



## 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 high-skilled team that can support you for comprehensive project approach with focus on strategic services and supply for the **international pharmaceutical market.**



**STAFF 165**



Sales,  
Administration & HR

25



Engineering  
& GMP Services

85



Clean Rooms Construction  
Management

15



Fine Chemical Intermediates  
and API Trading

5



Technical Department  
5  
Rigid and Flexible Isolator

10



Mechanical & Automation Design  
8  
Mechanical Workshop & Process Skid

12

## Locations



• **INTERNATIONAL  
CUSTOMER NETWORK**

### ○ **Milan**

CORPORATE OFFICES  
AND TECHNICAL DEPARTMENT

### ○ **Rome**

MECHANICAL WORKSHOP

### ○ **Naples**

TECHNICAL OFFICE

### ○ **Turin**

ISOLATORS  
ASSEMBLING  
AND FAT AREA

### ○ **Capetown**

BRANCH OFFICE

### ○ **Athens**

BRANCH OFFICE

## LAST 10 YEARS' TURNOVER



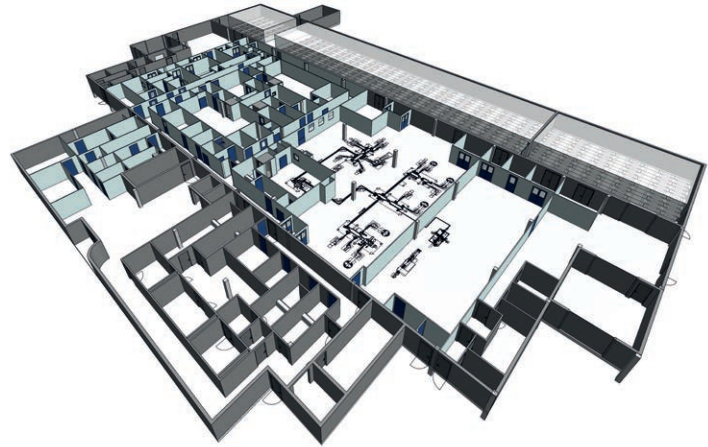


# FACILITY PLANNING

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 Consumption Evaluation
- Estimate and Scheduling

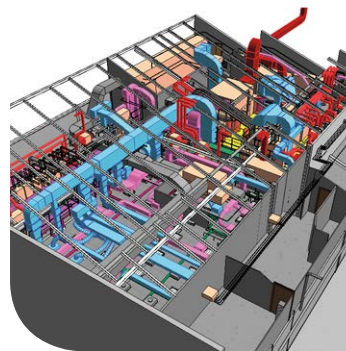
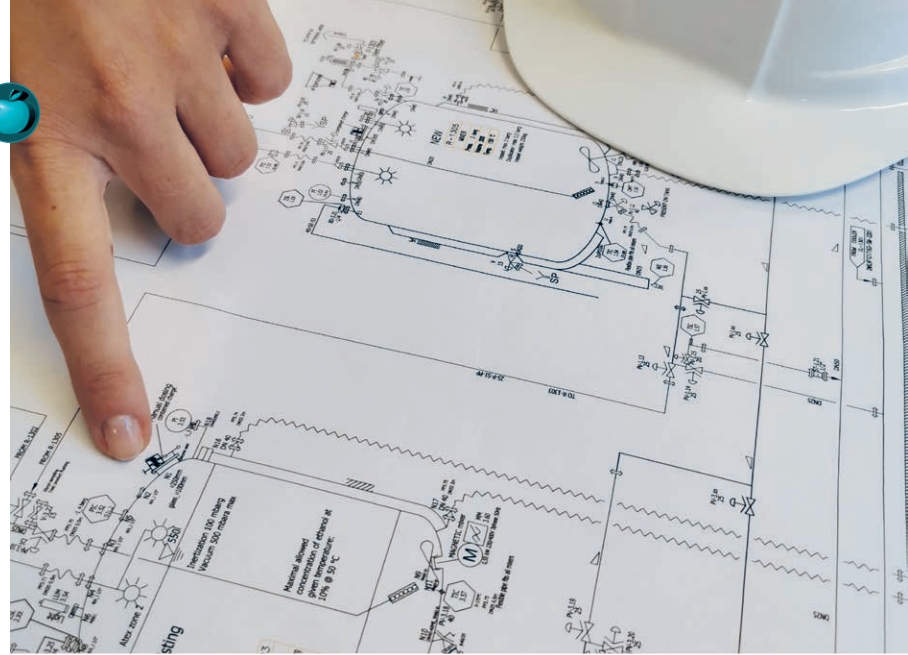
Strategic decisions support: the core of our facility planning activities, aimed to a better and more conscious definition of your new or upgraded process needs.



# 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

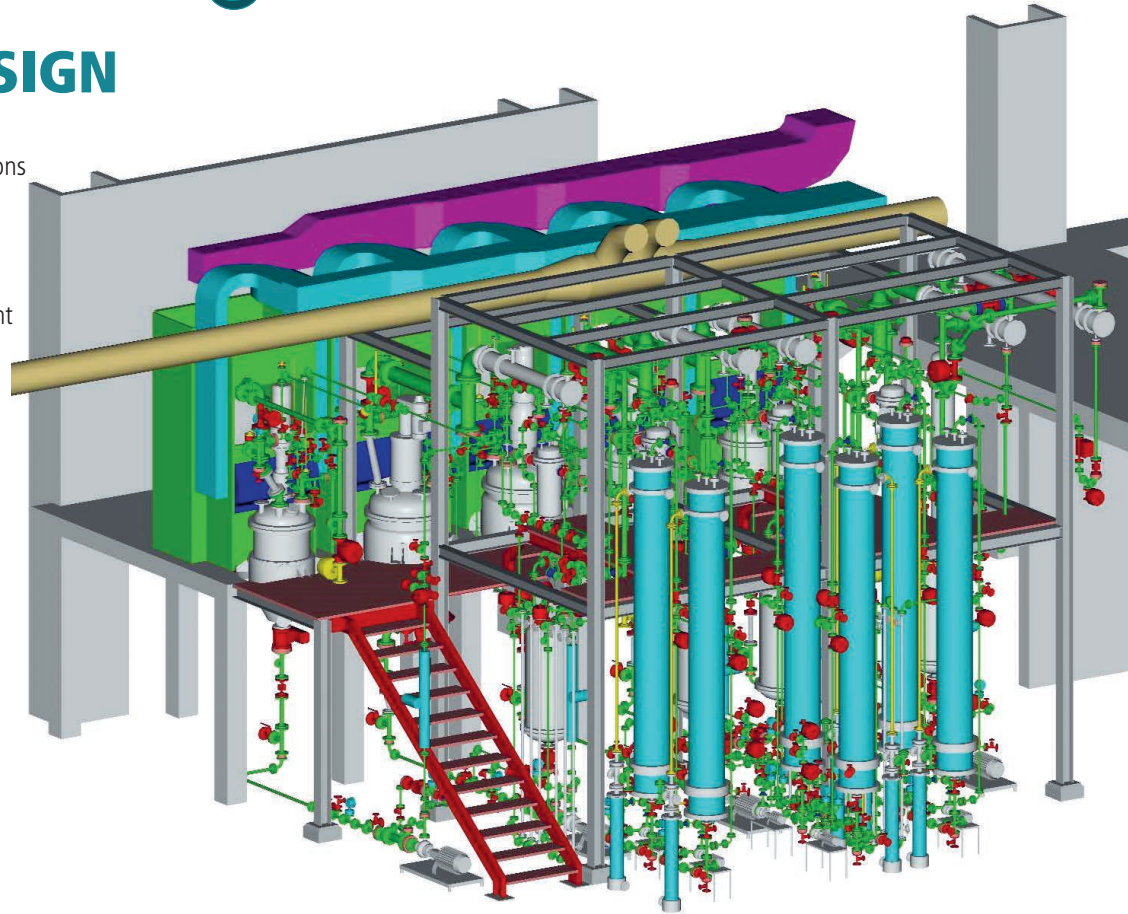






# PROCESS DESIGN

- 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 deviation)
- 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

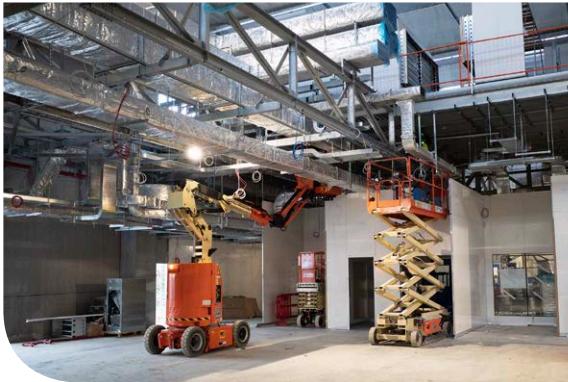
Gap Analysis, Risk Assessment and other ICH Q9 risk analysis tools are routinely used.





# 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 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 to 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 manufacture
- Exposure control procedures definition
- Atex design
- SMEPAC testing for isolator release

## DIT

- Patented technology
- Docking system for multiple diameter drums
- Seal of excellence of European Commission





## ISOLATOR

- Materials:
  - 304/316/316L Stainless steel
  - Hastelloy C-22
  - Polycarbonate
  - 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

Recently included, Officine Galesso is a mechanical workshop near Rome that has been operating in the pharmaceutical sector for over 50 years and has enabled the Group to produce all equipment for isolation technology and liquid preparation. This acquisition allows the group to control all stages of its production processes.

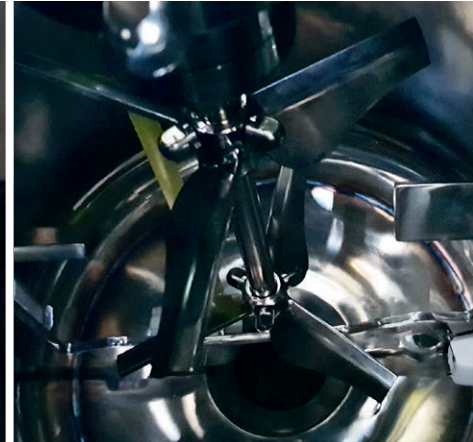
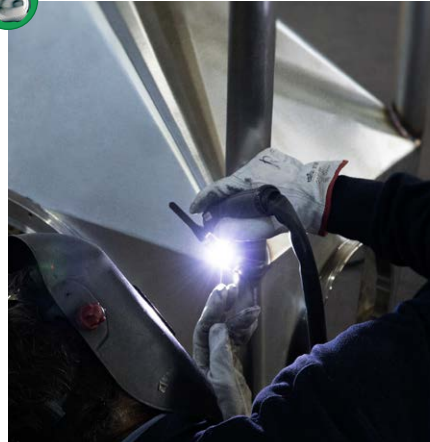
- Process Vessels
- Reactors and tanks
- Heat Exchangers
- Carpentry
- LAFs Hoods
- Special tools for pharmaceutical sector

#### 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 to CFR21 part 11





# DESIGN AND MANUFACTURING OF PROCESS EQUIPMENT

Pharma Hub, thanks to its knowledge of Good Manufacturing Practices 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.





[www.csv-ls.com](http://www.csv-ls.com)

**CORPORATE**

Via Selvanesco 75 | 20142 Milan | ITALY  
Phone: +39 02 274393.1 | Fax: +39 02 27439320  
[info@csv-ls.com](mailto:info@csv-ls.com)

