THE GROUP

CSV Life Science over the years has built a group of companies and professionals able to provide integrated solutions to the pharmaceutical market.

The know-how and skills of CSV's specialists can ensure the success of a project from the early stages from the strategic decisions up to the development of engineering activities, processes development to contain all the exposed operations to the construction up to final validation.

CSV Life Science

www.csv-ls.com

Engineering | Construction | Compliance | Containment | API & Intermediate | Validation

CSV Active is a qualified Worldide Partner with high competence in Fine Chemicals Intermediate and API sourcing in the full respect of the latest GxP Regulations.

CSV Construction supports customers in construction phase, suppling plants on Lump Sum Turn Key (LSTK) basis, and/or providing on site project management and construction supervision.

CSV Containment is a leading company in powder containment and aseptic transfer, providing custom made solutions based on flexible and rigid technology.

Pharma Hub follows with more attention the request of our clients located in the south of Italy with engineering, construction and validation services.

FasLab is a reference point for companies which are looking for custom-made solutions for calibration, validation and measuring.

FasInternational have a big experience in thermal validation. They also have a leading position in temperature, relative humidity, pressure, electrical magnitude and HVAC parameters monitoring.

THE RIGHT PLATFORM, PEOPLE AND KNOW-HOW FOR SAFE HIGH-POTENCY APIs CONTAINMENT.

FROM **ENGINEERING** TO **VALIDATION** THROUGH **CONSTRUCTION.**

CSV Life Science

CSV Life Science Srl
Via Selvanesco 75, 20142 Milano ITALY
www.csv-ls.com
info@csv-ls.com
Tel. +39 02 274393.1
Fax. +39 02 27439320

CSV Life Science

HPAPIs SOLUTIONS
TO MEET ALL YOUR NEEDS

www.csv-ls.com

THE HPAPIs CHALLENGE

Highly potent active pharmaceutical ingredients (HPAPIs) represent a significant shift in the pharmaceutical market. This change has not only led to a pipeline of more effective medicines that require lower doses and lead to fewer side effects, but also to new manufacturing challenges.

Each production phase has to be carefully evaluated as for its related risk, initial planning of production facilities should take into consideration all the measures needed to remove this risk.

The working environment is the sum of the room, the equipment and the people working in it. According to regulatory guidelines, it is necessary to adopt suitable protections for the working space and the equipment, in order to facilitate as far as possible the free movements of the workers.

OUR KNOW-HOW

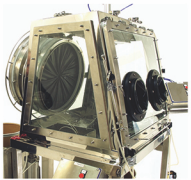
Our know-how both in the pharmaceutical and chemical industries brings our clients total peace of mind, in the knowledge that they can rely on a complete solution with a synergistic integration of validation and engineering expertise.

It has likewise gained us recognition for delivering the benefits of validation services that are mainly orientated to resolving rather than simply identifying any non-conformities encountered.

CSV Life Science is an ideal partner for companies seeking the highest standards of professionalism together with outstanding operating flexibility. CSV has the experience and specialist to provide integrated solutions covering the entire product manufacturing cycle.

Our team understand the realities of the pharmaceutical and chemical engineering fields and develop tailored solutions using innovative and flexible containment technology, all specially designed for HPAPIs production plants.

CSV remains faithful to the principles on which our company was founded: **BETTER PERFORMANCE THROUGH RESEARCH AND INNOVATION.**



TOXICOLOGICAL STUDIES | EXPOSURE CONTROL PRACTICES | ADVANCED ENGINEERING | CONTAINMENT SYSTEMS | CONTAINMENT TESTING (SMEPAC)

TOXICOLOGICAL STUDIES

We can evaluate the toxicity of the substance in order to select production units and processes that are optimally suited to the product hazards. Once workplace limits have been defined for a chemical, the required technical procedure can be defined thereby minimising investment and operating costs.

- Collection and analysis of toxicological data
- Data gaps filling by in silico/vitro/vivo methods
- PDE (Permissible Daily Exposure) assessment
- OEL quantitative assessment
- OEL qualitative assessment
- Proposal of the most appropriate containment strategy based on the potential exposure

EXPOSURE CONTROL PRACTICES

Our process engineering, based on toxicology conclusion, can define the right exposure control strategy to target the identified CPT/OEL. These services, starts from a safety risk assessment to support as the phase in the process of developing and/or restructuring industrial manufacturing sites.

- OELs assessment review
- Batches sizes identification
- Process operations analysis
- Transfer operations analysis
- Equipment pre-selection
- Layout and architectural requirements
- Material and personnel flows
- HVAC and utilities definition

ADVANCED ENGINEERING

We can design and realize concept identified during the exposure control practise. Layouts, P&IDs and specification will identify the final solution to be adopted. Our team always dedicate great attention to operating, cleaning and maintenance, as well as, initial and periodic validation.

- Layout, material and personnel flows
- Isolation equipment specification
- Cost estimate
- P&ID
- 3D design
- GMP and safety review
- Interactive sessions

CONTAINMENT SYSTEMS

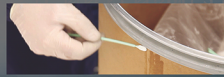
We provide custom made containment solutions based on flexible or rigid technology. Since 2009 CSV Life Science is the exclusive ILC DOVER agent while on 2015 represents THE CHARGEPOINT split butterfly valves. On 2016 CSV developed its own proprietary DRUM IRIS TECHNOLOGY.

- Preliminary survey discussion, front end design
- Containment engineering
- 3D modelling, mock-up and ergonomic test
- Design review and manufacture
- Flexible containment
- Rigid isolator
- CSV drum iris technology

CONTAINMENT TESTING (SMEPAC)

We offer services for testing performed according to ISPE's SMEPAC guideline (Standardised Measurement of Equipment Particulate Airborne Concentration), starting from laboratory scale for process research up to large scale manufacturing.

- Risk analysis
- Sampling and validation plan design
- SMEPAC and validation protocol development
- Technical support
- Containment system FAT/SAT and installation
- SMEPAC and validation
- Laboratory analytical tests



WE PROVIDE SAFE SOLUTIONS FOR HIGH POTENCY PLANTS.

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