OPC DAY
FINLAND 2025
10.12.2025

Possibilities of OPC UA from the Sterilizer Equipment Technology Perspective

Juha Mattila
Sr. Manager, Technical Services
STERIS Life Sciences

FINNISH SOCIETY OF AUTOMATION
SUOMEN AUTOMAATIOSEURA RY

SPONSORS:

aws BECKHOFF Microsoft OPC FOUNDATION PROSYS OPC STERIS Valmet FORWARD Wapice

Juha Mattila is Senior Manager, Technical Services. At STERIS Juha is SME on terminal sterilization applications, equipment, and process technologies for STERIS Life Sciences including Moist Heat and VHP Sterilization and biodecontamination technologies, and related critical utilities (WFI and Pure Steam Systems).

Education and experience: B. Sc. in HVAC and Process Engineering, and M. Eng in Business Informatics. Over 25 years of experience within pharmaceutical and medical device industries and related research, including R&D, engineering, engineering management and product management. Overall process industry experience exceeding 30 years.

Organizations: Active member of PDA, ISPE and Finnish Biosafety Network and subject matter expert member in relative international standard work groups of ISO, AAMI, SFS, BSI and CEN, representing Finland and co-author at DUODECIM (Sairaaloiden välinehuollon kirja).

Currently in the following Technical Committees:
ISO TC 198 WG 16 (VH2O2 sterilization)
ISO TC 198 WG 3 (Moist heat sterilization)
ISO TC 198 WG 4 (Biological Indicators)
ISO TC 198 WG 6 (Chemical Indicators)
CEN TC 102 WG 6 (Gas Sterilizers)
YTL/TR 301 (Välinehuollon palvelustandardi)
ISO TC 198 WG 11, WG 13, WG 14 (new work groups being established for ISO 14937 and new process standards)
PDA TR 48 revision group (Guideline for moist heat sterilizers) and PDA VH2O2 Surface Sterilization group
ASTM A55 (Process standard)

Agenda

- About STERIS Life Sciences
- Regulatory Landscape and Conformance
- Example Case: Sterilizer Control and Monitoring
- OPC UA Implications
- Conclusions

ABOUT STERIS / LIFE SCIENCES

STERIS: Who We Are

STERIS is a leading global provider of products and services that meet the needs of growth areas within Healthcare: procedures, devices, vaccines, biologics.

Our mission is to HELP OUR CUSTOMERS CREATE A HEALTHIER AND SAFER WORLD by providing innovative healthcare and life science products and services around the globe.

Life Sciences Segments

Life Sciences Segments

CONSUMABLES

Process Cleaners
Surface Disinfectants & Sterilants
Sterility Assurance Products
Barrier Products

CAPITAL EQUIPMENT

Moist Heat & VHP Sterilizers
VHP Biodecontamination Equipment
Washers
Pure Steam/WFI Systems

SERVICE

Installation & Maintenance
OEM Parts
Feasibility Testing
Cycle Development
Specialty Services

REGULATORY LANDSCAPE AND CONFORMANCE

Regulatory Landscape

World Health Organization

ECHA
EUROPEAN CHEMICALS AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FDA

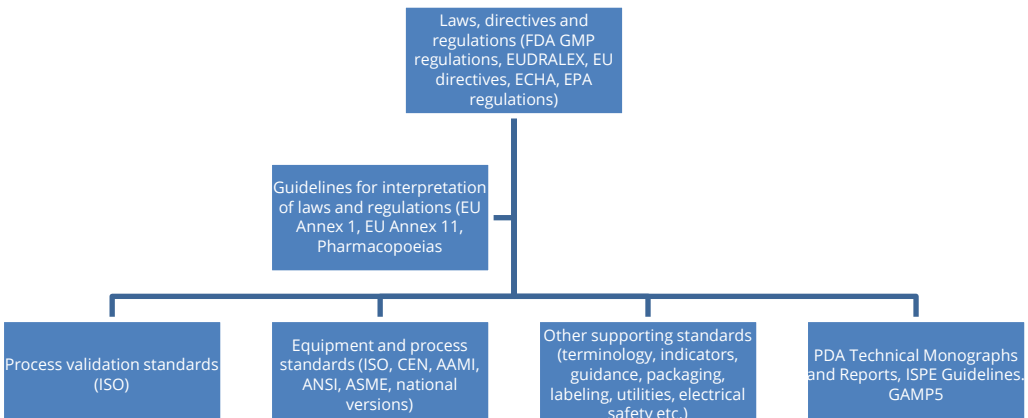
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

usp

EUROPEAN PHARMACOPOEIA

aws BECKHOFF Microsoft OPC FOUNDATION PROSYS OPC STERIS Valmet FORWARD Wapice

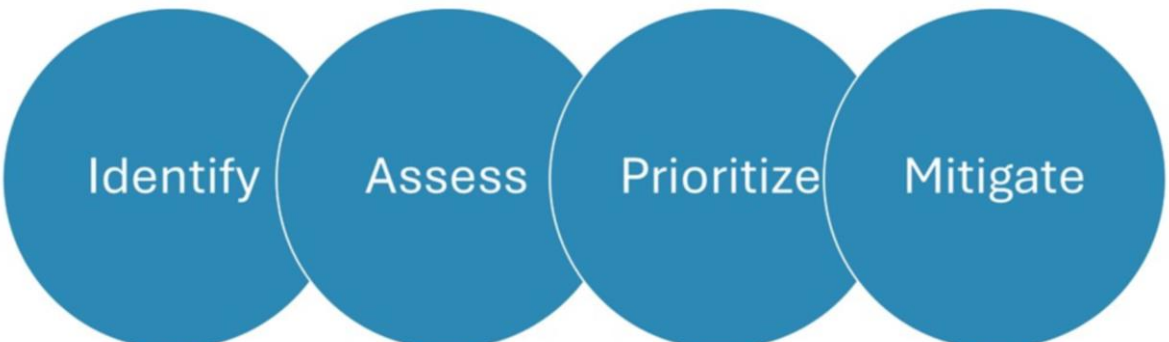
Regulatory Conformance



Conformance to regulations can be subject to interpretation and there can be several potential approaches…

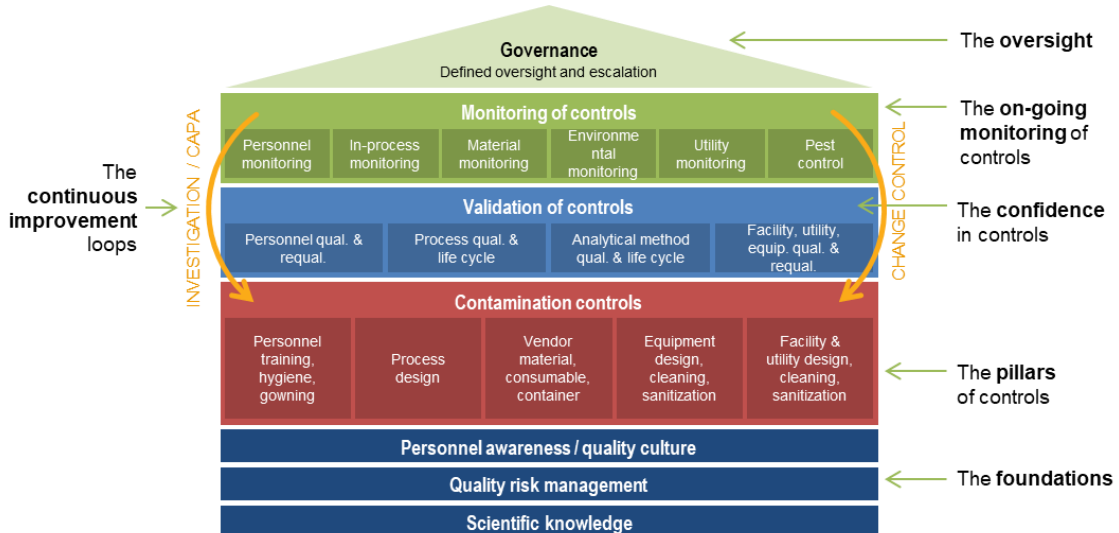
In any case – the required criteria must be fulfilled and proven!

Everything related to GMP equipment and process design must be considered through a risk assessment
(Especially emphasized in EU Annex 1:2022)



Meaning: Everything.

Holistic CCS - Contamination Control Strategy (EU Annex 1:2022)

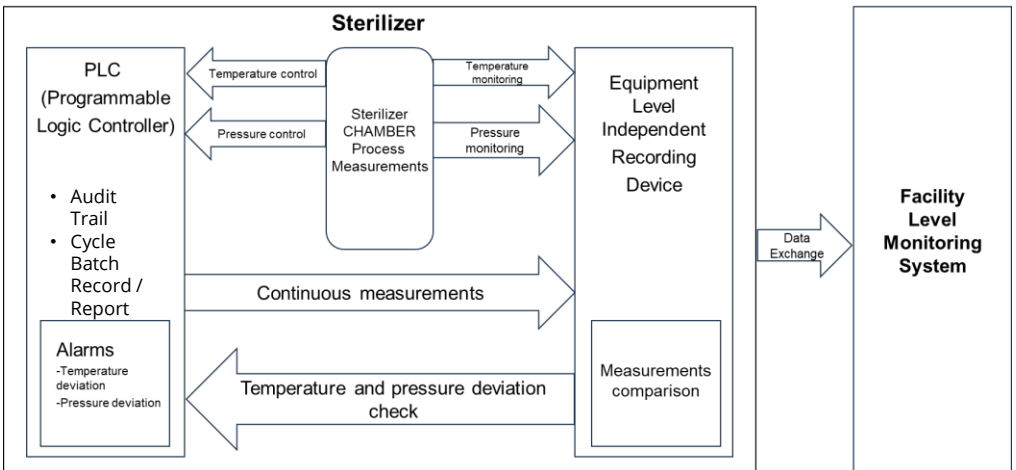


EXAMPLE CASE: STERILIZER CONTROL AND MONITORING

Drivers behind the developments: Independent Control and Monitoring Becomes Mandatory for Sterilizers

- New requirements in industry standards and regulatory guidelines
- Ultimately – Improving risk mitigation for improved **patient safety**
- Major Pharma and Medical Device companies also want **sterilizer batch release based on parametric monitoring** instead of using biological indicators
- Independent control and monitoring of sterilizer process is also required to achieve **minimum readiness** for parametric release

Sterilizer Level Independent Control and Monitoring



- Control sensor measurements to PLC and electronic recorder
- Reference sensor measurements directly to recorder. The recorder compares these measurements against allowed deviations
- Deviations are sent to PLC for generating potential alarms
- Alarms are recorded and printed in the batch report
- Batch reports retrieved and archived to Facility Level Monitoring System

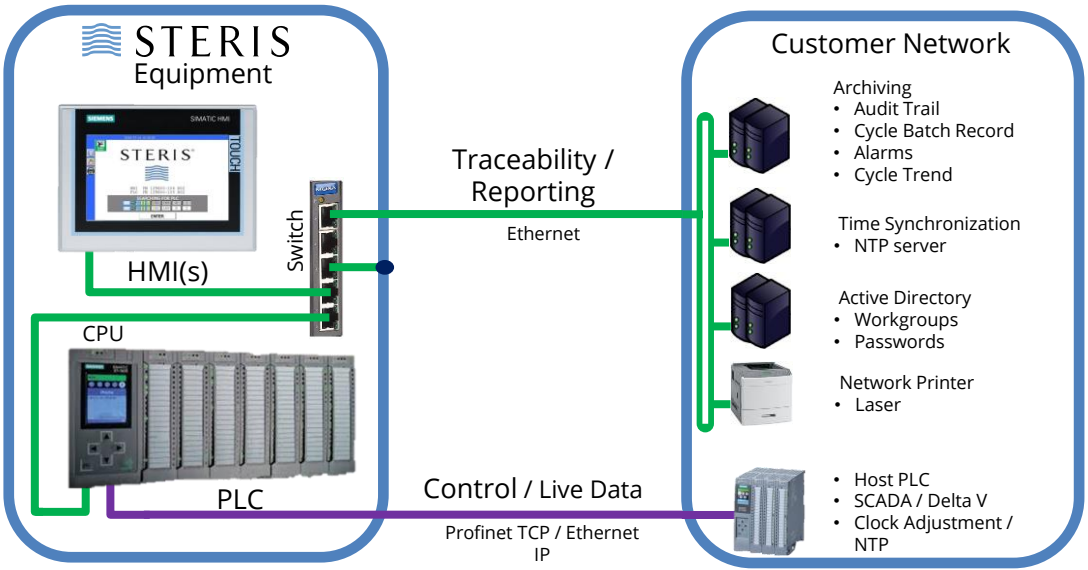
OPC UA IMPLICATIONS

OPC UA provides industrial automation with a standard communication protocol ***that allows communication with devices and systems of different vendors and seamless communication of important information.*** *It enhances security by utilizing public and private key encryption, safeguarding sensitive information shared within a facility. OPC UA allows for* ***real-time monitoring of devices*** *within a facility due to the publish-subscribe model, allowing subscriptions to be notified when specific events occur. Facilities can add more devices to the OPC UA network without overloading it. New devices can* ***integrate quickly*** *and begin receiving required information seamlessly.*

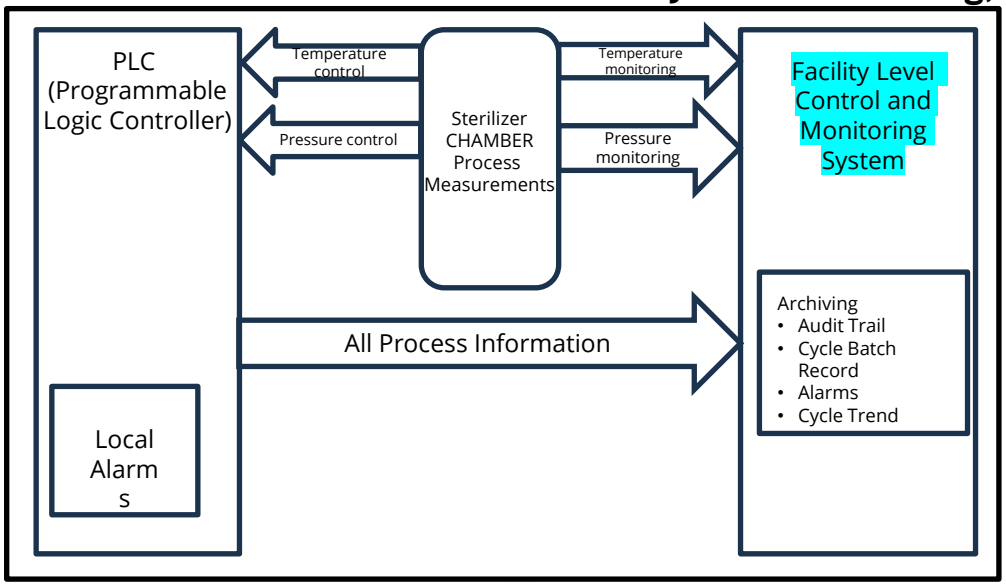
OPC Unified Architecture (OPC UA) is a machine-to-machine communication protocol developed for industrial automation. It stands as a comprehensive, secure, and ***platform-independent framework that*** *facilitates* ***seamless data exchange*** *across diverse platforms and devices.*

OPC UA (Open Platform Communications Unified Architecture) is an ***industrial communication standard*** *designed for secure, reliable, and* ***platform-independent data exchange between machines,*** *devices, and systems in automation and industrial environments.*

Industrial Pharma Equipment Control Interface with Facility



Moist Heat Sterilizer Process – Facility Level Monitoring, Trending and Reporting



- Control sensor measurements to PLC and Facility Control and Monitoring System
- Reference sensor measurements go directly to Facility Control and Monitoring System. The system compares these measurements against allowed deviations
- Deviations are evaluated for generating potential alarms
- Alarms are recorded and electronic batch report generated by facility system

CONCLUSIONS

Conclusions

- OPC UA to simplify and standardize sterilizer equipment control configurations
- Drives further implementation of remote process control and reporting, trending, predictive maintenance measures and monitoring
- Standardized integration to facility system
- Simplifying the entire data exchange between equipment and facility
- Primary equipment development focus for equipment control and performance improvements and better use of trending data

THANK YOU! QUESTIONS?

juha_mattila@steris.com