Pharma Process

COMPANY PROFILE

We carry out **design**, **installation**, **validation** and propose our senior expertise and **quality** services to our customers so that they can manufacture safe drugs.

Our values

Teamwork

Effective communication, collaboration and support within and between teams are key to our company success. Nobody is perfect, but a team can be.

Passion and innovation

We promote openness, curiosity and agility to improve our skills every day. We embrace obstacles to better understand their contents and provide the best and most appropriate solutions.

Excellence and integration

Our sustainable success is built upon experience, accountability and continuous training thanks to our integrated competences all along the pharmaceutical portfolio.

Trustworthiness

We approach our work as if we were in our own home, maintaining the same level of dedication and care in every context we are involved in.

Leadership team

Marco Alberio

Engineering Director

More than 20 years spent in leadership functions (CapEx manager, Engineering Director) for pharmaceutical industries mainly focused on sterile manufacturing for both the EU and US Market.

Renato Picchi

Pharmaceutical Project Master Manager

More than 20 years serving pharmaceutical companies in a leading consultancy firm. Consolidated and proven experience in Validation, Process Development, and cGMP compliance.

Fabio Geremia

QP - Quality & Compliance Director

More than 20 years spent in QA functions in both pharmaceutical companies as well as in leading consultancy companies. Lead Auditor and QP for EU and US FDA approved facilities.

Filippo Baviera

CSV & Data Integrity Manager

More than 25 years of on-field experience, expert in CSV and Data Integrity serving pharmaceutical industries since the ‘90s. Leading remediation projects and the setting of data integrity systems.

Senior staff

More than 40 Senior Pharmaceutical Professionals

Biotech Senior Process Engineer

More than 10 years of experience in the pharmaceutical field as Process Engineer and Process Manager. Main experience in Biotech and Sterile manufacturing facilities.

CSV Senior Consultant

More than 10 years of on-field experience. Expert in CSV and Data Integrity serving Pharmaceutical industries. Involved in remediation projects and development of Data Integrity approach.

C&Q Manager

More than 20 years spent in C&Q management functions in both pharmaceutical companies as well as in leading consultancy companies. Strong expertise in on-field management.

Pharma Senior Process Engineer

More than 10 years of experience in engineering companies and OEM with focus on process development, facility and utility design, and revamping activities. Strong expertise in Process Design.

QA/QC Senior Consultant

More than 20 years of experience as QA and QC manager for EU and US FDA approved Sterile Manufacturing Facilities. More than 50 EU and US FDA Inspections performed.

Project & Construction Manager

More than 20 years spent as Project Engineer and Project Coordinator for the construction of new Chemical and Pharmaceutical facilities. Strong expertise in HVAC and utility design and commissioning.

Services

Pharmaceutical Engineering

From strategy to execution with OPEX in mind

Highly experienced staff coming directly from leading pharmaceutical manufacturing industries. We can offer our expertise in process definition, layout development and process design, clean utilities and HVAC design, construction management with focus on cGMP aspects. Thanks to our direct experience on field, we can design new facilities and perform revamping activities with particular focus on final user point of view, all with state of the art technologies.

STRATEGIC PHARMACEUTICAL ENGINEERING SERVICES

- *Pharma Project Management*
- *EHS Impact Evaluations – Containment Experts*
- *EHS and General Site Business Continuity Plans*
- *Sterility Assurance Engineering*

5.0 Calibration & Validation

Paperless - Papersoft

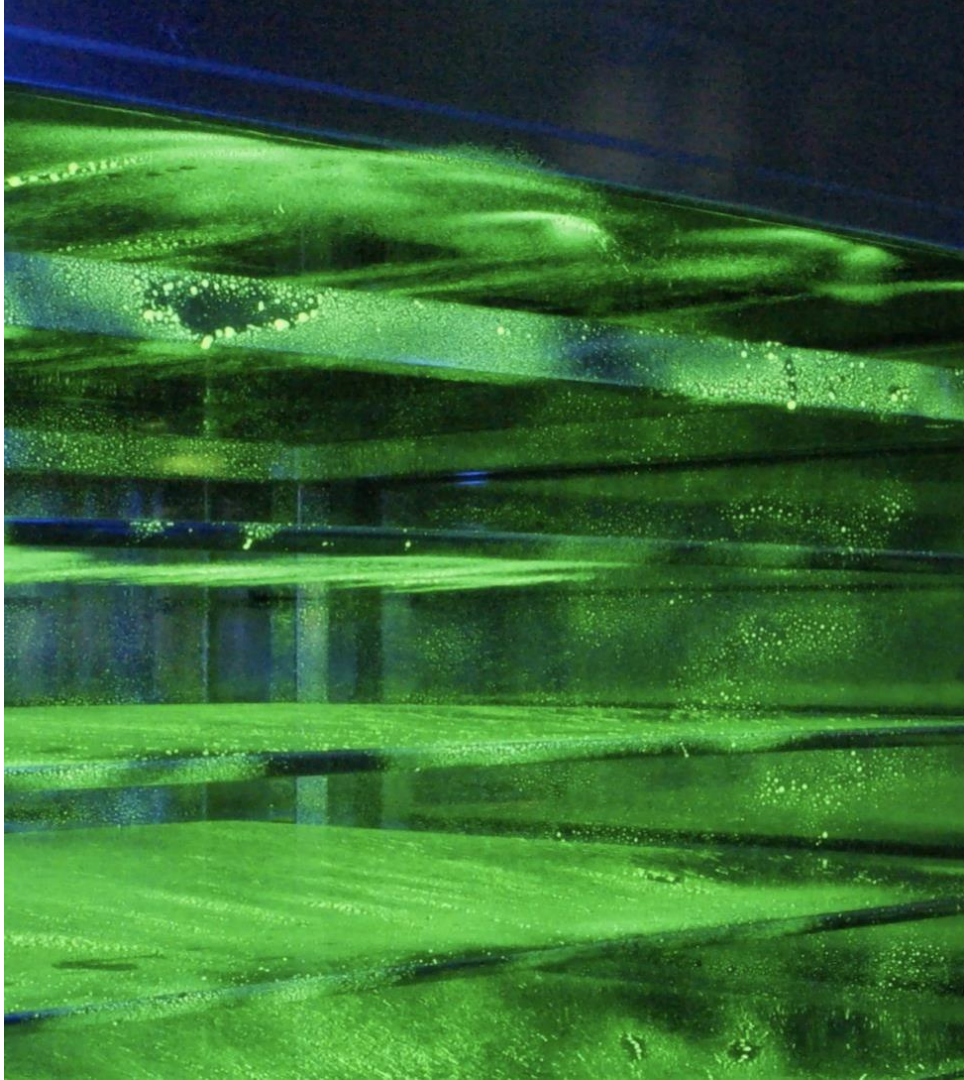
New tools for safe and compliant results

Senior experienced staff and innovative tools to create automatic GMP calibration reports and protocols, able to increase the efficiency and data integrity, all in compliance with the latest regulations.

Cal_Pro – Qual_Pro – Compliance 100% PaperLess - PaperSoft

We have an owned full set of certified instruments to perform all the Validation Service:

- Thermal Validation (Sterilization and Depyrogenation)
- HVAC and Classified areas
- Clean Utilities
- Calibration of GxP critical instruments
- Smoke Sudies for Aseptic Simulation



Auditing & GxP Compliance

Quality experts

Our senior staff have been directly involved in leading successful PAI and cGMP EU and FDA inspections. We support companies in sterility assurance development, Contamination Control Strategy implementation and GMP remediation projects, as well as setting up of structured GxP systems.

We are experts in management of Quality Systems for pharma companies, as well as healthcare companies, following GLP or ISO requirements (ISO 9001, ISO 13485/MDR, ISO 15378, ISO 22716 etc).

Auditing is usually performed involving lead auditors and Qualified Persons. We cover more than 100 audits per year and we have experience of more than 500 audits performed worldwide. We can provide several references in FDA and EU Agencies inspection readiness.

Data integrity & CSV

Flexible approach for compliant solutions

We are focused on delivering flexible solutions to guarantee the compliance with EU and FDA requirements. We support and drive companies through process transformation from paper-based systems to electronic recording.

SERVICES DELIVERED

- *Control System Periodic Review*
- *CFR 21 Part 11 Assessment*
- *IT Infrastructure Assessment and Validation*
- *ERP Systems Validation*
- *Software Selection and Software Development*
- *Excel Sheet Validation through dedicated and properly designed tools*
- *Preventive Maintenance and Calibration Timetables Software Development (compliant with CFR 21 Part 11 requirements)*
- *Lab Data Management and Development of Tools for Compliant Data Management*

SERVICES PROVIDED BY RAMP

Pharmaceutical Turnkeys

Thanks to our experience in HVAC, Cleanroom, Clean Utilities Design and Project Management, we can serve our customers with state-of-the-art turnkey solutions. We involve only reliable, skilled and selected contractors with strong experience in the pharmaceutical environment.

cGMP Preventive Maintenance

We propose a new Strategy for Contamination Control so to maintain the proper functionality of the whole pharmaceutical facility and prevent, when applicable and possible the impact on validation activities, out of services, monitoring OOTs and preventing OOS.

Pills of Pharmaceutical Courses and Training - Whitepapers

We offer a wide range of trainings to meet all needs, such as basic and advanced training, GxP training, on-demand training, online basic training and more.

Contamination

- Contamination - General Aspects
- Aseptic Techniques - Good practices
- Process Risk Analisys
- Contamination Control Strategy
- GMP Preventive Maintenance

cGMP Training

- GMP Preventive Maintenance
- Introduction to GMP
- Risk Assessment and URS
- Validation steps from DQ to PQ
- FMEA Techniques
- Guidelines: MHRA WHO FDA PICS GAMP
- New ANNEX 1 2022 – ISPE CoP Coordination

CSV Data Integrity

- Data Integrity
- ER management - Case Studies
- ALCOA
- ER management for automation systems
- CFR 21 Part 11 compliance

Sterilization

- Water and Steam System – Clean Utilities design and Validation
- Autoclaves and Tunnels
- Steam for Pharmaceutical purposes – tests for Steam Quality
- Steam sterilization
- Dry Heat Sterilization

Main References

Contacts

Pharma Process
SWITZERLAND

Pharmaprocess GmBH
Pharmaceutical Engineering

Via Gaggiolo, 12
CH - 6855 Stabio
SWITZERLAND
info@pharmaprocess.ch

Pharma Process
ITALY

Pharmaprocess S.r.l.
Validation - Quality - CSV

Via Bazzoni, 8
20123 Milano
ITALY
info@pharmaprocess.it

RAMP

Ramp S.r.l.
GxP Preventive Maintenance & Construction

Via San Giuseppe, 26
21047 Saronno (VA)
ITALY
info@ramp.srl


Pharma
Process