Fedegari Clean Machines Powered by Wind River

VxWorks Helps Standardize Control of Sterilizing Machines

Fedegari Autoclavi S.p.A.

Company Profile

- Leading provider of high-end sterilizing machines for global pharmaceutical manufacturers
- Headquarters in Lombardia, Italy

Industry

Medical

Solutions

- Wind River Platform for Industrial Devices, VxWorks Edition
- Wind River Workbench, On-Chip Debugging Edition

Benefits

- Built a stable control system offering high performance, stability, security, and ease of use
- Delivered a certified FDA 21 CFR part 11 system on time and on budget
- Reduced development and validation costs
- Gained flexibility to meet customer needs and ability to support customers during the entire product lifecycle

Fedegari produces high-end sterilizers for biopharmaceutical and health care applications. The primary purpose of these machines is to sterilize drugs and other products used for sterile filling operations.

Fedegari sterilizers are the only sterilizers entirely designed and manufactured in-house and are known all over the world for their performance and reliability.

Since its inception, Fedegari has fostered a close relationship with Parenteral Drug Association (PDA), the U.S. association that represents major pharmaceutical manufacturers and promotes information and training about news, technologies, and industry rules.

The Challenge

No Room for Error

Sterilizers execute very critical and sensitive processes in the life-sciences industry, especially when sterilizing injectable drugs.

During the past 55 years, all of the major pharmaceutical companies have used Fedegari sterilizers to sterilize their most critical drugs. These customers constantly challenge Fedegari to develop innovative, cost-effective solutions.

Pharmaceutical manufacturers must follow strict rules and guidelines such as the U.S. Food and Drug Administration (FDA) Title 21 Code of Federal Regulations (21 CFR Part 11) and the Good Automated Manufacturing Practice (GAMP), which set manufacturing principles for machines, require stability for the control software, and protect process data and safety.

Manufacturers look to Fedegari to help them meet these stringent regulations and, especially today, the process controller is achieving ever growing

importance in the overall performance of sterilizers. Not only must it allow the process to be controlled with strict tolerances, it must assure high flexibility and security and integrate into end-user information technology networks for a variety of critical functions. Finally, it must perform all these tasks in a fully validated way.

> *"Since 2004, we have standardized on Wind River Platform for Industrial Devices, VxWorks Edition tondeliver our reliable and high-performing sterilizing machines on time and on budget."*
>
> *— Massimo Ghelfi,*
> *Automation Manager, Fedegari*

The Approach

Robust, Reliable RTOS

To effectively certify products, the pharmaceutical industry requires a control system with a highly stable architecture. This is why Fedegari decided to standardize its entire control system. The company uses three hardware platforms, each based on commercial off-the-shelf products by major manufacturers. Fedegari built the control system software in a real-time environment on Wind River® Platform for Industrial Devices, VxWorks® Edition with a set of functional modules that allows Fedegari's customers to choose the combination of functions that best fits their needs.

Fedegari first joined forces with Wind River in 2004 because of its reputation as a global real-time operating system (RTOS) leader. Fedegari chose VxWorks because it's a commercial RTOS with the ability to manage a wide range of hardware devices. Unlike other operating systems, VxWorks ensures robustness, reliability, and versatility, meeting all of Fedegari's critical business requirements.

Every Fedegari machine is managed by a process controller that runs the sterilizing machine and supports various modules. The newest version of the control software, Thema4, delivers reliability, speed, and product integrity— the cornerstones of Fedegari's ongoing success as a company. It meets manufacturer requirements for machine safety, performance, and ease of use.

"Thema4 offers the power of a standard industrial computer and the determinism of an RTOS," says Massimo Ghelfi, Automation Manager. "It's responsive and precise, with an intuitive user interface that makes it easy for the people who configure, maintain, monitor, and operate the machine daily."

Investment Protection, Ongoing Support

Because Thema4 is backward-compatible, customers may choose a software "revamping" to achieve an up-to-date system on a 10- to 20-year-old machine. This helps both Fedegari and its customers protect their investments, since the average lifetime of a sterilization machine is at least 15–20 years.

"Without Wind River's VxWorks standard operating system, this investment savings would be impossible," Ghelfi says. "Wind River also ensures the required continuity so we know we'll receive support in the future."

When it came to choosing an RTOS, strong support was always a critical deciding factor for Fedegari. In this regard, the company has been very pleased with Wind River.

"We quickly found that Wind River was more than just an RTOS provider," Ghelfi explains. "They helped us develop the Thema4 Java graphical interface and find new solutions daily, and they've provided outstanding ongoing technical support."

Customization, Flexibility

Powered by the Wind River platform, Thema4 is able to provide a wide range of control, visualization, and reporting functionalities. It also allows a high degree of customization and communication with machine I/Os and other external devices.

Because the software runs on a standard platform, Fedegari can easily develop and integrate new control and communication modules that satisfy specific customer needs and enhance the machine's efficiency. Customers can choose the functional modules that meet their needs, and when they want to extend system functionalities they simply activate new modules.

The Result

Tools for Today, Tomorrow

Using Wind River's VxWorks allowed Fedegari designers to implement Wind River Workbench, On-Chip Debugging Edition—which includes Eclipse-based software development and diagnostic tools that led to a remarkable reduc-tion in the software release time. Thema4 took only one year versus the two to three years Fedegari spent developing an earlier version of the control software before it employed the Wind River platform.

Fedegari appreciates Wind River's validated, maintained middleware, and it looks forward to using new features provided by VxWorks 6.x. These new features include virtualization and other technologies that allow testing and prototyping modifications without compromising system integrity, communication technologies via web server, wireless communication, and industrial Ethernet.

"Today we appreciate the flexibility and modularity thanks to this advanced, safe, and easy-to-maintain operating system," Ghelfi says. He and his team look forward to using new functionalities of the VxWorks platform.

"Tomorrow we plan to enhance our control software by using VxWorks' new ability to partition it at the operating system level," Ghelfi concludes. "This will enable us to execute critical functions with higher priority than noncritical functions so we can better manage communications, remote updates, devices, and hardware and software configurations without affecting critical functions."

For additional information about the products mentioned in this case study, visit www.windriver.com and www.fedegari.com.