Navigate the Global Audit Landscape with Confidence

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NAVIGATE THE GLOBAL AUDIT LANDSCAPE WITH CONFIDENCE

Setting the Stage ---------- **MONICA BURT**

Global Audit Landscape and Best Practices ---------- **KIM TRAUTMAN**

Manufacturer Challenges and Opportunities ---------- **SCOTT SHANKLE**

The Audit Experience - Minimizing Risk and Ensuring Compliance ---------- **ROD PARKER**

Moderated Q&A Session ----------

SETTING THE STAGE

DID YOU KNOW THERE ARE 196 REGULATORY AUTHORITIES WORLD WIDE?

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Global Audit Landscape and Best Practices

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GLOBAL REGULATORY AUDITS

ISO 13485:2016

Mar. 1, 2019 → **Mar. 1, 2025** → **2028**

Likely Reaffirmation of ISO 13485:2016 for addition 3 years

Likely Next Revision of ISO 13485

MDSAP

Mar. 1, 2019 → **Feb. 2, 2026**

MDSAP Certificate to
ISO 13485:2016 Mandatory in HC

FDA QMSR Effective with ISO 13485:2016
and folded into MDSAP

UK BREXIT – UKCA CERTIFICATION

Dec. 31, 2027

UKCA marking deadline

EU MDR AND EU IVDR CERTIFICATION

May 26, 2024 → **Dec. 31, 2027** → **Dec. 31, 2028**

MDR-compliant QMS and submit their MDR applications

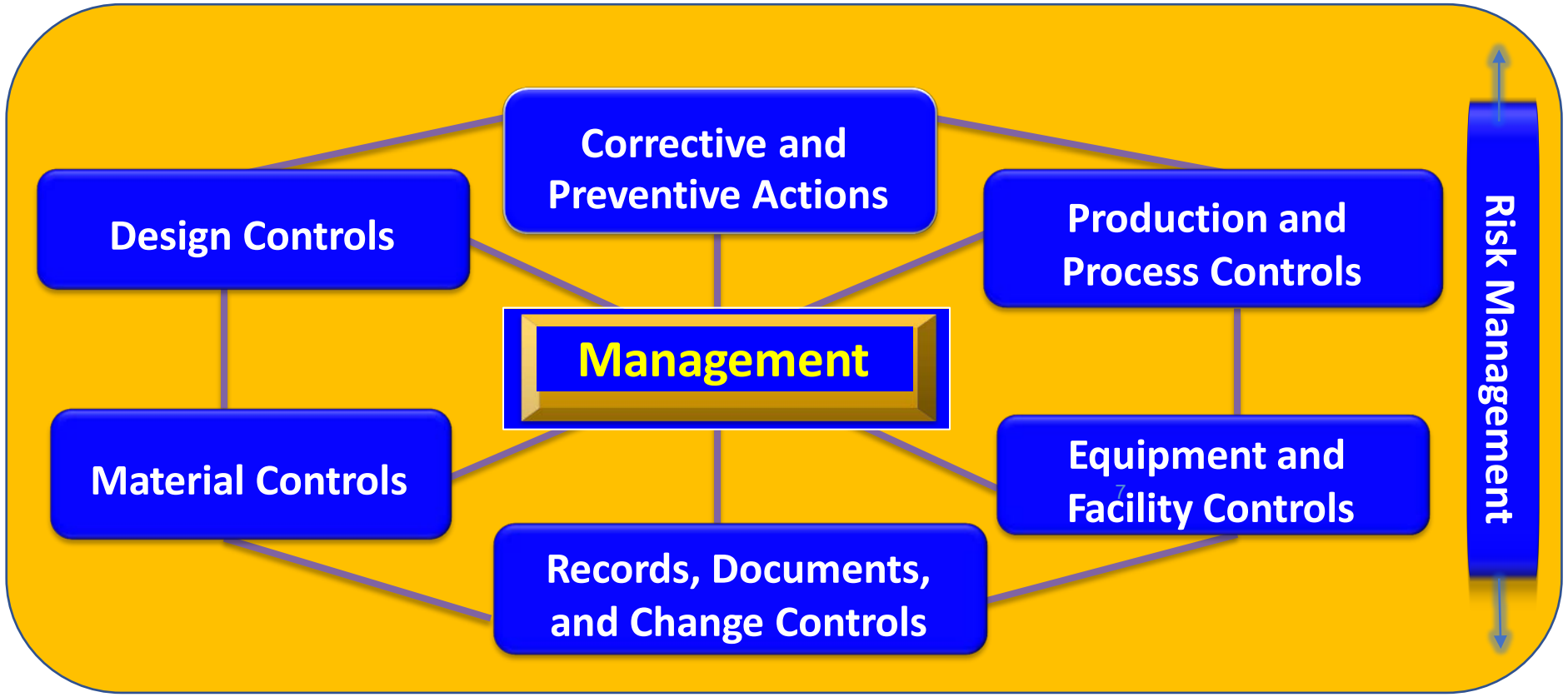
Class III and IIB implantable devices

Class IIA and
Class I devices

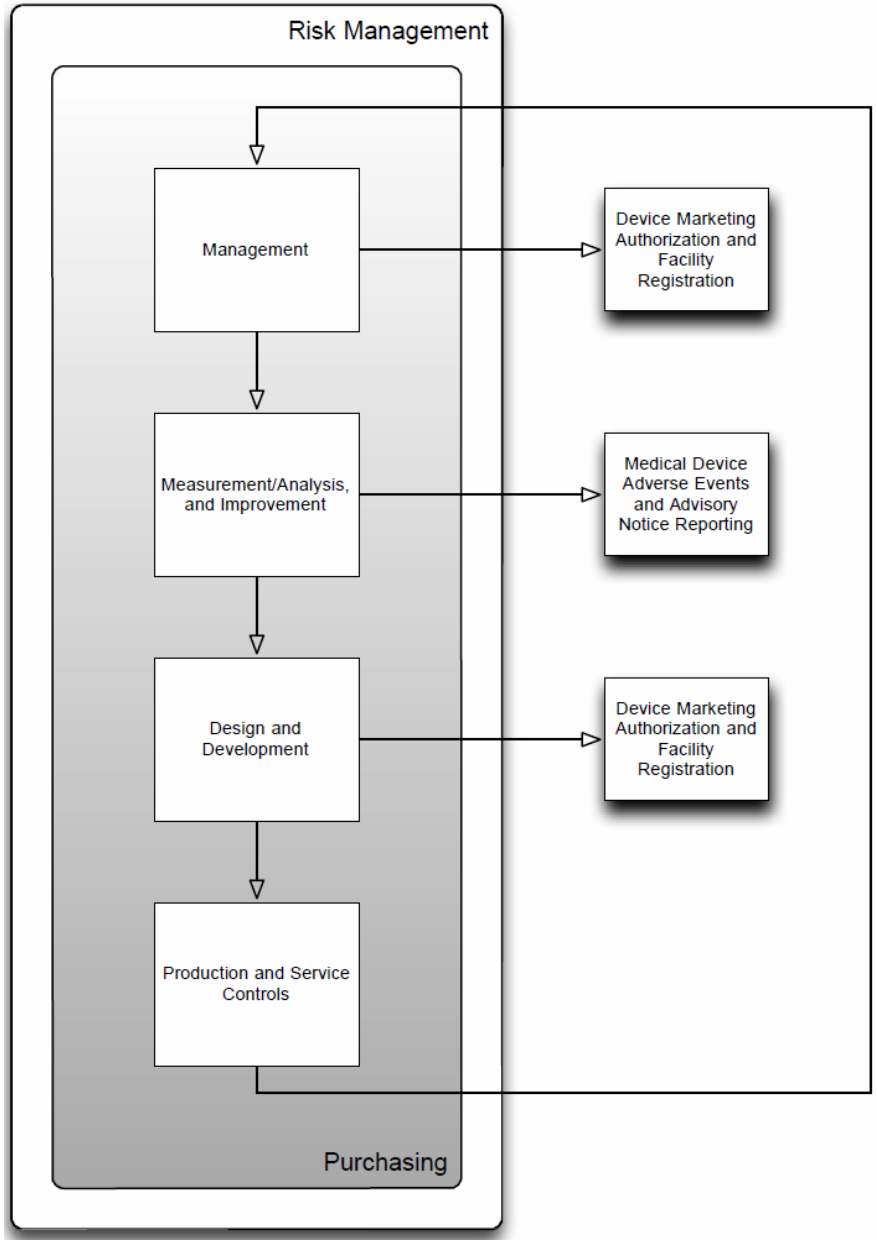
ASEAN MEDICAL DEVICE DIRECTIVE (AMDD) + BRIC AUDITS + PAN AFRICAN HARMONIZATION WORKING PARTY (PAHWP) AUDITS +++

Global Audit Approaches

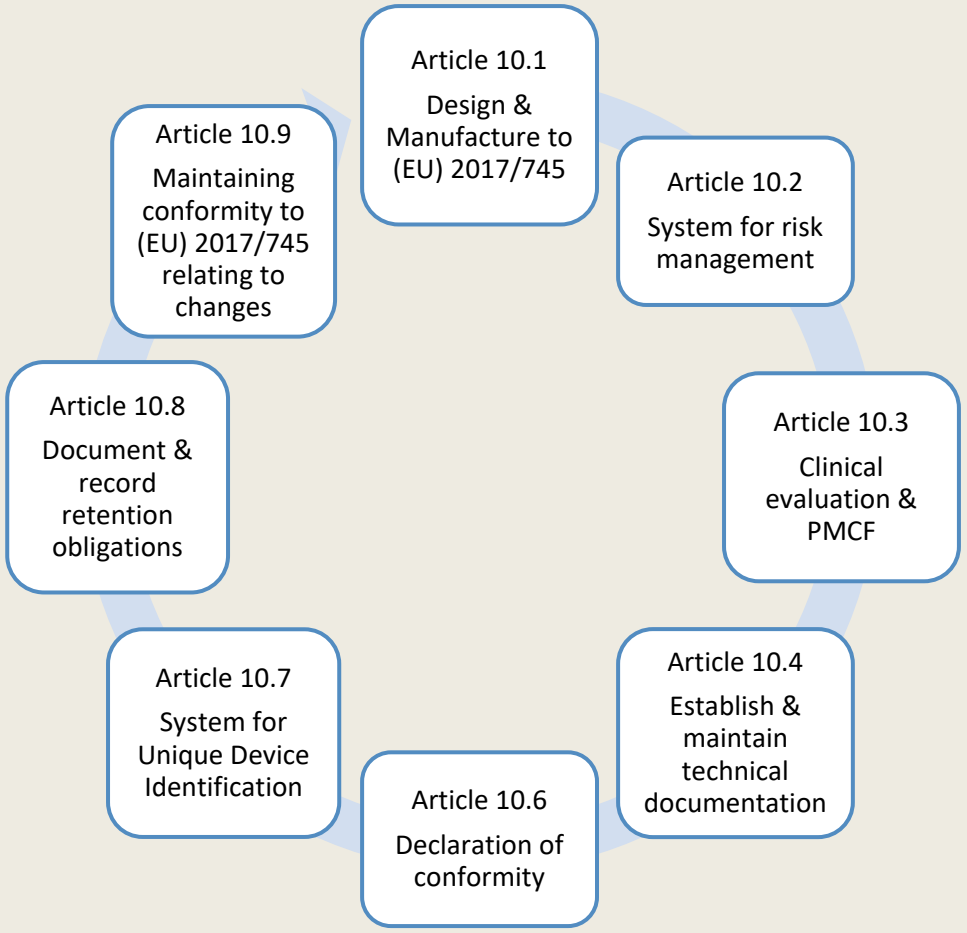
FDA QSIT - Subsystems of a Quality Management System

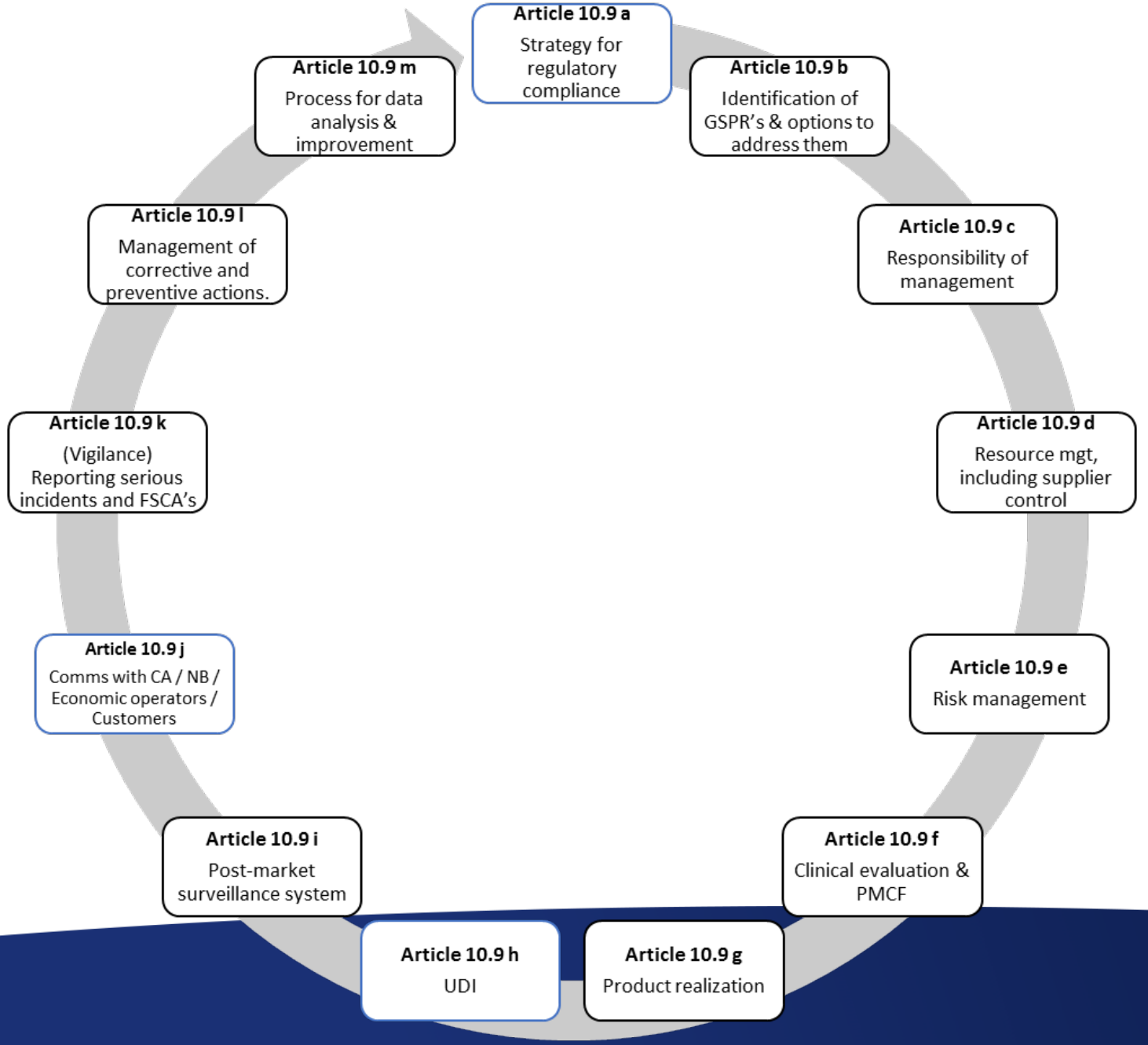


MDSAP Audit Model



EU MDR: Article 10 – General requirements





EU MDR: Article 10(9) Components Basic Quality Management System Requirements

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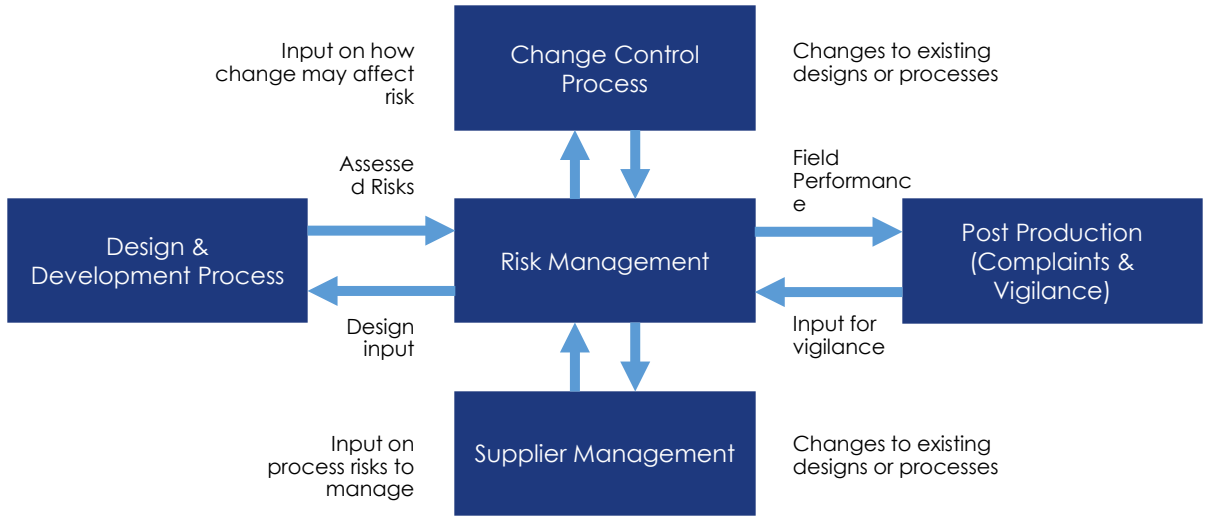
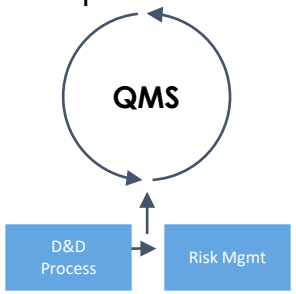
Integration of QMS and RMA with New Global Regulatory Expectations



Maturity Model: Stages of Integration

Stage 1
Separate Analysis

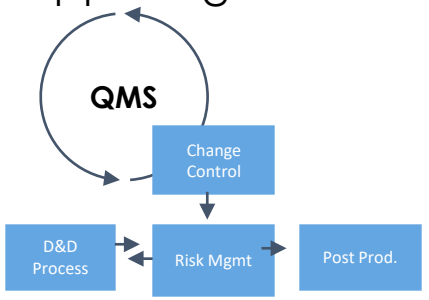


Completed as a separate project – often after the fact.

Included in regulatory submission, limited further use.

Prepared and owned by specialized team.

Stage 2
Supporting Role

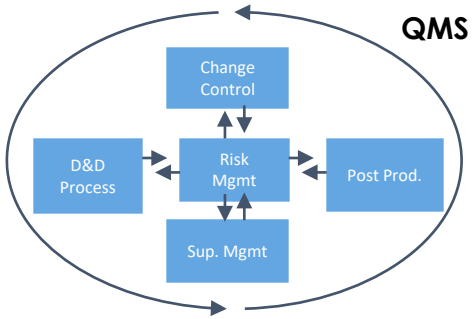


More integrated into development process.

Outputs used to support a few other QMS processes.

Broader team involved in developing and using the data.

Stage 3
Integrated Process



Fully integrated into the QMS.

Outputs guide decisions across the QMS system.

All relevant teams provide into to, and make use of, risk information.

Audit Preparation Best Practices

Before the Audit / Inspection

- Know the routine audit / inspection questions and requests
- Understand your audit / inspection history
- Prepare for your most feared questions
- Frame answers using your procedures and records

Know Your History

Previous audit and inspection history

- Previous registrar / notified body findings (major, minor, observations, comments made during audit)
- Site 483, Warning Letter, comments made in Establishment Inspection Report (EIR)
- Near misses from previous audits and inspections
- Sister facility or corporate registrar / notified body findings, 483s, etc. (learn from these!)
- Know the commitments you made, and where you may have deviated OR where systems have changed since those commitments were rolled out

Recent field actions

Your Most Feared Questions

You know your systems weaknesses


Identify the questions you are afraid to be asked


Develop answers (it may not avoid an observation but…)


Gather objective evidence as appropriate


Practice


Practice again

Frame Your Answers

When possible – use your objective evidence

Frame answers using your procedures (or records)

Make the conversation about the process

The answer *should* be in your procedure or record

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Manufacturer Challenges and Opportunities

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Current Challenges & Opportunities

Opportunity #1: Proactive Compliance & Organizational Readiness	✓ Comprehensive Risk Management ✓ Regulatory Intelligence ✓ Continuously Monitor Quality Metrics – PDCA ✓ Maintain "Audit-Readiness"
Opportunity #2: Collaborative Culture	✓ Cross-Functional Cooperation ✓ Partnership w/ Agencies & Customers ✓ Culture of Quality & Compliance
Opportunity #3: Strategic Planning	✓ Choosing the Right Notified Body(?) ✓ Strategy for Global Compliance

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The Audit Experience- Minimizing Risk and Ensuring Compliance

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Auditing Critical Validated Processes

- What is a critical process?
- Processes that are only measured by steps through a validation and not by physical inspection.
- Examples: Sterility, Cleaning, etc.

What needs checking and what you physically hold.

Example: Cleaning

What needs checking:

- processing chemicals,
- residue levels,
- endotoxins (implants, etc.),
- visual cosmetics,
- microbiological concerns (bioburden)

What you physically hold:

- Protocols
- Validations
- Testing (if shared)

Example: Sterility (radiation)

What needs checking:

- “Box” count (if not by shipped qty.)
- Monitoring condition (dosimeters)
- Placement
- Dose
- Release as ‘sterile’

What you physically hold:

- Certificate of Sterile Processing
- Shipping manifest
- Processing record (if requested)

What helps this NOT be an issue at audit time.

Whoever's name is on the product holds responsibility for these functions.

Documented compliance to product validations is required.

Supplier Agreements

- Detailed to include what is checked to the products processed, not just the process itself.
- Details of who is responsible for checked items
- Including auditing of the secondary processing supplier.

Key: Control of critical processes by suppliers is documented to every product number processed.

Panel

Questions & Answers

THANK YOU

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