CSV
Life Science

CSV Life Science

ENGINEERING & GMP SERVICES

CSV Life Science is the historical branch of the Group offering **Engineering and GMP Services for the Life Science** market

CSV Active

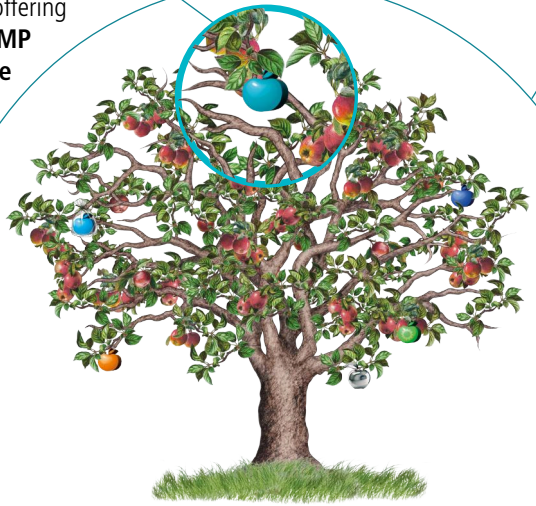
API TRADING

PHARMA HUB

PROCESS EQUIPMENT SUPPLY

CSV Containment

CONTAINMENT SOLUTIONS



1998 - 2023 ANNIVERSARY 25

CSV Life Science Group

OFFICINE GALESSO

EQUIPMENT MANUFACTURING

CSV Construction

CONSTRUCTION

Locations

CSV Life Science

- **INTERNATIONAL CUSTOMER NETWORK**

Milan
CORPORATE OFFICES AND TECHNICAL

Rome
MECHANICAL WORKSHOP

Naples
TECHNICAL OFFICE

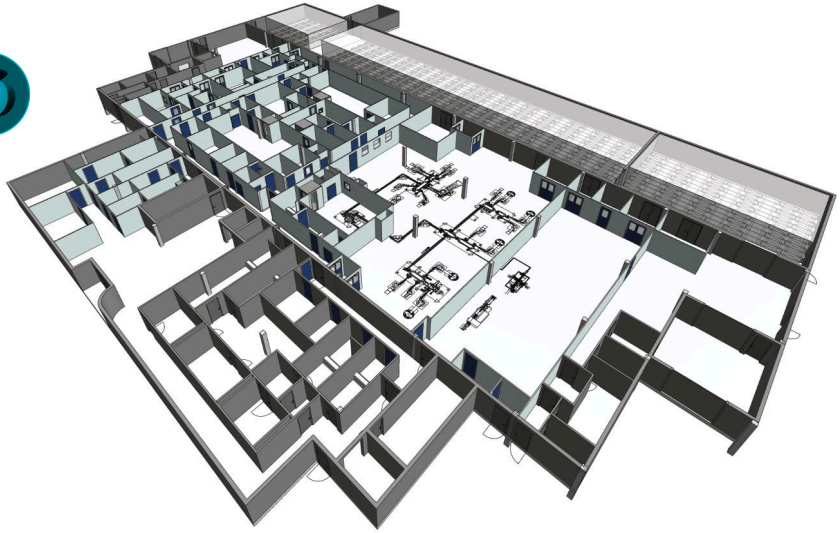
Turin
ISOLATORS ASSEMBLING AND FAT AREA

Capetown
BRANCH OFFICE

Athens
BRANCH OFFICE

FACILITY PLANNING

- URS Definition and Data Collection
- Capability Check and Gap Evaluation
- "What if" Analysis
- Containment Strategy Definition
- Bubble Layout and Alternative Solution Development
- SWOT Analysis and Reference Scenarios Definition
- GMP Layout & 3D View
- Utilities Capacity and Gap Studies
- Cost & Timing Evaluation



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.

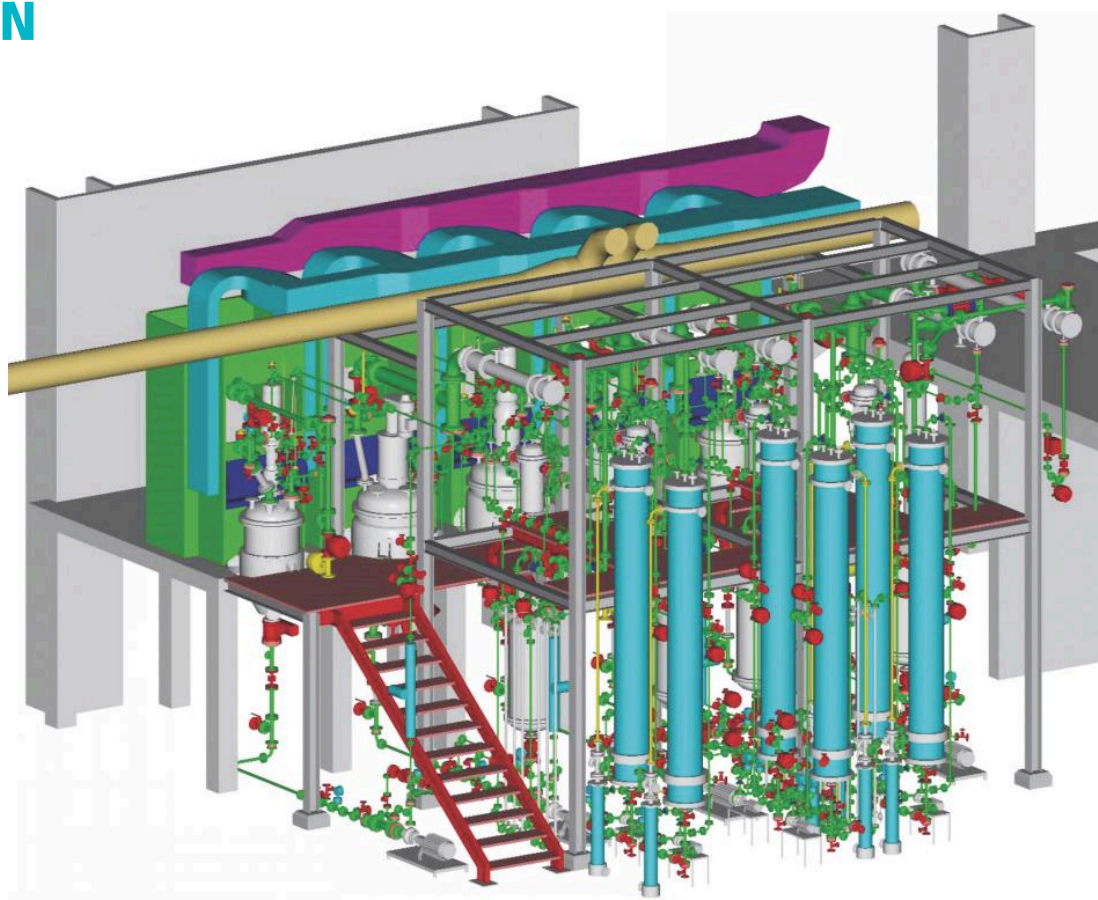
ENGINEERING

CSV Life Science Group can support you for:

- Basic Design
- Advanced Basic Design
- Detail Design
- Project Review
- CFD Simulation
- Full 3D Modeling and BIM
- Engineering Procurement Construction Management Services
- Scheduling and Total Investment Cost Evaluation

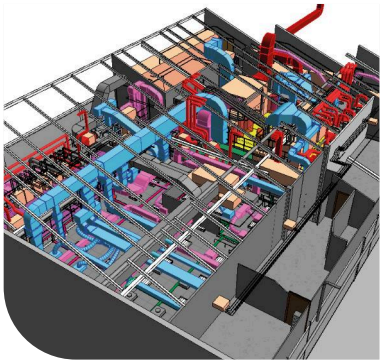
PROCESS DESIGN

- URS Definition
- Production Capacity Review
- Process Description and Calculations
- Process Flow Diagrams Design
- P&IDs Design and Review
- HAZOP Review
- Containment and Bio-containment Strategy Identification



PHARMACEUTICAL FACILITIES

- Architectural and Structural Design
- Civil and Pharma/Cleanroom Finishing Design
- HVAC and Mechanical Design
- GMP Utilities Design
- Electrical and Low-current Design
- Automation I&C Design
- Rendering
- Energy Saving Evaluation
- Long Term Expansion Design



QUALIFICATION

- GMP review
- Project Management
- VMP/VPP and Validation Strategy Definition
- Risk and Impact Assesment Strategy
- DQ, IQ, OQ and PQ Protocols Writing and Execution
- Validation SOP Writing
- Deviation Management and Remediation Plan
- System Requalification (HVAC, Utilities, Sterilization System, …)
- Periodic Review
- SMEPAC Test

METROLOGY

- Calibration Plan Definition
- Metrology SOP Writing
- Instruments Calibration
- Calibration Data Management on Customer Database

COMMISSIONING

- Project Commissioning Strategy Definition
- FAT and SAT Assistance and Support
- System Startup and Fine Tuning
- Cleanroom & HVAC Balancing and Troubleshooting

HVAC PREVENTIVE MAINTENANCE

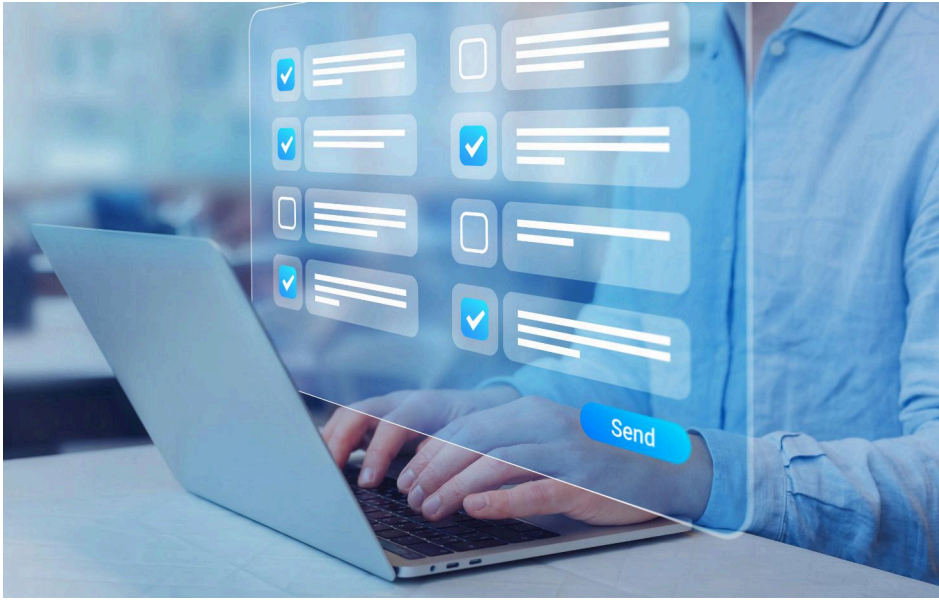
- Evaluation and Troubleshooting of HVAC System for Requalification
- Filter Furniture and Replacement for AHU Cleanrooms and Hoods
- Release of Technical Reports
- Maintenance SOP Writing

DATA INTEGRITY AND COMPLIANCE

- Risk Assessment (Project RA and Functional RA)
- Gap Analysis
- Remediation Plan
- Data Integrity Gap Analysis
- Support for Regulatory Inspection Preparation
- Supplier Audit
- SOP Management for Manufacturing and IT System
- Feasibility Studies for Processes and Flow Definition (ERP, LIMS, EDMS, MES, Datawarehouse)
- Supplier Selection (Platform and Architecture)
- Audit Trail Review and Process Optimization
- Supplier Level Agreement Writing and Review

COMPUTER SYSTEM VALIDATION

- Project Management
- ERP Validation
- QMS Validation (EDMS, CAPA System, Deviation Tracking System, SOP Management System)
- LIMS Validation
- MES Validation
- Centralized System Validation
- Custom Field Configuration and Implementation for Labs Centralized System
- Laboratory Instruments Validation
- Visual Inspection and Serialization
- IT Infrastructure Validation
- Virtualization Projects Management
- Computer Systems Periodic Review
- Data Migration
- Computer System Decommissioning
- Computerized System Inventory



QUALITY ASSURANCE

Support for implementing PQS key elements:

- CAPA system (and deviation)
- Change management system
- Process performance and product quality monitoring system
- Management review
- Training and personnel qualification procedure
- Supplier qualification
- Quality and Technical Agreement
- Complaint Management

FDA and EU GMP mock inspections and remediation plan.

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

QUALITY CONTROL

- Analytical method transfer
- Analytical method validation (advanced statistical tools for data analysis).
- Assessment on GMP and regulatory compliance to current/new ICH analytical method guidelines
- Nitrosamine regulation compliance

OPERATION QUALITY SUPPORT

- Contamination Control Strategy Assessment
- Gap Analysis vs Annex 1

PROCESS & MANUFACTURING

- Technology Transfer
- Process Validation
- Cleaning Validation
- On-site QA Operation Support

GMP COMPLIANCE COURSES

- cGMP Introduction and Recurrent Refresh
- QMS and Document Management System
- cGMP Application for OSD Production
- cGMP Application for Sterile Production
- cGMP Application for Medical Gases
- Risk Analysis Approach in Pharmaceutical Industry
- Cleaning Validation
- Change Control Management

AUDIT

- Supplier Qualification and External Audit Management
- Audit Induction for Regulatory Inspections

REGULATORY AFFAIRS

- CTD and Regulatory Variations Management

CSV Training Academy

DATA INTEGRITY AND COMPLIANCE

- Data Integrity and Data Management
- Computer System Validation and GAMP 5 Ed. 2
- Manufacturing Computer System Validation

C&Q

- Annex 15 and Validation Principles
- Process Validation
- Metrology
- Annex 1 Cleanroom Validation for Sterile Production
- Clean Utilities and Process Gases Validation
- Sterilization Process Validation

HPAPI

- Principles and Regulations for HPAPI Containment

CSV Training Academy

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NEWSLETTER