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WEBINAR SERIES#4

ISO 13485 certification as a motor to improve MD Reprocessing Efficiency

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CONTINUOUS EDUCATION

WEBINAR 3

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intro

Manual labor is necessary for the daily operation of a CSSD. Many of the critical processes remain without automation. Additionally, customer requirements can increase workloads and define the process flow within our departments.

How can we change this inefficient use of resources based on random customer demands?
By introducing ISO13485[1] quality system requirement standards in your department, you are able to strictly define your own processes and continuously improve them.

ISO13485[1] standards allow you to use various types of data to conduct process analyses, and identify areas where improvements should be made. The fundamental idea is to "secure our qualitative sterile end-product in the most efficient way.

01. Developing a data management system to analyze your daily operations:

We all understand the principles of traceability and its importance in patient safety. However, is traceability within the CSSD sufficient to call it a data management system?
To objectively assess your process performance, you need data.

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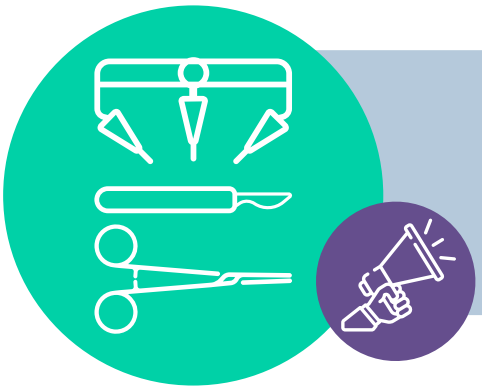
This data should not only come from your traceability system but also from other sources. Developing a data management system involves finding the right balance between measuring and obtaining the correct data and conducting analyses.[2] What do you need to know to have an objective view of your process? Is it turnover times, the number of sets reprocessed per day, distribution of sets over operational working hours, etc.? We used all this data to make changes in our department's policy and make it more efficient. One example of change we made is optimizing staff dispersion efficiently through the department.

> ***"To objectively assess your process performance, you need data."***



Collecting and analyzing data is an essential part of identifying inefficient processes, detecting necessary changes to keep your efficiency or point out possibilities to increase efficiency.

Developing a data management system

DATA SELECTION AND REGISTRATION

DEFINING AVAILABLE DATA

- **Traceability system**
- **HR database**
- **Back office/ logistic system**

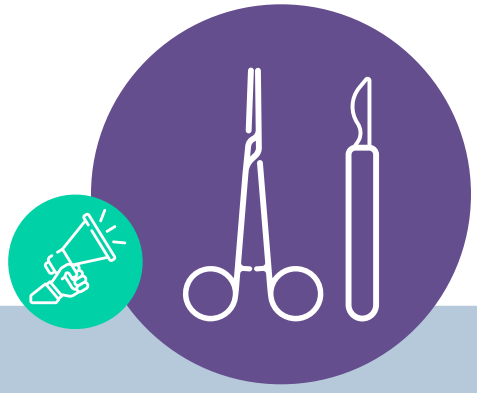
↓

Data Warehouse

Source: https://www.freepik.com/free-photo/server-racks-computer-network-security-server-room-data-center-d-render-dark-blue-generative-ai_38095230.htm#query=datacenter&position=0&from_view=search&track=sph

02. Risk analyses as the basis for improving efficiency:

Identifying the risks within your CSSD process is an important aspect of ensuring the daily operational activity is secure. We employ methods like FMEA (Failure Modes and Effects Analyses) or risk matrix[3] to assess various aspects of our department and process, including energy, infrastructure, human resources, IT, and the CSSD process itself. These analyses trigger the drafting of action plans to control these risks and often result in increased efficiency as a side effect. For instance, digitalizing the control process to reduce the risk of releasing non-sterile loads not only enhanced safety but also brought about significant time and economic savings.



Risk analyses need to prevent possible bad outcomes but often give a base for improvement due to developed action plans.

These analyses trigger the drafting of action plans to control these risks and often result in increased efficiency as a side effect."

03. Policy plans and management review[4] to ensure top management support:

Policy plans play a crucial role in the development of your CSSD department. Creating a 10-year plan focused on equipment, increasing capacity, and optimizing staff deployment is essential. Thinking and working on both short and long-term ideas are key to improving efficiency. As a confirmation of these ideas, a yearly management review is performed to provide an overview of the department's present activities and ensure top management's support. Both of these components share the same goal: ensuring top management is on board with the improvement efforts.

> ***"Thinking and working on both short and long-term ideas are key to improving efficiency."***

Increasing efficiency sometimes is long term work with availability of extra resources. Policy plans and management reviews help to ensure support of top management.

Policy plan:

Project optimizing flow loaner sets.

GOAL

Building an efficient operational process

Ordering , invoicing, reprocessing and tracing

Financial analyses sterile vs non sterile delivery

Efficient instrument storage

- Simplifying picking and registration
- Inventory
- Yearly financial analyses

- Infrastructural change
- Software support, link to traceability system

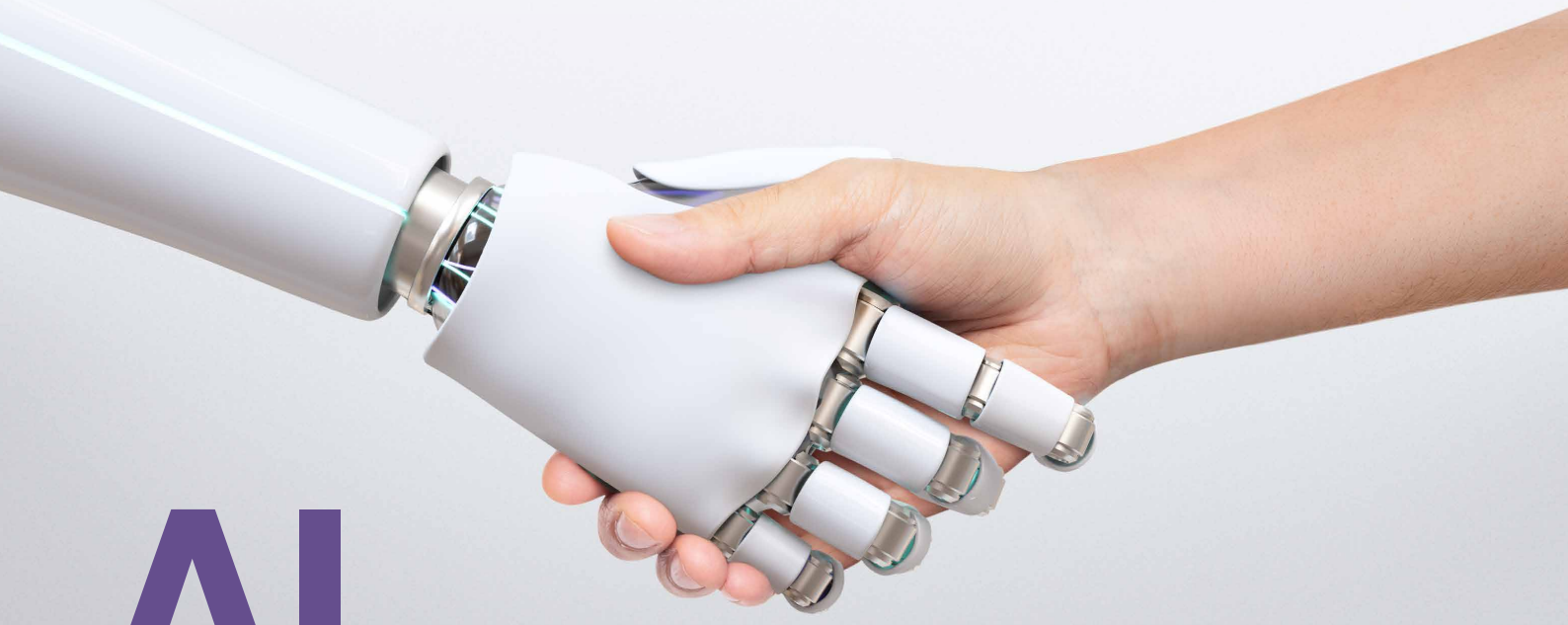
- Time saving, reducing searching times
- Economical benefits

04. Automation and robotization: How far can we go?

CSSD has always been a department heavily reliant on manual handling, which demands a considerable workforce. Manual handling can be costly and not always efficient, also manual labor is more sensitive to errors with an decrease of quality outcomes, staff members are not robots. However, due to advancements in technology, CSSD can now embrace automation and robotization.[5] By utilizing AI, RFID, and robots in the CSSD process, efficiency can be improved. The question remains as to what impact automation and robotics can have on the daily workflow of a CSSD and what is possible as technologies advance.

> *"By utilizing AI, RFID, and robots in the CSSD process, efficiency can be improved."*

AI, automation, robots, RFID: new technologies are becoming more available for the CSSD processes. Reducing human error, increasing quality and efficiency. Make sure they are in balance with the economical reality



AI
artificial intelligence

- Control of human handling | Error reduction | Procedural handlings, set content, cleanliness, loading releases (...)
- Taking over human handling | Error Free – continuously improvement)

Source: https://www.freepik.com/free-photo/robot-handshake-human-background-artificial-intelligence-digital-transformation_17850420.htm#query=ROBOT%20GREY&position=35&from_view=search&track=ais

Resume

WORKING ON EFFICIENT PROCESS FLOWS WITHIN THE CSSD IS A MULTI FACTOR AND CONTINUOUS PROCESS

DATA, RISK ANALYSES, POLICY PLANS AND NEW TECHNOLOGIES ARE TOOLS TO IDENTIFY POSSIBLE PROFITS

WORKING ON EFFICIENCY IS SOMETIME THE DIFFICULT BALANCE BETWEEN NEW TECHNOLOGIES AND ECONOMICAL REALITY

OUR GOAL STAYS THE SAME: "DELIVER A QUALITATIVE STERILE END PRODUCT ON A TIMELY MATTER WITH FOCUS ON ABSOLUTE PATIENT SAFETY"

01 Collecting and analyzing data is an essential part of identifying inefficient processes, detecting necessary changes to keep your efficiency or point out possibilities to increase efficiency.

02 Risk analyses need to prevent possible bad outcomes but often give a base for improvement due to developed action plans.

03 Increasing efficiency sometimes is long term work with availability of extra resources. Policy plans and management reviews help to ensure support of top management.

04 AI, automation, robots, RFID: new technologies are becoming more available for the CSSD processes. Reducing human error, increasing quality and efficiency. Make sure they are in balance with the economical reality.

Take home

MESSAGES

ISO 13485
CERTIFICATION AS A
MOTOR TO IMPROVE
REPROCESSING
EFFICIENCY

References:

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2. Wouter Meert – University Hospital Leuven CSSD | SAP Bevragingstool
3. Wouter Meert – University Hospital Leuven CSSD Reports | Graphics: UZ Leuven, FMEA excel CSSD, 2023
4. Wouter Meert – University Hospital Leuven Reports (Beleidsplan E995 Centrale sterilisatie afdeling 2021-2025 and Management Review CSA 2023)
5. Wouter Meert – University Hospital Leuven | Image: courtesy of R-solutions, Duomed and Digital folder KEN hygiene systems

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