Overview of MDSAP

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Course Objectives

- Designed to train & qualify applicable staff on relevant MDSAP requirements.
- Highlights significant MDSAP requirements
- Helps you plan and carry out QMS changes so that your company can demonstrate it addresses MDSAP compliance requirements.

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Overview of MDSAP

- Background
- Participants and Observers
- Players and Roles
- Audit Criteria
- Audit Model
- Nonconformity Grading
- Timeline
- Audit Logistics

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Overview of MDSAP (con'd)

- Summary of MDSAP Differences
- What Happens to CMDCAS?
- Where is MDSAP accepted?
- Where is MDSAP not?

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Background

- Nov 2012: Statement of Coop for single audit program signed by ANVISA, FDA, HC, TGA.
- Mar 2013: Accelerated plan resulting in 3 year pilot program to start Jan 2014
- Jun 2015: Japan (MHLW/PMDA) joins as participant
- Dec 2015: 3 Year Pilot Ends, Operational Phase Begins

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Participants & Observers

- Australia (TGA)
- Brazil (ANVISA)
- Canada (Health Canada)
- Japan (MHLW/PMDA)
- USA (FDA)

Observers: WHO and EU

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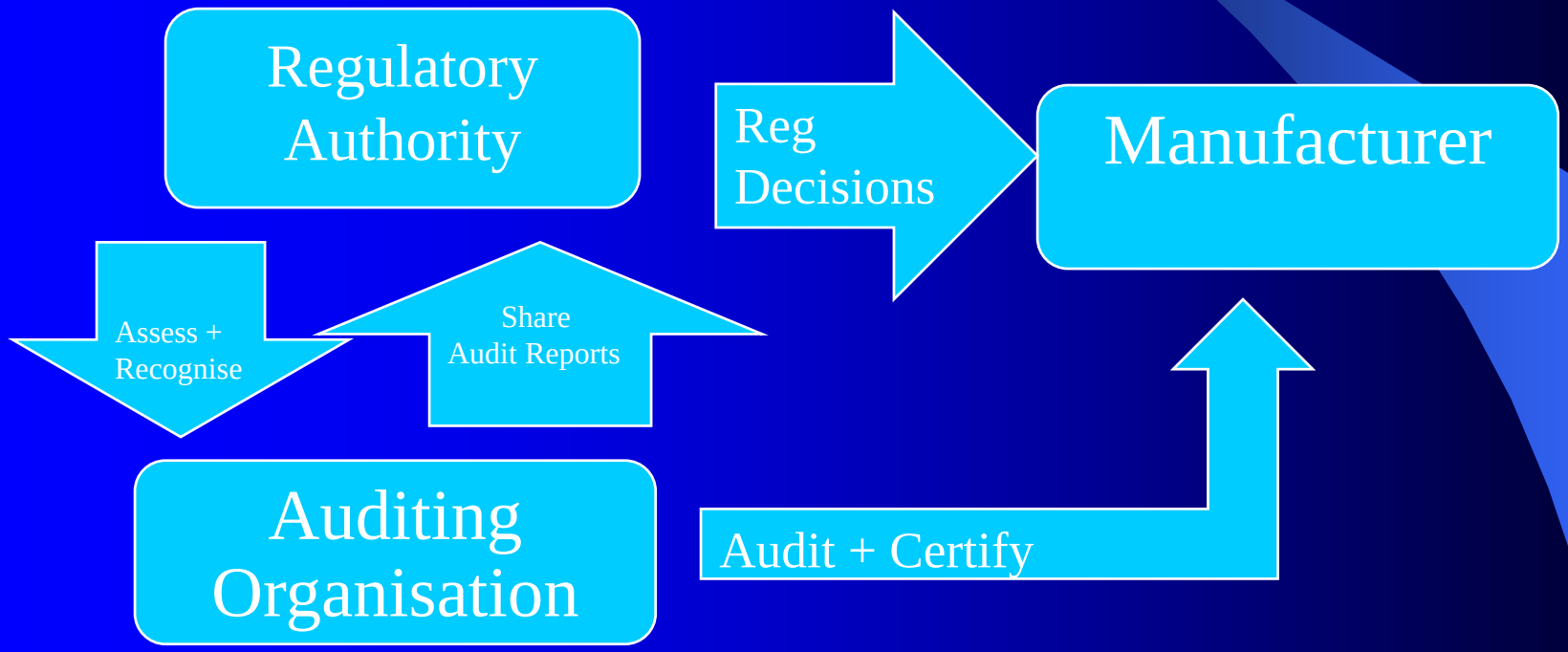
Players and Roles



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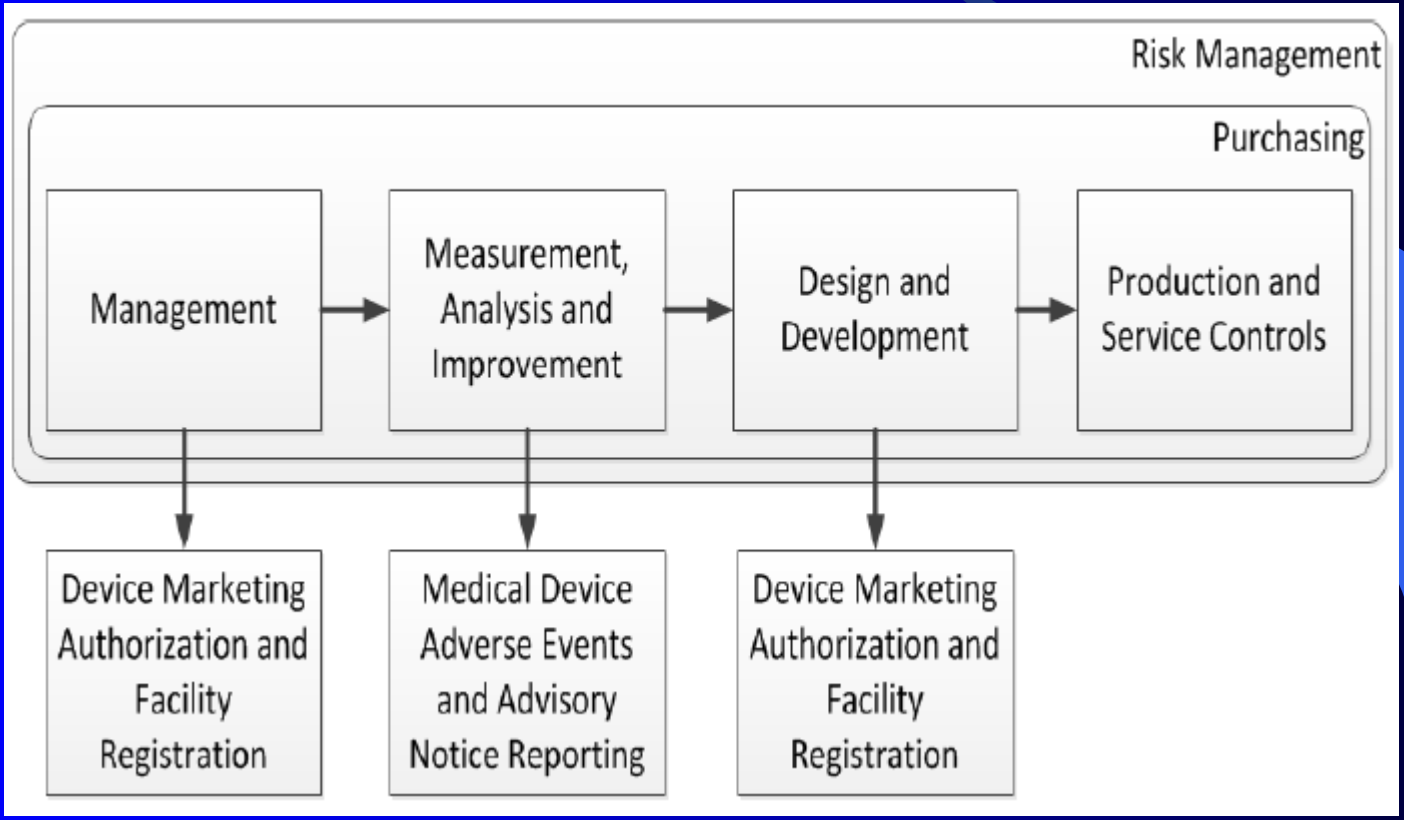
Audit Criteria

- ISO 13485:2003→2016
- Regulations
  - Australia
  - Brazil GMPs (ANVISA RDC 16)
  - Japan MAH (MHLW MO 169)
  - USA QSR (21 CFR 820)
  - Canada CMDR (SOR 98-282)

Audit Criteria

- Specific National Requirements
  - Manufacturer site registration (ALL)
  - Medical Device Licensing/Clearance (ALL)
  - Design Essential Principles / Controls (TGA/Brazil)
  - Risk Management (TGA, Brazil & FDA)
  - Post Market/Adverse Event reporting (ALL)
  - Issuance of Advisory Notices (ALL)
  - Device tracking (TGA)

Audit Model/Method



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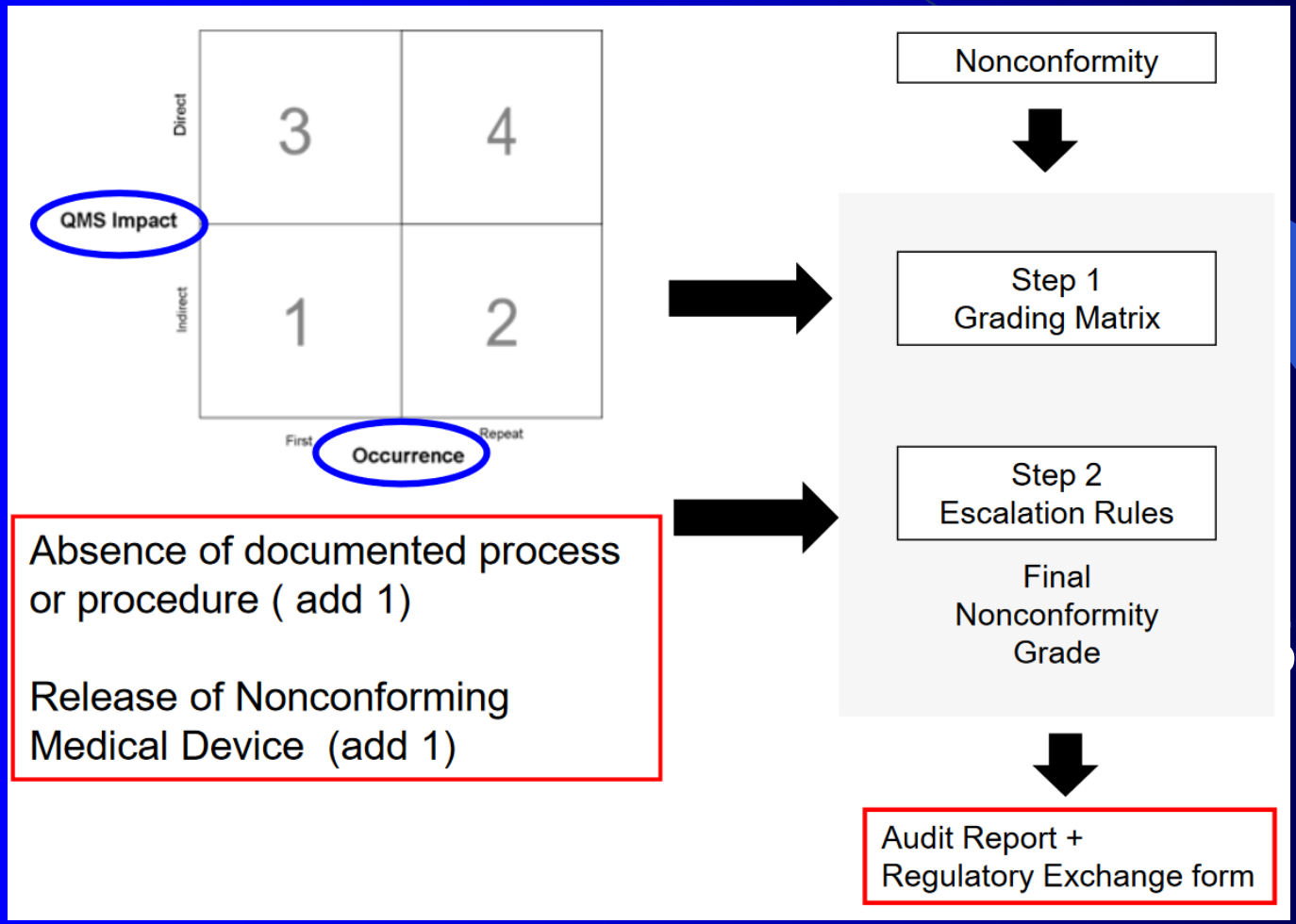
Nonconformity Grading



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MDSAP

- Thanks for reviewing our MDSAP Prep seminar.
- The full seminar is available in Powerpoint slides and is helpful both for constructing your plan as well as general training in MDSAP prior to the MDSAP AO Assessment.
- For more information, email us at info@crogroup.com

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