

IMA Active chooses iFIX HMI/SCADA and Proficy Historian to meet data integrity requirements in regulated industries



Results



100%

Data integrity



28
Machine families in just one division



Compliance

Machines for regulated industries



Easy customization

Specific global customer requirements

About IMA Active

Pharmaceutical products, cosmetics, food, tea, coffee: the IMA Group has been designing and manufacturing automatic machines for the processing and packaging of all these products for 60 years—since 1961 to be precise—and today it is the undisputed leader in this field.



The company, whose name derives from the acronym of Industria Macchine Automatiche, is based in the heart of the Packaging Valley, the cluster of advanced mechanics and industrial automation in Emilia Romagna.



Since the 1960s, IMA has achieved continuous growth thanks to its operations but also and above all to constant research and development of innovative technological solutions that the market appreciates.



Delivering maximum reliability, quality and compliance

iFIX HMI/SCADA and Proficy Historian, both developed by GE Digital and supported in Italy by ServiTecno, allow IMA Active to have a standard engine for the machine interface and industrial data management across its entire portfolio of machines for regulated industries.

Flexibility and reliability as values

For a company that combines organic growth and acquisitions (recently, the Emilian Group acquired 82.5% of Tissue Machinery Company, 70% of Ciemme, 60% of Perfect Pack, and majority of Atop, world leader in the automation sector for the production of electric motors for E-traction), it is essential to be able to make use of an ecosystem of partners who are able to support the company in its mission to add value to its customers.

In the sectors IMA addresses, there are many complexities and critical issues – very different from each other – and all must be given a solid and reliable solution, which delivers the highest quality and compliance of the final product.

For this reason, the partners must support IMA not only in technologies with proven effectiveness, but also high quality and, above all, reliable support in the long term.

Customers often turn to IMA in the Post-Sales phase even after tens of years from the original purchase, both for maintenance activities and for those "revamping" operations that allow these machines to remain in step with the continuous technological transformation and to reduce downtime and training time of less and less specialized operators. It is no coincidence that one of IMA's inspiring slogans is: "Different markets. One flexibility on a global scale."

The pharmaceutical sector and the experience of IMA

In the Life Sciences and Pharma sectors, the Emilian company currently operates with four brands: IMA Active, IMA Life, IMA Safe and IMA BFB.

IMA Active, in particular, designs, develops and manufactures machines for the production of solid oral forms, while IMA Life deals with liquid drugs and freeze-dried products.

In these areas, "the times that mark the activities are often not short: everything must be planned and then proceeds in the order of months and even years," Marco Minardi, Automation Manager of IMA Active, points out. "In our sector, for example, it takes more than a year between the order of the machine and the first product being ready for patients, mainly due to the regulations that frame the sector. Vision, strategies and actions are therefore necessarily medium and long. With a view to an expected life of 15 or 20 years for machines and systems, having and being able to count on solid partners is a very important value: in our case these evaluations have a significant impact."

In the past, the IMA Group used custom technology platforms for the various machines in the Pharma and Food sectors. Then in the pharmaceutical sector, the Emilian Group made some acquisitions, including those of BOC Edwards, with plants in the Netherlands and the United States, and of the Zanchetta of Lucca, both companies that used the iFIX platform as an HMI solution.



Subsequently, the idea was born in IMA Active to create a new HMI solution that could be used on all the machines in its broad portfolio, which would provide brand recognition and a high standard of usability and reliability of the operator interface.

Choosing iFIX HMI/SCADA as the brain between machines and users

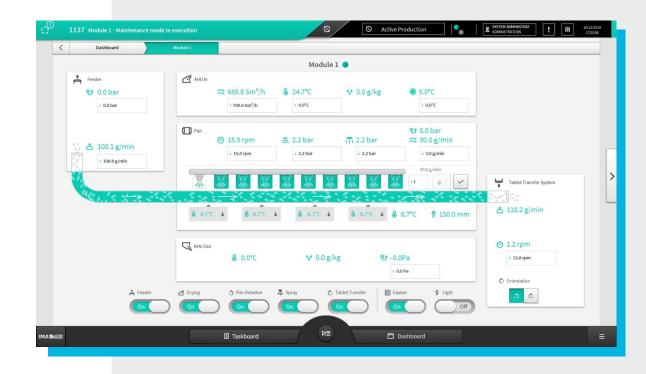
It is in this context that the collaboration between the IMA Group, GE Digital and ServiTecno (an Alliance Partner that distributes and supports GE Digital software in Italy) comes to a decision: after an intense analysis of solutions on the market, IMA Active decided to focus on iFIX as a pillar to build the Kortex MAX HMI/SCADA platform.

"The interface is the way in which the machine communicates with the operator: it is therefore a strategic element in the overall design of a product. It always has been, but it is even more so today, with the advent of mechatronics and the increase in the engineering complexity of the machines. All these conditions have determined the need to find an adequate, flexible and efficient product, which led us to choose iFIX as the technological base on which to develop our platform that we have called Kortex MAX with reference to the concepts of 'cerebral cortex and maximum usability,' which are two essential characteristics of the system," Minardi explains.

In choosing GE Digital and ServiTecno, a fundamental activity was the evaluation of the characteristics of the product and the profile of the two partners. "In our choices," underlines Minardi, "we look for both up-to-date technology and the reliability of the supplier, its ability to support us. What ServiTecno does is a fundamental value for us: it helps us to solve the technical and technological problems that inevitably arise, present by following us in the various design and implementation activities. This is for us a value at least equal to the technological specifications. "

And so today, within the IMA Group, the two divisions IMA Active (specialized in machinery and solutions for the production of oral solids) and IMA Life (specialized in the sector of liquid drugs), having partly overlapping characteristics and needs, are both standardized on iFIX as the HMI/SCADA platform.

"Focusing activities on a single platform also allows us to manage resources at production peaks in a flexible way, dynamically allocating them to orders, precisely because of the choice of a common platform," explains Minardi.



"With the continuous growth of the IMA Group, the industrialization of processes has become very important. Just to give an example, in our division alone we manage 28 families of machines for process and product treatment, each of which has various sizes and a considerable degree of customization. When we choose the solutions to use for our automation, we always make a 360-degree, holistic assessment of the technology, the product and its resources: the specific technical potential is obviously the basis, but the related services are no less important including long-term support," Minardi says.

Meeting Regulatory and End Customer Requirements with Automation

There are several technical characteristics of iFIX that led IMA to choose it as the pillar of its operator interfaces.

The first essential point to be addressed, when adopting a technology in the pharmaceutical field, is the management of Data Integrity. Here, GE Digital has accumulated over thirty years of product development experience, which makes the difference.

"In the world of Life Sciences and Pharma, iFIX has always been a recognized and recognizable player, its reputation was therefore a tangible value."

– Marco Minardi, Automation Manager, IMA Active

In a regulated sector such as the pharmaceutical sector, the data is fundamental: "Without the data, the lot must be thrown away," effectively summarizes Minardi.

iFIX also integrates seamlessly with GE Digital's Proficy Historian, an industry-leading process data management solution .

"Proficy Historian plays a central role in the qualification of process data and to keep track of data integrity, which includes data traceability, for both regulatory and process engineering purposes to optimize parameters and improve the quality and repeatability of operations."

- Marco Minardi, Automation Manager, IMA Active

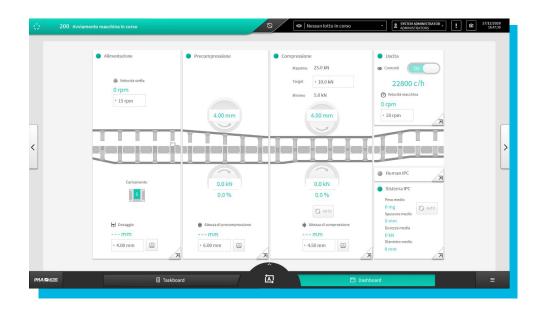
iFIX and Proficy Historian also allow seamless integration with relational databases and contextualize the information collected and stored over time, such as for the purposes of alarming production systems.

Another added value of iFIX is its modularity and adaptability in relation to the machine and line architectures, characteristics that determine how the machines are proposed to the customer in terms of integration with the plant floor and with the architecture of the management systems. iFIX natively supports all the main standards in use in the pharmaceutical sector, thus making it relatively easy for IMA to propose a solution that easily integrates into all scenarios.

For example, iFIX also supports the Terminal Server architecture. "With the increasingly strong integration between the OT and IT world, the use of the iFIX SCADA system in Client-Server architecture with multiclients is a value capability, for example for customers who have to install our machines between two different environments or to improve general ergonomics," explains Minardi.

Since, as noted, IMA Active produces a considerable variety of solutions, another added value of iFIX appreciated by Minardi is the ability to configure the HMI/SCADA system: "As for configuring the interface for a specific machine, iFIX allows us to reflect the configuration chosen by the customer, automatically generating an interface that includes all and only the features you need."





A look to the future

In the pharmaceutical world, teams are cautious about making changes, and the full evaluation of final results are fundamental before every innovation. The speed of adoption of the innovations must also deal with delivery times ranging from 8 to 24 months.

However, this does not mean that innovations are not considered, quite the contrary. "We have a specific agreement with ServiTecno: at each revision of iFIX, they provide us with a pre-analysis on the impact of the transition in our specific case; then there are test sessions, evaluation and verification of the various operational steps, and a verification of the real effectiveness of the systems updating and development."

Although operating with longer timescales than non-regulated industrial sectors, "we can never allow errors of any kind, so, as mentioned, operational caution must always be maximum. The renewal and improvement of systems and solutions are in any case in order of the day, both as regards the 'hard' technological components, the machinery, the operational 'muscles' of production, and as regards the control and software part," Minardi says.

The team is looking at next steps in this successful collaboration that continues to innovate and always deliver maximum reliability, quality and compliance. This will be a "further strengthening of the path with GE Digital and ServiTecno," anticipates the Automation Manager of IMA Active, "for a collaboration that goes well beyond the final

product, and necessarily brings together product and operational support in every phase and every evolution of the production systems."

Another possible area of development concerns frontier technologies such as Data Analytics and Artificial Intelligence. "In this field too, the IMA Group is moving with interest and attention: if there is an interesting software product, we will immediately take it into consideration," remarks Minardi. "These are technologies and solutions that must be highly customized, according to the specific needs to be met, and for this reason the availability of the technological and digital partner must be total. The goal is always very concrete: we must give the end customer a lot of added value, strong and tangible."

The quality of data in the pharmaceutical sector

In a highly regulated production environment such as pharmaceutical, quality and data integrity are critical elements because they are closely related to human health.

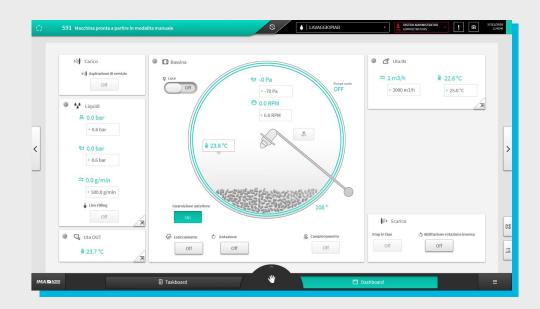
Data Integrity can be defined, in relation to data management, as the guarantee that a set of data is correctly managed during the production process and in relation to all operational areas (production, laboratories and warehouses).

To be considered healthy, data must meet various criteria throughout its life cycle. The Food and Drug Administration (the agency in charge of controls on the food and pharmaceutical sectors) provides for the ALCOA criteria, an acronym that derives from the initials of the five qualities that the data must have: Attributable, Legible, Contemporaneous, Original and Accurate.

In addition, ALCOA Plus (ALCOA+ or CCEA) criteria has also been defined, adding that the data must also be Complete, Consistent, Enduring, and Available.

It is clear that software technologies that natively support and manage these requirements in a standardized way, such as GE Digital's Proficy Historian, can be of great support in the system validation process.

Proficy Historian, for example, allows through its collector system to generate data records already associated with identifiers (e.g. product and lot) and time stamps and to send them, in a secure-by-design and encrypted manner, to the storage server. The data record, once generated, cannot be changed without codified procedures and is completely compatible with the reference legislation.







About GE

GE (NYSE: GE) is the world's Digital Industrial Company, transforming industry with software-defined machines and solutions that are connected, responsive and predictive. GE is organized around a global exchange of knowledge, the "GE Store," through which each business shares and accesses the same technology, markets, structure and intellect. Each invention further fuels innovation and application across our industrial sectors. With people, services, technology and scale, GE delivers better outcomes for customers by speaking the language of industry.

Contact Information

www.ge.com/digital





