Legal Obligations applicable to medical device NRAs

INTER-AMERICAN COALITION FOR
REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

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03.03.2022

Good Regulatory Practices (GRP): International obligations

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Good Regulatory Practices

- GRPs **aren't about more regulation or less regulation**. They're about facilitating better regulatory outcomes.

- GRPs create a **professional process to rule-making** that follows the political course set during the process. Adherence to a **transparent and participatory rule-making process, and to evidence-based decision making.**

- GRPs are an important precursor to **international regulatory cooperation**. Only quality regulatory outcomes avail themselves of regulatory cooperation opportunities.

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GRP components

1. Issue a Regulatory Forecast
2. Have a National Regulatory Register
3. Provide Opportunity for Public Comment
4. Publish Evidence and Conduct Regulatory Analysis
5. Respond to Stakeholder Input
6. Use Quality Data and Sound Science
7. Employ Risk-Based Approaches
8. Conduct Regulatory Impact Assessments (RIAs)
9. Conduct Pro-Competitive Analysis
10. Asses the International Impact of a Regulation
11. Use International Standards as a basis for National Regulations
12. Conduct Ex-Post Assessments of Regulatory Impacts
13. Establish a Central Regulatory Coordination Body

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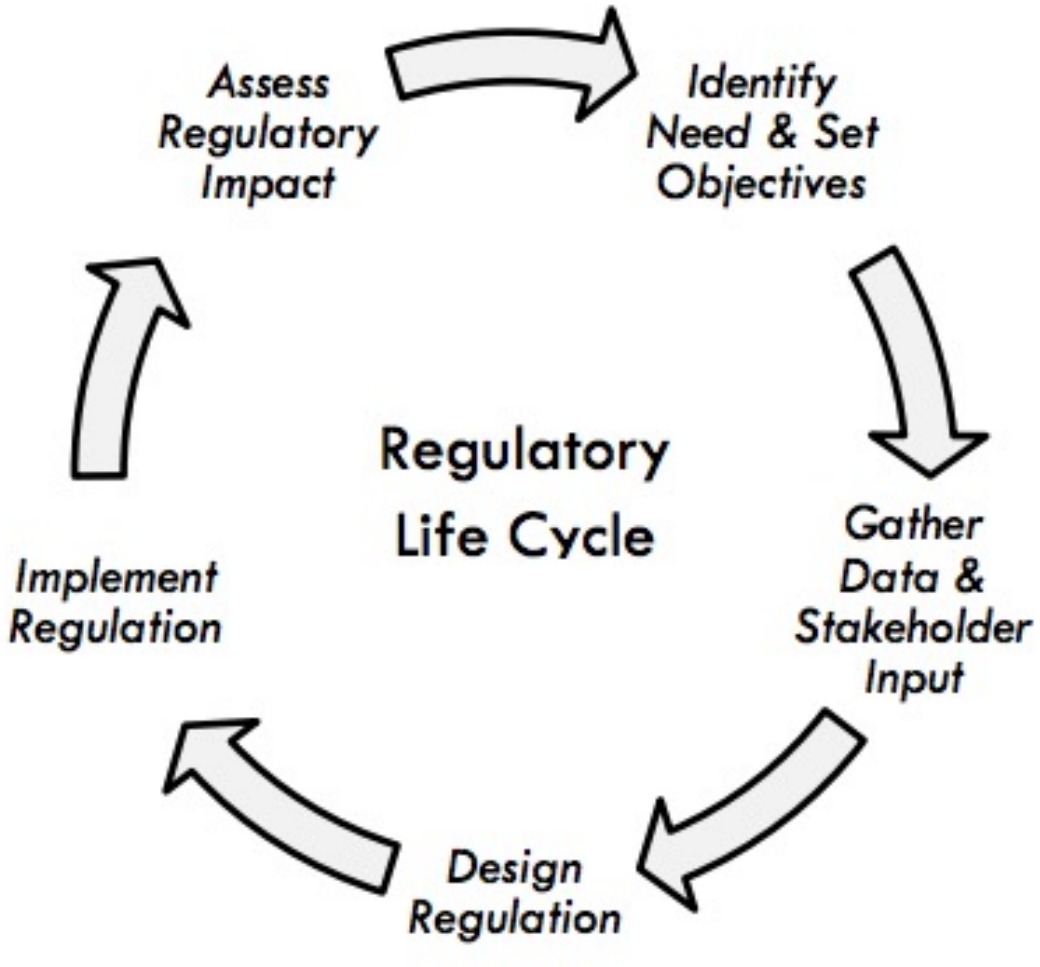
Basic Regulatory Life Cycle



GRP X Trade Costs

Good Regulatory Practices encompassing the use of **regulatory impact assessments, stakeholder engagement** and ***ex post*** **evaluation** are a critical tool in the hands of governments to ensure that regulation achieves its objectives.

Over the past several years, attention has grown for the **trade costs of regulatory divergence.** Diverging regulation may increase the costs to trade goods and services across borders.

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OECD Guidelines

The Organization for Economic Development and Cooperation (OECD) establishes several international benchmark documents regarding Good Regulatory Practices

The 2012 OECD Recommendation highlights a number of **principles and tools** that can help policy makers develop, implement and update regulations that promote their policy goals in the public interest

The recommendation recognizes the importance of **international regulatory cooperation for regulatory quality** and the relevance of the tools of regulatory policy – encompassing ***ex ante* Regulatory Impact Assessment (RIA), stakeholder engagement and *ex post* evaluation** – to base regulatory policy making on **evidence**, including the evaluation of the likely **benefits, costs and effects** of regulation and the consideration of the voice of the regulated.

https://www.interamericancoalition-medtech.org/regulatory-convergence/policy/good-regulatory-practices/oecd/

World Health Organization

- WHO Global Model Regulatory Framework for Medical Devices including In Vitro Diagnostic Medical Devices
- Good regulatory practices in the regulation of medical products
- Good Reliance Practices
- Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics

https://www.interamericancoalition-medtech.org/regulatory-convergence/policy/medical-device-sector-regulatory-convergence/world-health-organization-documents/

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International Trade Agreements

USMCA: *Chapter 28 on GRPs*

The same chapter is reflected in the agreements/protocols signed between the U.S. and Brazil, and U.S. and Ecuador.

Pacific Alliance: *Chapter 15 BIS on Regulatory Improvement*

CPTPP: *Chapter 25 on Regulatory Coherence*

https://www.interamericancoalition-medtech.org/regulatory-convergence/policy/good-regulatory-practices/trade-agreement-grp-tbt/

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THANK YOU

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