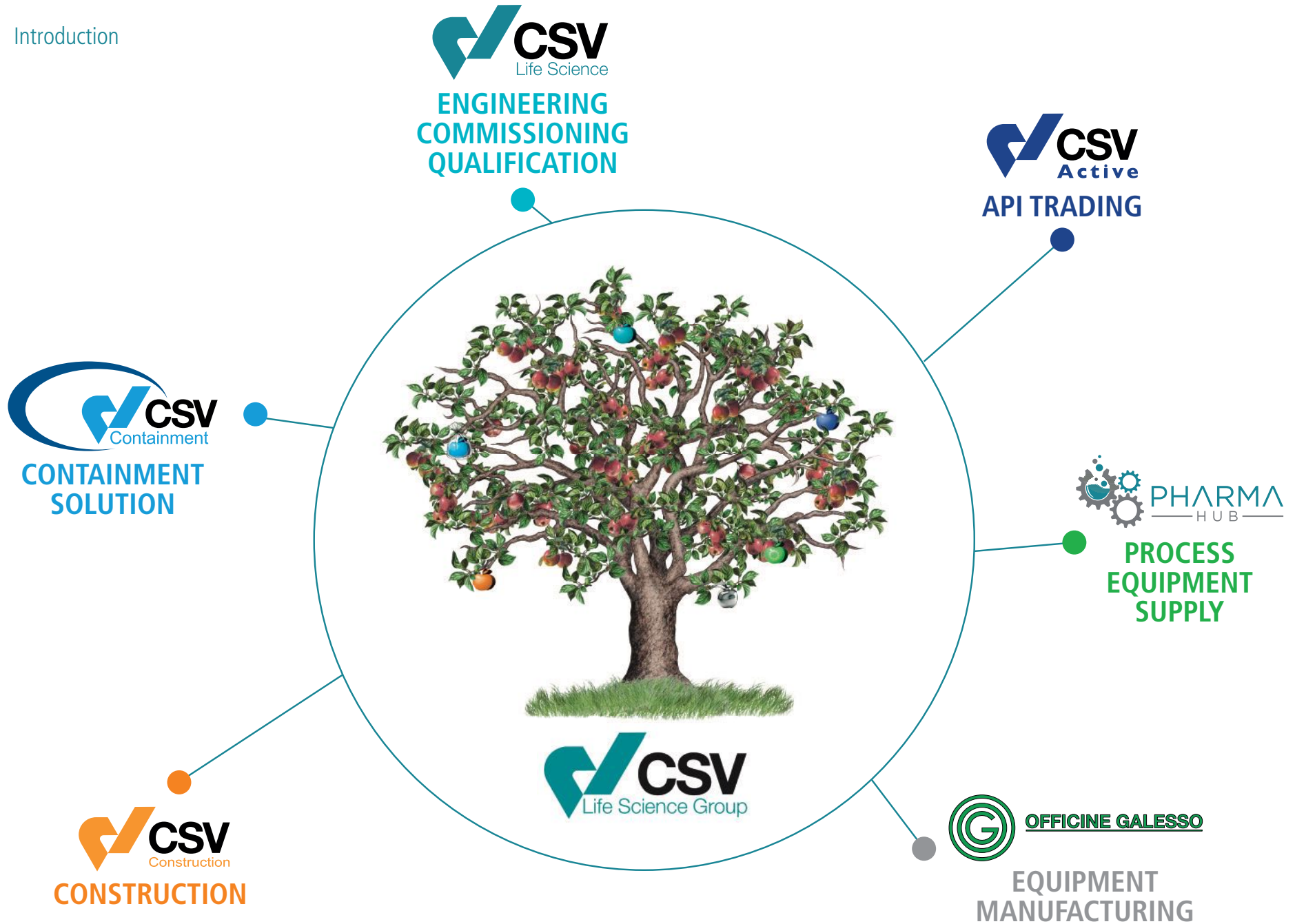




CSV

Life Science Group



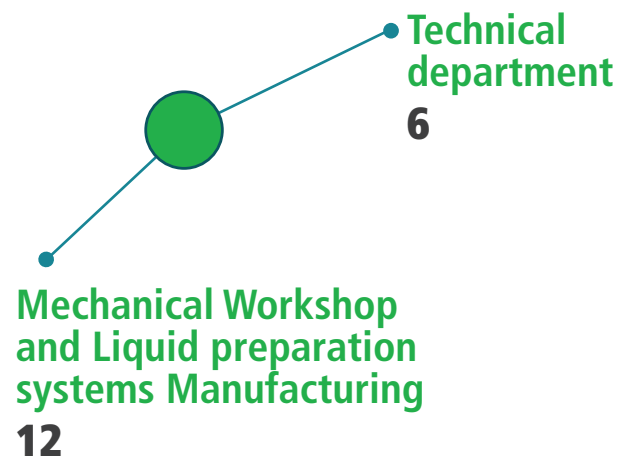
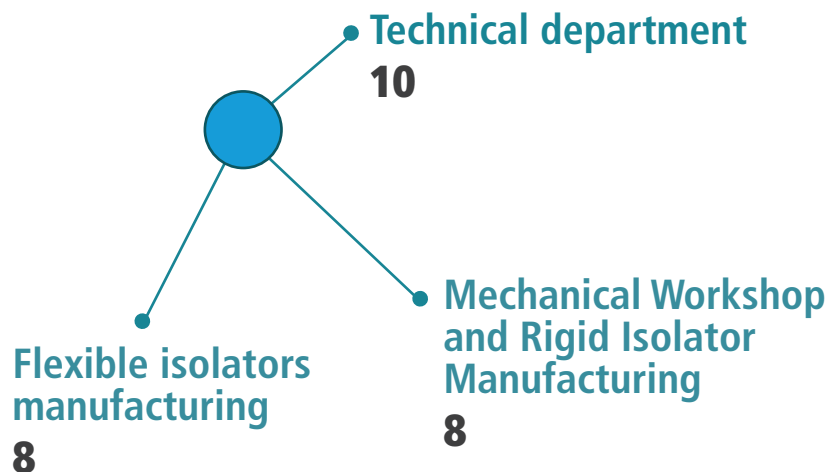
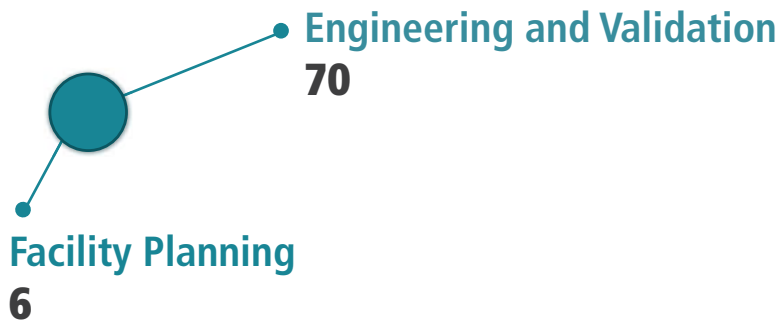
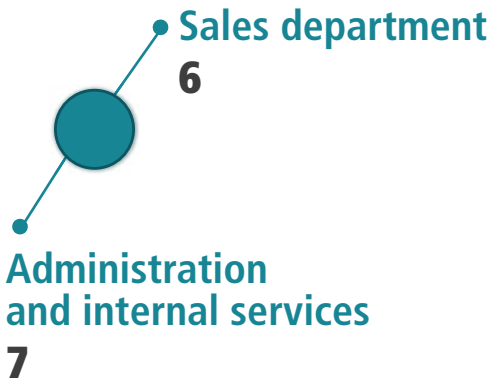




CSV life science group since its **foundation in 1998 has put the passion for work and the care for people at the core of its growing values.**

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 markets**.





Locations



• **INTERNATIONAL
CUSTOMER NETWORK**

○ **Milan**
CORPORATE OFFICES
AND TECHNICAL DEPARTMENT

○ **Rome**
MECHANICAL WORKSHOP

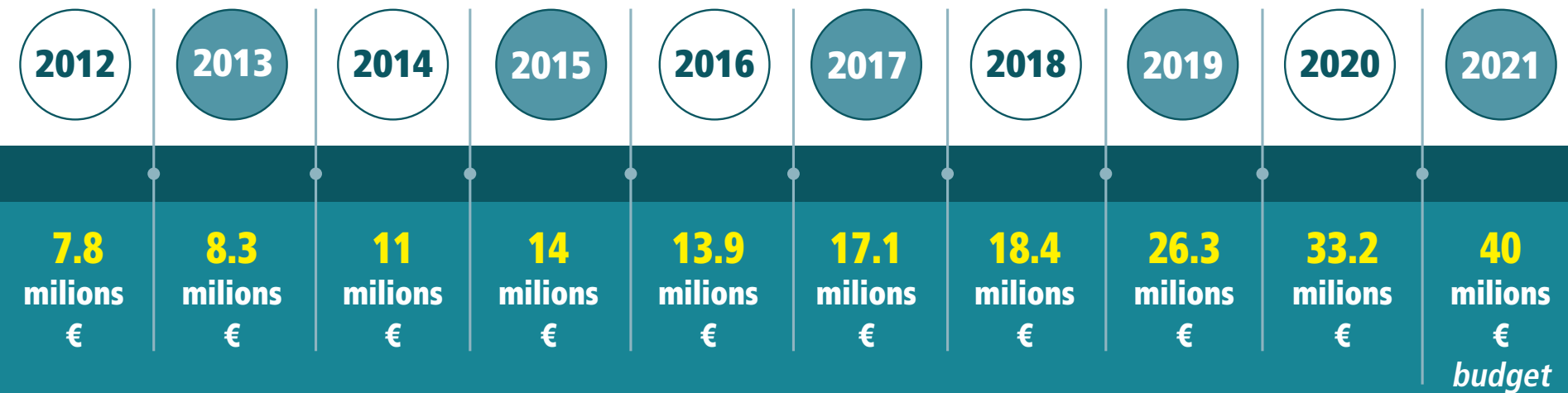
○ **Naples**
TECHNICAL OFFICE

○ **Turin**
ISOLATORS ASSEMBLING
AND FAT AREA

○ **Capetown**
BRANCH OFFICE
5



LAST 10 YEARS' TURNOVER

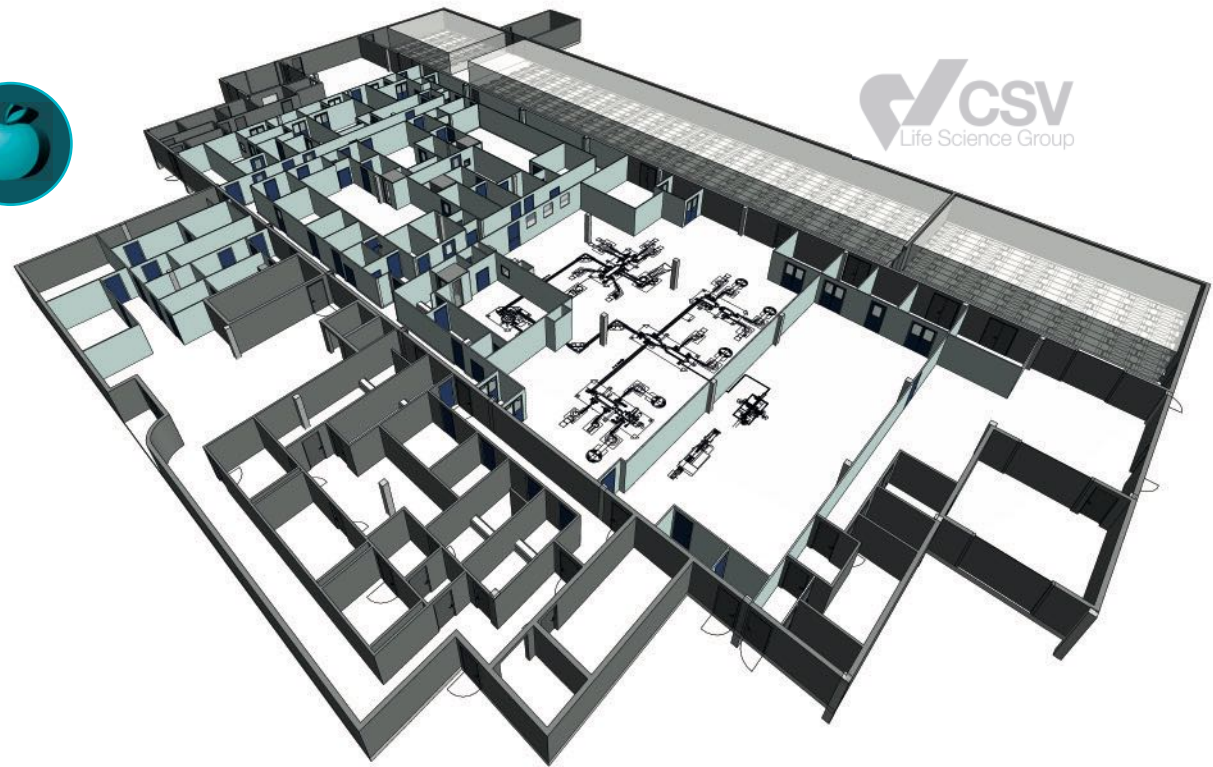


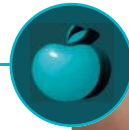


FACILITY PLANNING

- URS definition and data collection
- Capability check 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
- URS preparation for basic and detailed engineering

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





ENGINEERING

CSV Life Science Group can be at your service for:

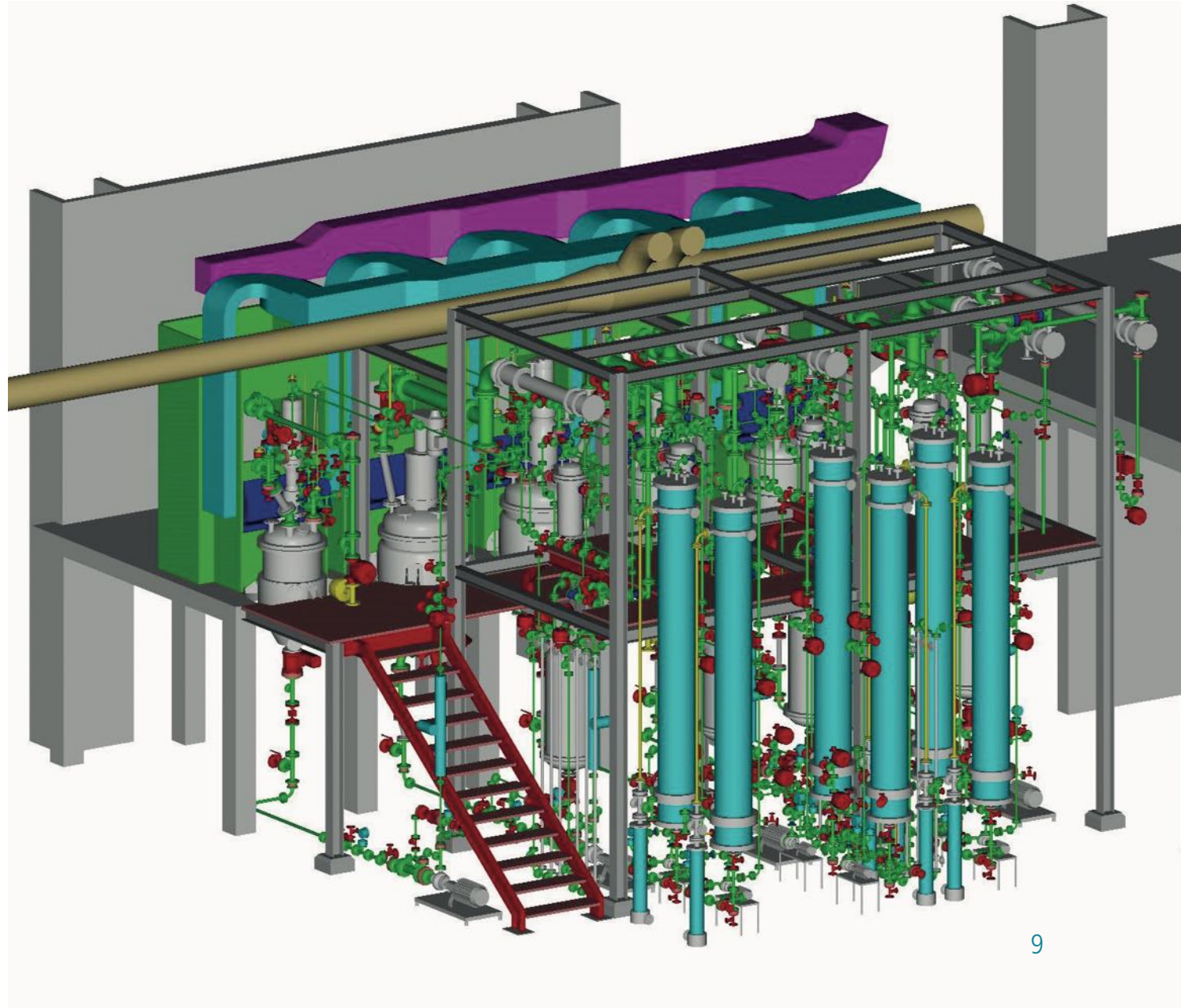
- Basic design
- Detail design
- Project review
- CFD simulation
- Full 3D modelling and BIM
- Engineering Procurement & Construction Management services
- Scheduling and Total investment cost evaluation





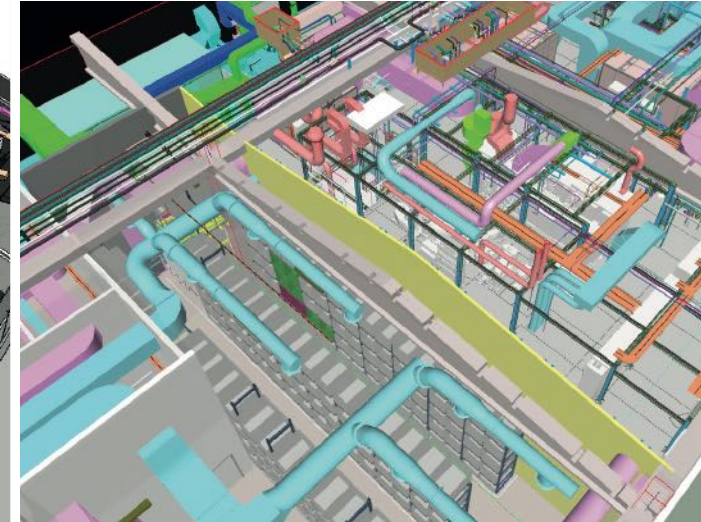
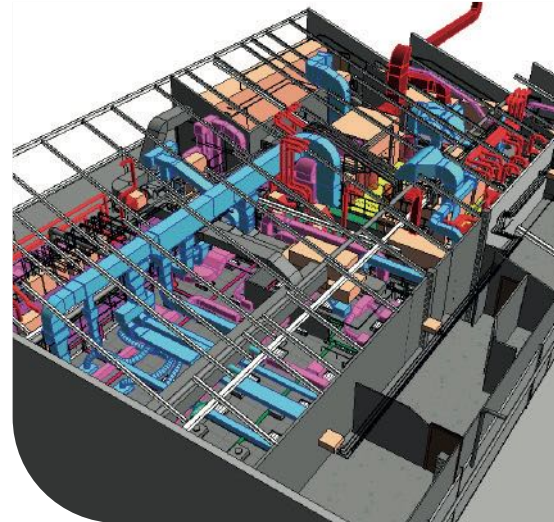
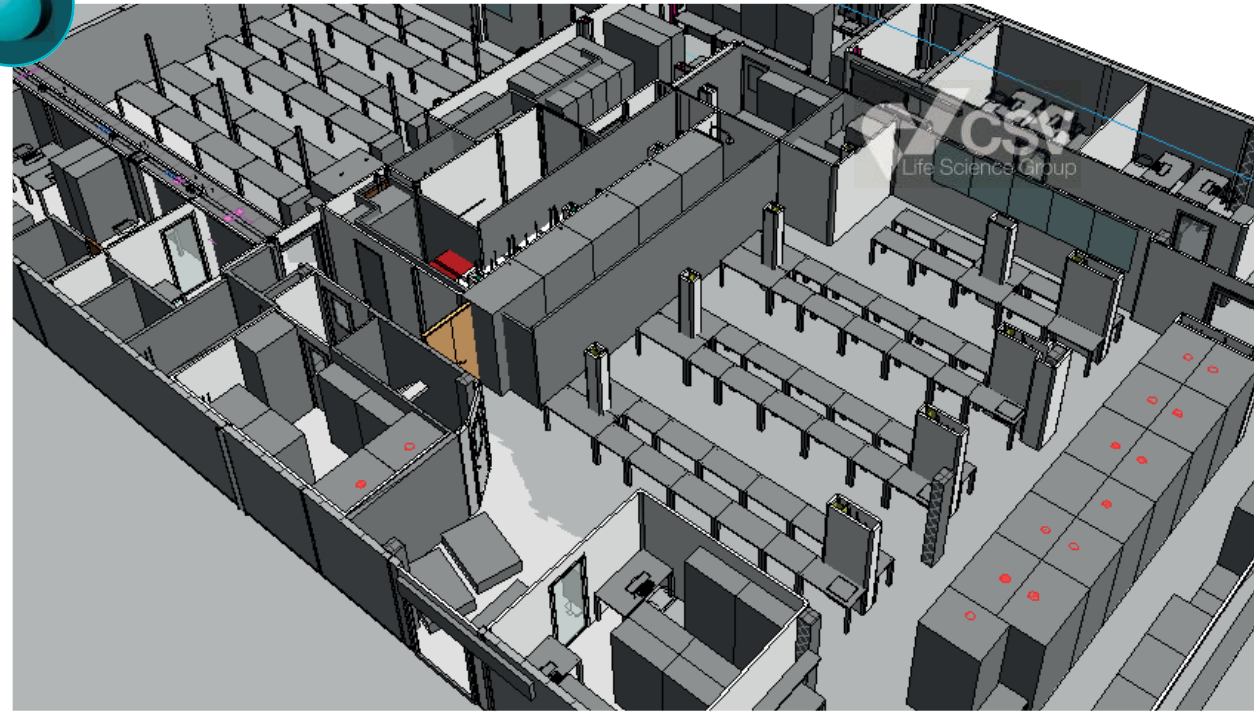
PROCESS DESIGN

- URS definition
- Production capacity review
- Process description and calculations
- Process Flow Diagrams design
- P&IDs design
- HAZOP review
- Containment and biocontainment strategy identification



PHARMACEUTICAL FACILITIES

- Architectural and structural design
- Civil and Pharma/clean room finishing design
- HVAC and mechanical design
- Electrical and low-current design
- Automation I&C design
- Rendering design
- Energy saving evaluation
- Long term expansion design





CONSTRUCTION

The construction division of CSV Life Science 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





COMMISSIONING

- FAT/SAT assistance/support
- System balancing and troubleshooting
- Instrument calibration

QUALIFICATION

- URS
- VMP
- GMP review
- DQ, IQ, OQ, PQ protocols writing and execution
- Risk and impact assessment strategy
- Process, cleaning and methods validation
- QA & QC SOP writing
- Computer system validation
- Data integrity assessment

Skilled and experienced staff at your service, operating through a large stock of technical instruments, for a fast and smooth completion of massive projects.

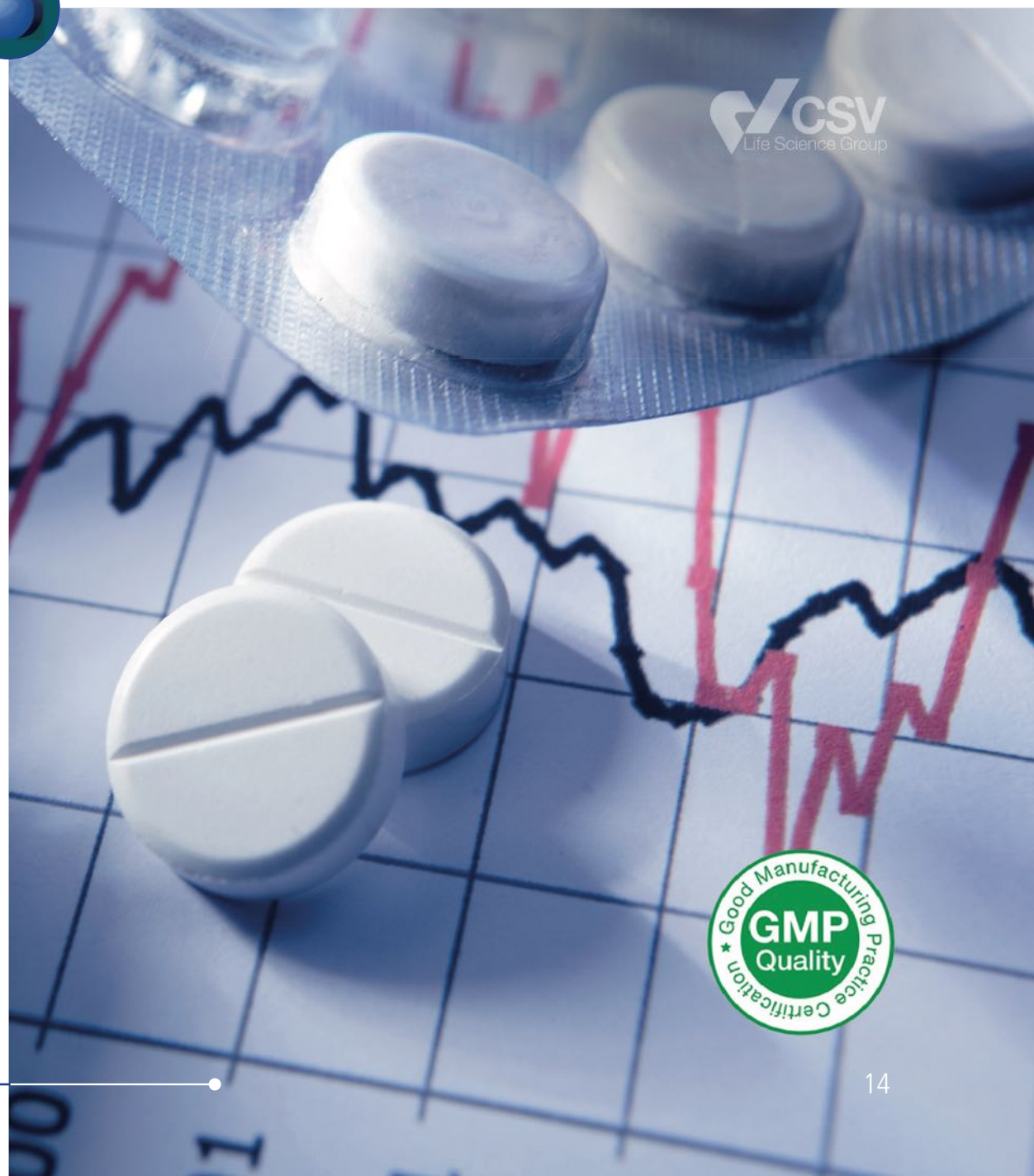




API TRADING

- 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.



CONTAINMENT SOLUTIONS

20 years' experience in process defining has provide 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
- 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





EQUIPMENT MANUFACTURING

CSV Life Science Group, aiming at controlling all the steps of its production processes, **manufactures all the equipment for isolation technology as well for liquid preparation through its Rome based metal workshop fully dedicated to pharmaceutical machine.**

- Process Vessels
- Reactors
- Heat Exchangers
- Cylindrical and spherical tanks
- Rigid isolator carpentry
- Special tools for HP handling
- PED tested solutions
- Materials:
 - 304/316/316L Stainless steel
 - & Hastelloy C-22

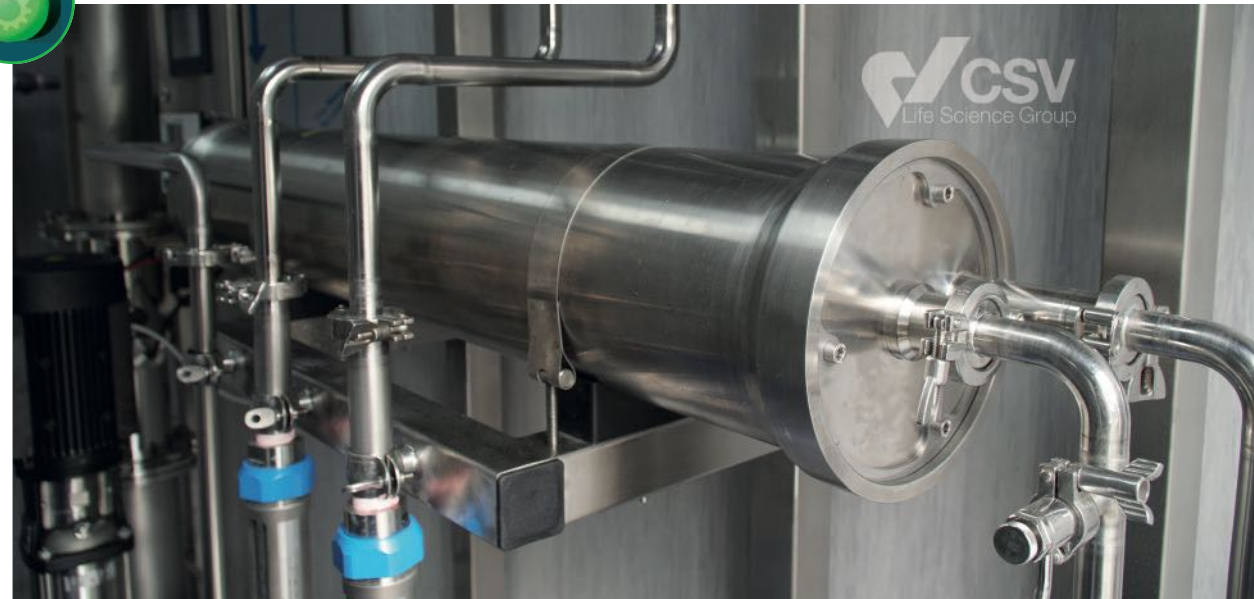




PROCESS EQUIPMENT FOR LIQUIDS

PharmaHub, as part of CSV Life Science Group, is a **reliable supplier for a wide range of equipment for liquids drugs preparation.**

- Mixing tanks
- Solution preparation packages
- Transfer lines
- CIP/SIP skids
- Turboemulsifiers
- Mobile stirred vessels
- Full CFR21 part 11





MAIN PROPOSALS

- Norms and guidelines
- GMP assessment methods
- Risk based approach and risk assessment
- Commissioning and Qualification
- Pure Fluids
- Computerized Software Validation
- High Containment Processes and SMEPAC testing

Knowledge sharing and training are key elements for an organic growth.

For this reason, CSV Life Science Group truly believes in CSV Academy, an organization born not only to inform, but also to form and to make the culture surrounding the Pharma world grow globally.

The newly founded branch of the group is addressed to both national and international audiences and is aimed at covering a wide range of topics, relying on the knowledge of all the Company professionals and experts as well as of its partners.



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