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GMP COMPLIANCE SERVICE

Valicare GmbH / 2025

A member of the **Syntegon Group**
enables the pharmaceutical and biotechnological
industry in GMP projects worldwide

ABOUT US

GMP and ISO compliance services for the fields:

- **Daughter company of Syntegon Technology GmbH** a leading supplier of process and packaging technology
- **Support for pharmaceutical and biotechnology industry and for manufacturer of medical devices**
- Over **100 employees** work on **national and international GMP projects**
- **Permanent senior consultants** with **many years of GMP expertise** offer high quality compliance services
- **Multidisciplinary engineers and scientists** provide planning and execution of risk-based qualification and validation projects

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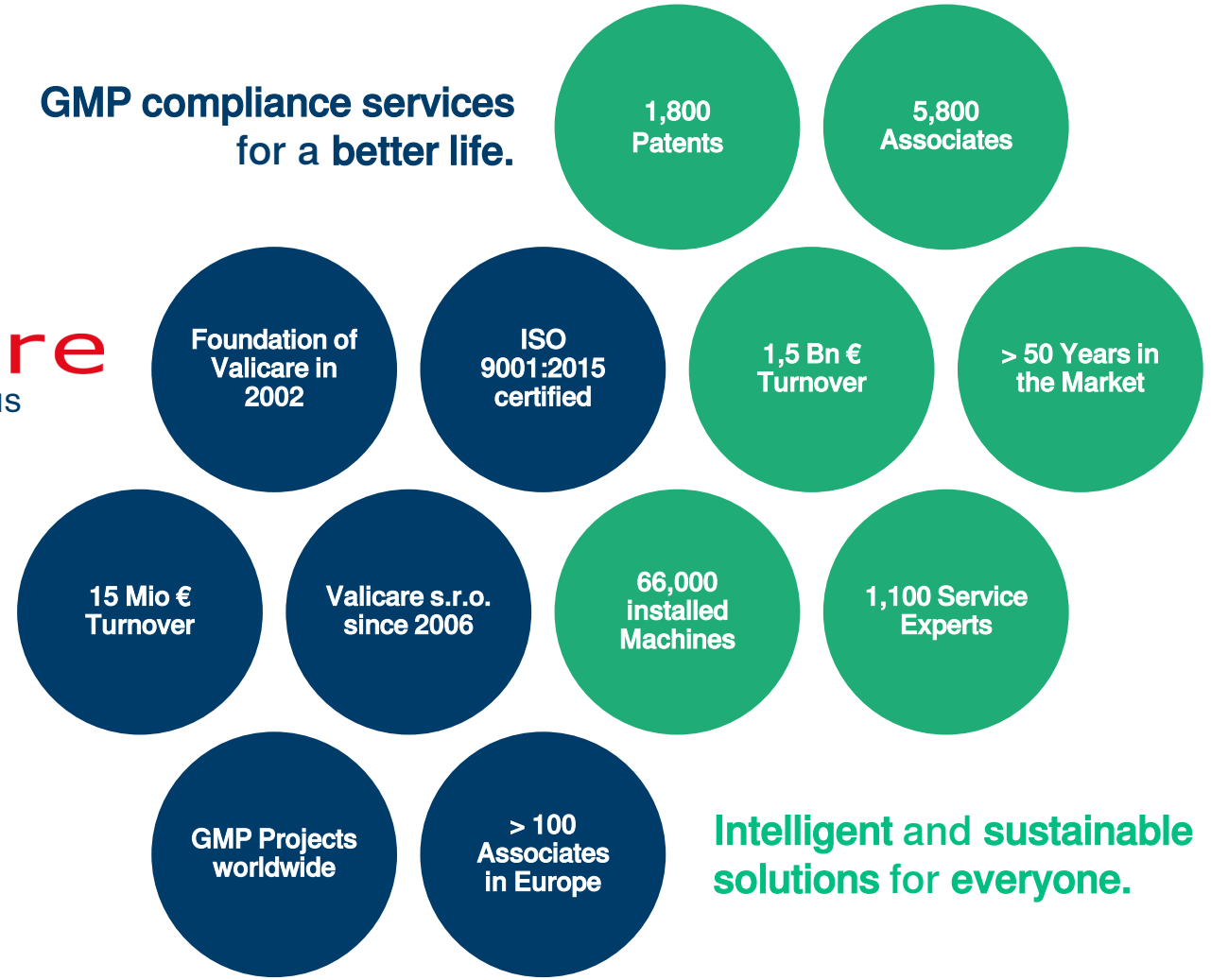
THE COMPANY

Valicare & Syntegon

GMP compliance services for a better life.



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SERVICES & SOLUTIONS

SYNTEGON
PROCESSING & PACKAGING

Intelligent and sustainable solutions for everyone.

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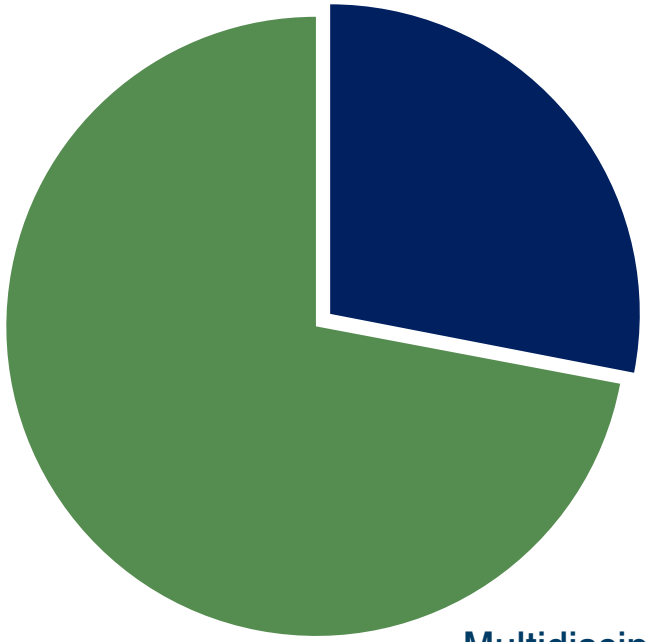
OUR EXPERTS

Competence Profile



28 %
Natural scientists

72 %
Engineers

> 100 employees in EU

Multidisciplinary teams of **engineers** and **natural scientists** with PhD in pharmacy, biology and (bio)chemistry

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OUR LEAD CONSULTANTS

Competence Profile

Our permanent lead consultants with over 120 years of GMP experience:

Dr. Hans-Georg Eckert

Managing Director / Senior GMP Consultant

- Consulting and project management of GMP and quality projects
- Former head of production sites (GMP; ATMP)
- Experienced GMP auditor

Dr. Berthold Düthorn

Senior GMP Consultant / Senior GMP Project Manager

- Vice President at Syntegon
- Consulting and project management of GMP and quality projects
- Qualified Person (EC GMP) & ISO 9001 certified auditor

Dr. Katherina Pfister

Senior GMP Consultant / Senior GMP Project Manager

- Planning and execution of qualification, validation and GMP projects
- Quality management support
- Quality management representative (DEKRA)

Dr. Carsten Boerger

Senior GMP Consultant / Senior GMP Project Manager

- Qualification and validation projects of API production, quality control and GMP systems
- Former head of production site (API)
- GMP certified auditor

Dr. Claudia Papewalis

Senior GMP Consultant / Senior GMP Project Manager

- Planning and execution of qualification, validation and GMP projects
- Former head of production site (ATMP)
- ISO 9001 & GMP certified auditor

Dr. Mario Ramos

Senior GMP Consultant/ Senior GMP Project Manager

- Planning and execution of qualification and validation projects
- Quality control and GMP projects
- Former head of quality control (ATMPs)

Dr. Hana Moustamsik

GMP Consultant/ GMP Project Manager

- Consulting and project management of ATMP
- Chemistry, Manufacturing and Controls (CMC) specialist
- Regulatory affairs specialist

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OUR EXPERTS

The Valicare **multi-disciplinary team** (~ 100 associates) comprises natural scientists, engineers of different disciplines and **skilled technicians** with **profound expertise** and **experience** in the regulated pharmaceutical, biotechnology and medical device industries.

Our **GMP consulting**, **qualification and validation experts** act in Europe, Asia and America. 400 **GMP projects** are carried out **annually.** Mainly in **qualification and validation** but also in different **GMP consulting projects**, including gap analyses, risk management, GMP compliance, upgrades and concepts, trainings, audit and inspection support.

Since **2016** a strategic focus has been placed on **Advanced Therapy Medicinal Products** (ATMPs). Our experts accompany customer throughout the **entire life cycle** from development to marketing authorization and manufacturing of ATMPs.

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GMP/GxP COMPLIANCE SERVICES

Service Portfolio

Consultancy Service Portfolio:

- GMP Expert Discussion
- GMP Concept and Implementation
- GMP Compliance Analysis
- GMP Audit
- GDP & GLP Concepts & System Upgrades
- GMP/GxP Topic Related Training
- Risk Assessment & Risk Management
- Contamination Control
- Pharmaceutical Quality Management System
- CAPA Project Management and Execution

General GxP Service Portfolio:

- GMP Project Management
- GMP / GxP Basic Training
- GMP Documentation / GMP System SOPs
- Risk Analysis
- Qualification (Rooms, Equipment & Supply Systems
- Qualification Management
- Process Validation (Manufacturing Processes)
- Computerized System Validation
- Analytical Method Validation
- Cleaning Validation

Quality Management:

- EN ISO 13485 & 9001 Compliance Support
- Assessment, Update & Implementation of QMS
- Preparation of QMH & SOPs

Interims Management:

- Head of Production / Head of QC
- Head of QA / External QM Department
- DIN EN ISO 9001:2015 / 27001

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GMP/GxP BUSINESS AREAS

Service Portfolio

ATMP & Biotech:

- GMP Process Development
- ATMP-GMP and PQ-System Introduction
- Definition of Specifications
- Validation (Transfer, Processes, Systems & Methods)
- Manufacturing Authorization Support
- GMP Layouts & Turnkey Production Solutions

Pharma:

- Design Review
- URS, FS & Q-Plan
- DQ, IQ, OQ & PQ (Rooms, Equipment & Supply Systems)
- FAT, SAT, Alarm & Function Tests
- Requalification & Recalibration
- Bio-Decontamination Process Development & Validation

Medical Devices:

- Regulatory Compliance and Strategy (EU MDR, IVDR)
- EN ISO 13485 Compliance Support
- Risk Management (ISO 14971)
- Product Development and Design Control
- Qualification & Validation
- Lifecycle Management

CSV Services:

- Computerized System Validation Preparation & Execution
- CSV Documentation Creation and Maintenance
- Coverage of the Complete SDLC
- CSV & IT Interims Management
- CSV / GAMP® Training
- CSV Audits (GxP, GAMP®, QMS, ISMS)

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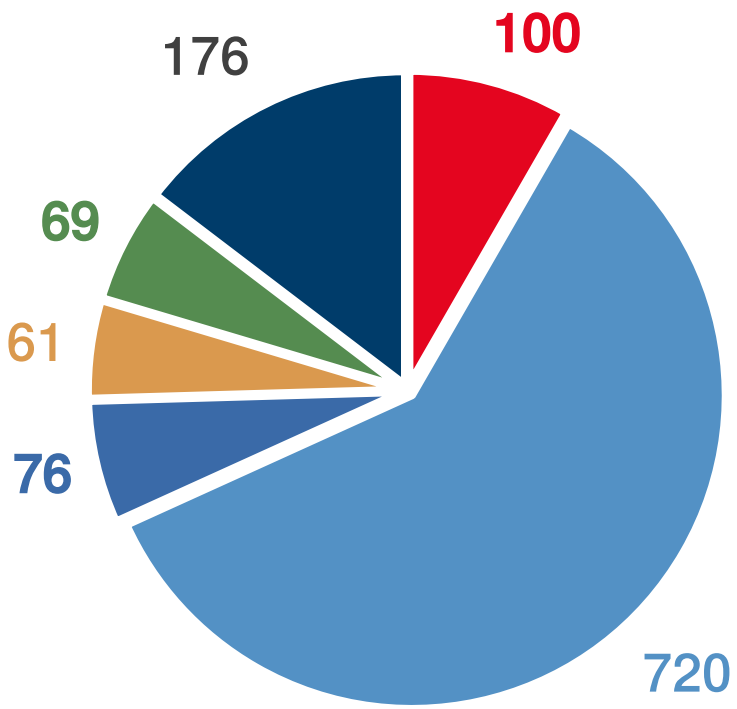
WE ACCOMPLISHED IN THE LAST YEARS

Competence Profile

1.202 GMP projects have been carried out by Valicare within 3 years



- **Qualification & Validation:** (Re)-Qual. & Re-Val.; (Re)-Calibration; AFTs
- **Risk Analysis:** Technical Risk Analysis
- **Site & Factory Acceptance Tests**
- **Isolator Process Develeopment & Validation:** Workshops, Documentation & Execution
- **Computer system Validation:** AFTs of HMI and PLC
- **GMP-Consulting:** Concept, Implementation, Audit, Training…

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GMP COMPLIANCE SERVICES

Service Portfolio

Our **GMP Compliance Services** consists of – but is not limited to – the following:

- **GMP** consulting
- **Risk assessment** and **quality management**
- **Qualification** and **validation** projects
- **Audits** and **preparation** for GMP inspections by international authorities
- **Inspections** remediation

We are experts in the application of the current industry standards and requirements, such as: EU GMP, **(c)GMP, PIC/S, WHO, ICH, DIN EN ISO 9001, 13485 and 14971.**

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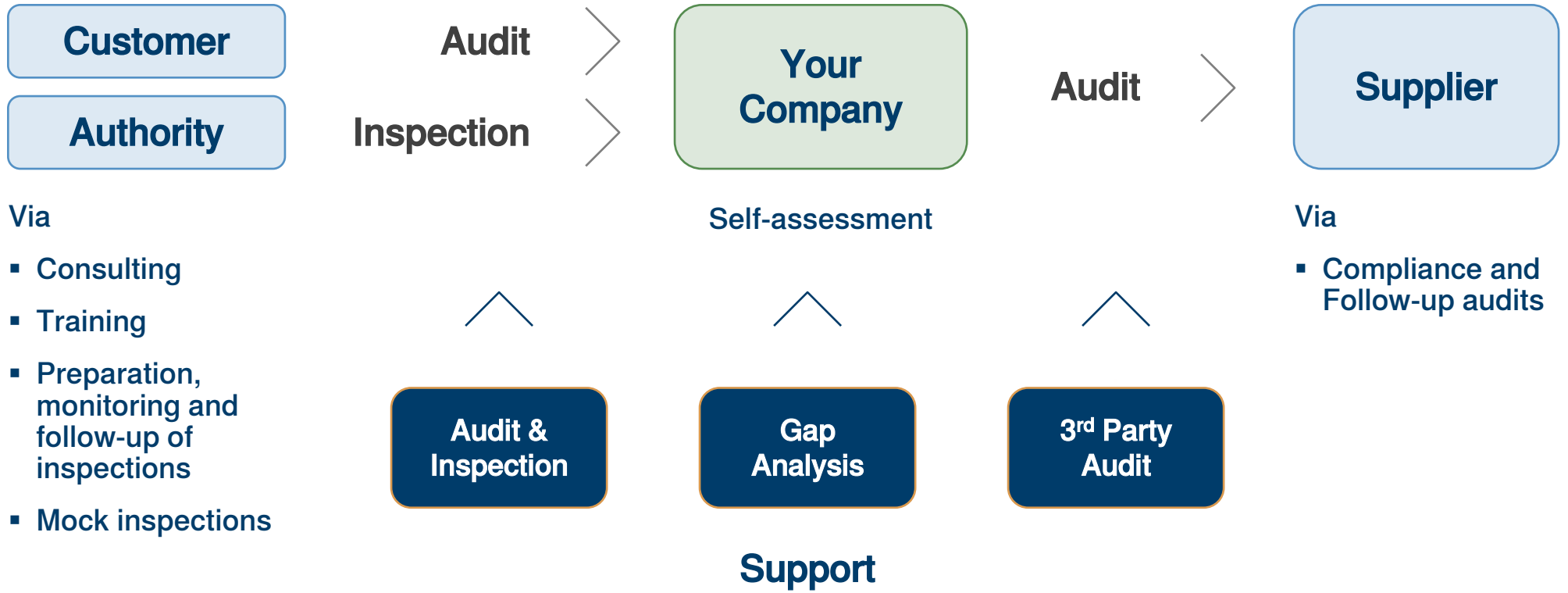
GMP INSPECTIONS & AUDITS

Service Portfolio



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AUDIT AND INSPECTION SUPPORT

Our Services

Audits we offer:

- GMP, GDP and GLP compliance audits
- Gap analysis including status of computer system validation
- Supplier qualification of equipment suppliers, contract manufactuers, contract laboratories and service provider
- DIN ISO 9001:2015 compliance audits
- ISO 13485 compliance audits
- JACIE accreditation audits

- GMP, Good Manufacturing Practice
- GDP, Good Distribution Practice
- GLP, Good Laboratory Practice
- JACIE (Joint Accreditation Committee)

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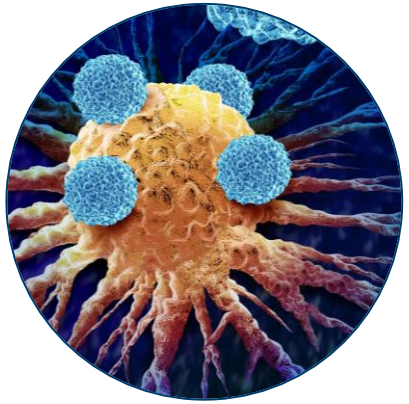
AUDIT AND INSPECTION SUPPORT

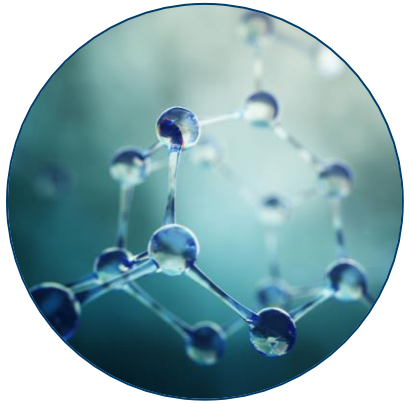
Range of Products

Our portfolio includes advanced therapy medicinal products (ATMPs), pharmaceuticals, active pharmaceutical ingredients (API), excipients, intermediate products, biologicals and medical devices.

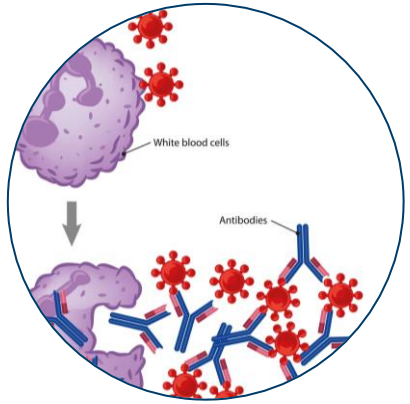


ATMPs

Pharmaceuticals



APIs



Biologicals

Medical Devices

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AUDIT AND INSPECTION SUPPORT

Our Services

What we offer:

- Preparation, support, implementation of internal and external audits
- Preparation and support of inspections by authorities
- "Mock" inspections, e.g., as a preparatory measure before authority inspections
- Training of employees in preparation for audits and inspections
- Audit or analysis report with deviations
- Definition of Corrective and Preventive Action (CAPA) measures
- Proposal of corrective measures and review of their implementation by follow-up audits

Our **auditors** know what is important **during inspections**!

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OUR AUDITS

Performance of the last Years

Our **certified auditors** have conducted a **large number of successful audits worldwide since 2020** in the following countries:

- **Germany**
- **Austria**
- **Spain**
- **Portugal**
- **Italy**
- **Netherlands**
- **Belgium**
- **Estonia**
- **Hungary**
- **India**
- **Taiwan**
- **Canada**
- **USA**

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COMPLIANCE CHECK OF SYSTEMS IN OPERATION

Our Services

Valicare offers the **execution** of **gap analyses** at your site in use as follows:

- **Document review** (quality, production, lab, qualification & validation)
- **Plant check** (production, warehouse, utilities, lab)

The gap analysis focuses on review of the **GMP compliance completeness**. We can check all or defined sub-areas of the entire system.

Existing gaps and deficiencies with regard to **international GMP compliance standards** (EU, US, PIC/S) at your site will be identified.

A **gap analysis report** with to-do lists based on facility as well as documentation reviews and **recommendations** for **improvements** will be submitted.

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THE LIFE CYCLE APPROACH

Service Portfolio

Valicare supports you to be compliant with the life cycle approach mandatory for pharmaceutical companies.

Based on **classical V-Model** and the integrated qualification and validation approach, time and costs can efficiently be reduced.

Rely on our **long-term expertise**.

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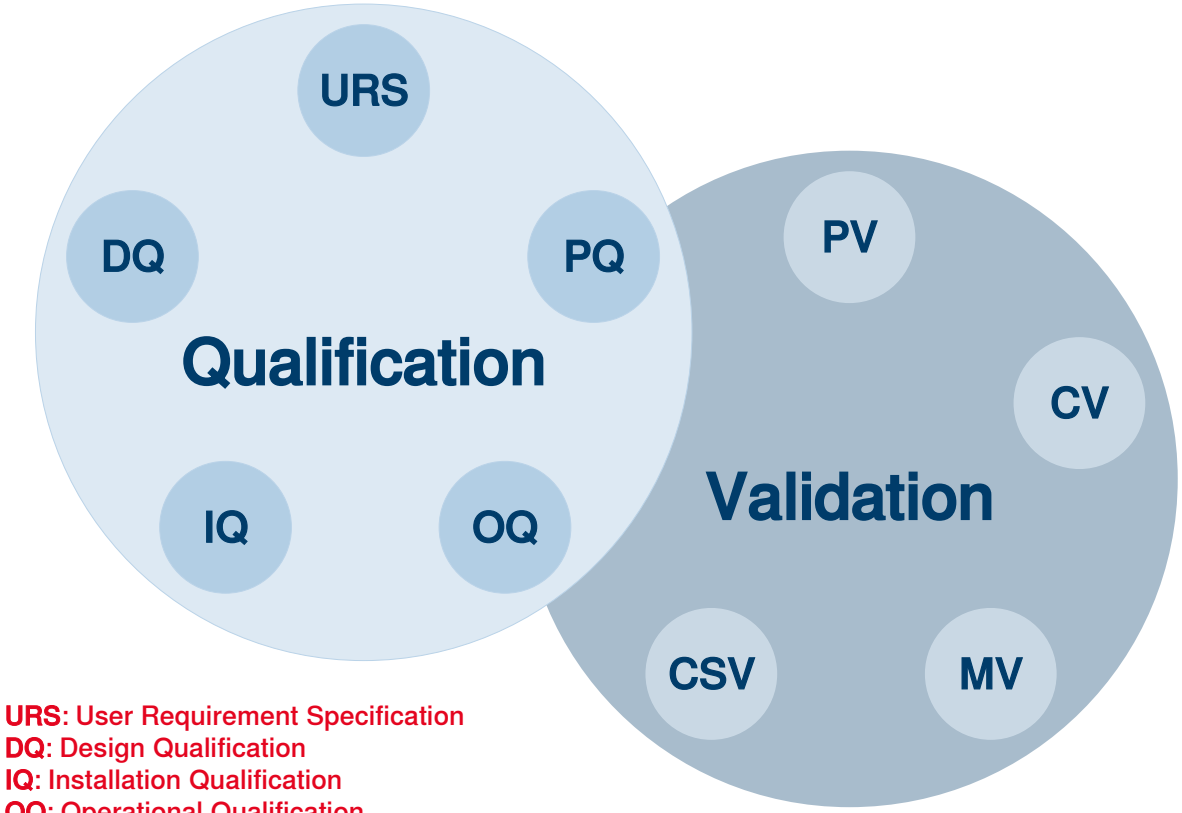
QUALIFICATION & VALIDATION

Service Portfolio

Qualification of **equipment** and **GMP facilities** as well as **validation** of systems, **methods** and **processes** is the daily business of our engineers.

- More than **1,000 qualification** and **validation projects** are executed successfully
- **Areas**:
  - **Active** pharmaceutical ingredient production
  - **Production** of drug products
  - **Medical** devices
  - **Quality** control

Efficiency through **proficiency!**



URS: User Requirement Specification
DQ: Design Qualification
IQ: Installation Qualification
OQ: Operational Qualification
PQ: Performance Qualification

PV: Process Validation
CSV: Computer System Validation
MV: Method Validation
CV: Cleaning Validation

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QUALIFICATION PROJECTS

Service Portfolio

Valicare offers **GMP-compliant risk-based qualification: consulting** and **execution** in all **project phases!**

- **Validation Master Plan**
- **Risk Assessment** (technical Risk Analysis)
- **URS** – User Requirement Specification
- **DQ** – Design Qualification
- **IQ** – Installation Qualification
- **OQ** – Operational Qualification
- **PQ** – Performance Qualification

In-depth background expertise in process technology, manufacturing, primary packaging, high purity media systems, sterilization equipment, automation systems, HVAC and cleanroom technologies through **close cooperation** with our parent company **Syntegon Technology**.

Our **customer-specific documentation** is based on **GMP** requirements.

An **efficient system for change and deviation handling** guarantees documented evidence for executed actions and changes. **Trained** and **experienced personnel** will qualify the equipment on site. Measured **values and raw data** are **completely documented**, exactly evaluated, and **are traceable at any time**.

Preparation of qualification documents, management or execution support are provided as well as review or preparation of the qualification **reports. Efficiency** through **proficiency!**

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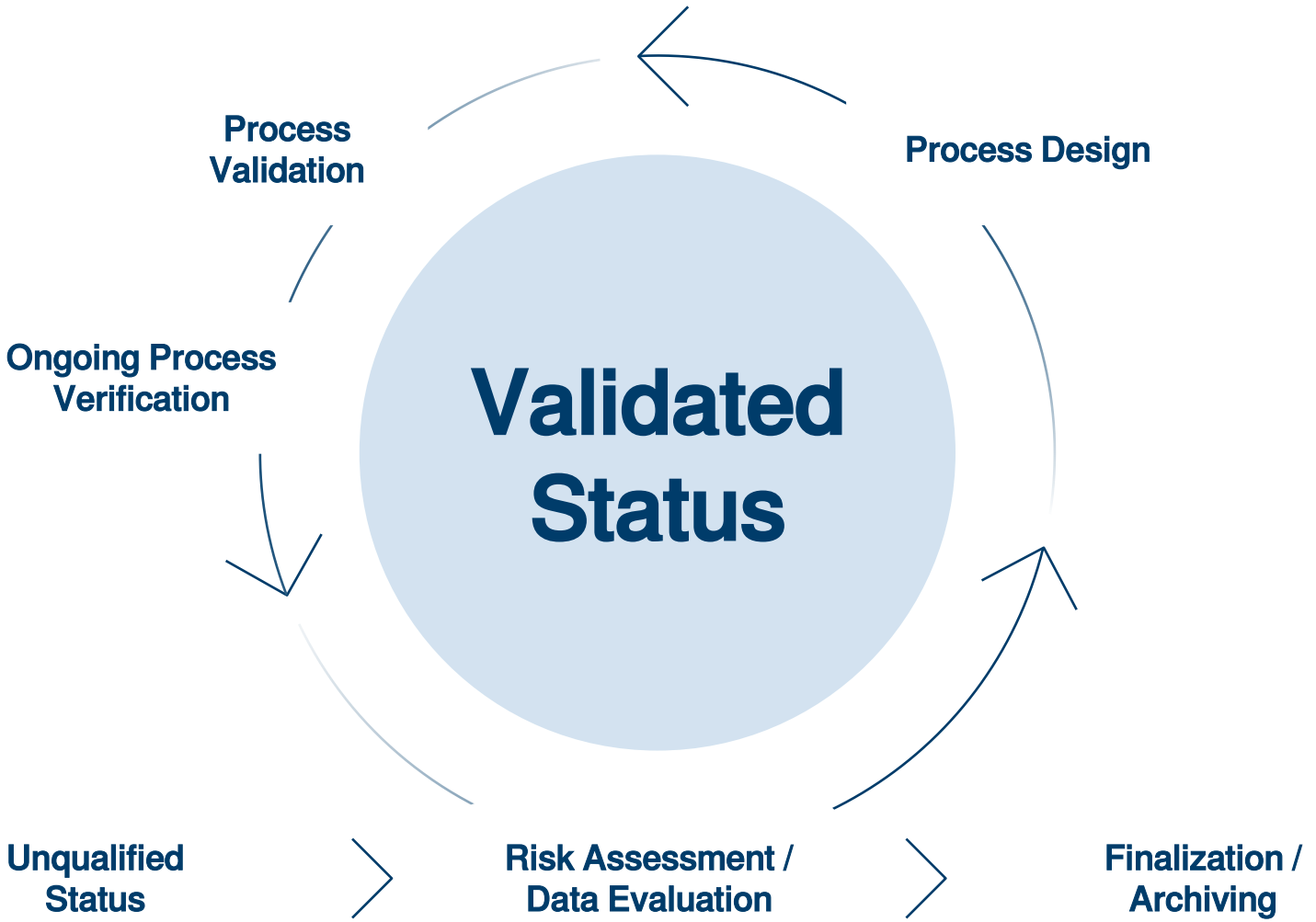
THE LIFE CYCLE APPROACH

Service Portfolio



Life cycle approach is also **required for validation:**

- Mandatory **since 2011** by **FDA**
- Permitted (hybrid) since 2015 in Europe

Valicare set up a **validation concept** and accompanies you through the entire validation life cycle approach.

Benefit from our **expertise** and save time and human resources to **fulfill compliance.**

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VALIDATION PROJECTS

Service Portfolio

Valicare offers comprehensive consultancy and **execution support** for GMP-compliant validation of:

- **Process Validation (PV),** e.g. of manufacturing processes, bio-decontamination processes of isolation systems
- **Cleaning Validation (CV),** e.g. sterilization processes (autoclaves and dry heat sterilizers)
- **Analytical Method Validation (AMV)**
- **Computer System Validation (CSV)**

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VALIDATION OF BIO-DECONTAMINATION PROCESSES

Service Portfolio

Valicare's engineers:

- Teams with distinctive technical **know-how** for **isolators** & **bio-decontamination processes**
  - **longterm practical experience** in the development & validation
  - **experts** in the **optimization** of the main parameters
- Modern testing laboratory meets GMP & GLP requirements and the DIN EN ISO 14644 cleanroom standard
  - equipped with a Klenzaids®STI-isolator using hydrogen peroxide for decontamination placed in an ISO Class 8 clean room
- Incoming **control** of biological indicators in our own pharmaceutical laboratory according to **DIN EN ISO 11138-1** and **DIN EN ISO 14161**

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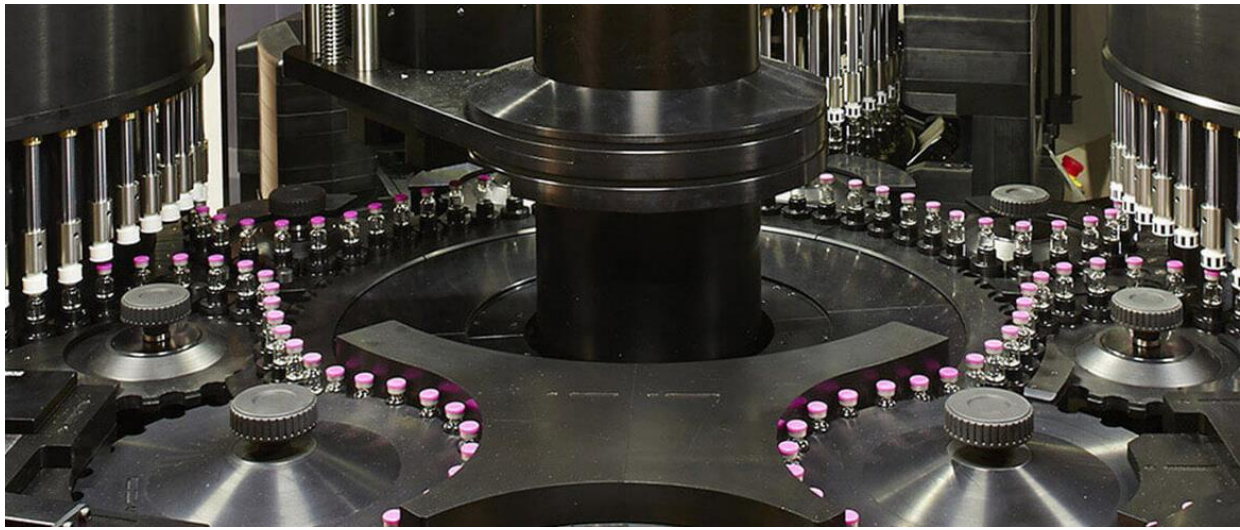
INSPECTION TECHNOLOGY

Service Portfolio

Valicare's engineers:

- In-depth **knowledge** of fully **automated** inspection systems
- Excellent **independent system** for validation and qualification support
- **Facilitation** of workshops at customer site to define **validation strategy**
- **Definition** of parameters for process **optimization** and **routine application**
- Guidance or execution of **Knapp Kushner** tests
- **Performance qualification** (PQ) support



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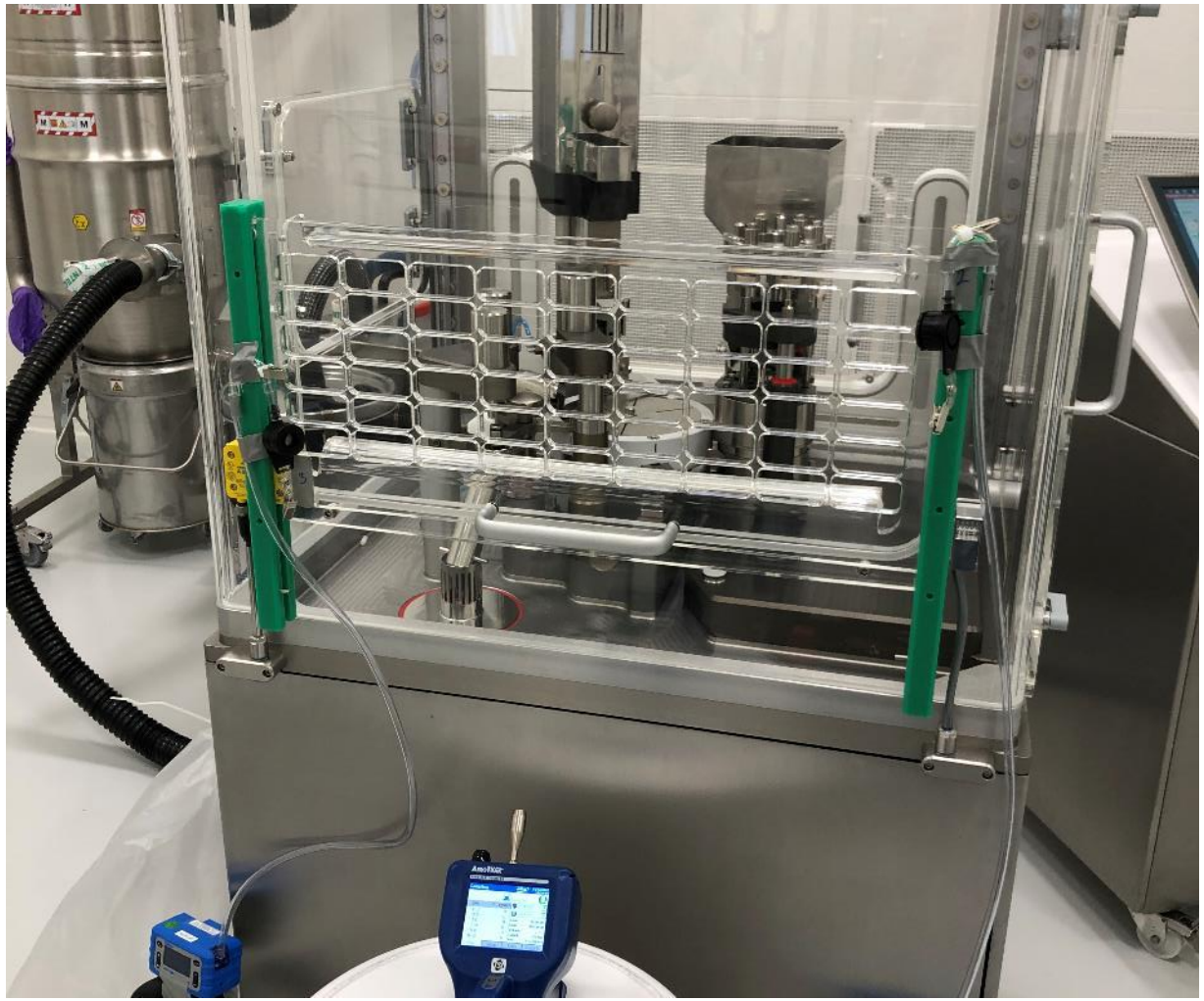
Specials: SMEPAC TEST (Standardized Measurement of Equipment Particulate Airborne Concentration)

Service Portfolio



Purpose

The purpose of SMEPAC testing is to evaluate particulate emissions of pharmaceutical systems and equipment. The measurement provides a set of principles for the capability to prove that installed containment equipment functions as a EHS safety barrier.

Test basis

ISPE Good Practice Guide(2012): Assessing the Particulate Containment Performance of Pharmaceutical Equipment

Result calculation basis

EN 689:2018 - Work place exposure - measurement of exposure by inhalation to chemical agents-Strategy for testing compliance with occupational exposure limit values

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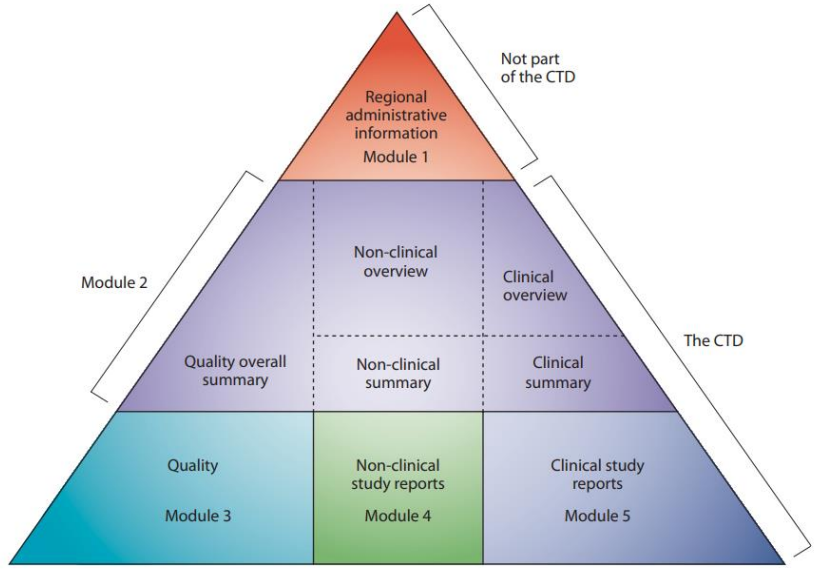
CMC & Regulatory Affairs

Service Portfolio

I **R&D** > II **Production** > III **Clinical Trials** > IV **Marketing Authorization** > V **Market Access**

IMPD / IND > **CTD** > **Regulatory Maintenance**



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

The CTD Triangle

Source : *ICH Official web site : ICH*

Valicare offers comprehensive consultancy and execution support through the **whole lifecycle**,

always keeping the marketing authorization in mind,

through our **knowledge and experience** in regulatory affairs and in the the Chemistry, Manufacturing and Controls (CMC) area

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ATMP SERVICES & SOLUTIONS

Service Portfolio for Cell and Gene Therapy

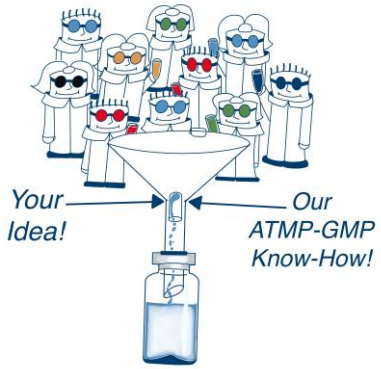
The Valicare team supports along the entire value chain!

I R&D

- Process standardization & GMP compliance
- Process transfer & validation
- Manufacturing authorization & §4b AMG approval

II Production

- Interims management
- Turnkey production solutions



III Clinical Trials

- Evaluation, planning & logistics
- Management iATMPs
- Upscaling & automation

IV Marketing Authorization

- Pharmaceutical development
- Finalization & archiving

V Market Access

- Post-Marketing surveillance

VI GMP Training

VII Strategic & Regulatory Consulting

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TURNKEY PRODUCTION CONCEPTS

Service portfolio for cell and gene therapy

& RELATED SERVICES

We support from **development** to **manufacturing** your **ATMP** in a **turnkey facility.**

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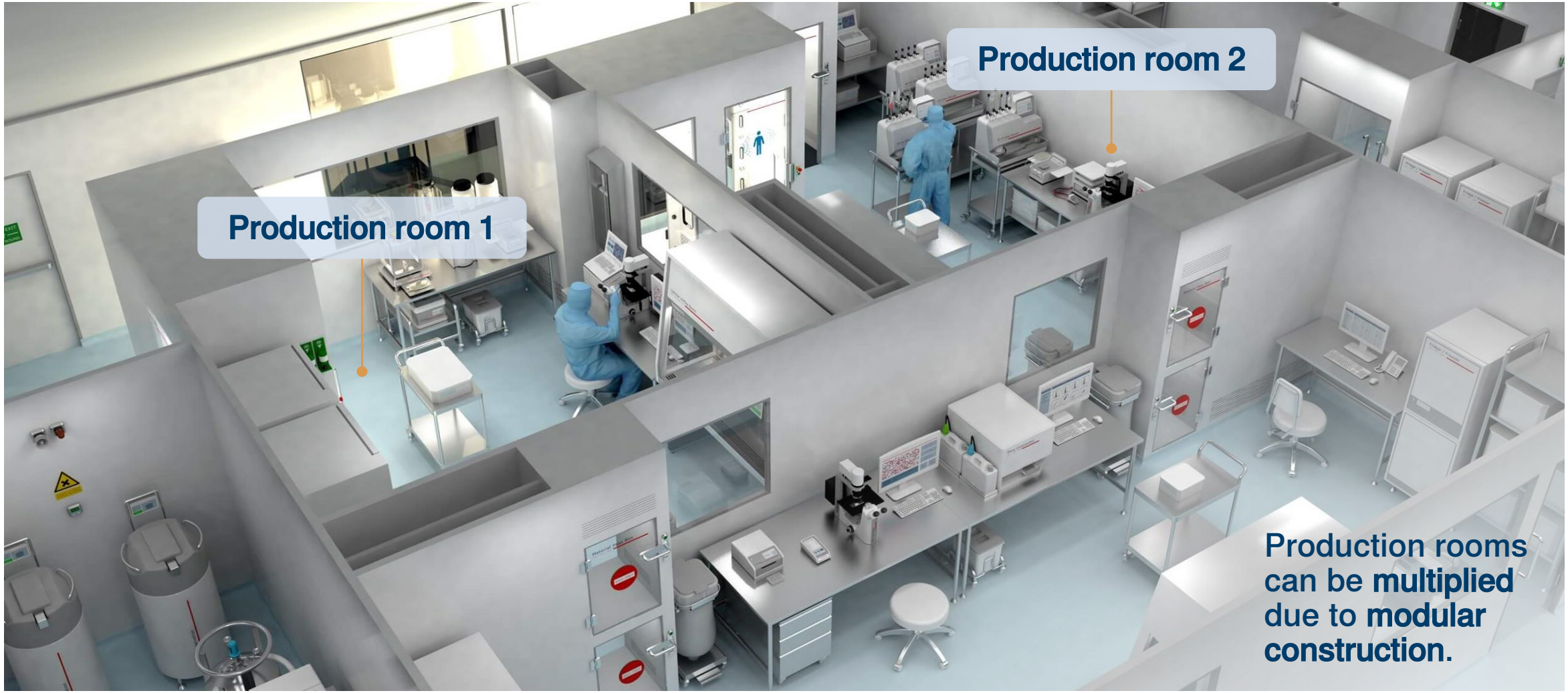
TURNKEY PRODUCTION SOLUTIONS & RELATED SERVICES

Service Portfolio_valicare.tainer



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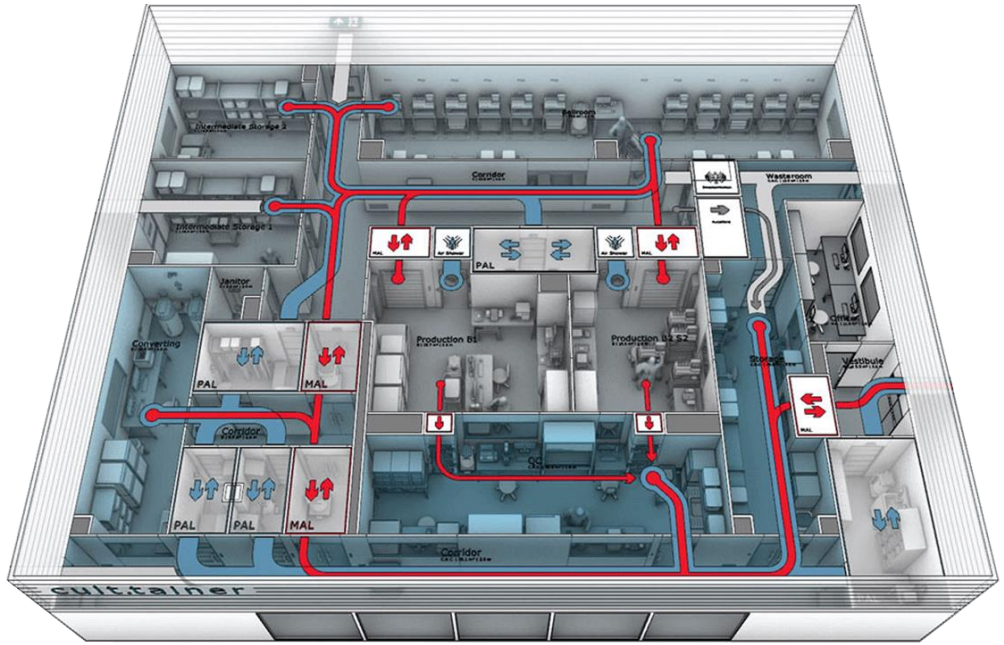
cult.tainer® – a modular concept



- **Aseptic manual manufacturing** (cells & tissues)
- **Automation optional** (culture systems, IT, EBR)
- **Phase III clinical study** and **market supply** for limited indications optional
- Office, storage, QC lab, N2 Freezing, clean rooms class D, C, B, waste disposal

- Business case „**Stand-Alone-Unit**“
  - Required land plot of **~1,000 m²**
  - Modular unit of approx. **470 m²** with rooms of grade D to B according to GMP guidelines for manufacturing of ATMPs / iATMPs and development of QC methods for release of products
  - Equipment for manufacturing, quality control and **storage available** in **close proximity**
  - **12 – 18 month** for facility setup up to manufacturing licence (start of production)

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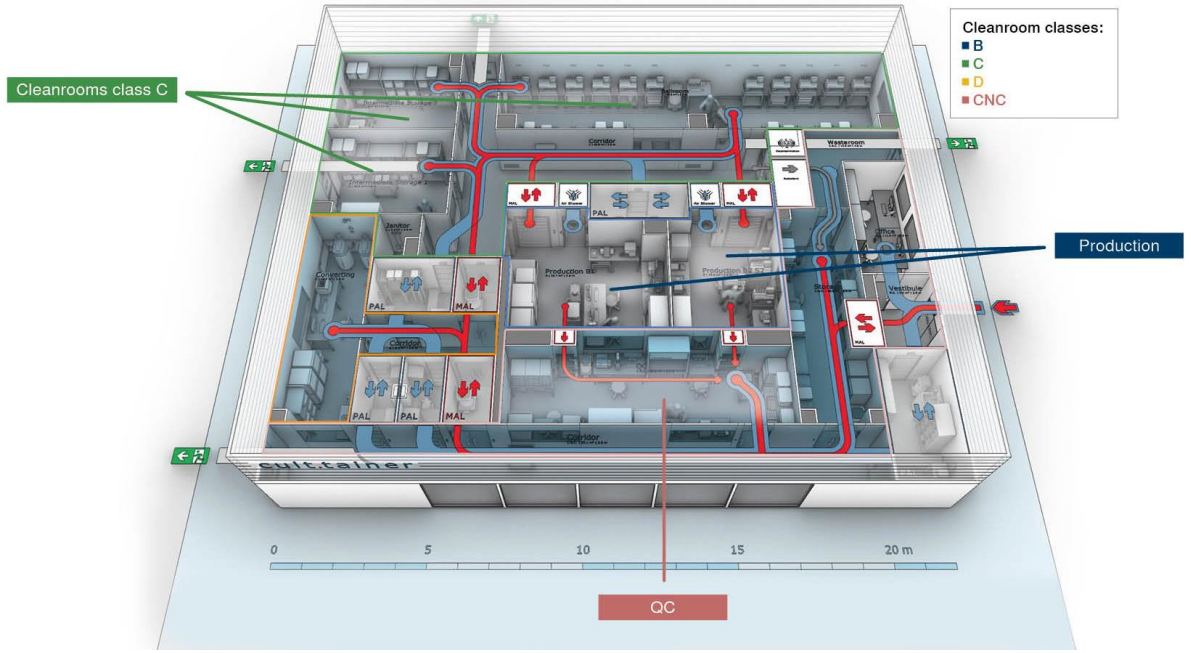
cult.tainer® in 3-D



- **Flexibility** for **different manufacturing systems** realized by
  - **Three separated** clean rooms **class C**
  - **Mobile walls**
  - **Simple space expansion options**
  - **Technical installations** on the roof
- Small batch size **vector manufacturing** (seed, single-use system up- / downstream, F&F)
- Up to **100 L production volume** with single-use bio-reactors in combination with closed production systems
- **Freeze / thaw** or **lyophilization** options

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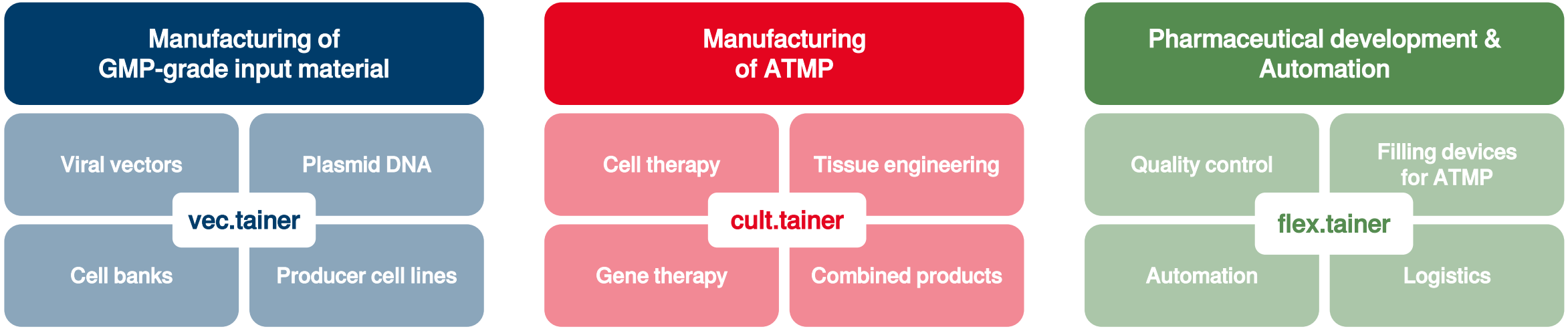
Expansion prospects for the .tainer concept in the ATMP environment



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

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

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

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MEDICAL DEVICE CONSULTING

Service Portfolio

Valicare experts are your trusted partner for medical device compliance and the market success of your products:

- **Strategic guidance for market access:** Navigating MDR ((EU) 2017/745), FDA (21 CFRs), and other global regulations
- **Ensuring regulatory compliance:** Expertise in EN ISO 13485, EN ISO 14971, ISO 10993, and IEC 62366
- **Supporting the entire product lifecycle:** From concept to market approval and post-market surveillance
- **Process optimization & innovation:** Enhancing efficiency, safety, and usability for long-term success
- **Customer-oriented solutions:** Tailored services designed to meet your specific needs, ensuring seamless compliance, product safety, and market success

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MEDICAL DEVICE CONSULTING

Service Portfolio

Regulatory Compliance
Expertise in MDR ((EU) 2017/745), FDA (21 CFRs), and global standards

Quality Management Systems (QMS)
Implementation & optimization of EN ISO 13485 compliant systems

Risk Management (EN ISO 14971)
Comprehensive risk assessment throughout the product lifecycle

Usability Engineering (IEC 62366)
Human factors analysis, usability testing & compliance strategies

Biocompatibility Assessment (ISO 10993)
Ensuring product safety & regulatory acceptance

Process Validation & Qualification
Ensuring consistent high-quality manufacturing

Supplier Management
Evaluating & maintaining a compliant supply chain

Training & Education
Practical seminars on GMP, quality management & regulatory updates

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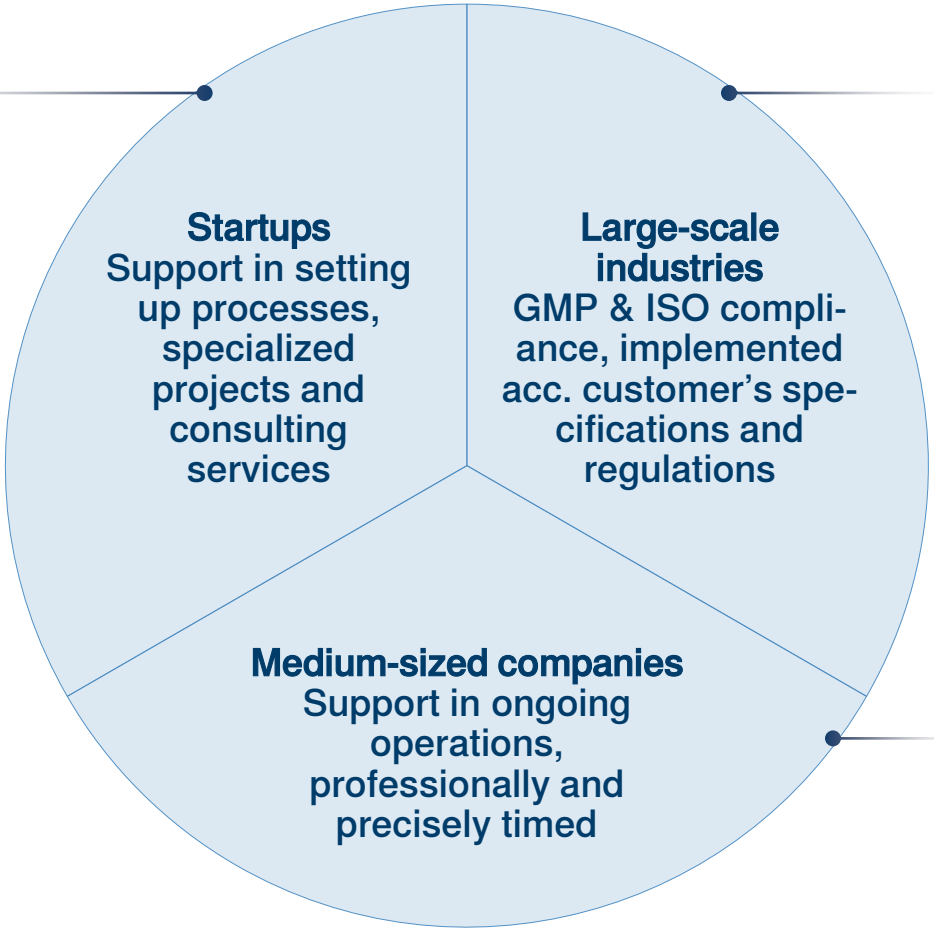
PHARMA, BIOTECH & MEDICINAL TECHNOLOGY

Customer Portfolio

- Development of **GMP concepts** and **processes** & **method transfer**
- **Security profiles** for your products
- Definition of **specifications**
- **Manufacturing** authorization according to **§ 13 AMG**
- **Qualification** and validation of exceptional equipment & **novel processes**
- Creation of QM **systems, SOPs** & **master batch records**



- **Risk analysis**, calibration, qualification & validation and **design reviews**
- **Process technology**, primary packaging, sterile filling & isolators, inspection technology, pharma & biotech production facilities

- **Gap analysis** & **GMP upgrade projects**
- Risk **assessment** & **analysis**
- **Qualification** & **validation**

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PHARMA, BIOTECH & MEDICINAL TECHNOLOGY

Our Customers

8/10 of the top players are **our customers**

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WHY CHOOSING VALICARE AS A PARTNER?

Contact the Experts

Because Valicare convinces through:

- **Lead consultants** working more than **20 years** successfully in the GMP area always **up to date** about the European and international com-
pliance standards for the regulated industry.
- **Multidisciplinary expert teams for** qualification and validation with deep technical background in manufacturing and packaging.
- **Natural scientists** expertised with **GMP transfer and validation** of biological and biotechnological processes.
- **Long-term experience through management and execution** of **> 5,000 GMP-projects worldwide** since founding.

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WE ALWAYS FIND SOLUTIONS!

Contact the Experts

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competent, reliable & efficient

+ 49 69 153 293 700

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competent, reliable & efficient

CONTACT OUR EXPERT

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