



CSV

Life Science Group

DESTINATION PHARMA 





- Engineering CQV Services
- Construction
- Process Equipment Supply
- Equipment Manufacturing
- Api Trading
- Containment Solutions

**CSV Life Science Group since its foundation in 1998
has put the passion for work and the care
for people at the core of its growing values.**

Today the Group has become a multidisciplinary company with highly skilled team that can support you for comprehensive project approach with focus on strategic services and supply for the **international pharmaceutical market.**

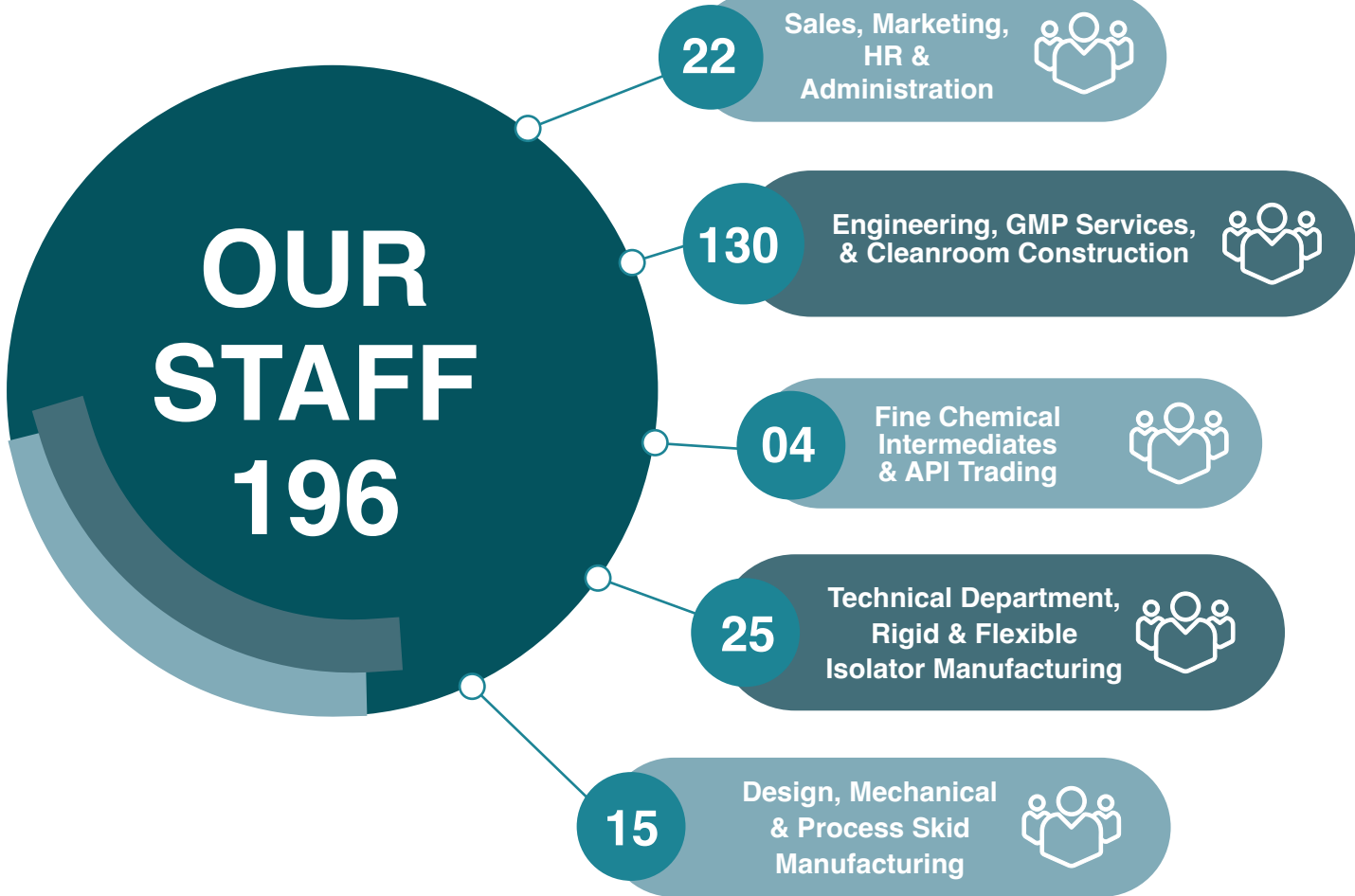


Our Vision

We bring our passionate approach to humanity into the pharmaceutical market.
We face the industry's challenges by placing quality of life at the center.

Our Mission

We want to grow with our clients realizing custom-made solutions for the pharmaceutical world.
We focus on the human factor and on the value of its uniqueness.





ITALIAN OFFICES

MILAN

Registered office
and technical office

PARMA

GMP services
technical office

FIRENZE

GMP services
technical office

FORMIA

Technical office

ANAGNI

Mechanical workshop

LATINA

Engineering and GMP services

ALESSANDRIA

Clean rooms, Isolator assembling



INTERNATIONAL OFFICES

SPAIN

GREECE

LOCAL REPRESENTATIVES

- Austria
- Brazil
- Canada
- Czech Republic
- Egypt
- France
- Germany
- Greece
- Ireland
- Poland
- Saudi Arabia
- Scandinavia
- Slovakia
- South Africa
- Switzerland
- Turkey
- United Kingdom
- United States

LAST YEARS' TURNOVER



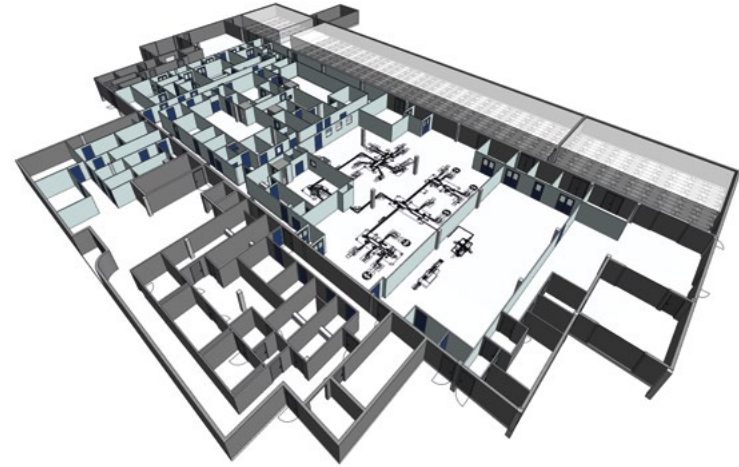
11 2014
million €

62 2025
million €

FACILITY PLANNING

URS definition and data collection

- Production capacity study and gap evaluation
- “What if” analysis
- Bubble layout and alternative solution development
- SWOT analysis and reference scenarios definition
- GMP layout & 3D view
- Utilities capacity and gap studies
- Cost & timing evaluation
- Estimate and Scheduling



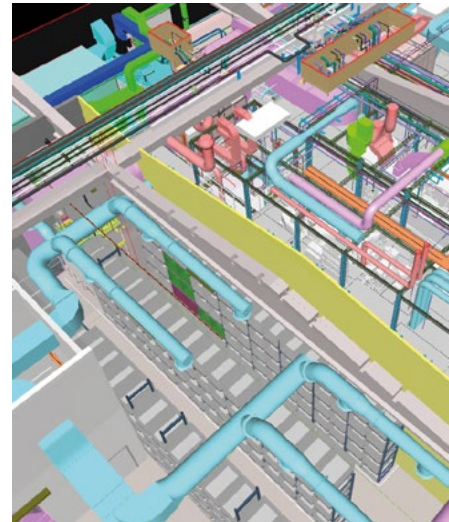
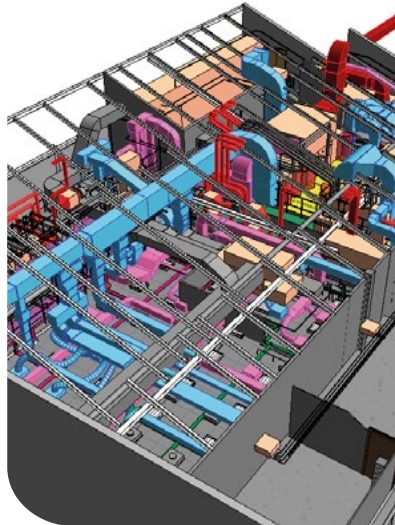
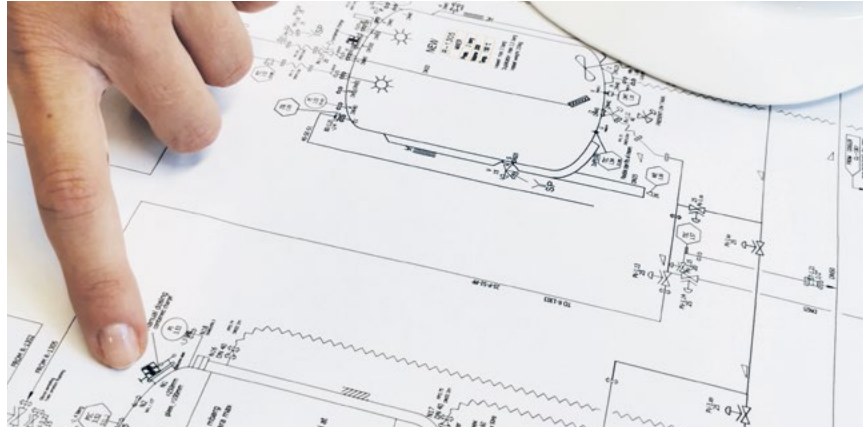
Strategic decisions support:
the core of our facility planning activities, aimed to a better and more conscious definition of your new or upgraded process needs.



ENGINEERING

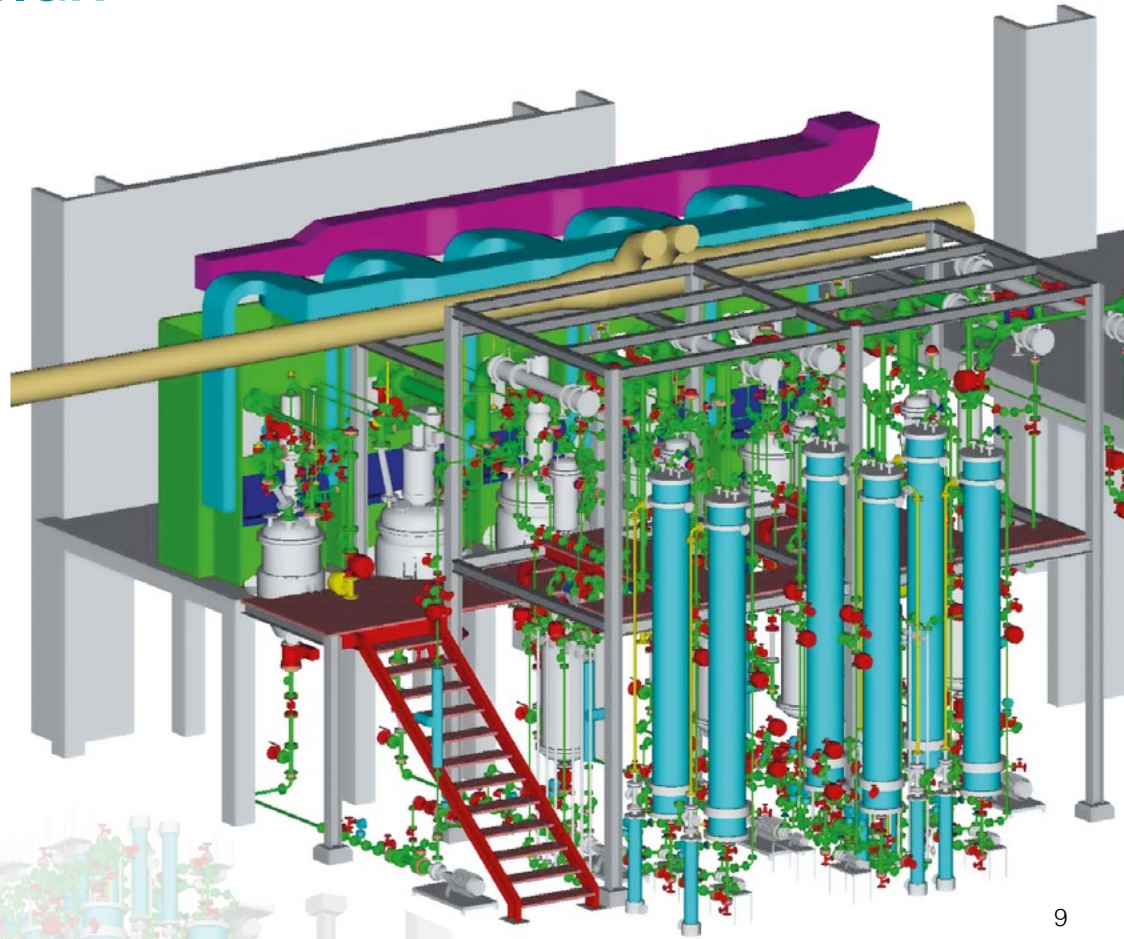
**CSV Life Science Group
can be at your service for:**

- Basic design
- Detail design
- Project review
- CFD simulation
- Energy saving evaluation
- Full 3D modelling and BIM
- Engineering Procurement & Construction Management services
- Scheduling and Total investment cost evaluation



PROCESS DESIGN

- URS definition
- Process description and calculations
- Process Flow Diagrams design
- P&IDs design
- HAZOP review
- Containment and bio-containment strategy identification



COMMISSIONING & QUALIFICATION

- FAT/SAT assistance/support
- Instrument calibration
- VMP
- Risk and impact assessment strategy
- Equipment validation
- Utilities validation
- Facilities validation
- Periodical qualification



COMPUTER SYSTEM VALIDATION

- ERP Validation
- QMS Validation
- LIMS Validation
- MES Validation
- Laboratory Instruments Validation
- Visual Inspection and Serialization
- IT Infrastructure Validation
- Computer Systems Periodic Review
- Data Migration



QUALITY & COMPLIANCE

Development of PQS key elements (e.g.):

- CAPA system (and deviations)
- Change management system
- Management review
- Personnel qualification
- Supplier qualification
- Quality and Technical Agreement
- Complaint Management

Analytical method validation
Nitrosamine regulation compliance
Contamination Control Strategy
Technology transfer

Gap Analysis, Risk Assessment and other ICH Q9 risk analysis tools are routinely used.



CONSTRUCTION

The construction division of CSV Life Science Group is able to support clients during the construction phases, providing turnkey plants (Lump Sum Turn Key, LSTK) as well as Project Management and Construction Supervision site services.

For each project, CSV Construction relies on a team of experts, led by a Construction Manager who is responsible for coordinating all on-site activities for the entire working time.



OUR SOLUTIONS

- Clean rooms
- HVAC
- Laboratories
- Warehouses
- High potent production departments
- R&D facilities



CONTAINMENT SOLUTIONS

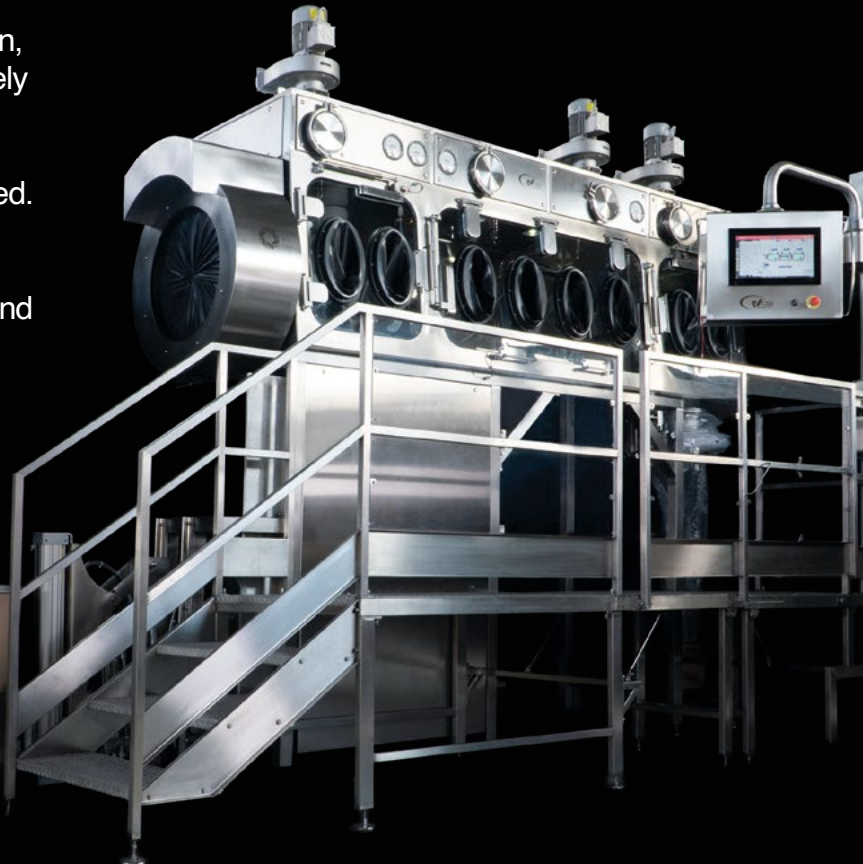


20 years' experience in process defining has provided our team with strong expertise in containment systems for High Potent API design, construction and integration. Our solutions entirely realized in our Italian facilities, are able to satisfy the most demanding requirements thanks to the deep knowledge of the processes to be contained.

- Full CGMP design and CFR 21 part 11 compliance
- OEB 4 to 6 containment strategy definition and equipment manufacturing
- Exposure control procedures definition
- Atex design
- SMEPAC testing for isolator release

DIT®

- Drum Iris Technology
- Docking system for multiple diameter drums
- Seal of excellence of European Commission



ISOLATOR

- Materials:
 - 304/316/316L Stainless steel
 - Hastelloy C-22
 - Polycarbonate
 - q< LDPE and PU for flexible isolators
- Wide range of models



GLOVE BAGS

- Design, in-house manufacture and installation
- Primary and secondary process equipment containment
- Wide range of low density antistatic polyethylene available in different thicknesses and formats, tested on income



API TRADING

- Intermediates and API sourcing and supplying
- AIFA authorization for API import and storage (API - 137/2021)
- Worldwide activities especially in Middle&Far East
- F&F Dossier trading
- Full strategic services, like:
 - Product search
 - Regulatory Services
 - Price and quality oriented supplier selection
 - Verification of supply capacity and delivery times
 - GxP audit execution
 - Sampling
 - Storage

CSV Active offers a complete side-by-side service for API and Fine Chemicals strategic sourcing, complying with its cGMP quality system, which is constantly subject to audits of regulatory authorities.



EQUIPMENT MANUFACTURING

The most recent addition is a mechanical workshop based in Anagni. Its purpose is to assist the Group in producing all equipment for isolation technology and liquid preparation. This acquisition allows the group to control all stages of its production processes.

- Process Vessels
- Reactors and tanks
- Heat Exchangers
- Carpentry
- LAFs Hoods
- Special tools for pharmaceutical sector

Referring Norms:

- PED Normative
- ASME BPE

Materials:

- 304/316L Stainless Steel
- Hastelloy c-22
- DUPLEX / SALF



PROCESS EQUIPMENT FOR LIQUIDS

PharmaHub, as part of CSV Life Science Group, is a reliable supplier for a wide range of tailor made and standard equipment for pharmaceutical products preparation by means of an accurate process construction design

- Stirring vessels (fixed and mobile)
- Solution Preparation skid
- Transferring and filtration lines
- CIP/SIP skids
- Turbomixers
- Control Systems fully compliant with CFR21 part 11



DESIGN AND MANUFACTURING OF PROCESS EQUIPMENT

Pharma Hub, thanks to its knowledge of GMP and its specific know how on different areas (Validation, Engineering, Chemistry, Maintenance, etc.) related to the process, is the ideal partner to design and manufacture specific process equipment with particular attention to each stage of the production process and the utilities available at the customer's site.





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HEADQUARTERS

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