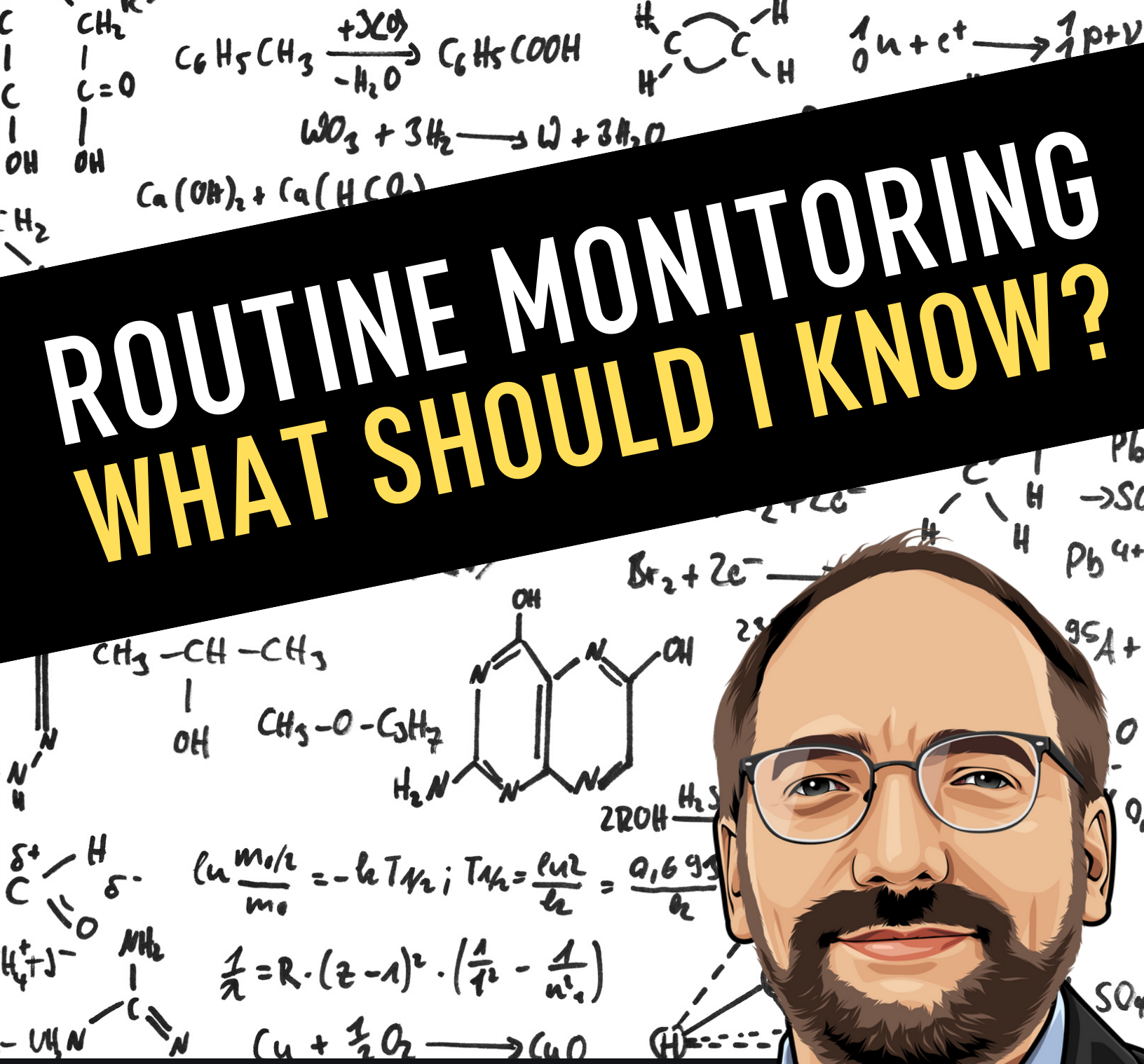
ROUTINE MONITORING
WHAT SHOULD I KNOW?



LOW TEMP STERILIZATION EXPERT

BEYOND CLEAN

Jean-Luc Lemyre | Senior Manager R&D | Stryker

Beyond Clean Low Temp Sterilization Expert™:

ROUTINE MONITORING - WHAT SHOULD I KNOW?

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In our last post, we addressed the idea that the sterility of devices cannot be directly verified before using them on a patient. For this reason, sterilization processes are subject to rigorous validations by manufacturers, which in turn are reflected in a sterilizer's instructions for use. Successful sterilization relies on the routine monitoring that must be carried out by healthcare facilities. We'll be dedicating two posts on this topic as there are several things to consider.

Up first is the direct monitoring of a sterilizer's physical parameters (e.g. temperature, pressure, time) through the use of sensors that examine a sterilizer's conditions and detect any deviations from specified operating ranges. The operator is alerted of any deviation. Additionally, indirect monitoring is performed using chemical indicators (CI), biological indicators (BI) and process challenge devices (PCD). Be aware! Despite the valuable information these all provide about sterilant exposure conditions during a low-temp cycle, if only viewed individually they will not tell us EVERYTHING about the potential sterility of the devices. Therefore, effective infection prevention must rely on the big picture that results from looking at all indicators, together. Know what each one does and doesn't do.

The most common CIs for VHP are Type 1 and rely on a visual color change to distinguish processed from unprocessed items based on exposure to the sterilant, regardless of its intensity or duration. Such CIs tell the operator that the sterilant made an appearance, but not if it completed its task of killing bugs. At least one CI should be placed inside each sterile package. Another best practice is to affix a CI to outside packaging to differentiate processed from unprocessed items without opening them. We'll pick up next post on BIs and PCDs and how they all work to build the big picture on sterilization monitoring.

Have more low temp sterilization questions? Contact Jean-Luc at: jeanluc.lemyre@stryker.com

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JEAN-LUC LEMYRE

SENIOR MANAGER RESEARCH & DEVELOPMENT

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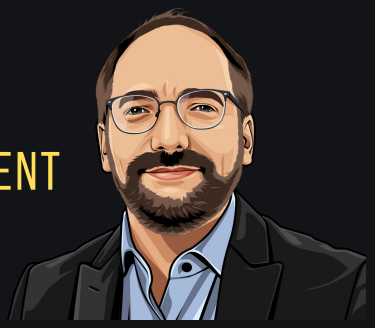

Jean-Luc is passionate about science and innovation and has been involved in R&D for two decades, ranging from fundamental academic research to product development. He joined TSO3 in 2016 where he was introduced to low-temperature sterilization of medical devices using hydrogen peroxide and ozone. Today, Jean-Luc is a Senior Manager of R&D at Stryker following the acquisition of TSO3. In this role, he leads a team of scientists and engineers dedicated to innovating for the benefit of sterile processing professionals. During his career, Jean-Luc has been involved in several product improvements along with the associated regulatory clearances. He is also an active member of standards development committees with AAMI and ISO.

Before discovering his passion for sterile processing, he started his career doing R&D in the field of personal protective equipment. He has a PhD in chemistry from Université Laval in the beautiful Québec City, where he still lives with his family.

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