

# Management and Monitoring of production

experience history

## FEDEGARI AUTOCLAVI : report conformino to CFR 21



FEDEGARI AUTOCLAVI is considered one of the few global producers of hot sterilizers working in humidity, in drought and systems for fluid processes in a dense mode. From its birth, during the initial years of 1950s, the company has conserved an artisan mentality that can be expressed as extreme flexibility coupled with the needs of an avant-garde industrial system. The machines, the systems and the components produced by Fedegari are characterized by originality of project that can be noticed in their reliability. The offerings are fruits of a continuous collaboration either with clients or most-important suppliers, so called real “co-producers” that have helped the company grow and obtain various expertise as knowledge without which the results could not have been reached.



From its birth, the company has been specializing progressively and is structured in the design and production of machines, systems of make-to-order by diversifying the know-how in the area of fluids in the dense mode for diverse industrial projects. Fedegari works mainly in the pharmaceutical industry by supplying sterilizers for specific applications. Other fields of activity are health and laboratories. Its products could be grouped in 2 principal areas: Sterilization and Fluids in Dense Phase. Regarding the sterilization, the production is concentrated on autoclaves and furnaces that cover the needs of the pharmaceutical, food and chemical sectors.

A critical aspect noteworthy in the realization of make-to-order machines is the guarantee of the sterilization of the product by varying the packaging continuously and the configuration of the load.

Different packagings require the employment of diverse processes. The thing that distinguishes Fedegari from other machine constructors is the capacity of realizing a machines particularly flexible without increasing the structural complexity.

## THE REQUIREMENT OF THE COMPANY AND COLLABORATION WITH INSPIRING

In 2005, Fedegari had to modernize its own system for the data collection for production and the presses. Until now, the system mounted on the machines produced was not web-based and it was not conforming to part 11 of CFR21. Therefore, after a search among the offerings of the same type in the market, Fedegari has chosen Inspiring Software for the data collection, visualization and archival.

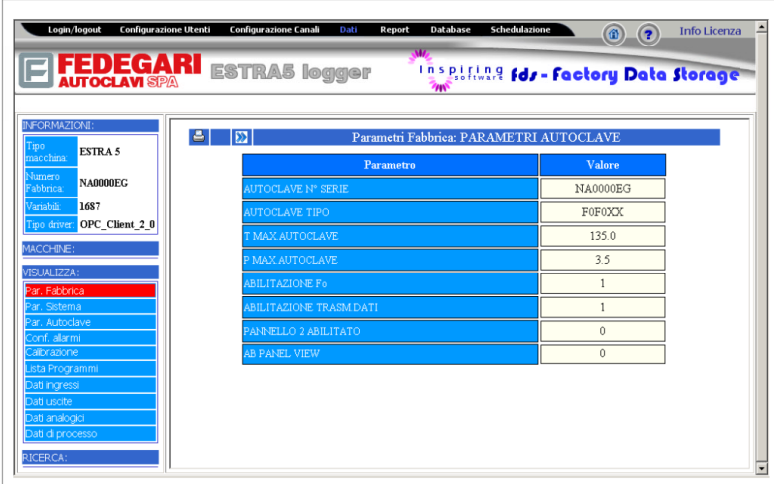
The requirement of Fedegari was to provide to the final client a solution with an added value related with the purchasing of sterilizers. Indeed, it is indispensable to certify the full conformity of the processes of sterilization carried out, especially in the sectors pharmaceutics, chemical and health. The fact that the software used until now was not conforming to the part 11 CFR 21, which is a crucial aspect for the activities of the companies involved, has forced Fedegari to the search of a new solution capable of satisfying all the requisites.

The priority requirement was to collect the related data at the cycles of sterilization of 4 diverse product lines. The data to collect with FDS were of type analogical (temperature, pressure, time...) and digital (alarms, entry, exit...). They had to be reorganized in a printable ad-hoc report, so that they could be archived by the client company that is to certify the correct development of the process or eventual defects. Before adopting of **FDS**, an industrial panel for the process control of the machine and a thermal printer were installed on board which handle the realization of the paperwork of the work carried out by the sterilizers. The printer did not guarantee a particular resistance to time and use of paper documents which are indispensable for the sectors which Fedegari serves. Therefore, the first objective of the company was to guarantee a greater “lifespan” of the documents and the possibility of archiving them for a future reference.

## WHAT BENEFITS AND WHAT ADVANTAGES

Concerning the archival, FDS helps memorizing the executed cycles. The PC that is going to have the FDS server is linked serially or via ethernet to the sterilizer. The software collects the data from the machine and produces reports that contain information related with any cycle run by the sterilization and they are archived in a sort of a book where they are classified based on their production data. Besides, the electronic archive solves the problem of usage of the presses, because every process is memorized on DataBase of FDS and can be printed in any moment.

The process starts with the realization of some prototypes of configuration, one for each typology of machine indicated by Fedegari. The collected data are usable, can be consulted and archivable by reorganizing them according to the criteria defined by the company. In this way, the worthwhile reports are created. Furthermore, FDS makes the consultation of data about machine work available in real time. This is done via special pages where the user might view the data on the activity of the sterilizers in that precise instant. The same fact that FDS is a web based solution makes information collected by the server available to other PCs in the network. This is achieved by satisfying the requests of the final customer and their needs via sharing the process data among more users. The outstanding factor that characterizes this project has been to make FDS conform to CFR 21 Part 11, since the company must adapt its solutions to this normative. CFR 21 Part 11 is a document generated by FDA - Food and Drug Administration - which defines the minimum requisites, so that the electronic records and signatures put on the records are considered legally equivalent to the registration on paper and to the actual signature. These requisites are indispensable for the chemical, pharmaceutical and food companies that commercialize their products in American markets. Thus, it was necessary to adopt a solution that would help manage the records and signatures according to predefined parameters by FDA. This was to be done by guaranteeing the sequence



The screenshot shows a web-based interface for the FDS software. The top navigation bar includes 'Login/logout', 'Configurazione Utenti', 'Configurazione Canali', 'Dati', 'Report', 'Database', 'Schedulazione', and 'Info Licenza'. The main header features the 'FEDEGARI AUTOCLAVI SPA' logo, 'ESTRAS logger', and 'inspiring software fdr - factory Data Storage'. The left sidebar contains a menu with categories like 'INFORMAZIONI', 'MACCHINE', 'VISUALIZZA', and 'RICERCA'. The main content area displays 'Parametri Fabbrica: PARAMETRI AUTOCLAVE' with a table of parameters and values.

Parametro	Valore
AUTOCLAVE N° SERIE	NA0000EG
AUTOCLAVE TIPO	F0F0XX
T MAX AUTOCLAVE	135.0
P MAX AUTOCLAVE	3.5
ABILITAZIONE F0	1
ABILITAZIONE TRASMDATI	1
PANNELLO 1 ABILITATO	0
AB PANEL VIEW	0

of signatures, identification of the titles for each user profile and definition for each operator from the username correspondence and password for which the signature would be valid. The generated reports conforming to the aforementioned document, indicate the figures which must sign the document and the sequence of three signatures guarantees the validity of it during attesting the outcome of the sterilization process. In this way, the reports could be considered as real and valid according to these norms.

## CONCLUSION

Thanks to the implemented solution, Fedegari has obtained an advantage with respect to its competitors and a full satisfaction of its clients who can be offered complete machines and an instrument in line with the active normative. The collaboration with Inspiring has proven very profitable in developing new functionalities such as the possibility of integrating the control industrial panel on the machine with the FDS software. This is achieved by developing a real system of activity programming. At the moment, FDS reads the data regarding the functioning of the sterilizers and Fedegari would like to interact with the machine by writing data and manage the phases of sterilization cycles in order to increase the leanness of the production phases. They would like to assure a greater control on the machine. This way the client would be offered an instrument that is capable of programming and monitoring all the activities concerning the sterilization including the possibility of sharing this information with other users via the availability of FDS server data on the network.



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