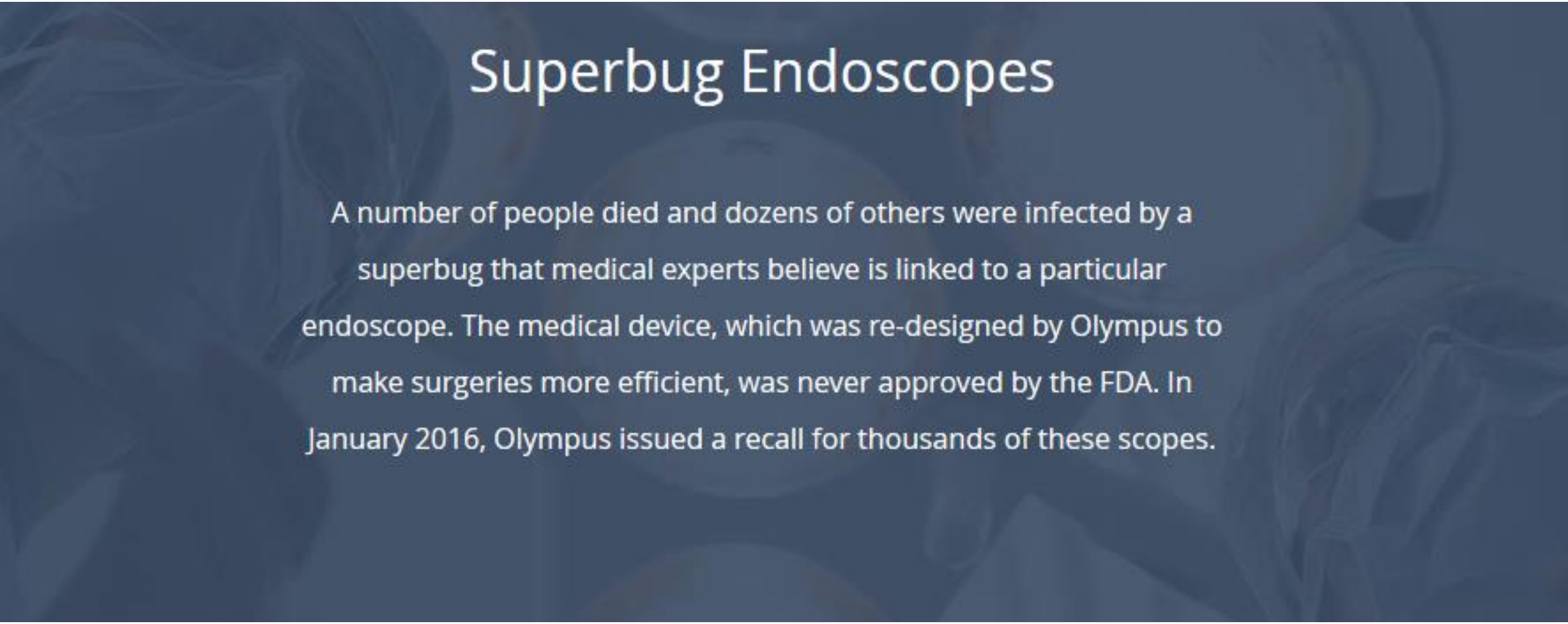
CLOSING THE GAP

Medical device manufacturers and healthcare facilities must work together

Anja Heidmann, Peter Drechsler

IN THE NEWS

https://www.drugwatch.com/ercp/superbug/



CAUSES

Common problems of inadequate reprocessing, that were reported, are among others:

- Inadequate reprocessing instructions that are hard to understand
- Complex devices hard to maintain
- Health care personnel not well trained
- Lack of validated reprocessing processes and properly addressed agents
- Missing resources or not state-of-the-art of the equipment
- Occupational high risk for hospital employees

Objective

Proposal of cooperation of Healthcare facilities and medical device manufacturers

Alignment of efforts for reprocessing by means of a quality management system

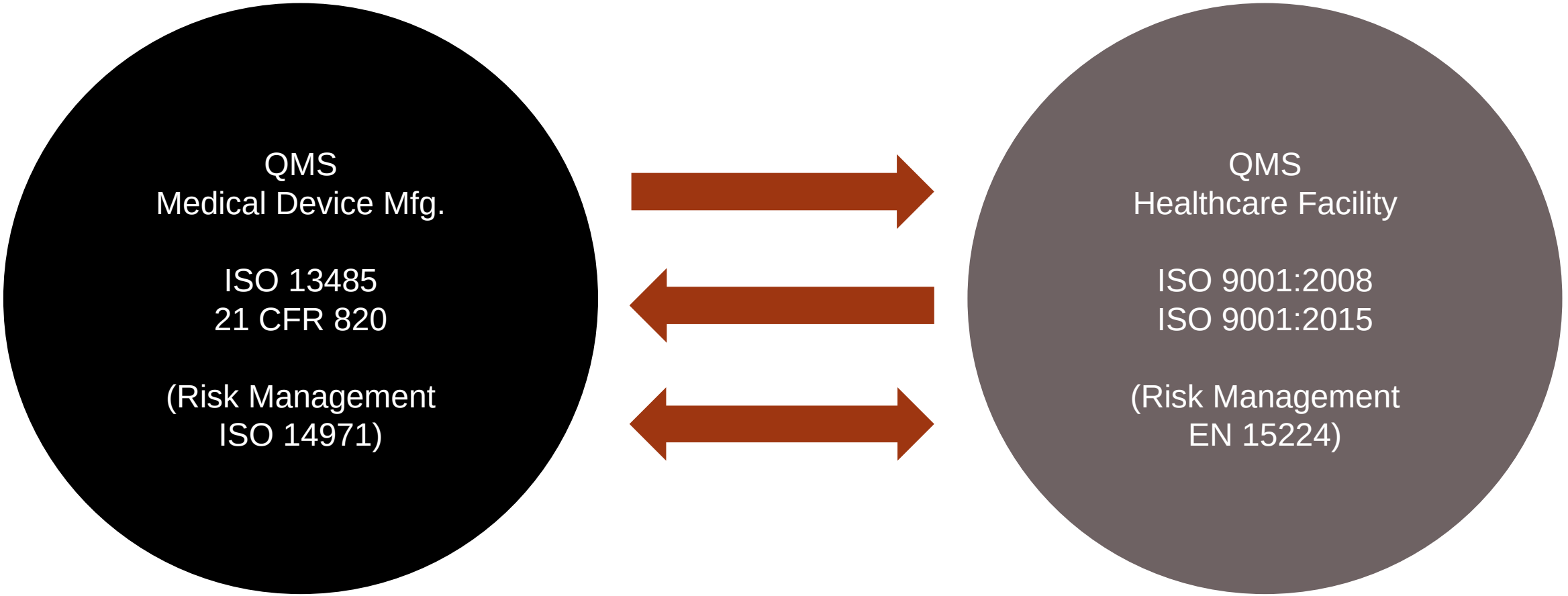
Regulatory requirements incl. Post Market Surveillance

Assumptions

- QMS for medical devices manufacturers based on ISO 13485:2016 and 21 CRF 820 (covers the most used QM-Systems in industry)
- QMS for Healthcare facilities is based on ISO 9001:2008 or ISO 9001:2015
- Only intentional reusable medical devices covered
- Single use devices that are reprocessed are out of scope

INTERFACES

Between two quality management systems



RISK MANAGEMENT

Manufacturer

ISO 13485-7.1 Planning of product realization and 21 CFR 820.5

The manufacturers shall implement risk management according to ISO 14971.

Healthcare Facilities

ISO 9001:2008-7.1 Planning of product realization, ISO 9001:2015-8.1 Operational planning and control

The hospitals shall/should implement a clinical risk management according to EN 15224.

It might be wise to align the risk management.

NOTE?

[Note] FUJIFILM cannot assure the successful reprocessing (cleaning, high-level disinfection and sterilization) of the endoscope and/or accessories if reprocessing methods, chemicals, packaging and/or conditions other than those described in this manual are used. Users are responsible to ensure that if any alternative reprocessing methods, chemicals, packaging and/or conditions are used, appropriate efficacy validation studies have been performed.

RISK MANAGEMENT

Healthcare Facilties -- Reprocessing

Hazard	Mitigation	New risks
IFU not complete or not understandable (missing language)	Reprocessing validation Use of established standard reprocessing method	Impact on the device: • Incompatibility • Short term damage • Long term damage • Patient, users and financial risks
Reprocessing method not • applicable, • allowed or • available in your country		
CSSD not familiar with the device		

RISK MANAGEMENT

From a reprocessing manual

	For sterilization	Steam sterilization (autoclaving)
		Ethylene oxide gas sterilization (gas mixture 20% ethylene oxide gas/80% CO_2, for countries other than the USA)
		Ethylene oxide gas sterilization (100% ethylene oxide gas)
	For disinfection	ACECIDE disinfectant solution*3
		CIDEX® Activated Dialdehyde Solution (For the USA)*4
		2 – 3.5% glutaraldehyde
	For alcohol flush	70% ethyl or 70% isopropyl alcohol
	For cleaning	Detergent solution
		Ultrasonic cleaning
Endoscope 		*1

RISK MANAGEMENT

From a reprocessing manual

*1 The endoscope is only compatible with ultrasonic cleaning as performed in an **<companyname>**-recommended endoscope reprocessor such as OER-AW, OER-Pro (OER-AW and OER-Pro are not available in some areas). When using an AER that is recommended by **<companyname>** other than listed above, contact ….

*3 ACECIDE are not available in some areas.

Use a high-level disinfectant cleared by your national regulatory agency for use in reprocessing flexible endoscopes. Follow the disinfectant manufacturer's instructions regarding activation (if required), concentration, temperature, contact time, and expiration date**. For further information regarding the compatibility of glutaraldehyde-based or non glutaraldehyde-based disinfectant solutions, contact ...**

PURCHASING PROCESS

Manufacturer

ISO 13485-7.2 Customer related processes

The manufacturer must be aware on how its devices are used in the hospitals and if there are special statutory and regulatory requirements requested by national authorities.

Healthcare Facilities

ISO 9001:2008-7.4.2 Purchasing information, ISO 9001:2015-8.4.3 Information for external providers

Clear description of the expectation of the products.

Delivering input into the design.

Pass valuable information to the manufacturer, since users are familiar with devices in their daily use and the circumstances of reprocessing.

PURCHASING PROCESS

Manufacturer

ISO 13485-7.2 Customer related processes

The manufacturer must determine customer requirements that were not explicitly stated by the Healthcare facility.

Provision of actual IFU and reprocessing instructions to clients.

Healthcare Facilities

ISO 9001:2008-7.4.1 Purchasing process, ISO 9001:2015-8.4 Control of externally provided processes, products and services

Establish a process to be up-to-date regarding reprocessing instructions.

Evaluate device manufacturers.

Document Control

PURCHASING PROCESS

Manufacturer

ISO 13485-7.2.3 Customer communication

The manufacturer shall establish a substantial communication with their customers and evaluate their feedback.

Healthcare Facilities

ISO 9001:2008-7.4.3 Verification of the purchased product, ISO 9001:2015-8.6 Release of products and services

Verify that all purchased products satisfy your needs.

Report problems with the device like inadequate reprocessing instructions, bad maintainability etc. to the manufacturer.

DEVICE DESIGN

Manufacturer

ISO 13485-7.3.2 and 21 CFR 820.30 (c) Design Input:

Determination of all product requirements.

Invitation of doctors, nurses or CSSD staff to determine possible deficits of the medical devices.

Follow standards for cleaning, disinfection and sterilization.

Healthcare Facilities

ISO 9001:2008-7.5.2 Validation of processes, ISO 9001:2015-8.5.1 Control of production and service provision

Follow instructions provided by the manufacturers of the device.

Train your personnel.

Be familiar with respective standards.

DEVICE DESIGN

Manufacturer

ISO 13485-7.3.6 and 21 CFR 820.30 (g) Design validation:

Design validation with healthcare personnel:

- cleaning
- disinfection
- sterilization
- maintenance
- usability

Healthcare Facilities

ISO 9001:2008-7.5.2 Validation of processes, ISO 9001:2015-8.5.1 Control of production and service provision

Validation of processes regarding cleaning, disinfection, packaging and sterilization in order to prevent inadequate decontamination.

Invitation of manufacturers for design validation activities of the device and to gain experience in validation activities.

USER TRAINING

Manufacturer

ISO 13485-7.2 Customer related processes

The manufacturer must determine customer requirements that were not explicitly stated by the healthcare facility.

Provide device specific training of the healthcare staff.

Healthcare Facilities

ISO 9001:2008-6.2.2 Competence, awareness, training, ISO 9001:2015-7.2 Competence

Train the staff in the hospital.

Ask for device specific training by the manufacturer.

REPORTING

Reporting and Vigilance

Manufacturer

Post Market Surveillance/Vigilance by national regulations

The manufacturer must report incidents etc. to competent authorities.

Do proper Post Market Surveillance.

Evaluate customer feedback.

Healthcare Facilities

Obligation for reporting by national regulations or laws

Report to authorities about malfunctions, problems etc.

Report to the manufacturer.

THE REAL LIFE

Flexible duodenoscope case

January 2013 through December 2014, the FDA received 75 MDRs encompassing approximately 135 patients in the United States relating to possible microbial transmission from reprocessed duodenoscopes.

FDA started investigations.

In 2015 FDA issued a warning letter to the manufacturer concerning insufficient reprocessing instructions and missing adequate PMS.

Furthermore, failure to meticulously following the manufacturers instructions by reprocessers.

THE REAL LIFE

Flexible duodenoscope case

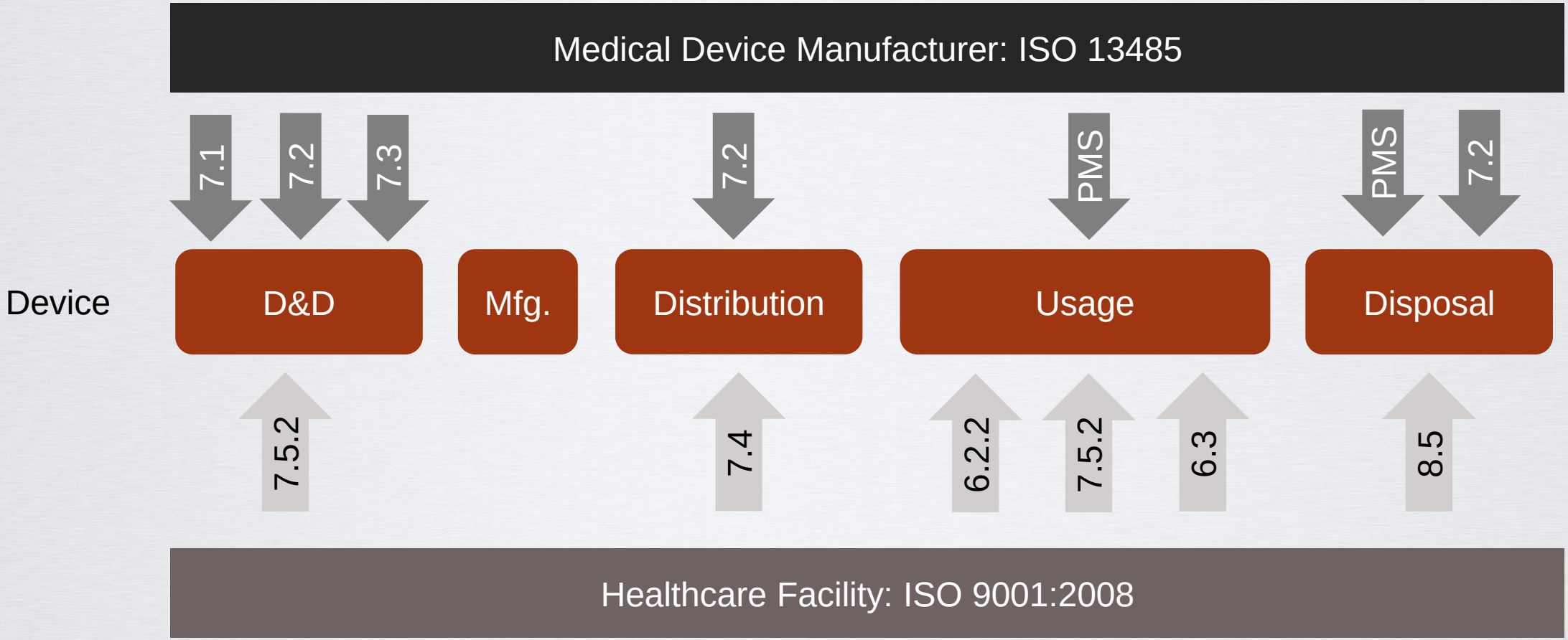
The manufacturer validated the revised reprocessing instructions in April 2015.

FDA approved the instructions in October 2015.

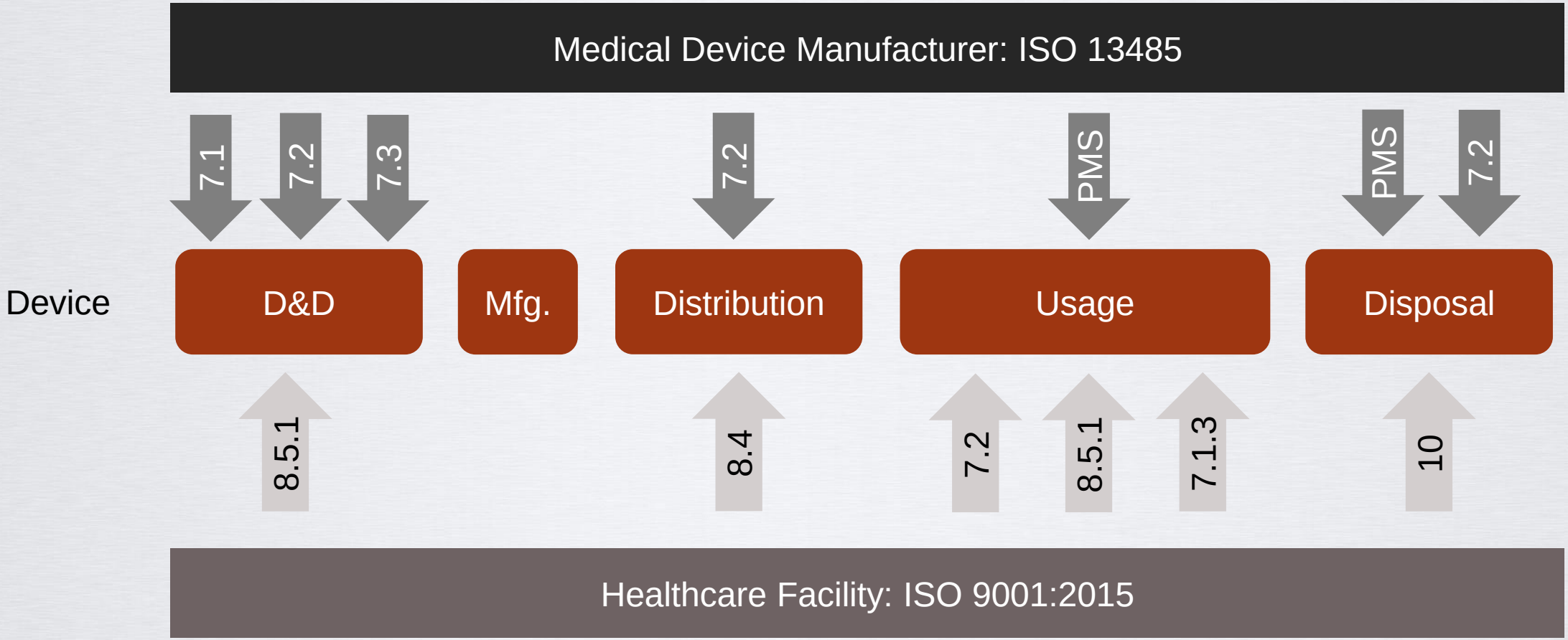
FDA issued recommendation to facilities that reprocess flexible endoscopes to take certain precautions:

- Strictly follow the manufacturers instructions,
- Train appropriate staff on the revised reprocessing instructions,
- Contact the sales representative if questions or concerns regarding the updated endoscope reprocessing instructions,
- Invite Clinical Sales Specialists (CSS) for an in-service training regarding these updated reprocessing instructions.

LIFE CYCLE


Medical Device Manufacturer: ISO 13485
7.1
7.2
7.3
7.2
PMS
PMS
7.2
Device
D&D
Mfg.
Distribution
Usage
Disposal
7.5.2
7.4
6.2.2
7.5.2
6.3
8.5
Healthcare Facility: ISO 9001:2008

LIFE CYCLE


Medical Device Manufacturer: ISO 13485
7.1
7.2
7.3
7.2
PMS
PMS
7.2
Device
D&D
Mfg.
Distribution
Usage
Disposal
8.5.1
8.4
7.2
8.5.1
7.1.3
10
Healthcare Facility: ISO 9001:2015

SUMMARY

Manufacturer

Listen to hospital staff.

Invite CSSD personnel during design phase.

Supply training.

Do proper post market surveillance.

Healthcare Facilities

Specify your requirements.

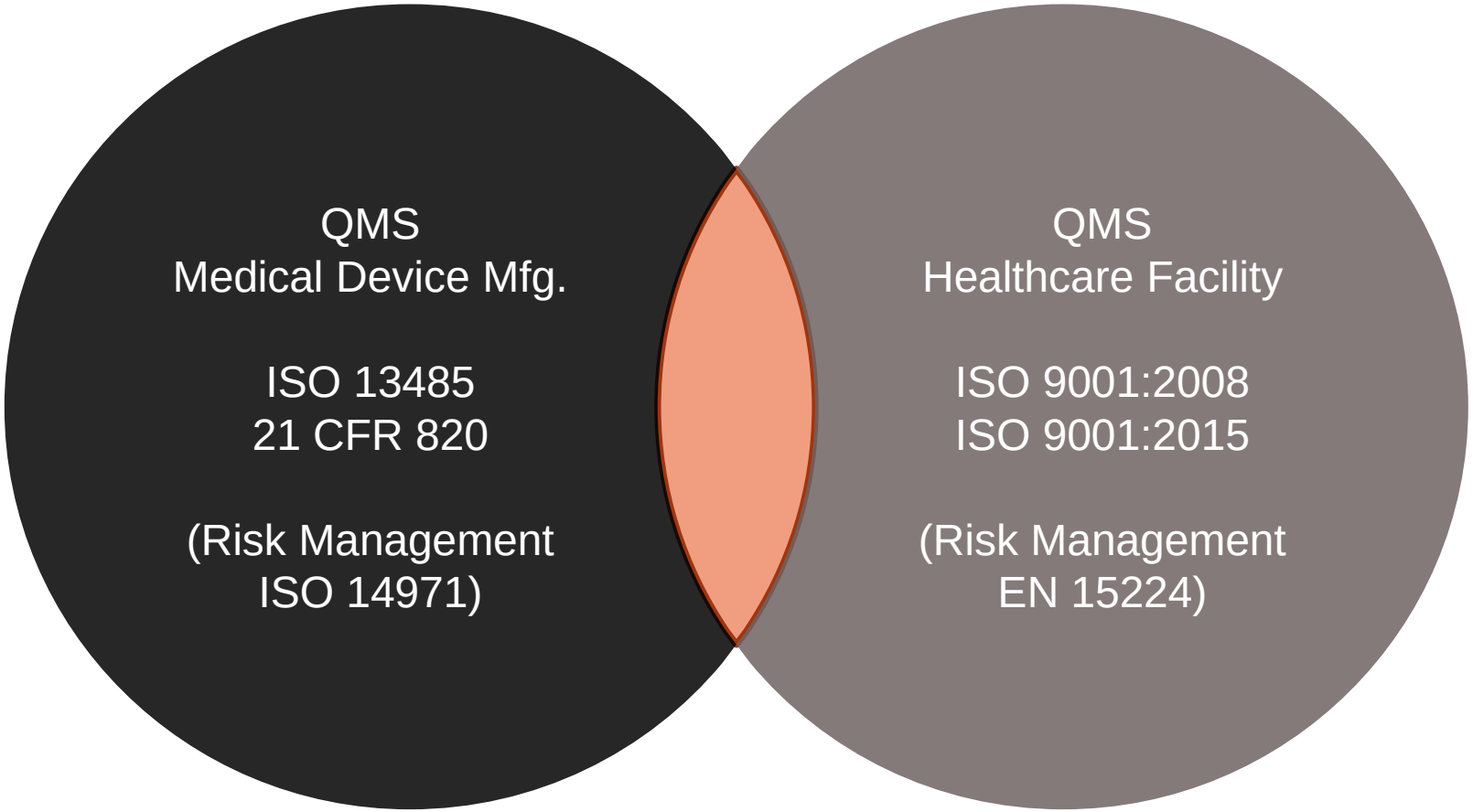
Train the staff in the hospital.

Ask for device specific training by the manufacturer.

Fulfill your reporting obligations.

INTERFACES

We need that intersection!



CLOSING THE GAP

To Close The Gap a substantial **communication process** between healthcare facilities and medical device manufacturers must be implemented, established and documented.

Thank you for your attention.

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