



SPAIQ VALUES

“There is only one way to explain a technology, validate it, test it and protect people from the consequences of process errors: gain a thorough understanding of it and learn every detail of the machine and the rationale behind its design”.

SPAIQ S.r.l. (hereinafter referred to as **SPAIQ**) follows a clear philosophy: to provide useful tools for **verifying**, **disseminating**, **maintaining** and **archiving** the information generated during the **design** and **testing** of automation systems.

SPAIQ has been operating for over twenty years in the following sectors:

- the packaging industry;
- the manufacture of equipment for pharmaceutical production and ancillary utility systems;
- the pharmaceutical industry;
- technical documentation.

SPAIQ's mission is to protect the health of the end user. A thorough understanding of processes and risks, combined with rigorous testing, ensures effective protection of human and animal health.

Therefore, pharmaceutical companies are granted authorisation to manufacture and package medicinal products only when they demonstrate that their processes comply with Good Manufacturing Practice (**GMP**) standards.

Such compliance is demonstrated not only through accurate and precise validation, rigorously documented at every stage, but also through the ability to maintain continuity and reliability across all critical business processes, even in the event of disruptions or adverse events.

For SPAIQ, business continuity objectives are therefore integral to quality: maintaining a high level of service and compliance with standards requires the ability to respond promptly to any crisis, minimising its impact on the delivery of products or services and on customer satisfaction. Effective risk management and operational resilience are therefore key to

ensuring that established quality standards can be maintained over time and under all circumstances.

SPAIQ supports pharmaceutical and packaging companies throughout the machinery validation process, carefully assessing risks and preparing the necessary documentation.

Validation is a highly sensitive process that addresses anything that may pose a risk to the person or animal receiving the medicinal product once it is placed on the market or supplied within the healthcare system. Machinery validation follows the machinery's life cycle.

During the contractual phase, the user (the pharmaceutical company) prepares a User Requirements Specification (URS), setting out its requirements for quality, production, safety and maintenance. The machine manufacturer, in turn, must specify how it intends to meet those requirements.

As part of validation, all parts of the system that affect quality and product safety must be described in detail. For each possible pharmaceutical defect, the risks that are expected to remain despite the specified actions, or that are deliberately accepted, must be carefully assessed.

In this regard, SPAIQ also supports the customer in **selecting and developing the most suitable validation strategy**. It therefore provides high-level consultancy, drawing on more than twenty years of experience in applying established risk analysis methodologies.

SPAIQ also carries out machinery testing and qualification using qualified personnel who receive regular training to maintain and update their skills.

To deliver such sensitive services, SPAIQ relies on a set of guiding values that define its corporate culture:

- **pursuit of excellence:** industry regulations and machinery technology are constantly evolving. SPAIQ is committed to consistently delivering high-quality service and striving for excellence, recognising that patient health and well-being are, and always will be, a priority;
- **customer satisfaction:** SPAIQ strives to ensure customer satisfaction, and its presence in the market for more than twenty years demonstrates that this is a top priority;
- **innovation:** SPAIQ believes in technology and has developed validation software that enables more accurate risk analysis, minimising the possibility of errors;
- **employees and experience at the heart of the project:** many of SPAIQ's employees have been with the company since its foundation and share their wealth of experience with new, young and dynamic staff. This experience is essential in such a complex sector;

- **training to broaden knowledge:** all SPAIQ personnel receive regular training to maintain and update their knowledge of both quality and the specific regulations governing the industry, which are constantly evolving;
- **attention to detail** in documentation and **care during testing** for pharmaceutical companies and the packaging industry: this is the only way to ensure high-quality service;
- **health is a non-negotiable value:** we know that SPAIQ's work affects human and animal health. Health is a non-negotiable value; the company is therefore proud of what it does, while remaining deeply conscious of the responsibility this entails;
- **responsibility:** SPAIQ believes that quality can only be achieved when every employee takes responsibility for the processes they carry out. SPAIQ strives to promote this sense of responsibility every day with the utmost dedication;
- **individuals matter, but the project matters most:** all SPAIQ personnel recognise that they are part of a project with a greater purpose: supporting companies in highly sensitive activities such as consultancy, validation and testing. They are therefore fully committed to this purpose, without compromise;
- **continual improvement:** SPAIQ pursues continual improvement because it recognises that this is the only way to manage complexity. Every day, it strives to improve its performance, whether through small steps or larger advances, to manage complexity in the sensitive, risk-prone fields of validation and testing;
- **operational resilience and reliability:** SPAIQ recognises that protecting human and animal health requires not only excellence in existing processes, but also the ability to ensure service continuity and stability across all operational scenarios through effective risk management and preparedness for adverse events;

SPAIQ recognises that improving its processes and integrated management system enables it to create value for customers, end users and people.

SPAIQ believes that quality and business continuity can only be achieved when every employee takes responsibility for the processes they carry out. Every day, SPAIQ strives with the utmost dedication to promote this sense of responsibility, including the responsibility to preserve the integrity and continuity of data and essential processes.

SPAIQ is based in the province of Bologna, at the heart of Italy's **Packaging Valley**.

Fabio Giovanni Farneti

SPAIQ CEO

