Health Canada Santé Canada

Canada

Convergence in Medical Device QMS Regulations

MDRC Webinar

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YOUR HEALTH AND SAFETY... OUR PRIORITY.

Case Study

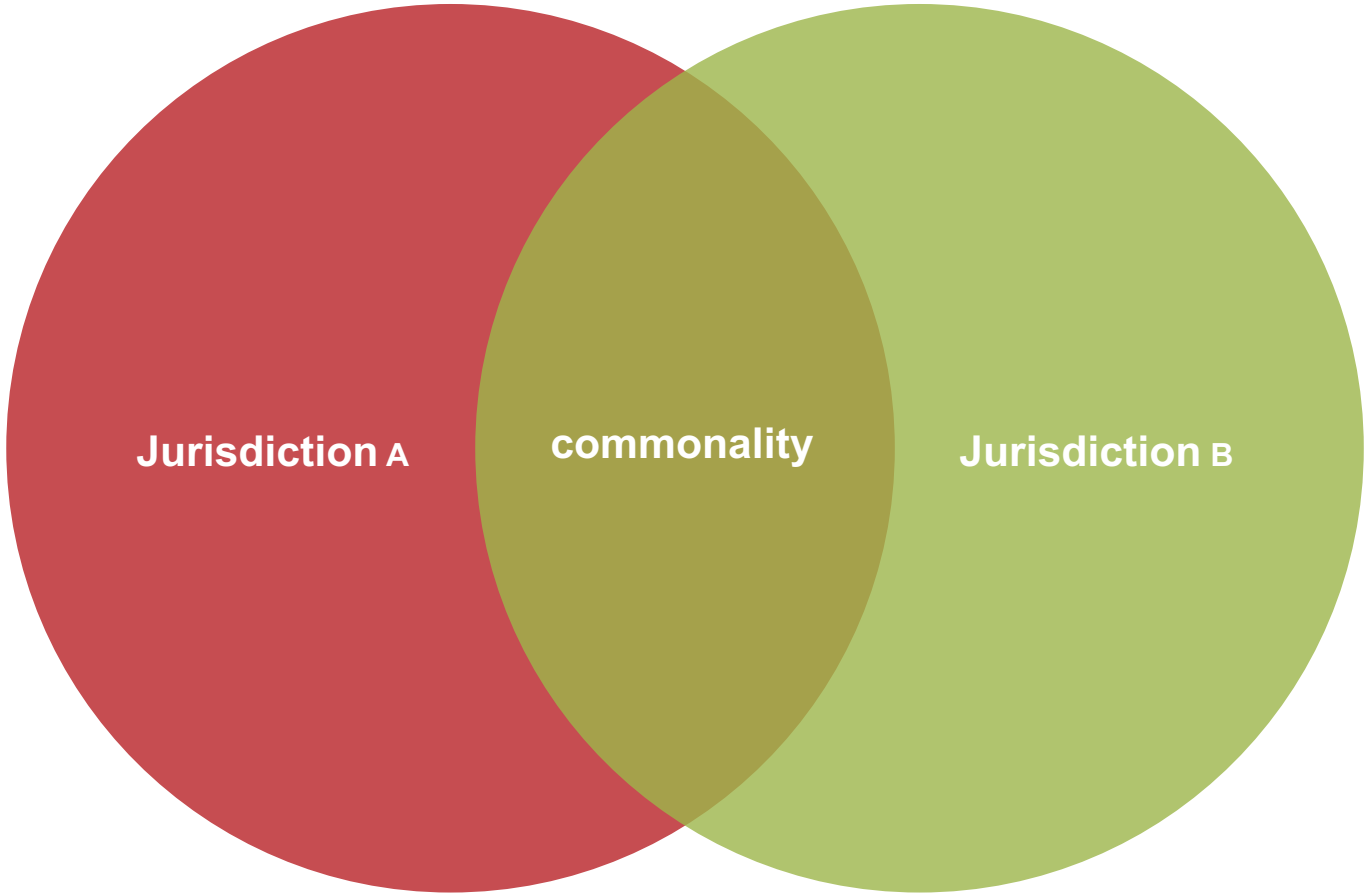
ISO 13485 and MDSAP: an example of regulatory convergence

Situation	Strategy	Results
Five countries used different approaches to conduct oversight of QMS leading to duplication, inefficiencies, and added costs.	Participating jurisdictions agreed on the use of ISO 13485 (plus some additional national requirements), a standardized approach to oversight, and a framework for recognizing 3rd party auditing organisations.	The five countries were able to develop a common program that fits into each countries regulatory system. This reduced duplication of efforts allowing for reallocation of resources.

“It's said that a wise person learns from his mistakes. A wiser one learns from others' mistakes. But the wisest person of all learns from others‘ successes.”

— John C. Maxwell

Scope of convergence



Inputs to convergence

Who?

Who is being regulated?

How?

How are entities and devices regulated

What?

What regulatory actions take place?

When?

When do regulatory actions occur?

Pitfalls and Barriers

Unachievable goals

Resources / Capacity
Unreasonable expectations

Incompatibilities

Scope issues
Incompatible requirements

Costs > Market

National requirements
Duplication
Industry characteristics

Loopholes

Multiple pathways
Path of least resistance

Infrastructure

Legal framework
Technical infrastructure.

Confidence

Regulatory partners
Industry
consumers

Success Factors

COMMUNICATION	Communication is key to stakeholder engagement and participation
TRANSPARENCY	Transparency is essential to establishing credibility and confidence
ADAPTABILITY	Course corrections and adjustments are inevitable
PATIENCE	Successful transformation is a long term endeavour

Contact Information

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