Spai

COMPANY PROFILE

MACHINE LEARNED

There is only one way to explain a technology, validate it, test it and protect people from the consequences of process errors: get inside and learn every detail of the machine and the reasons why it was generated.

Since 1998 Spai has been at the service of the packaging and pharmaceutical industry all over the world.

Our heart is in Bologna, Italy. Here, our know-how is enhanced thanks to a virtuous daily confrontation with the manufacturers and users of the most advanced solutions for the packaging and production of drugs, cosmetics, food and tobacco.

A UNIQUE KNOW-HOW, DEVELOPED IN THE PACKAGING AND MEDICAL ITALIAN VALLEY

TECHNICAL INFORMATION FOR INDUSTRY

Count on us for complete management and continuous data updating

With absolute confidentiality and maximum precision we are specialised in the development of tools for the verification, disclosure, maintenance and archiving of the information that is produced during the design and testing phases of automation systems.

The care and clarity of information is an opportunity to improve.

From design to testing of individual machine or complex integrated lines, we at Spai provide you with in-depth expertise and a service vision efficiency-oriented, while respecting the maximum confidentiality and industry regulations.

TOMORROW, NOW

We work today to provide effective responses to the needs of the future. Innovation requires the ability to listen to the customer and the ability to understand their vision of the future.

Show us your horizon, we probably already have the solution you are looking for

MORE SERVICES

The network we at Spai have built up over the years allows us to offer you a complete, competitive, efficient and always innovation-oriented service. Within a company, technical information is born, gathered, protected and allowed to circulate in a controlled manner. For this reason reason we work with carefully selected partners who are able to treat this information with the attention and methodologies appropriate to the particularities of Industry 4.0.

OUR TEAM

Mental elasticity, openness to change, the ability to find new solutions, continuous professional developmentcombined with a high level of know-how are the characteristics that allow our team to provide you with a service able to meet every need of yours.

PHARMACEUTICAL VALIDATION

An in-depth understanding of manufacturing production processes is fundamental to ensure pharmaceutical industries from the risk of compromising the product and to protect the health of consumers' health

The authorisation for the production and packaging of of the pharmaceutical products is released only when they demonstrate that their processes are in accordance with GMP (Good Manufacturing Practice).

This demonstration is only possible through a careful Validation, properly documented.

Validation is a formal activity of fundamental importance through which the entire production process is followed and analised, considering raw materials, machines, equipment, production methods, controls and environments.

In general, the Validation covers everything that may create a hazard for the person or animal that will use the medicine, once it is placed on the market or in the health system.

CARE IS NEEDED TO PREVENT RISKS OF CONTAMINATION AND AND DEFECTS, IN ORDER TO SAFEGUARD THE PRODUCT

THE PRODUCTION AND PACKAGING PROCESS

The process of bringing a pharmaceutical product to the sales shelves is long and and complex. This is why you need to pay attention to all the steps.
Each production process is defined by a combination of numerous factors, such as:

- **DRUG CHEMISTRY;**
  quantity, dosage and pharmaceutical form of active ingredients and excipients.
- **ELEMENTS OF PACKAGING**
- **MANUFACTURING PROCESSES**
- **PACKAGING PROCESSES**
- **QUALITY CONTROLS WITH THEIR RELATIVE REACTION**
- **UTILITIES**
- **ENVIRONMENTS**

GXP, GOOD PRACTICES TO RESPECT

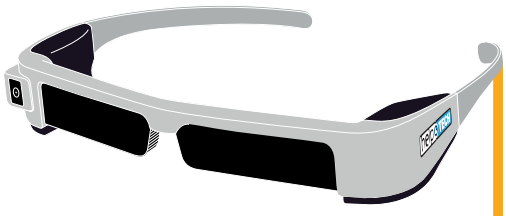
A set of basic rules for activities withwith medicines

There are many different types of drug-related activities, and for each of them, guidelines have been defined and issued by the regulatory bodies defining good practice.

They are known as GxP. They include:

- **GMP (Good Manufacturing Practice)** for the manufacture and packaging of the drug and its active ingredients
- **GCP (Good Clinical Practice)** for clinical activities
- **GLP (Good Laboratory Practice)** for laboratory activities
- **GDP (Good Distribution Practice)** for drug distribution

SPAI GUIDES YOU THROUGH THIS COMPLEX REGULATORY AND PROCEDURAL



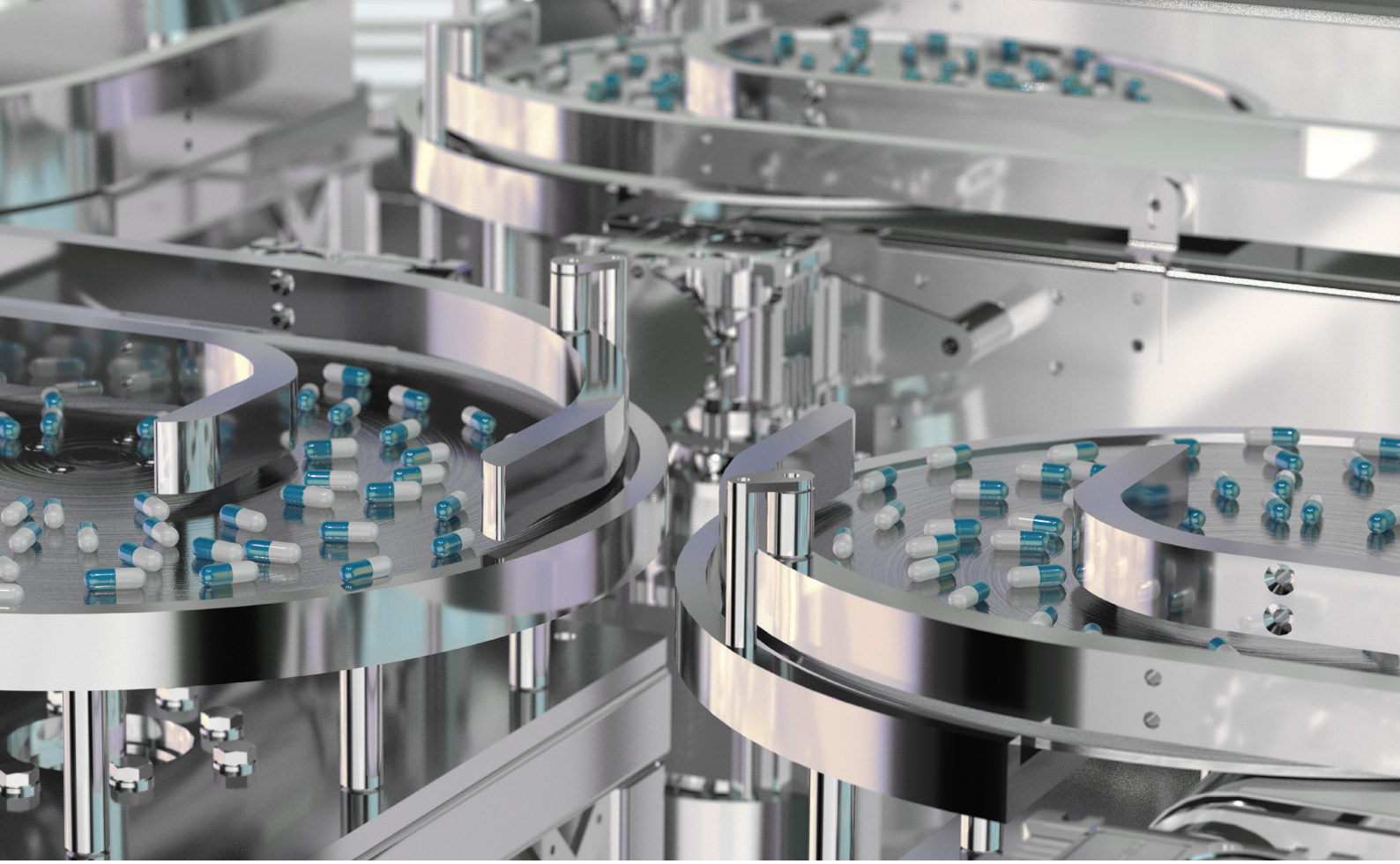
EVERY ASPECT OF VALIDATION CAN BE DONE REMOTELY

DISCOVER THE HELP FOR TECH SERVICE (PG16)

GAMP, THE GUIDELINES FOR AUTOMATION

GAMPs (Good Automatic Manufacturing Practice) are a set of guidelines for manufacturers and users of automated systems in the pharmaceutical industry. GAMPs are defined by the International Society for Pharmaceutical Engineering (Ispe) and are recognised worldwide.

GAMPs are the best point of reference in document and in all activities related to Validation.



VALIDATION OF PRODUCTION AND PACKAGING MACHINES

A correct risk analysis, carried out with professional expertise, is a guarantee of transparency

The validation of machines follows their life cycle. In the contractual phase the user (the pharmaceutical company) prepares the User Requirement Specification document (URS) in which the user in which it list its requirements in terms of quality, production, safety and maintenance.

The machine Manufacturer must specify how they intend to meet the user's requirements.

The validation must explain in detail all the parts of the system that affect the quality and the safety of the product. Finally, an assessment of the risks expected to remain despite the actions taken or the ones that are deliberately accepted for any possible pharmaceutical defect must be taken.

Depending on the complexity of the system the documents that can be produced are:

- **QPP** (Quality and Project Plan)
- **FS** (Functional Specification)
- **DS** (Design Specification)
- **HDS** (Hardware Design Specification)
- **SDS** (Software Design Specification)
- **RA** GMP (Risk Analysis GMP)
- **IQ** (Installation Qualification)
- **OQ** (Operational Qualification)
- **PQ** (Performance Qualification)
- **PV** (Process Validation)
- **TM** (Traceability Matrices)

INSTRUCTION MANUAL

A necessary tool, which we at Spai develop according to a criterion of maximum comprehensibility and ease of use.

The Instruction Manual contains all the information so that the system for which the document has been edited is used and maintained in complete safety.

When we talk about the Instruction Manual we mean information about the correct way of using the product.

It is a document made up of text, pictures, symbols, images, symbols or diagrams that are intended to explain to the customer how to transport, install, use use, and carry out the maintenance safely on the machine supplied by the manufacturer.

The instruction manual that we propose is designed to be easily understandable and at the same time complete in its instructions.
These quality standards allow perfect use of the machine in order to optimise production and at the same time guaranteeing the operators' safety.

OUR DRAFTING STAGES OF THE INSTRUCTION MANUAL:

CONFRONTATION WITH THE CLIENT COMPANY: this is the phase at the beginning of the work, necessary to understand the manufacturer's policy towards the product. From this meeting emerge the methods of use necessary for the end customer.

FINDING TECHNICAL INFORMATION to be included in the manual: assembly,disassembly, transport, installation, operation, critical points, maintenance, spare parts, etc.

DRAFTING AND GRAPHIC IMPLEMENTATION of the manual.

CHECKING AND VERIFYING THE CONTENTS AND THE EFFECTIVENESS OF THE COMMUNICATION through consultation with independent professionals not involved in the construction of the machine or the drafting of the manual.

PUBLICATION OF THE INSTRUCTION MANUAL.

REALIZATION OF THE MASTRO DOCUMENTS, which allow the use of parts already prepared and verified. This activity saves time and costs when new versions of the manual are needed.

EFFECTIVE MANAGEMENT OF LANGUAGE ALIGNMENT, starting with the legislative requirement to draft the manual in the language of the user within the European Community. Our management of this aspect leads to a significant reduction of costs.

CHARACTERISTICS OF OUR MANUAL

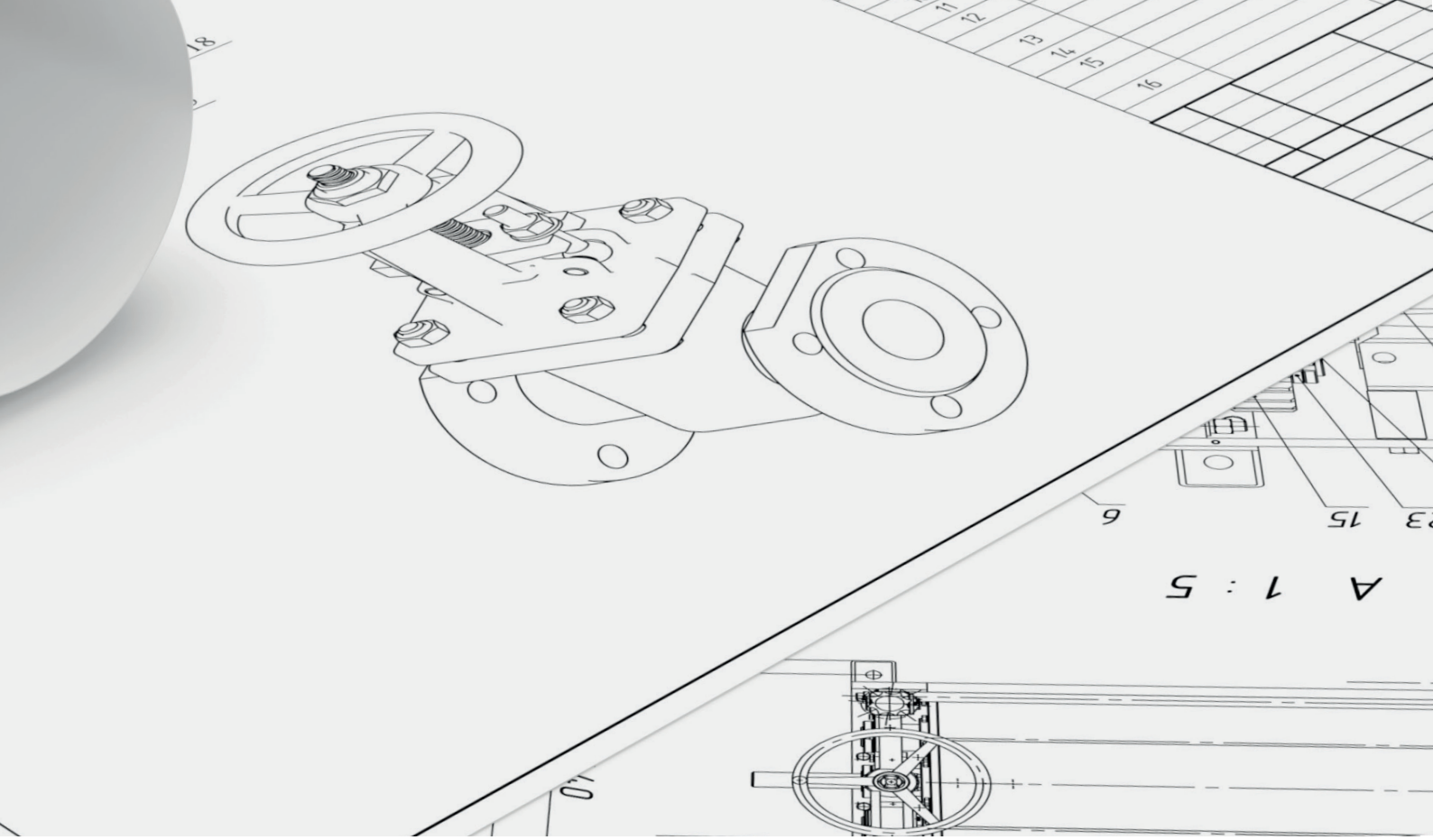
It is equipped with technical documentation to facilitate the user's tasks.

It focuses on worker safety, to prevent accidents

It complies with all Regulations, in particular with the Machinery Directive

AS REQUIRED BY LAW, IT IS DRAWN UP IN THE LANGUAGE OF THE END USER.

It is drawn up following a procedure which is the result of an in-depth knowledge of regulations and of the best communication practices



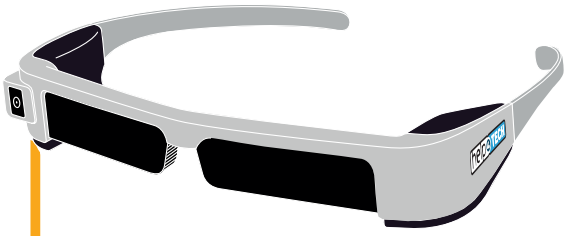
TECHNICAL FILE

An essential document for compliance with the Machinery Directive, it is important that it is complete, clear and easy to consult.

The Technical File must be kept for 10 years and it is the document that allows the manufacturer of the machine to prove, in retrospect, its good faith during construction. The Technical Construction File (FTC) demonstrates that the machine placed on the market conforms to the design and construction requirements established by the Machinery Directive (2006/42/EC).
The purpose of this Directive is to ensure the safety of people and the integrity of goods. The technical file explains solutions to possible problems arising from a foreseeable use of the machine.

It is therefore the cornerstone on which the assessment of the conformity of the machine is based on. Given the importance of this document for us at Spai, it is essential that it overcomes people's cognitive barriers and that it is easy to consult and understand.

The amount of information provided by the Technical Construction File, as well as its depth depends on the complexity and technical characteristics of the machine.



EVERY ASPECT OF VALIDATION
CAN BE DONE REMOTELY

DISCOVER THE HELP FOR TECH SERVICE (PG16)

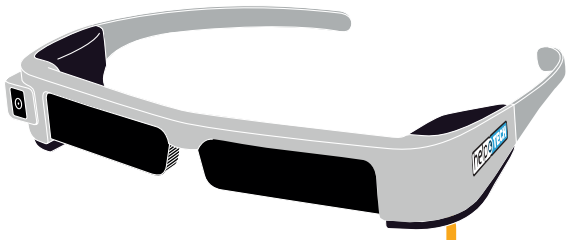
TECHNICAL CONSULTING

We can help you for your organisation's workflows for the efficient and secure management of technical information.

The technical information generated in your company is a treasure and as such it must be properly stored. Losing or having this wealth taken away would be an incalculable damage. We can help you eliminate these risks.We understand that your company is different from any other, like its uniqueness and peculiarities.

That is why we offer you our consulting services in the revision and setting up of the procedures that govern the company workflows, the true starting point starting point for all technical information.

The construction and assembly of systems is governed by constantly changing laws, directives and guidelines and that is why we make sure we are always up to date and can train your technical staff on how to operate correctly and safely, both in physical and regulatory term. Customers, suppliers, subcontractors, are some of the elements of a long chain that is strong only if each individual link is strong. We help you strengthen the value chain.



EVERY ASPECT OF VALIDATION
CAN BE DONE REMOTELY

DISCOVER THE HELP FOR TECH SERVICE (PG16)

DIGITAL INFORMATION SECURITY
Information is the real treasure of your company and like all treasures it needs to be guarded properly

COMPANY PROCEDURES
Our experts will help you review and and setting up procedures that govern the company's workflows

AUDIT
Customers, suppliers and subcontractors are some of the some of the elements of a long chain, we at Spai will help you strengthen the value chainre

TRAINING
Our experts train constantly and are themselves trainers. Laws, directives and guidelines are constantly evolving.

ASSISTED TECHNICAL MAINTENANCE

Help for Tech, all remotely, safely, without delays and saving money.

With our Help for Tech service you can remotely perform installation and Validation as well as assisted maintenance. assisted maintenance. Our team of technicians can guide you competently and safely

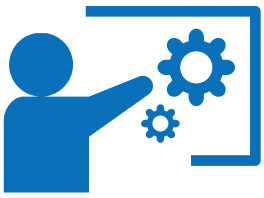
Our Help for Tech service includes:

- Checking the availability of a customer's wireless data network and of the requirements essential at the installation location.
- Provision or assistance in purchasing of Smart Glasses to be used during the service sessions.
- Technical support for the use of the software and translation of instructions to be given for the installation and/or Validation of the machine.

INSTALLATION

MAINTENANCE

SPARE PARTS



TRAINING

help4TECH

HOW WILL THE DIRECT CONTACT WITH THE END USER OCCUR?

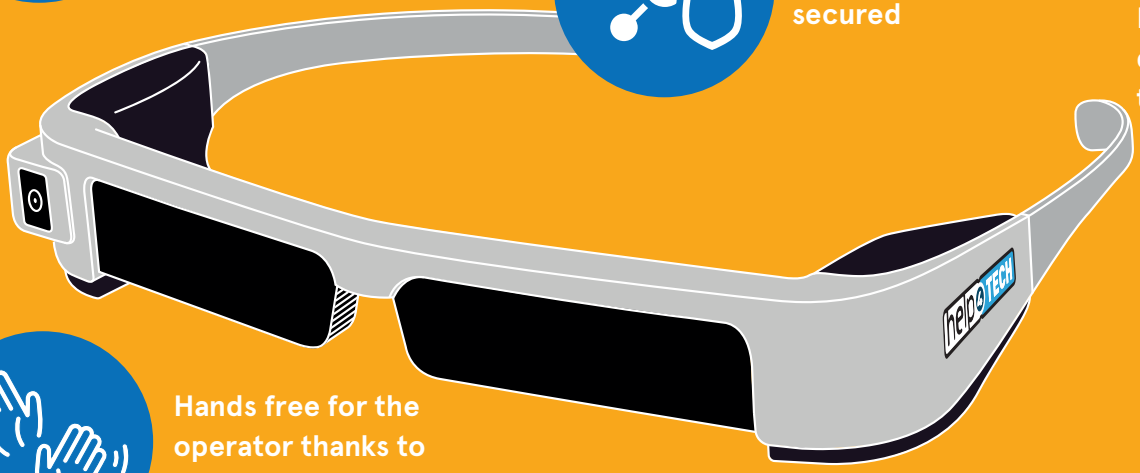
Through personal augmented reality devices such as glassesand headsets, it will be possible, using a private and secure data transmission network, to exchange audio and video information in real time both to the Help for Tech centre and to the end user.

The service can be activated at the times requested by the user (even 24 hours) and our specialised staff will communicate in the language requested by the user.

Service availability H24

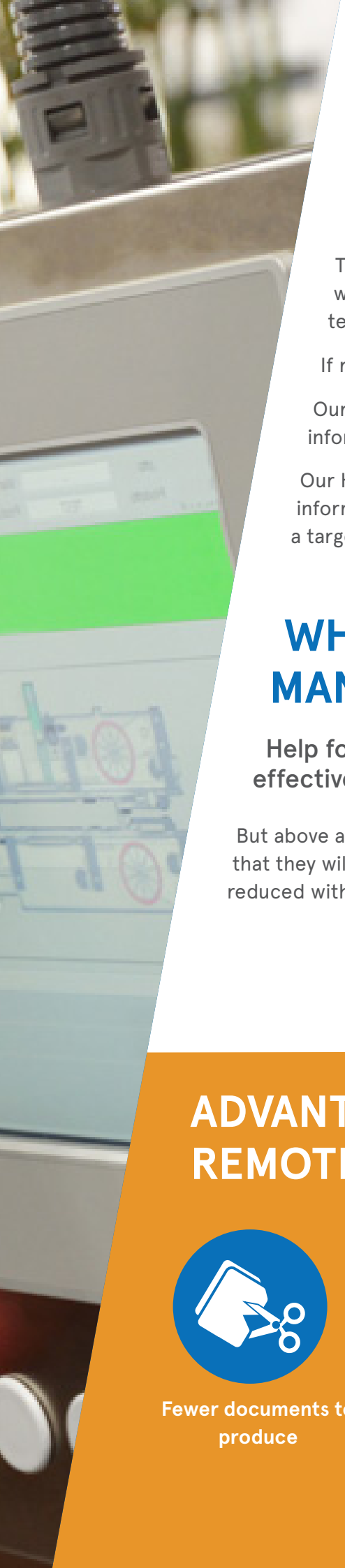
Data network and communications secured

Language dialogues in real time



Hands free for the operator thanks to augmented reality


help4TECH



A TECHNICAL SOLUTION WITH SOMETHING EXTRA...

The Help for Tech service involves coordination between our qualified staff, who have acquired the necessary machine skills, and the end customers' technicians.

If required, we can also provide interpreters in the user's language.

Our Help Desk complements and improves the provision of technical information

Our Help Desk complements and improves the provision of technical information, which is usually limited to use and maintenance manuals, allowing a targeted search for topics and easier and quicker understanding.

WHICH ARE THE BENEFITS FOR THE MANUFACTURERS?

Help for Tech means less travel, less risk, lower costs and greater effectiveness.

But above all Help for Tech is an innovative service to offer its own customers,service that they will appreciate and demand more and more, because downtime will be reduced with never-before-seen speed and effectiveness.

ADVANTAGES OF HELP FOR TECH REMOTE TECHNICAL ASSISTANCE:

Fewer documents to produce

Faster and more effective intervention

Reduced travel specialised staff

WE MANAGE YOUR TECHNICAL CONTENTS

A unique, secure and customizable management of information for many possible outputs.

We help you, through a sole management, to use the technical information of your company, so that you can manage it in different ways, at different times and through different channels, thus achieving your objectives more effectively.

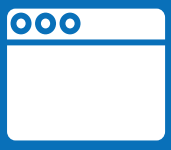
Your information is protected with us. We store it in secure and reliable data centres, managed through controlled access.

Access will always be allowed to your sales network and customers, with the limits your company considers appropriate.

The information that is generated in a company, while maintaining its own peculiarities, can be administered in different ways to achieve different objectives.

USER AND MAINTENANCE MANUALS
An obligation, a necessity, but also an opportunity

COMMERCIAL DOCUMENTATION
Reports on the effectiveness of the systems, feedback on customer satisfaction, requests for products and services from the market



DOCUMENTATION PORTAL
Networks and clouds enable faster and faster information, but let's do it the right way

ASSISTED MAINTENANCE
Operators experienced in solving all types of problems available 24/7 in the language you need. It's the secret dream of every one of your customers

TRANSPARENCY AND SECURITY

We provide you with every report, we show you how effective the system is, you can get feedback on customer satisfaction and collect their requests.

You will be able to constantly evaluate the products and services that Spai provides to your company.

COURSES AND TRAINING

Spai Training Program, to make your job easier.

We offer you the tools to better interpret the complex regulatory framework that accompanies the design of automatic machines for the pharmaceutical, cosmetics and food industries.

Thanks to our problem-solving skills and our technical know-how, we have grasped, analysed and understood the needs of the manufacturer and those of the user.
Two people with practical skills that do not always correspond with the unavoidable legislative obligations.

Thanks to the Spai Training Programme, your staff will have access to our courses dedicated to the automation industry.

WHAT WE OFFER YOU

PES-PAV COURSE
Work on electrical installations of distribution and machinery with and without voltage

EVALUATOR COURSE
Theoretical and practical training for qualified Evaluator on machine safety (work equipment)

PRODUCT TECHNICAL DOCUMENTATION
According to UNI 10893 and Annex I-art. 1.7.4 Directive 2006/42/EC

DESIGNER COURSE
Theoretical and practical training for Designer competent in the safety of machines (work equipment)

IDENTIFICATION AND EVALUATION OF DOCUMENTS
Identification and evaluation of documents relating to machine parts intended to come into contact with pharmaceutical and food products

DIRECTIVE 2006-42-EC
The safety of machinery control systems: Theoretical and practical course on the EN ISO 13849-1:2008. Technical innovations, procedures, controls and penalties: what's new in Directive 2006/42/EC Legislative Decree 17/2010)

MAINTENANCE ORGANISATION
Organisation of maintenance, of checks and inspections of electrical cabins new technical norm CEI 78-15:2015

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