

Complying With Life Science Sterilization Control Mandates

STAFFORD, UNITED KINGDOM, July 5, 2023 /EINPresswire.com/ -- The traceability of pharmaceutical manufacturing processes is critical to navigating the complexity of government regulations that impact the design, development, production and distribution of medications. The recent introduction of the EudraLex Volume 4 Annex 1 guidance regarding the manufacturing of sterile medicinal products is an example of good manufacturing practices (GMPs) that help ensure quality and safety. But the challenge comes with documenting the process, as Roberto Zerbi, global life sciences business development manager at [industrial technology](#) manufacturer Watlow, explains.

The [EudraLex Volume 4 Annex 1 guidance](#), which comes into effect in August 2023, illustrates how new regulations are introduced to grow trust in the life sciences business.

Sterilizers play a key role in producing injectable medicines like vaccines. Life science firms and the machine builders that support them must find the most efficient way to meet the data integrity principles applied to the records of each heat sterilization cycle.

Point 8.50 of the EudraLex Volume 4 Annex 1 states: "Each heat sterilization cycle should be recorded electronically or by hardcopy, using equipment with suitable accuracy and precision. The system should have safeguards and/or redundancy in its control and monitoring instrumentation to detect a cycle not conforming to the validated cycle parameter requirements and abort or fail this cycle (e.g., by the use of duplex/double probes connected to independent control and monitoring systems)."

Sterilization control challenges

When dealing with the challenges of heat and steam sterilization for monitoring and controlling activities, life sciences stakeholders and the OEMs supplying them with equipment are faced with multiple options for meeting the regulatory compliance mandate. But, there must always properly balance the trade-off between efficiency, cost and time-to-market.

The new Annex 1 changes the status quo for OEMs and potentially introduces more machine building cost, time and risk. OEMs must qualify any new device added to their equipment and minimise downtime risks, as well as ensuring staff are trained, expand their maintenance capabilities and manage delays in time-to-market due to extended testing procedures.

Changes have an impact on quality control managers too. They are confronted with thousands of pages of regulatory statutes that they need to recognise and manage, which is difficult as new regulations are published continuously. It is critical for quality managers to have access to reliable solutions to stay up-to-date and ahead of validation inspectors.

Qualification and validation

In the case of the new EudraLex regulation, the crux of the issue is the ability to document the positive completion of the sterilization process. This could be achieved through a separate monitoring system that provides the simplicity, robustness and accuracy expected by regulators. Organisations like Watlow, which designs and manufactures industrial technology for thermal applications, understand the impact of the new mandates on the sterilization process are in a solid position to meet this challenge.

In partnership with Eurotherm, Watlow has developed a paperless [sterilization quality management solution](#) that combines industry regulatory knowledge with hardware and software components. This makes it easy for OEMs to integrate the new EudraLex Volume 4 Annex 1 requirement into their production machines. The solution comprises a best-in-class sensor connected to a redundant solution, which delivers the mandatory monitoring and recording required for compliance. It then digitally feeds the control system simultaneously achieving simplicity, robustness and an extremely high level of accuracy.

Monitoring sensors are the most critical device in the sterilization process. If the sensor fails, the sterilization batch has to be put on hold. OEMs must invest in a high-quality sensor, like that from Watlow, and enable the high-availability redundant monitoring solution to provide the environmental measurements to the control system.

Compliance is key when it comes to pharmaceutical manufacturing processes, but recording and monitoring of critical process data can make life difficult for OEMs trying to keep up to date with constantly changing regulations. With the help of a reliable and robust paperless sterilization monitoring solution, OEMs can integrate the EudraLex requirements seamlessly to maintain quality and safety.

To learn more about Watlow, visit watlow.com, or to learn more about Eurotherm, visit eurotherm.com

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