Medical Device Single Audit Program (MDSAP)

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Client manager – Regulatory Services - APAC Assessment Delivery Operations

By Royal Charter

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Introductions

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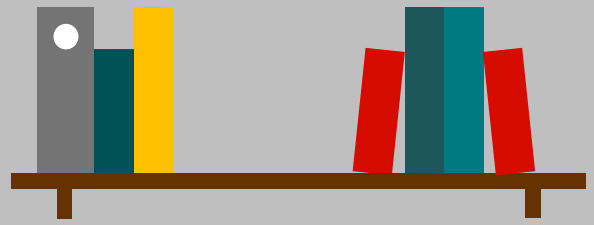
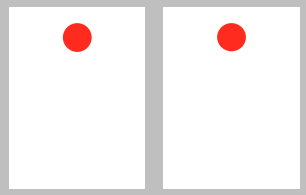
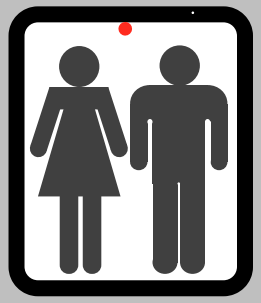
Welcome

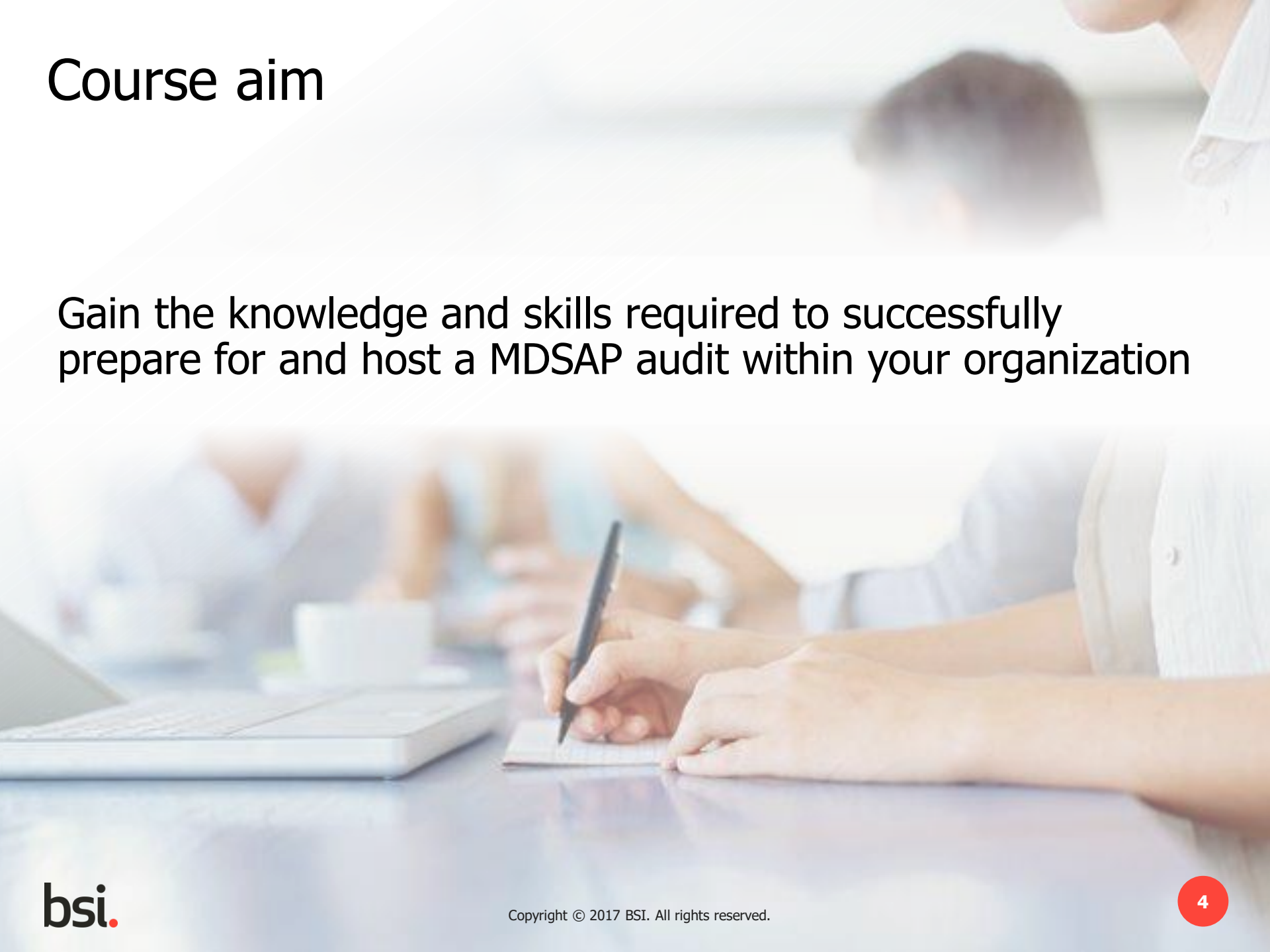




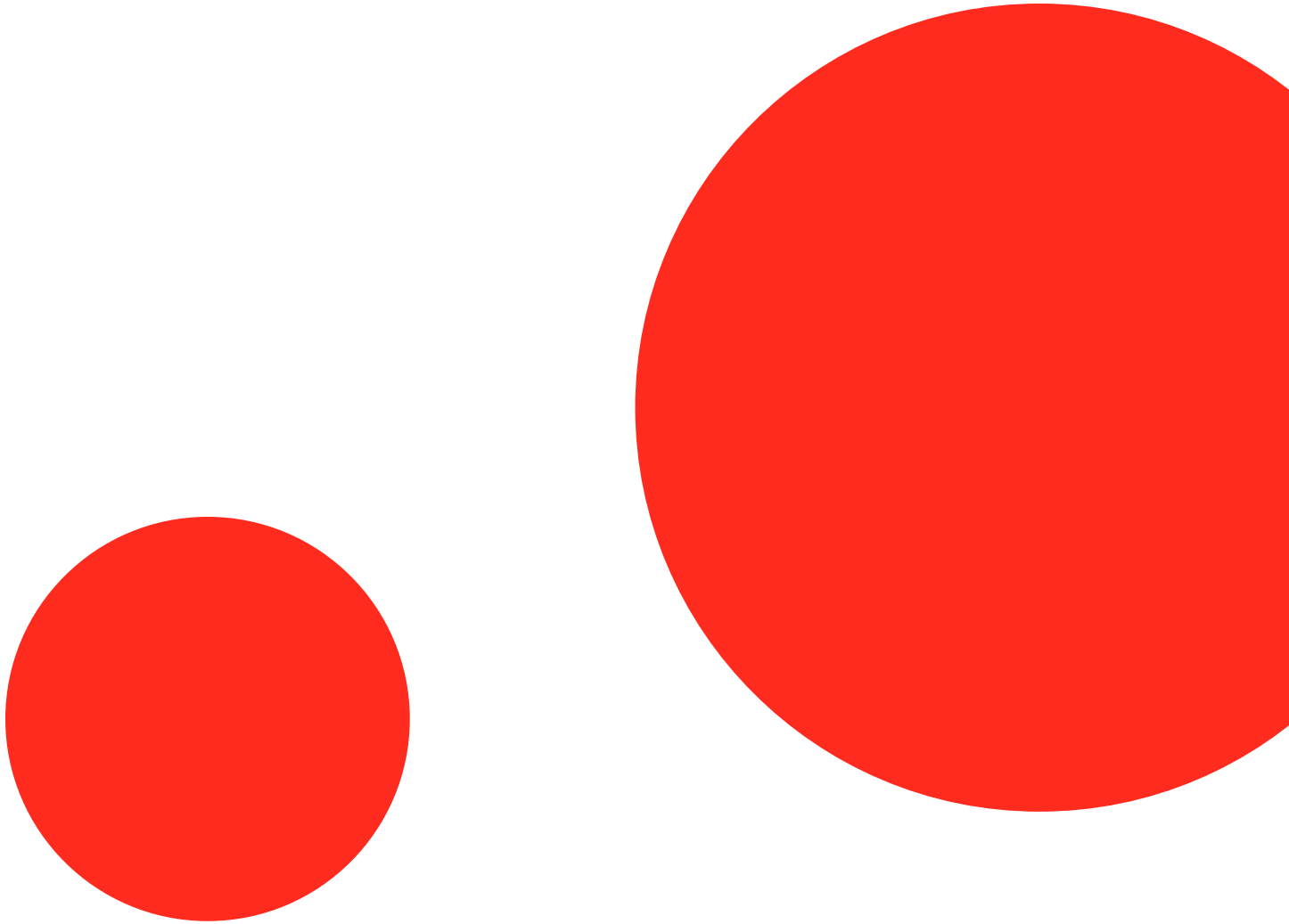


Course aim

Gain the knowledge and skills required to successfully prepare for and host a MDSAP audit within your organization



Fundamentals of MDSAP



MDSAP origin and objectives

Develop, manage and oversee a single audit program

Allowing a single regulatory audit to satisfy the needs of multiple regulatory jurisdictions

Promote greater alignment of regulatory approached and technical requirements

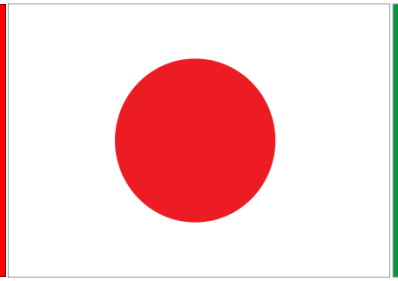
Promote consistency, and transparency of regulatory programs

MDSAP Regulatory requirements

ISO 13485:2016


Australia


Canada

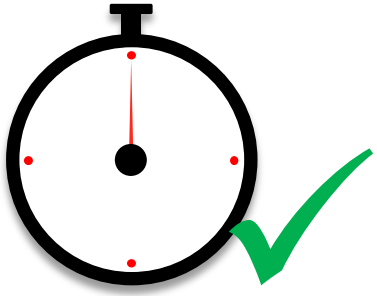

Japan


Brazil


USA

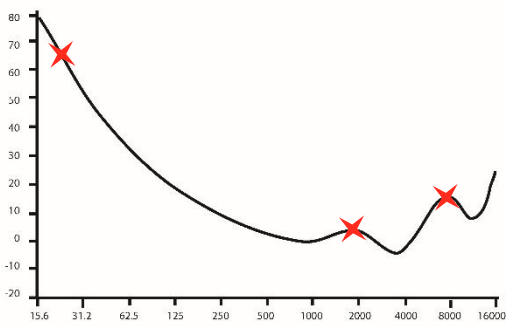
Manufacturer benefits in the MDSAP

No additional requirements for manufacturers

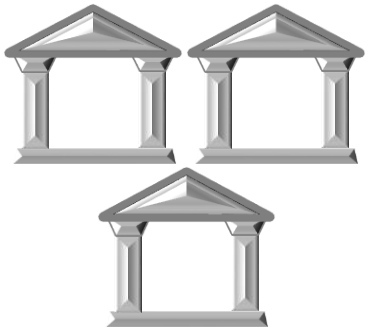


Single audit optimizes time and resources

Routine audits are scheduled/planned

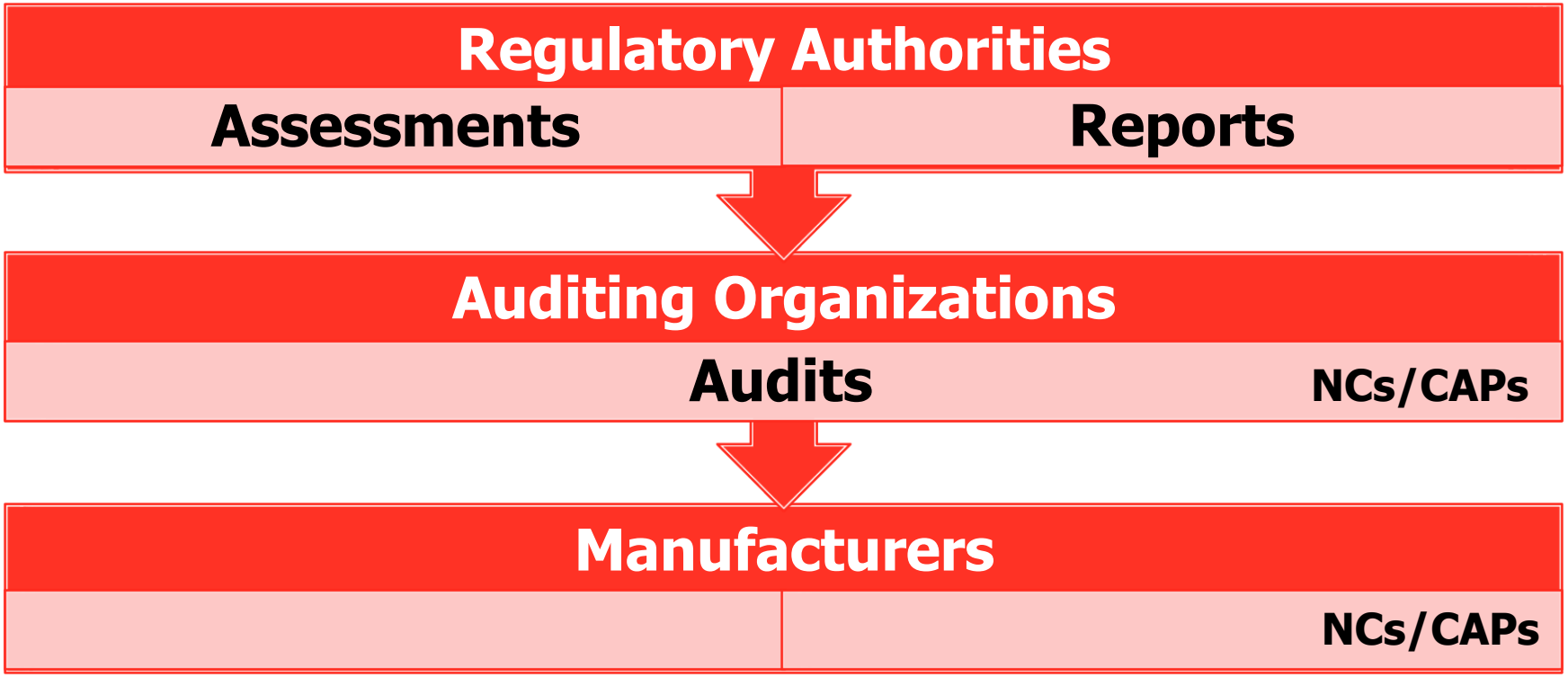


Expected to improve predictability

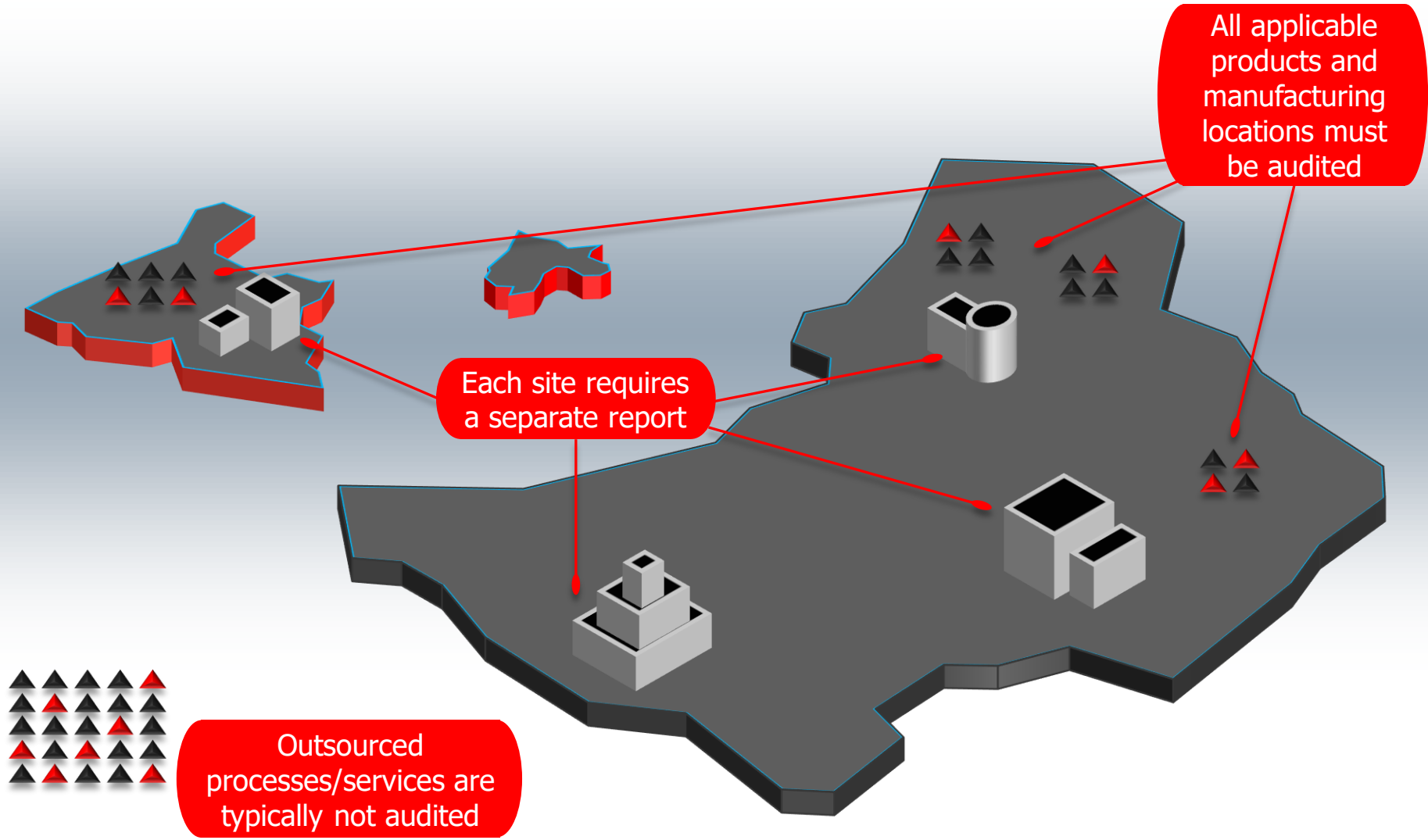


Expected to add additional RAs

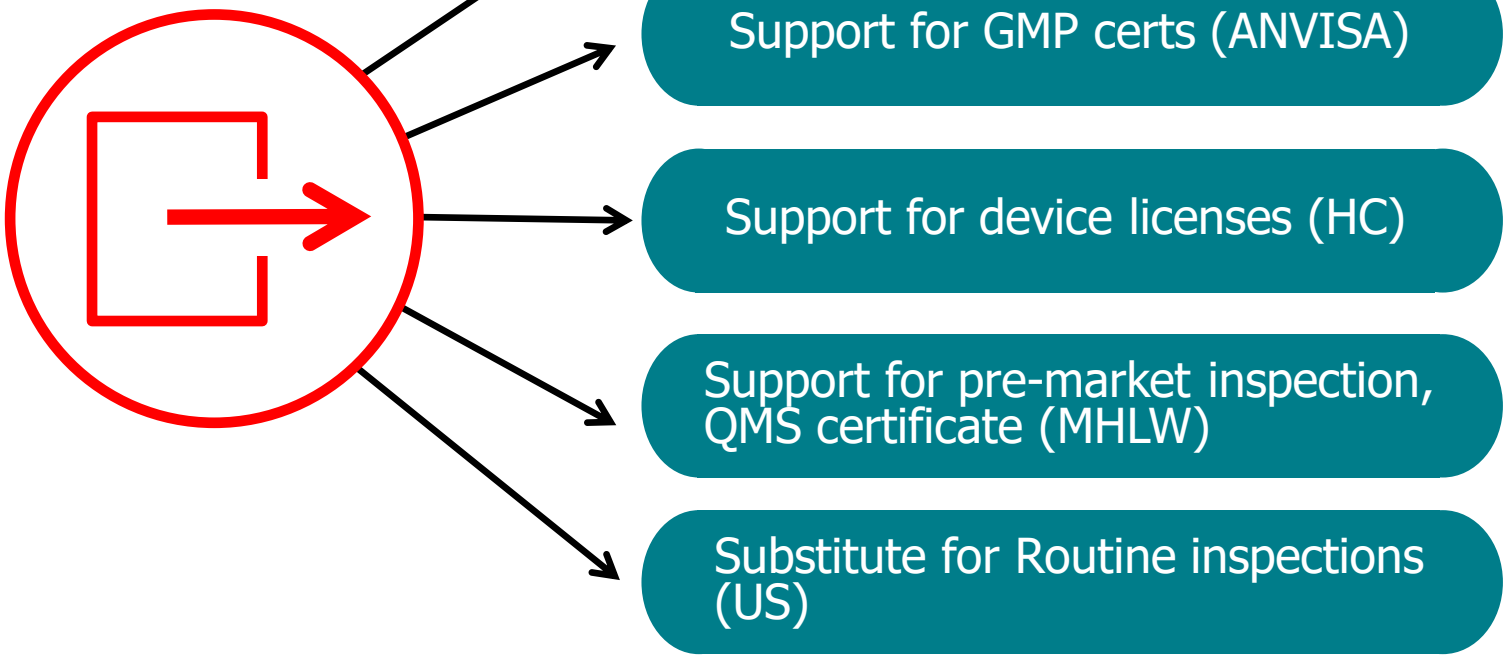
MDSAP structure



MDSAP requirements

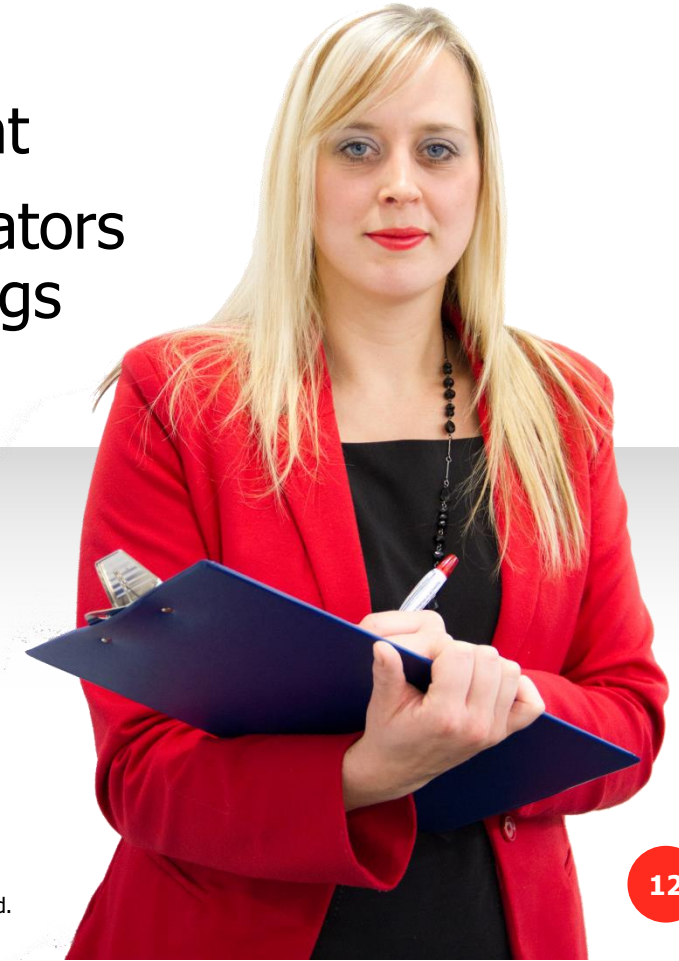


MDSAP outputs

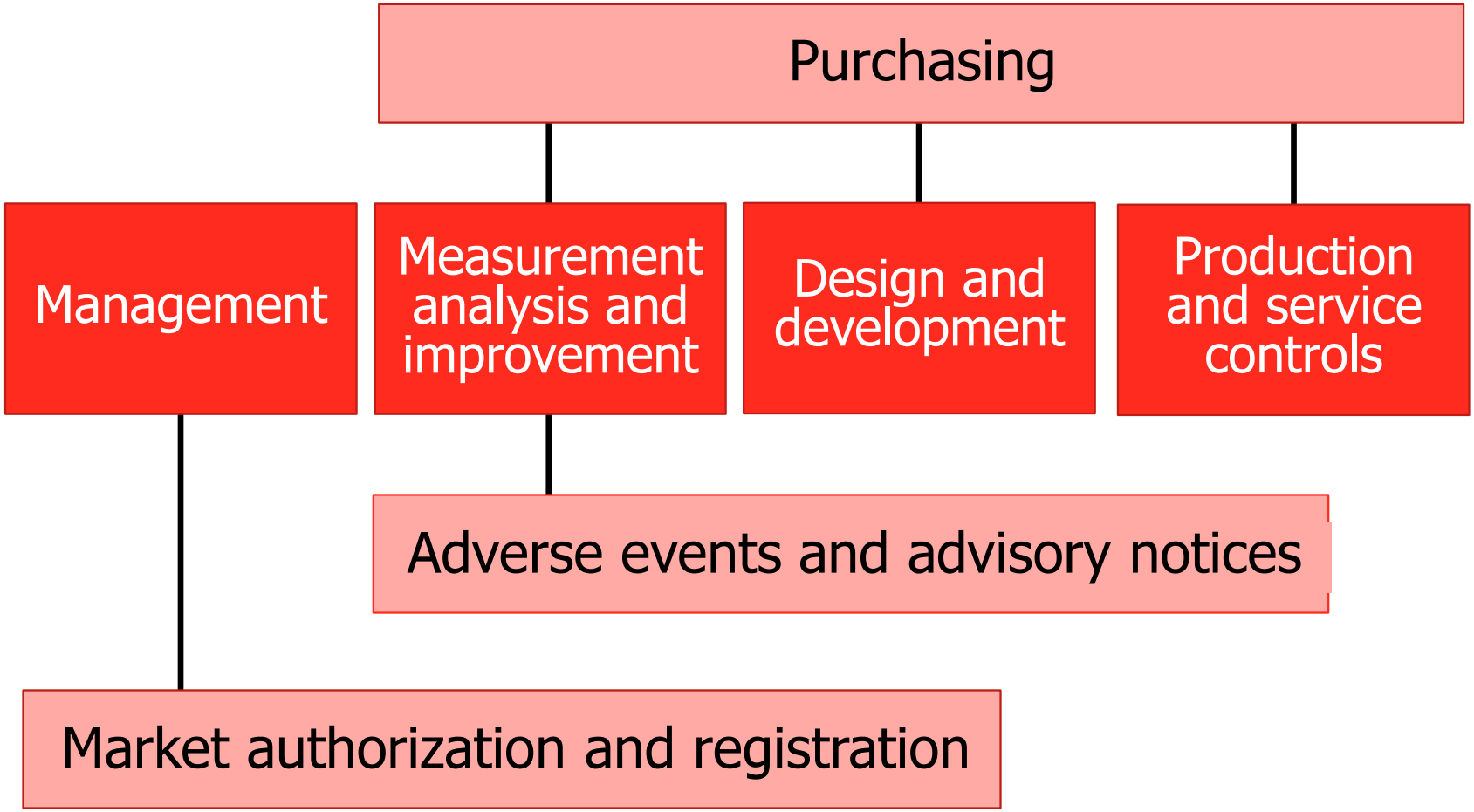


A MDSAP does not…

- Remove Product Approval Pathway requirement
- Have an unspecified duration
- Base on-site time on employee count
- Offer a way to avoid return of regulators to close out existing regulator findings



MDSAP audit processes



MDSAP process sequence and estimated durations

MDSAP Process	MDSAP Tasks per Process	Minutes per Audit Task
Management	11	28.8
Device marketing authorization and facility registration (DMA&FR)	3	28.0
Measurement analysis and improvement (MA&I)	16	30.4
Medical devices adverse events and advisory Notice Reporting (MDAE&ANR)	2	30.4
Design and development (D&D)	17	16.8
Production and servicing controls (P&SC)	29	35.2
Purchasing	12	12.0

Regulatory audit approach

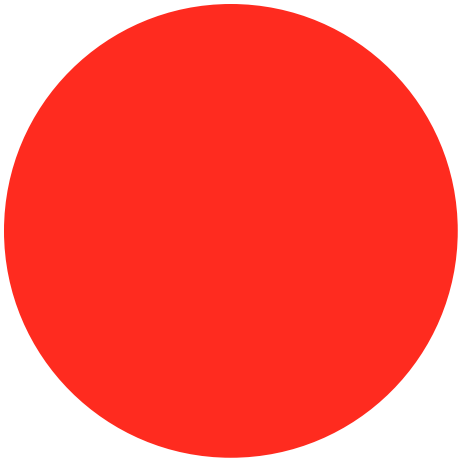
- Conforming devices and do not pose a threat to public health
- All products/processes in 3 year cycle
- Risk assessment consideration for evaluation and selection during audit
- Stage 1 is for 'discovery', Stage 2 is for 'substantiation'

Nonconformity grading

QMS Impact	**Direct** (6.4 thru 8.5)	**3**	**4**	**Absence of process or procedure**	**+1**
	Indirect (4.1 thru 6.3)	**1**	**2**	**Led to nonconforming devices on market**	**+1**
		First	**Repeat**		
		Occurrence		**Escalation criteria**	

MDSAP and other QMS audits

- MDSAP and auditing in the medical device industry
- ISO 13485 and ISO 14971



Summary of program distinctions

Criteria	ISO 13485	MDSAP
Program Customer	Manufacturer	Regulator
Output of success	Certificate	Report and Certificate
Auditing Organizations Qualification	Competent Body	Regulators
Nonconformance grading	Major/Minor	1, 2, 3, 4, 5
Scheduled Assessments	Yes	Yes + unannounced follow ups

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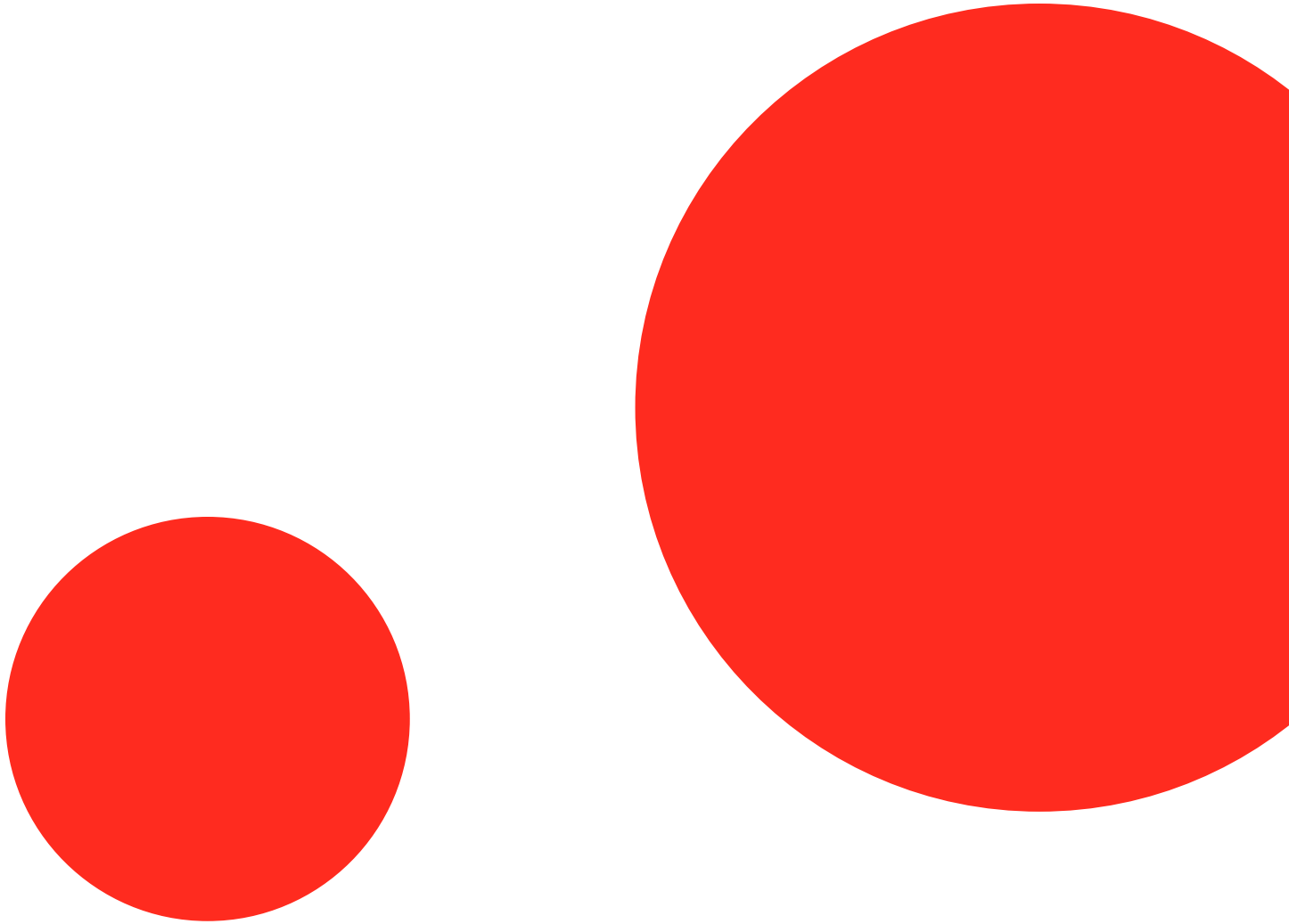
Auditing in the medical device industry

Scope of the audit is usually not only ISO 13485, but also includes regulatory requirements

Requirements other than ISO 13485 need to be covered in the audit

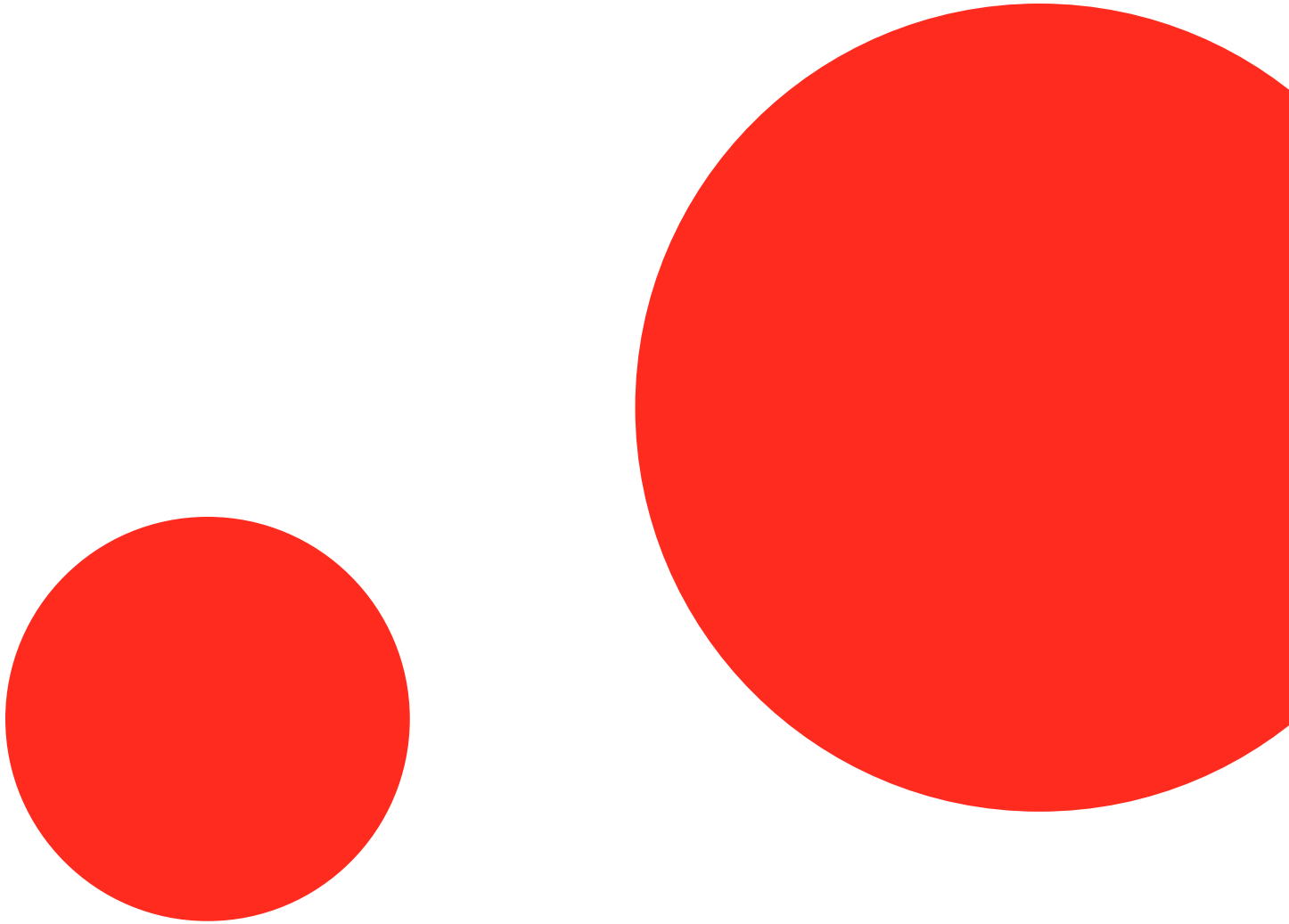
MDSAP documents



MDSAP documents (from the website)

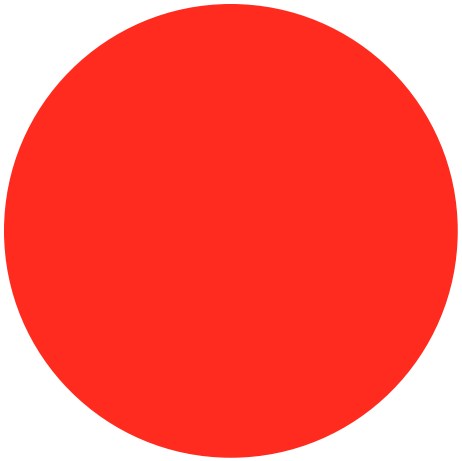
Click here for MDSAP FDA-hosted website

MDSAP Chapter



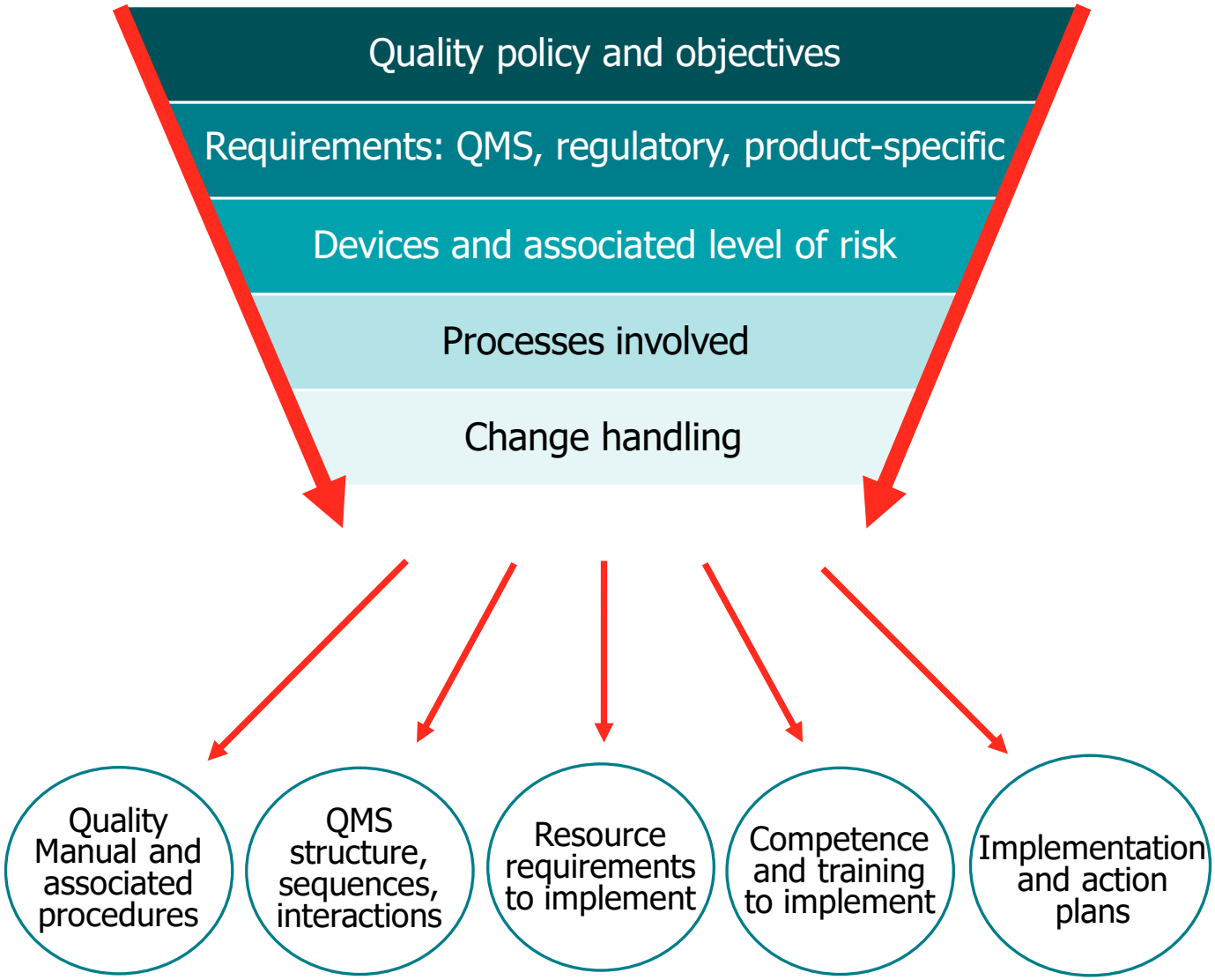
Management process

- Top management

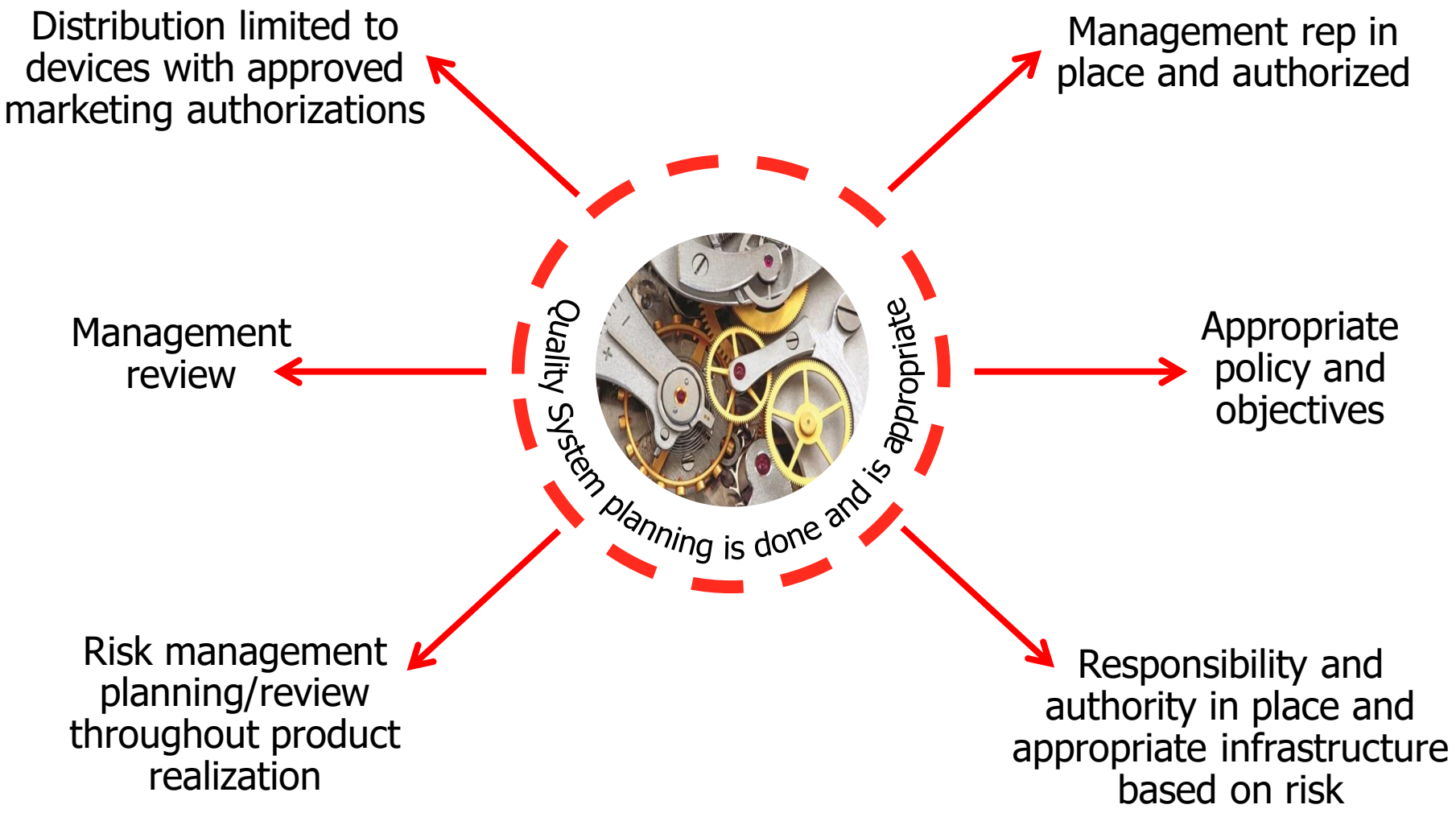


Purpose and outcomes: Management process

QMS planning



Top management



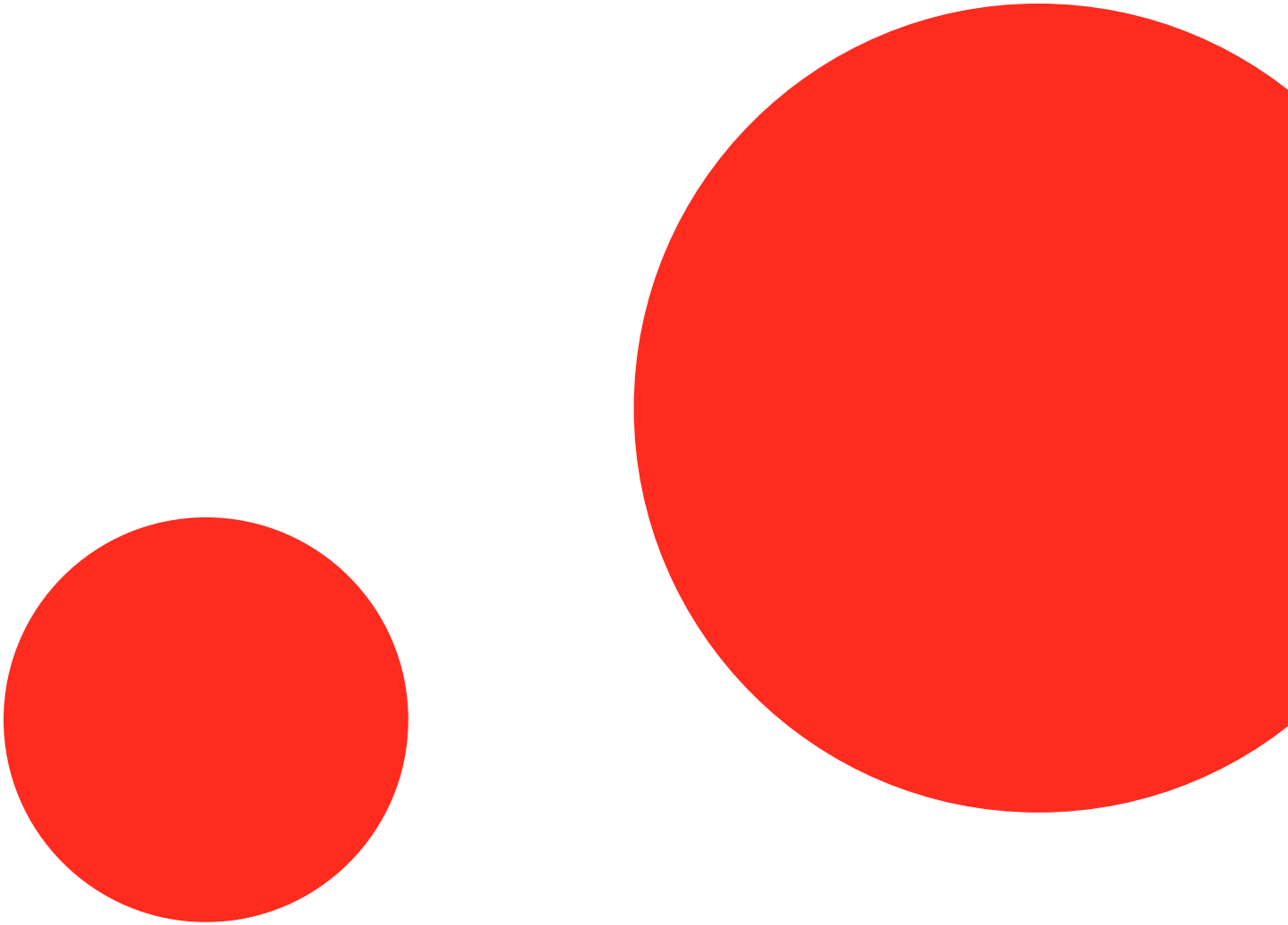
Sample Jurisdictional additions to ISO 13485 in management process

Outsourcing defined with appropriate controls (TGA, HC)

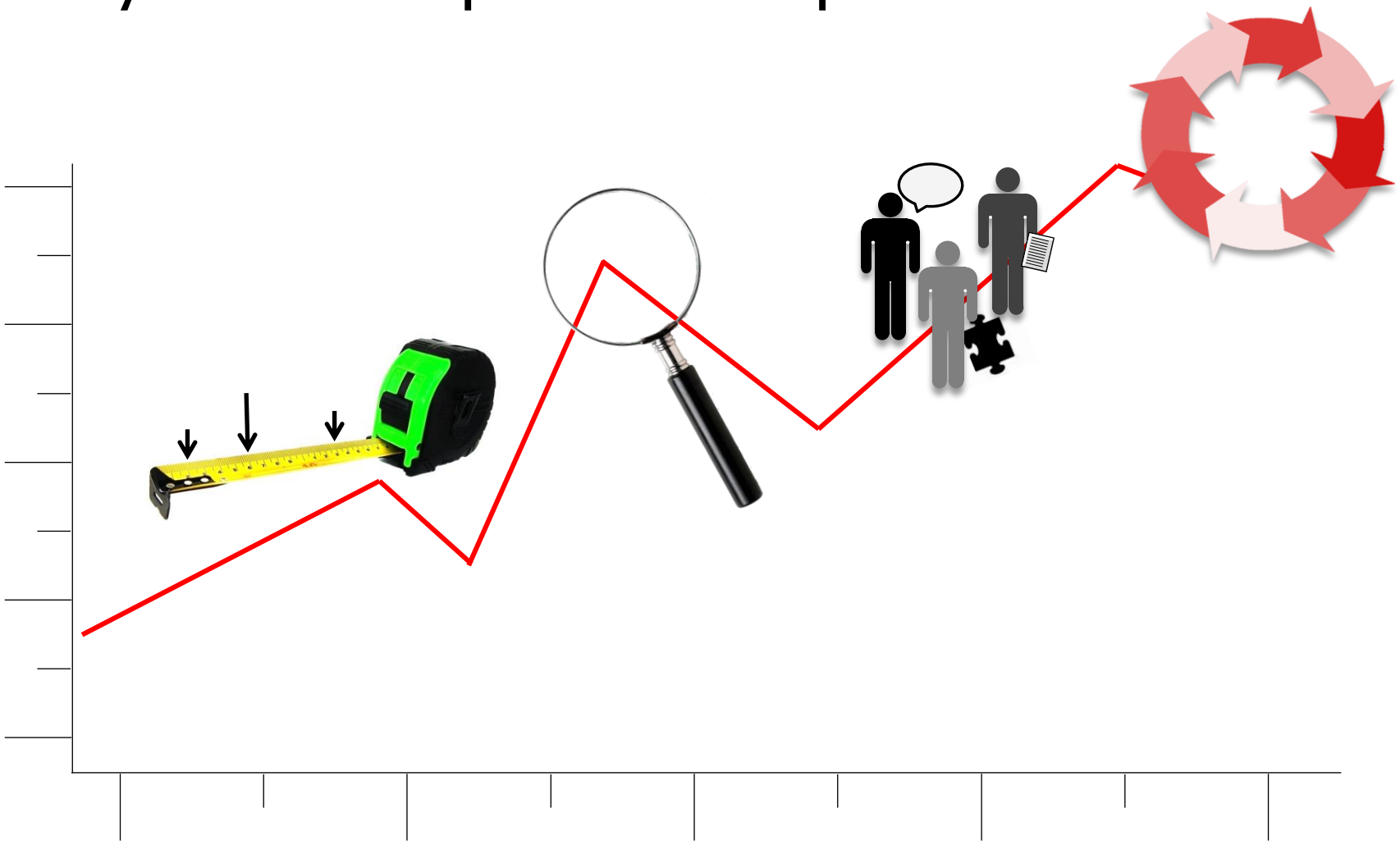
Document and record control includes external and record retention (TGA, ANVISA, MHLW, FDA)

Competence assessment (ANVISA)

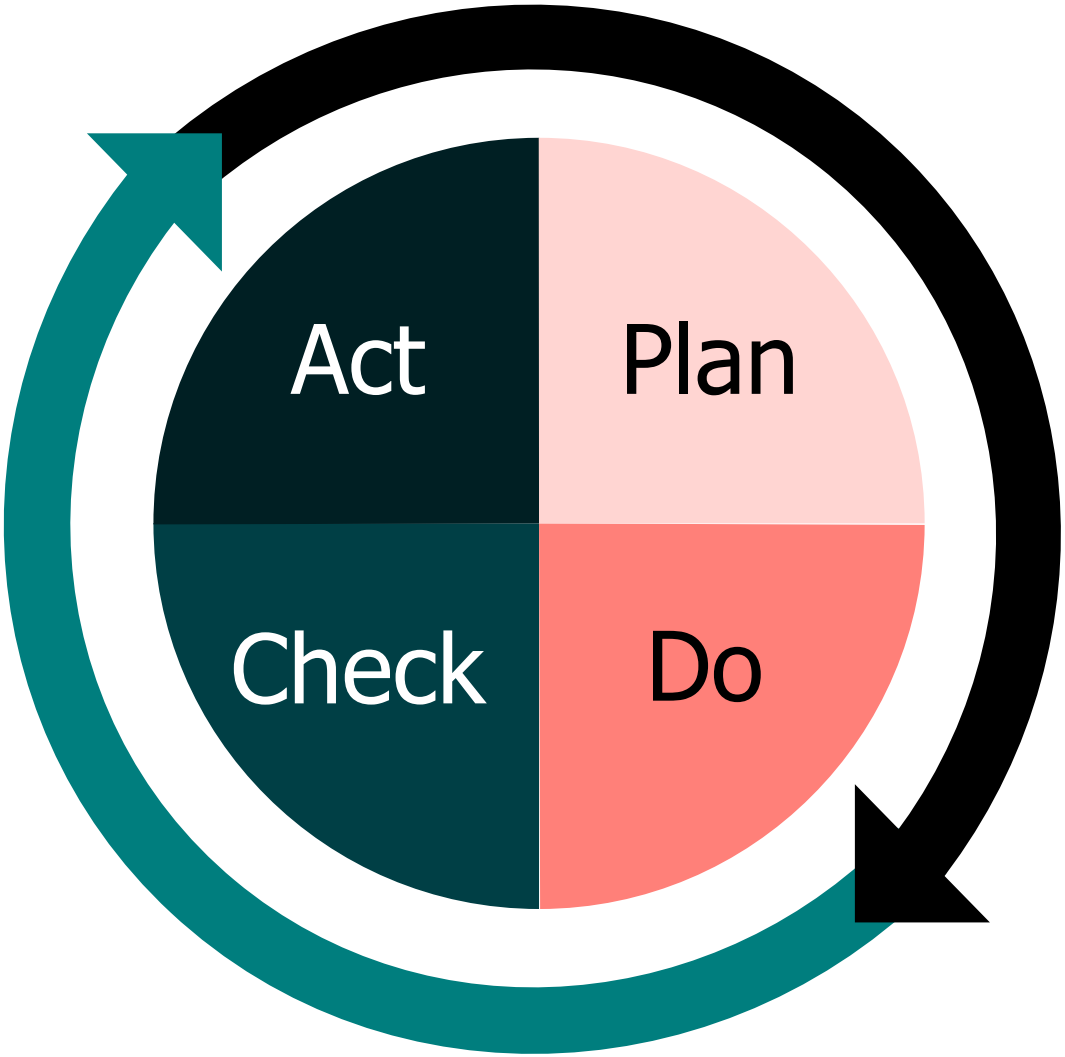
Measurement, analysis and improvement process



Purpose and outcomes: Measurement, analysis and improvement process

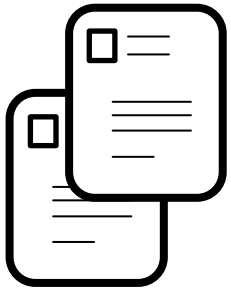


Analysis of data

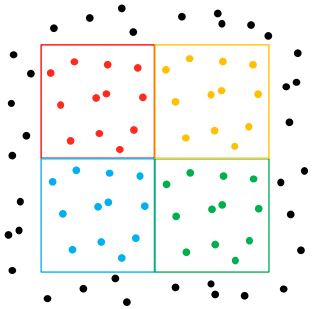


Control of nonconforming product

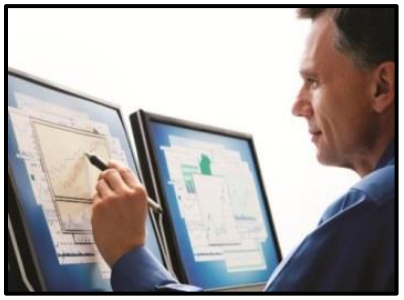
Identification



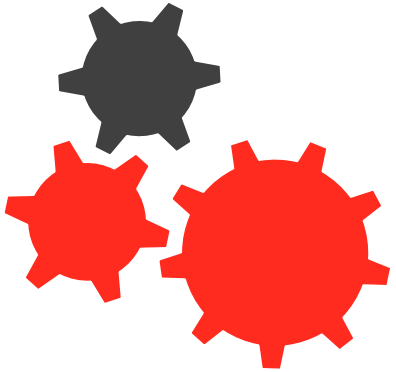
Documentation



Segregation

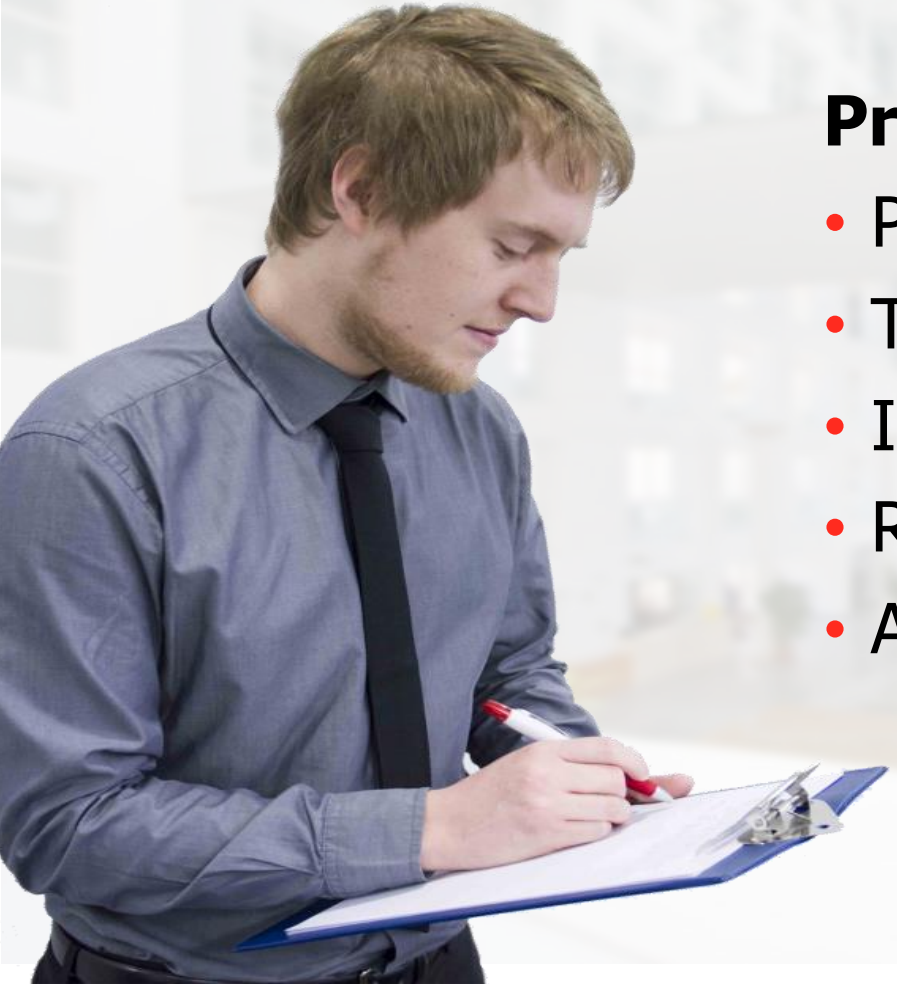


Evaluation



Disposition

Internal audits



Procedure should address:

- Planned (defined intervals)
- Trained auditors
- Independence
- Reporting
- Addressing of findings

Sample Jurisdictional additions to ISO 13485 in measurement, analysis and improvement process

Analysis of data

Primarily ISO 13485

- Communication of problem (ANVISA and FDA)
- Process changes notifications (TGA, HC, MHLW)

Nonconforming product

ISO 13485 requirements

Internal audit

ISO 13485 requirements

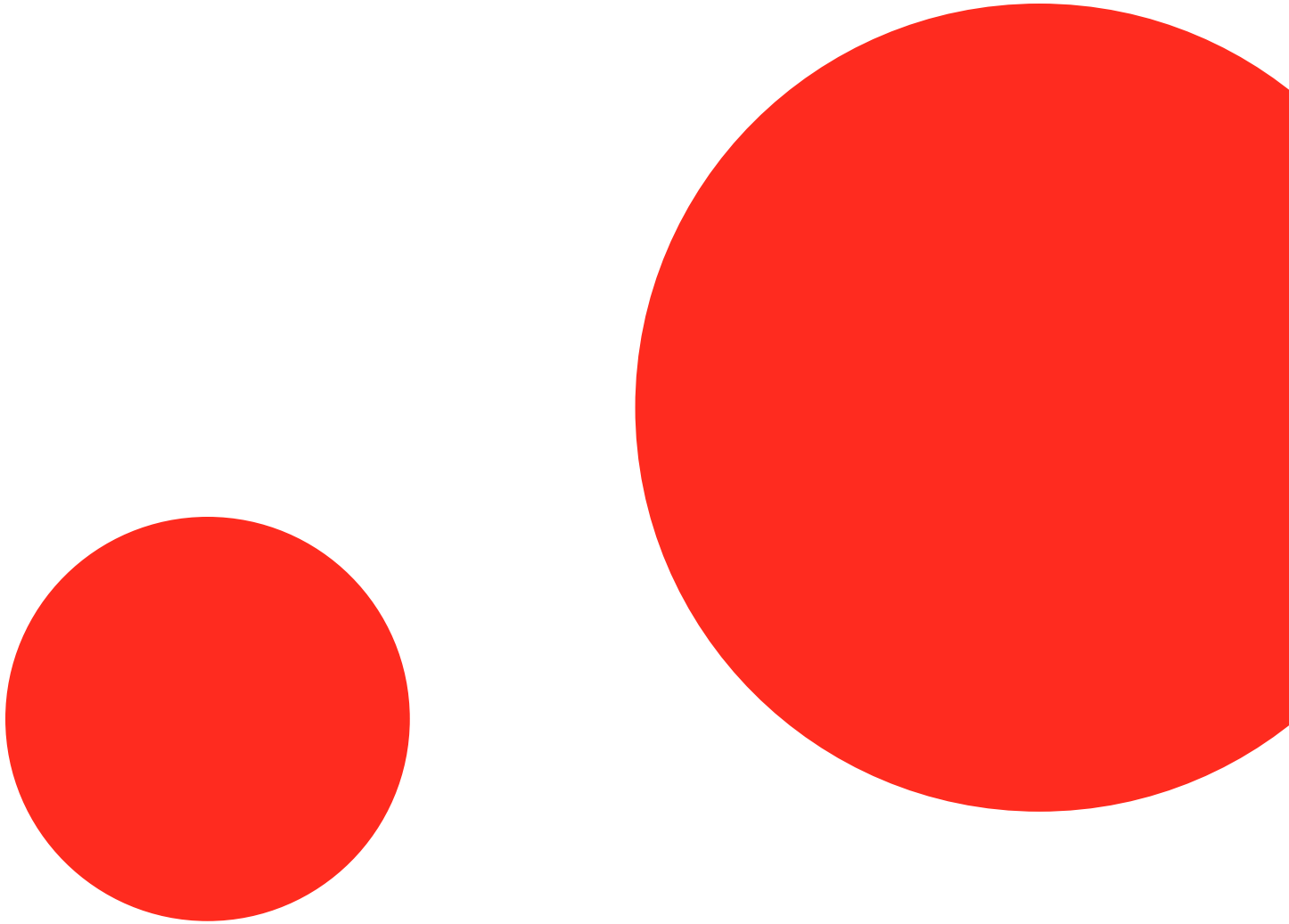
Feedback from the Post production phase

ISO 13485 requirements

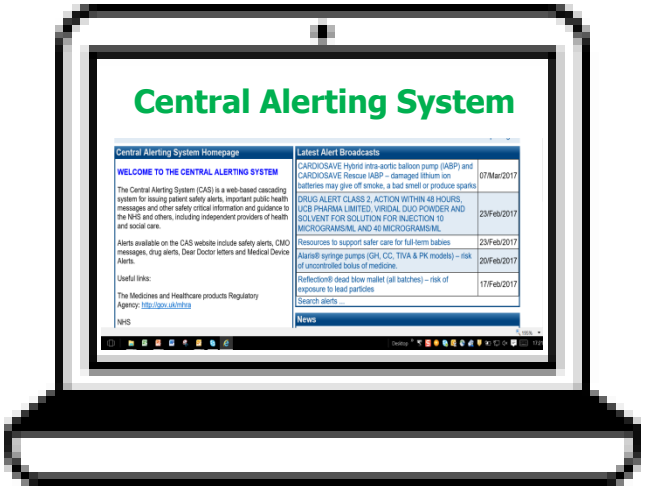
- **TGA**
- **ANVISA**
- **HC**
- **MHLW/PMDA**
- **FDA**

*See notes below

Design and development process



Purpose and outcomes: Design and development process



Design control and device classification

The extent of controls to be applied depends on the classification of the device in each jurisdiction.

Jurisdiction	Controls applied
Australia	Extent depends on conformity assessment route. All devices must comply with *Essential Principles of Safety and Effectiveness*.
Brazil	No exception to design controls. If outsourced manufacturer must have copy of DMR and records to design transfer.
Canada	Many Class II devices are not subject to D&D controls. Class II, III and IV verify that there is objective evidence of compliance to safety and effectiveness requirements.
Japan	Class I devices are not required to comply with D&D controls.
US	All Class II and III and selected Class I devices are subject to design controls.

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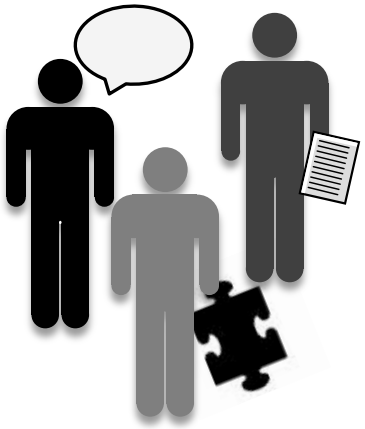
Risk management focus

An effective risk management process involves:

1. Proactive evaluation
2. Control and monitoring of product risk
3. Reactive measures in response to quality data



Understanding all aspects of risk is an important input to the device design. Information related (but not limited) to:

- Previous devices on the market
- Device use
- Distribution
- Production
- Materials of construction

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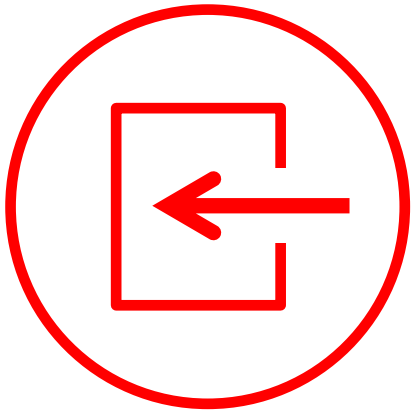
Sample Jurisdictional additions to ISO 13485 in design and development process

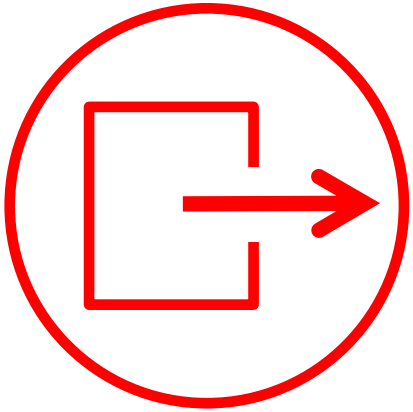
Design planning

(TGA ad HC: Quality plan)



Design inputs

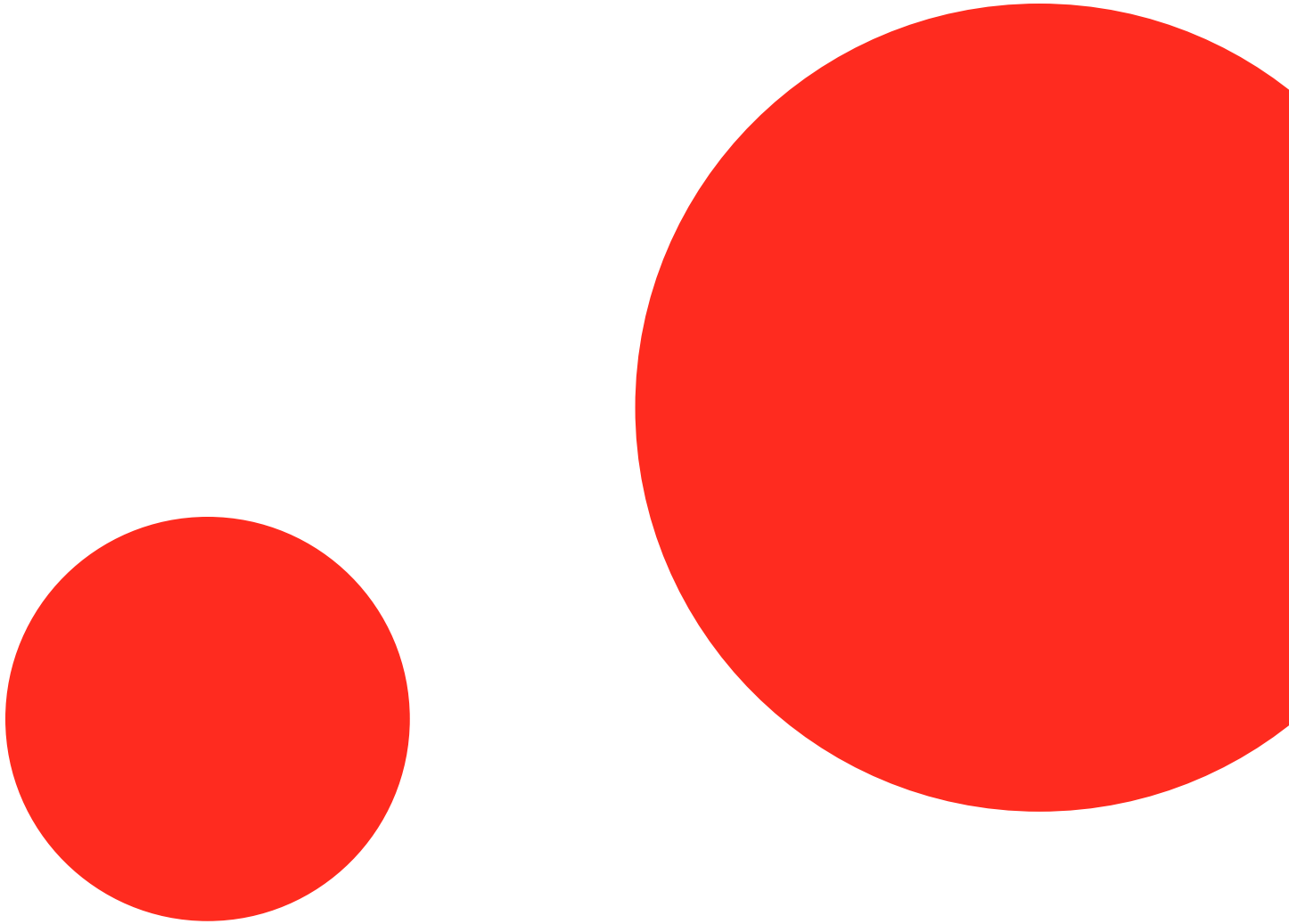
(TAG and US: ER and mechanism for address ambiguous)



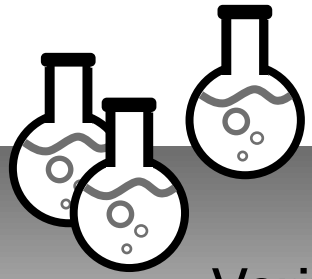
Design outputs

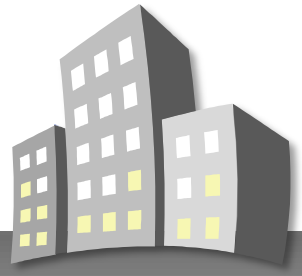
(TGA: state of the art standard)

Production and service controls process

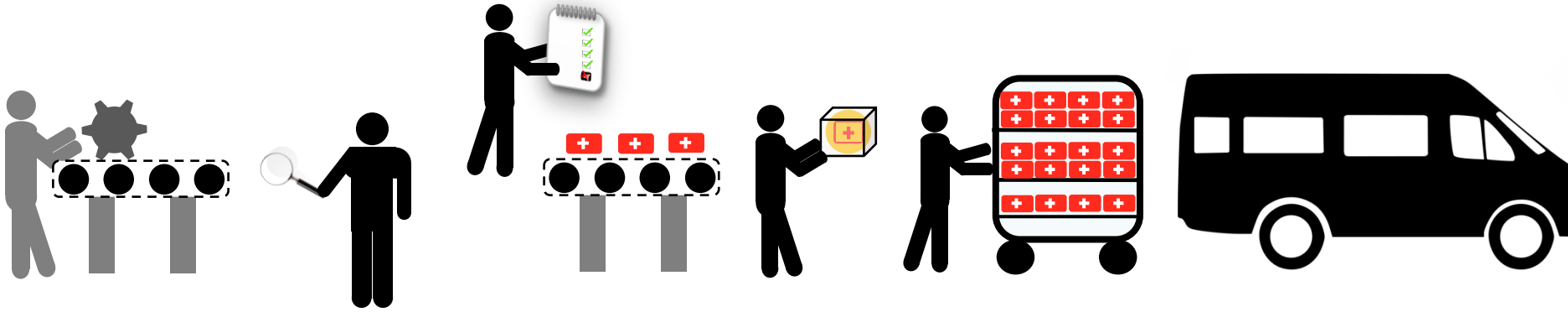


Purpose and outcomes: Production and service controls (P&SC) process





Verify processes including **testing**, **infrastructure**, **facilities**, **equipment**, and **servicing** have the ability to ensure products will meet specifications



Considerations for the audit of P&SC

- Corrective and preventive action indicators
- Production processes for higher risk products
- Essential reviews of production processes
- New processes or technologies employed
- Processes that are used for multiple products
- Processes that operate over multiple shifts
- Processes not covered in previous audit

Considerations for the audit of P&SC

- Availability of information describing the product
- Documentation
- Use of suitable equipment
- Availability and use of M&M devices
- Implementation of M&M during production
- Release, delivery and post-delivery implementation
- Defined labeling and packaging operations
- Change management requirements

Sample Jurisdictional additions to ISO 13485 in production and service controls process

Part of P&SC	Jurisdiction	Topic
Planning	US	Unique Device Identifier (UDI)
	Brazil	• Product cleanliness • Facility configuration • Biosafety standards
Process implementation	• US and Brazil • Australia	• Review of need for validation • Validation methods are per state of the art
Device master file	• Brazil • Canada • US and Canada	• Procedures for labeling • Language requirements (F&E) • Traceability in distribution

Sample Jurisdictional additions to ISO 13485 in production and service controls process

Part of P&SC	Jurisdiction	Topic
Records	Brazil	Device History Record (DHR)
Labeling	Brazil and US	Labeling controls
Implants	• Canada • US	• Implant cards • Tracking system
Acceptance activities	Brazil and US	Sampling methods
Customer requirements	Brazil, Canada and US	Distribution records
Servicing	• Brazil • Brazil and US • US	• Procedures • Analysis of reports • UDI

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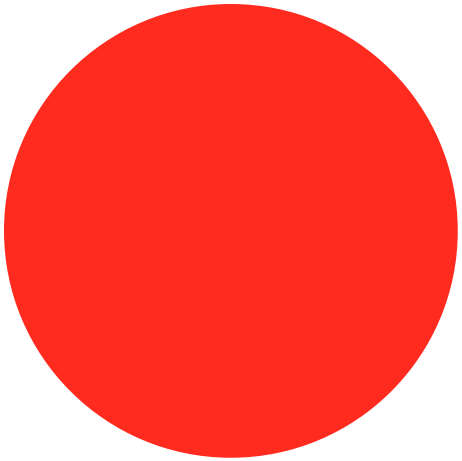
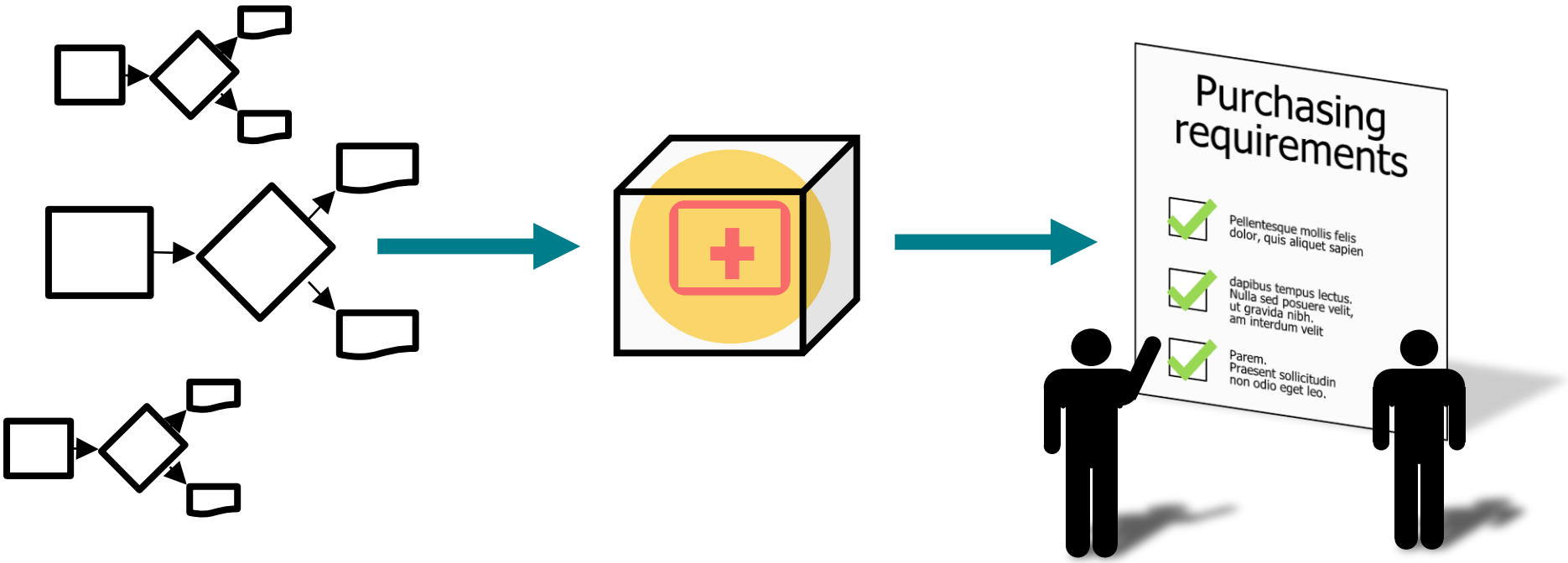
Purchasing process



Purpose and outcomes: Purchasing process



Manufacturer's processes ensure that products are in conformance with specified purchase requirements

Purchasing control considerations

Planning

Design and development

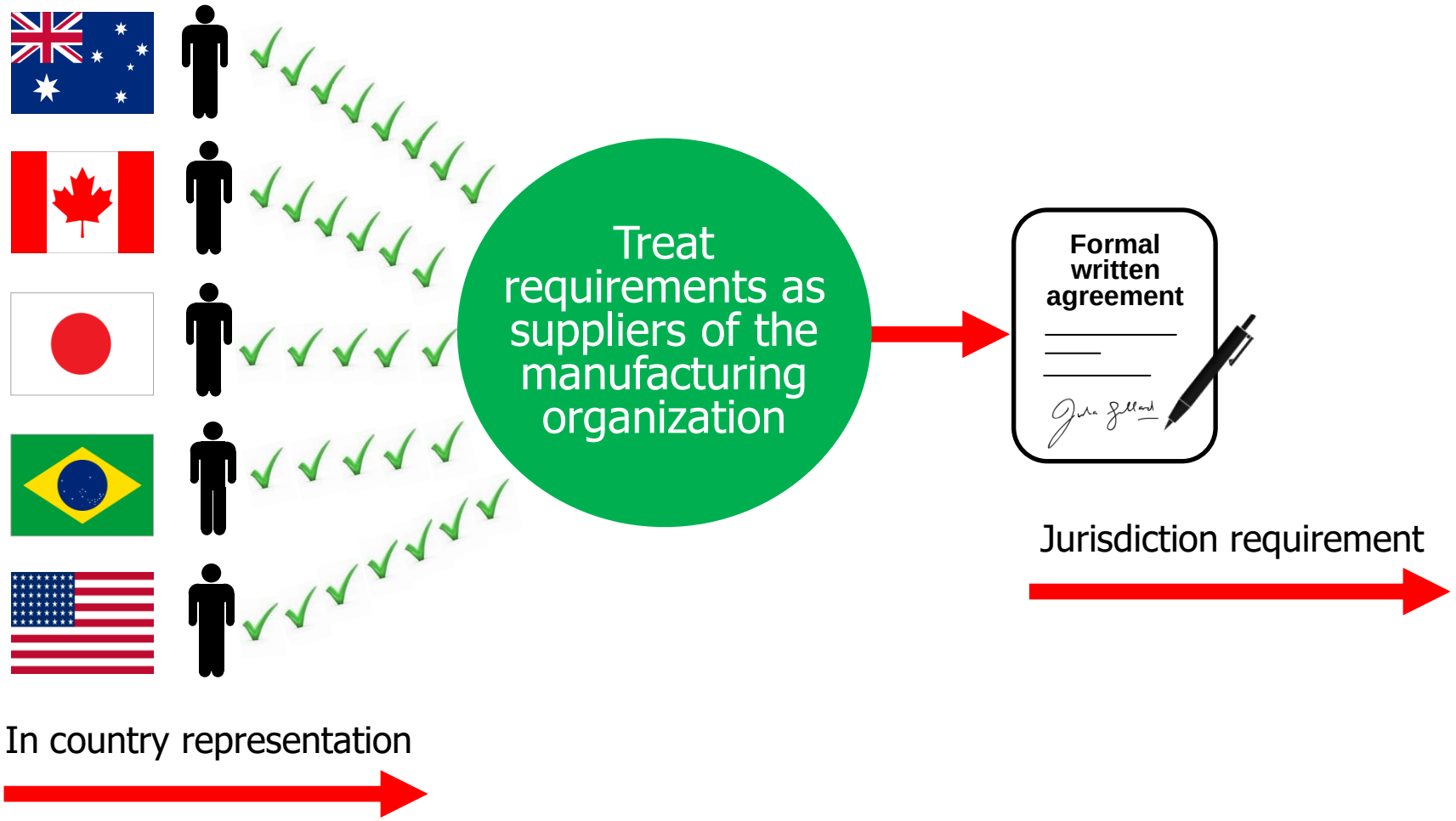
- Components
- Processes (internal and external)
- Distribution
  - HQ vs regional entities

Determination of controls

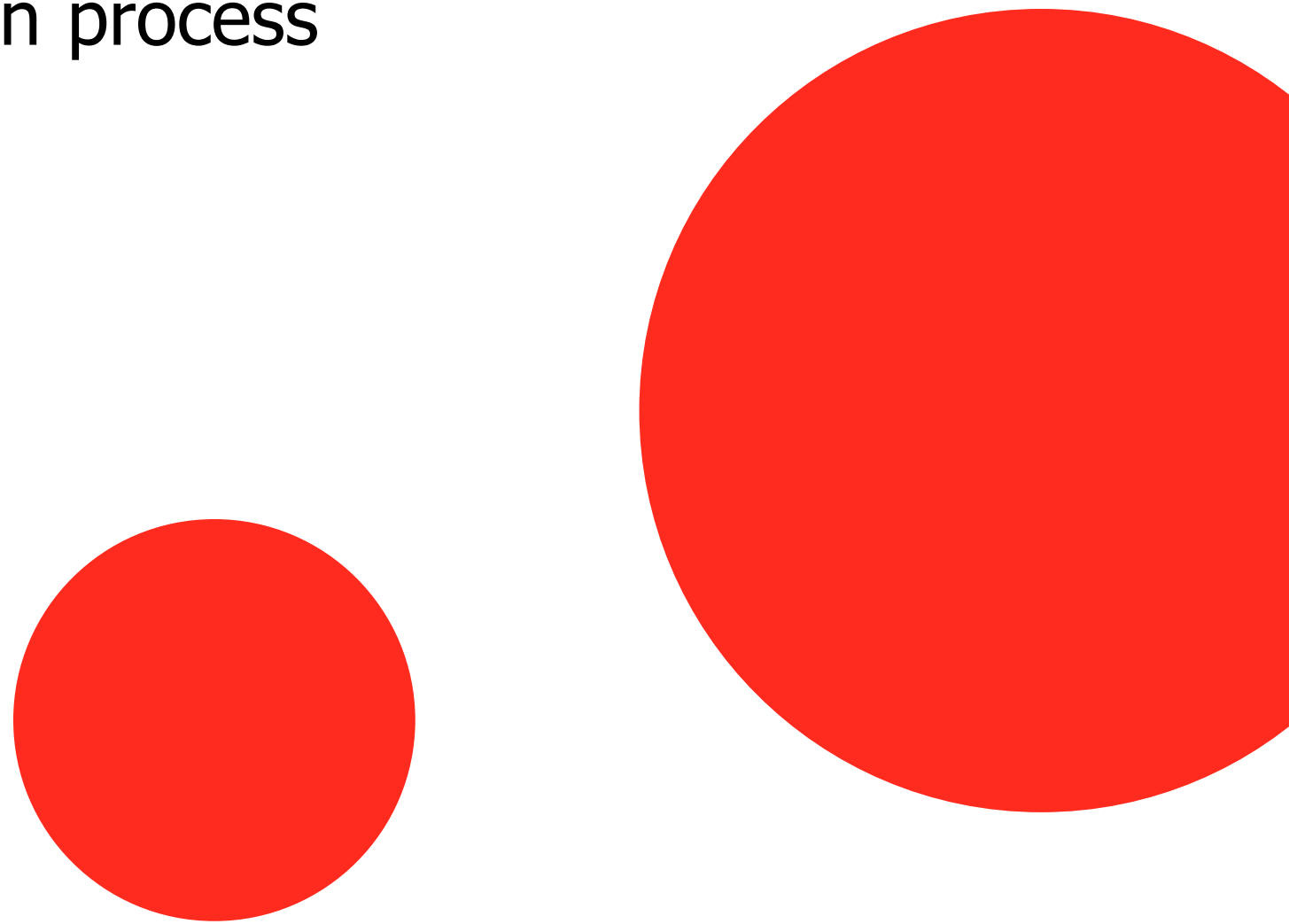
Risk management of supply to be purchased

- Ability to supply
- Ability to perform
- Effect on finished device quality

Sample Jurisdictional additions to ISO 13485 in purchasing process

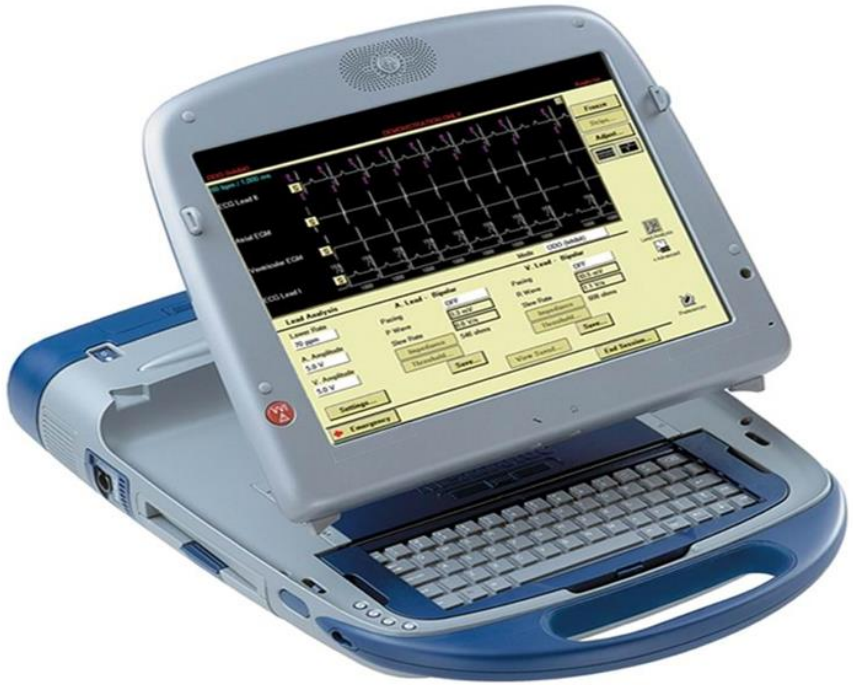


Device marketing authorization and facility registration process



Purpose and outcomes: Device marketing authorization and facility registration process

Activities with regulatory authorities participating in MDSAP:

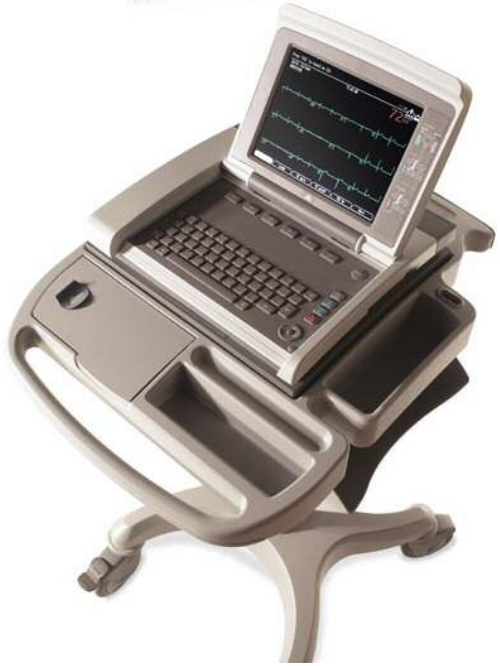


- ✓ Device marketing authorization
- ✓ Facility registration with regulatory authorities

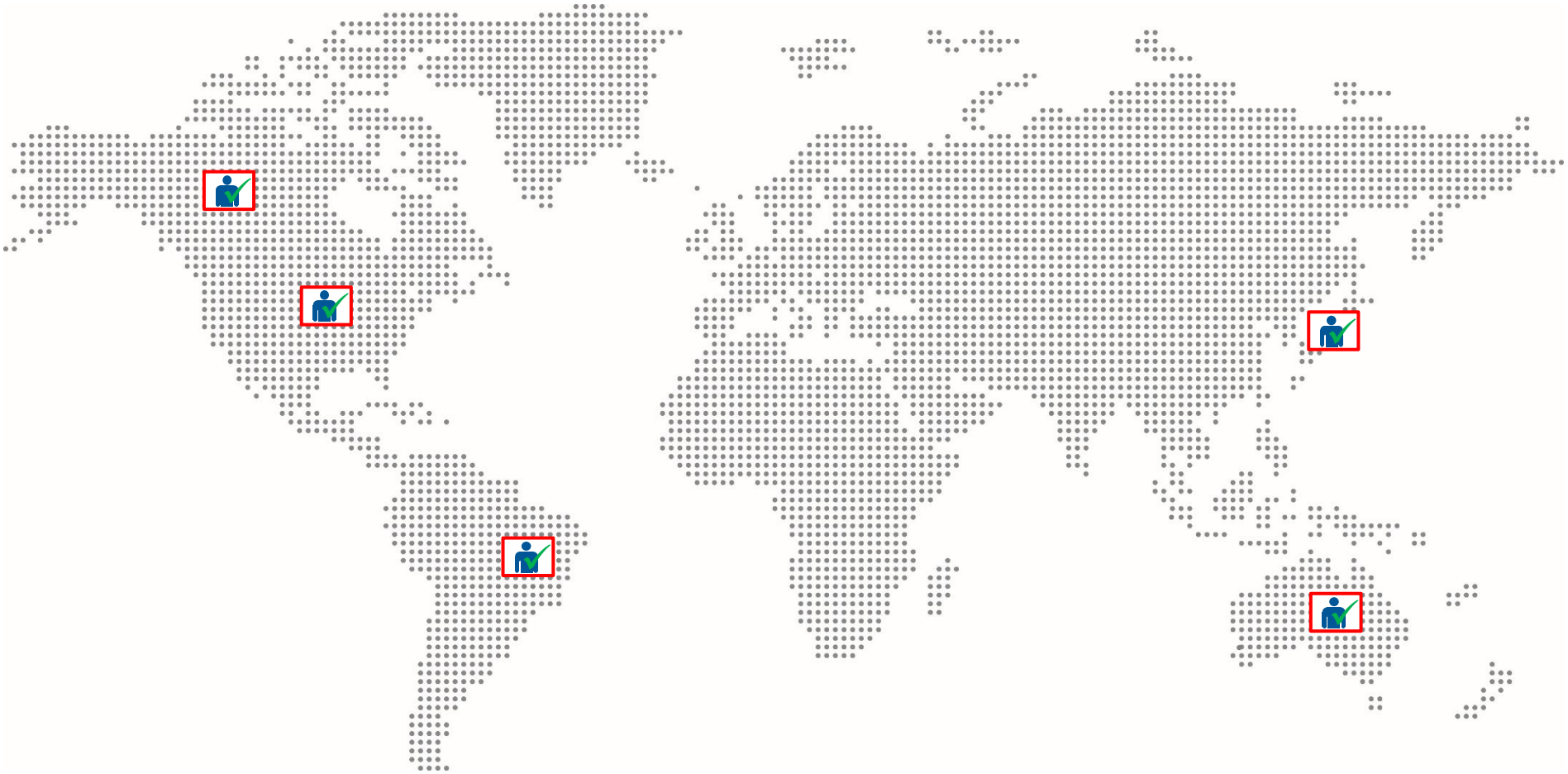
Device market authorization

Device approval

Licensing and listing



Facility registration



Change notification considerations

	Australia	Brazil	Canada	Japan	US
Who to contact	Assessment body	ANVISA	HC	PMDA	FDA
When to contact					
• Change to QMS	Yes	Yes	Yes	-	-
• Change to type of devices	Yes	-	Yes	-	Yes
• Proposed change to design of high class devices	Yes	-	Yes	Yes	Yes
• Manufacturing method	-	Yes	-	Yes	Yes
• Identification of device, manufacture site	-	Yes	-	Yes	Yes
• Indication for use	-	Yes	-	Yes	Yes
• Technical specification	-	Yes	-	Yes	Yes
Special considerations					
• Annual reporting			Yes		Yes
• Withdrawal, 30 days			Yes		Yes

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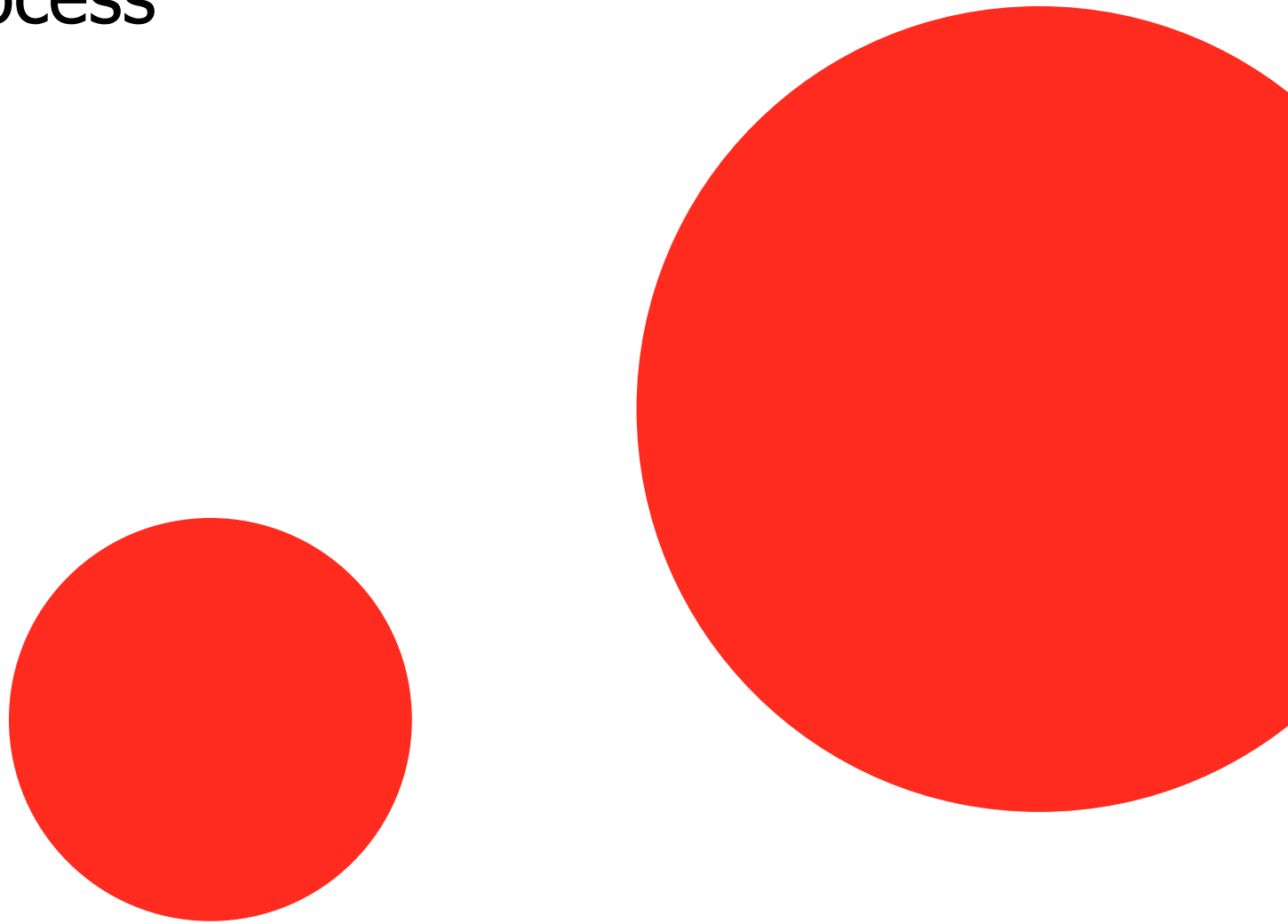
Medical device adverse events and advisory notices process



Purpose and outcomes: Medical device adverse events and advisory notices process

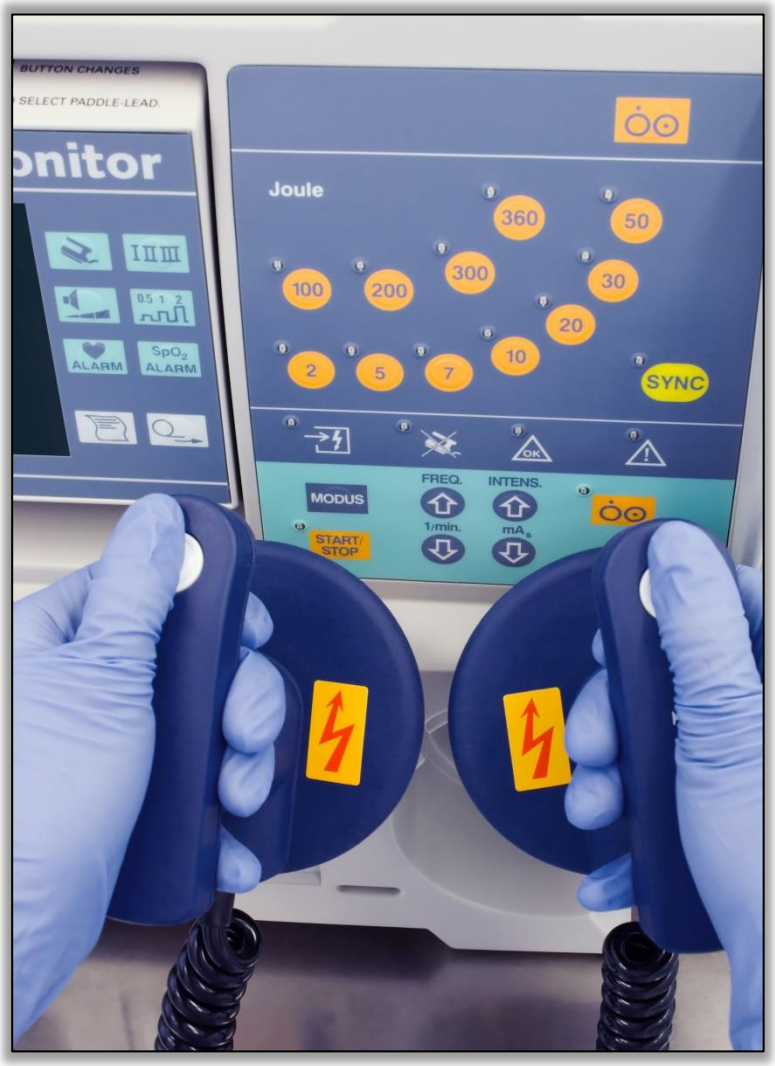
Terms used within the Jurisdictions

Adverse Events

- Complaints
- Serious threat to public health
- Serious injury and death
- Likely to lead to (above) if recurs
- Malfunction

Advisory Notices

- Recalls, corrections, device recovery
- Market withdrawals, removals
- Field actions

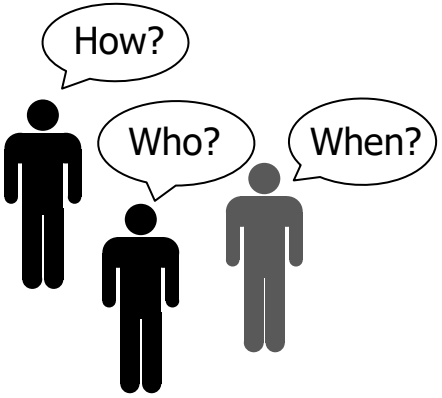


Adverse event reporting: General requirements of all jurisdictions

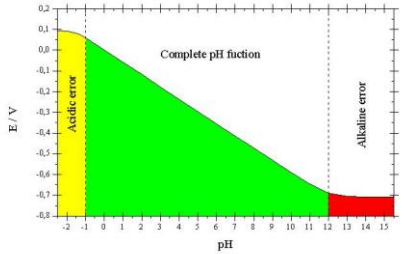
1. Post market information system in place

2. Reports of adverse events

3. Details of records to be kept

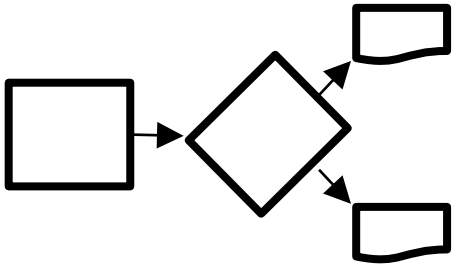


4. How, who and when to report and follow-ups



5. Annual reporting, as applicable (TGA)

Advisory notice reporting: General requirements of all jurisdictions



1. Procedures assure the plan for the process is fulfilled

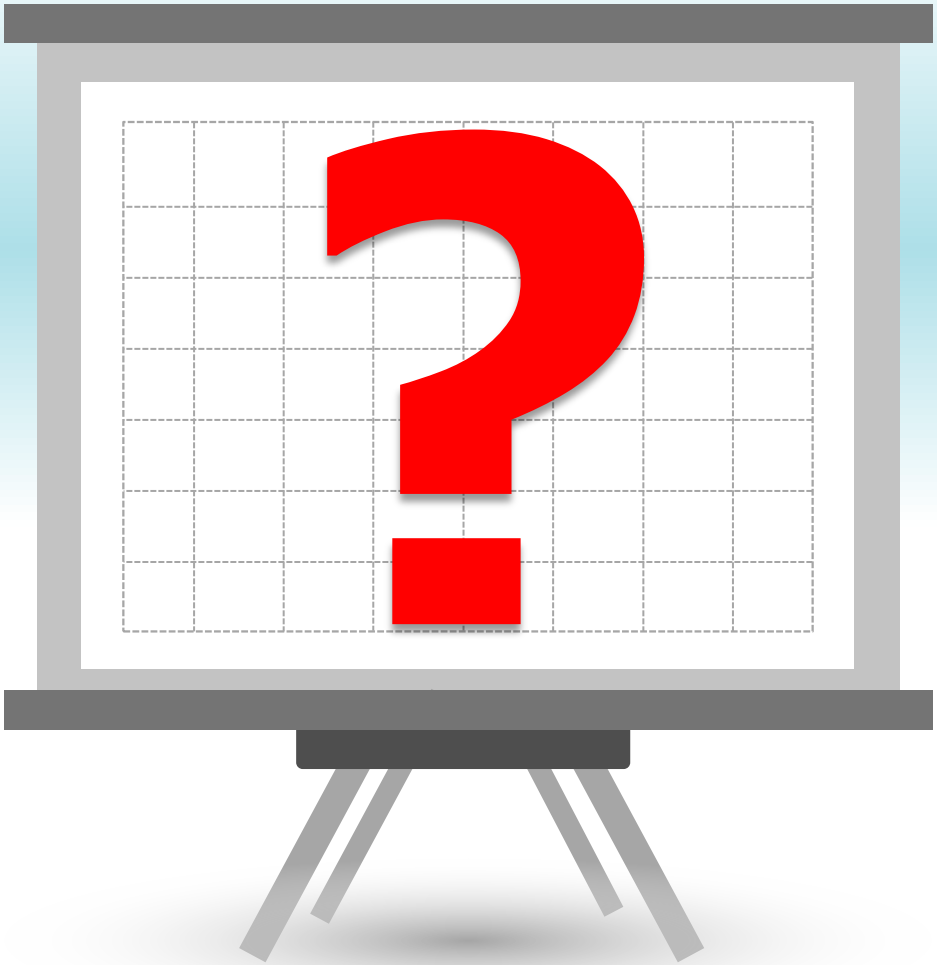
2. Records of how reporting decisions made

3. Verify appropriate notifications were made

4. Reports to regulators include various information

5. Jurisdictional reporting requirements

Course review and final questions



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