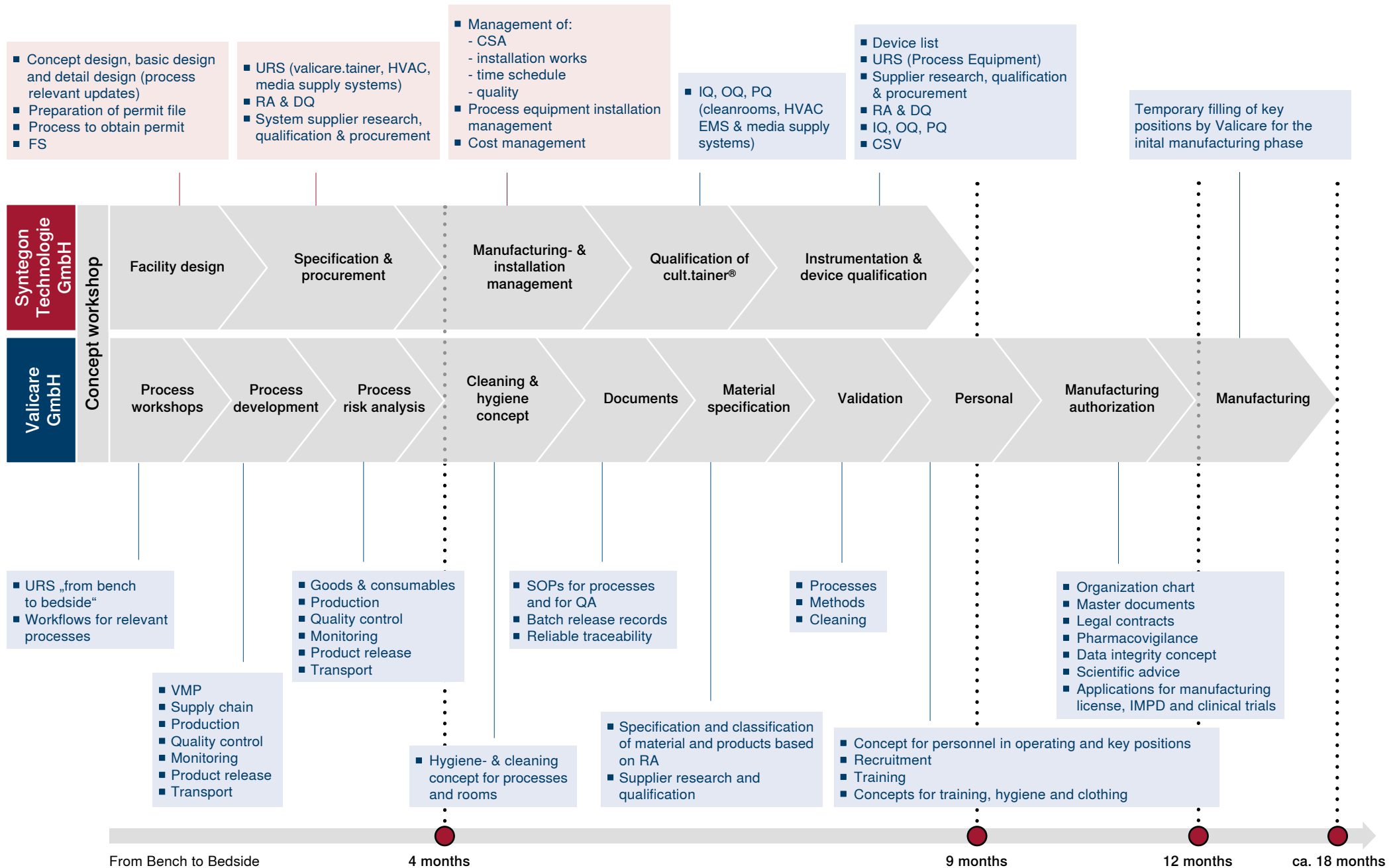
Save your time by getting all services from one source.
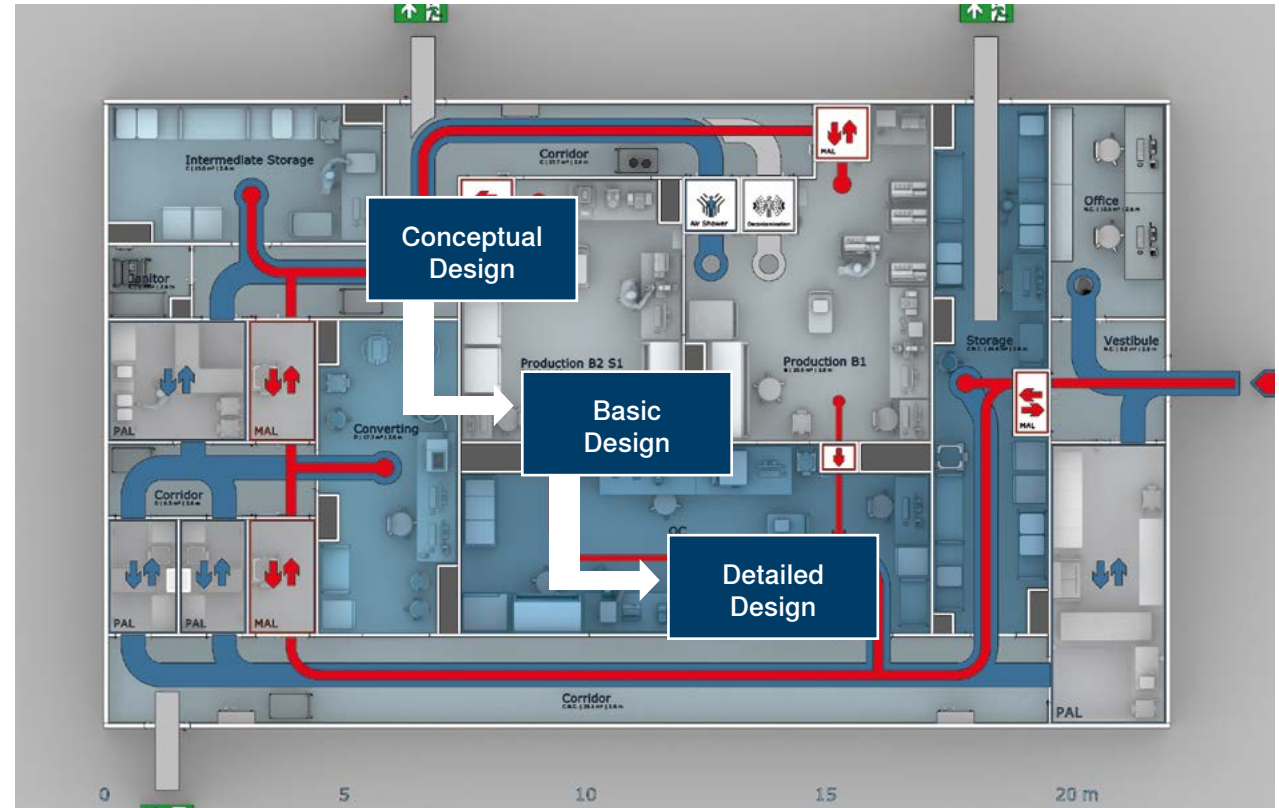
Our Competences:

- 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.

Top boxes (left to right):

- Concept design, basic design and detail design (process relevant updates)
- Preparation of permit file
- Process to obtain permit
- FS

- URS (valicare.tainer, HVAC, media supply systems)
- RA & DQ
- System supplier research, qualification & procurement

- Management of:
  - CSA
  - installation works
  - time schedule
  - quality
- Process equipment installation management
- Cost management

- IQ, OQ, PQ (cleanrooms, HVAC EMS & media supply systems)

- Device list
- URS (Process Equipment)
- Supplier research, qualification & procurement
- RA & DQ
- IQ, OQ, PQ
- CSV

- Temporary filling of key positions by Valicare for the inital manufacturing phase

Syntegon Technologie GmbH (process row):

Concept workshop | Facility design → Specification & procurement → Manufacturing- & installation management → Qualification of cult.tainer® → Instrumentation & device qualification

Valicare GmbH (process row):

Process workshops → Process development → Process risk analysis → Cleaning & hygiene concept → Documents → Material specification → Validation → Personal → Manufacturing authorization → Manufacturing

Bottom boxes (left to right):

- URS „from bench to bedside"
- Workflows for relevant processes

- VMP
- Supply chain
- Production
- Quality control
- Monitoring
- Product release
- Transport

- Goods & consumables
- Production
- Quality control
- Monitoring
- Product release
- Transport

- Hygiene- & cleaning concept for processes and rooms

- SOPs for processes and for QA
- Batch release records
- Reliable traceability

- Specification and classification of material and products based on RA
- Supplier research and qualification

- Processes
- Methods
- Cleaning

- Concept for personnel in operating and key positions
- Recruitment
- Training
- Concepts for training, hygiene and clothing

- Organization chart
- Master documents
- Legal contracts
- Pharmacovigilance
- Data integrity concept
- Scientific advice
- Applications for manufacturing license, IMPD and clinical trials

Timeline:

From Bench to Bedside — 4 months — 9 months — 12 months — ca. 18 months

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

Example for a Stand-Alone-Unit

- Required land plot of ~1,000 m^2
- Modular unit of approx. 470 m^2
- Aseptic manual manufacturing (cells & tissues)

- Automation optional (culture systems, IT, Electronic Batch Record)
- Capacity for up to Phase III clinical study and market supply
- Cleanrooms, QC-lab, office, storage including N2-tanks, waste disposal

Cleanroom classes:
- B
- C
- D
- CNC

Cleanrooms class C

Production

QC
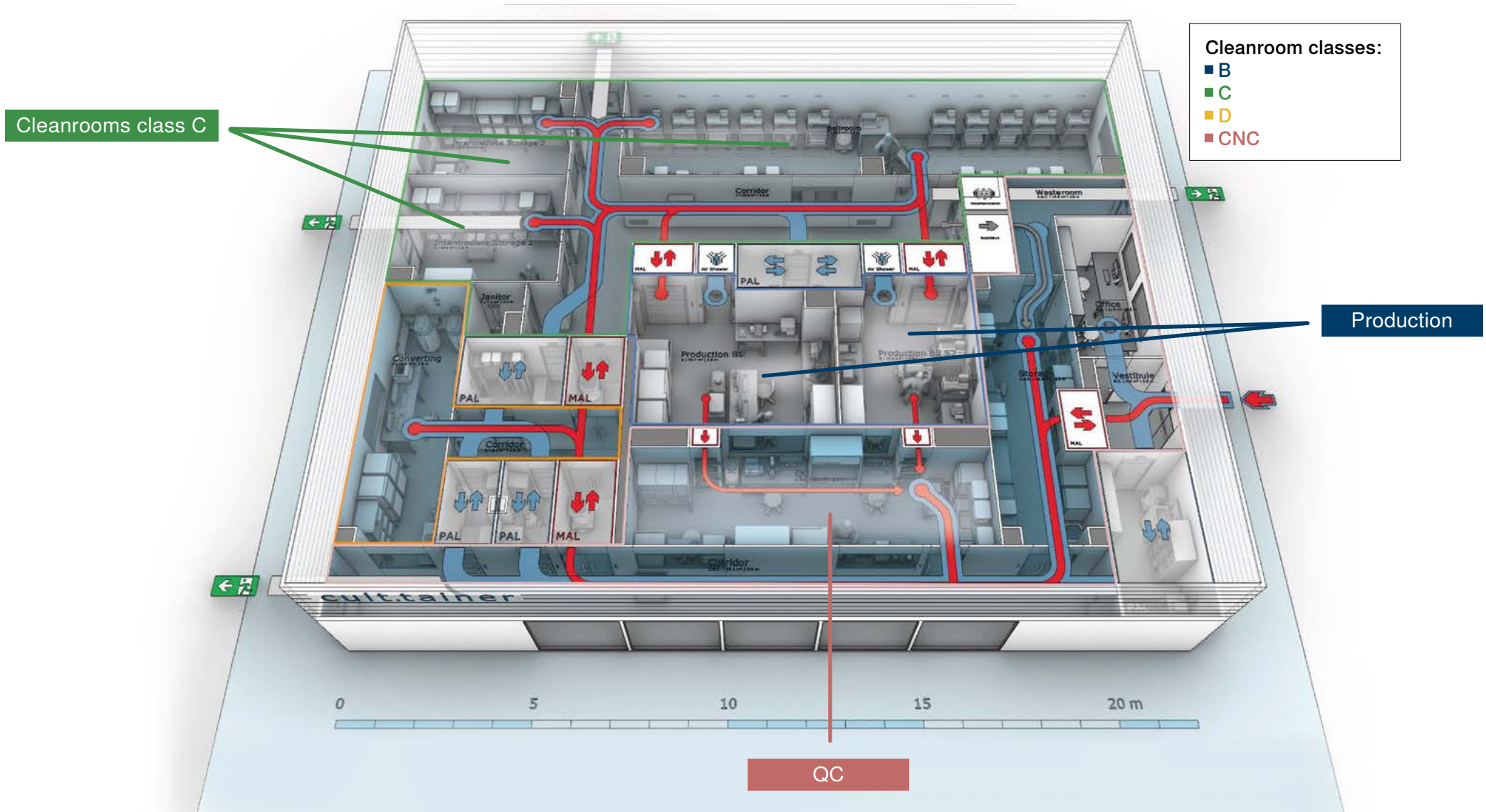
12 – 18 months for facility setup up to manufacturing licence and start of production

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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