Regulatory Convergence

From the Medical Devices Industry's standpoint

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Society, Regulators and Industry have well defined roles in the regulatory process. These roles are determined by the needs of each actor and create a cycle that must have balance to achieve success.

This balance is achieved when the actors work together as partners.

Actors in the Regulatory Process and their Roles

- Society
  - We are all actors here, whether as healthcare professionals (users) or as pacients.
- Regulators
  - Safeguard the rights of patients and users to have access to safe and efficient medical devices.
- Industry
  - Provide safe and efficient devices.

Actor’s Needs

- Users
  - Healthcare professionals are focused on the patient’s needs.
- Patients
  - Need safe and effective medical devices, as well as access to them.
- Regulators
  - Need to guarantee safety and efficacy of the medical devices, therefore their needs reflect the needs of society.

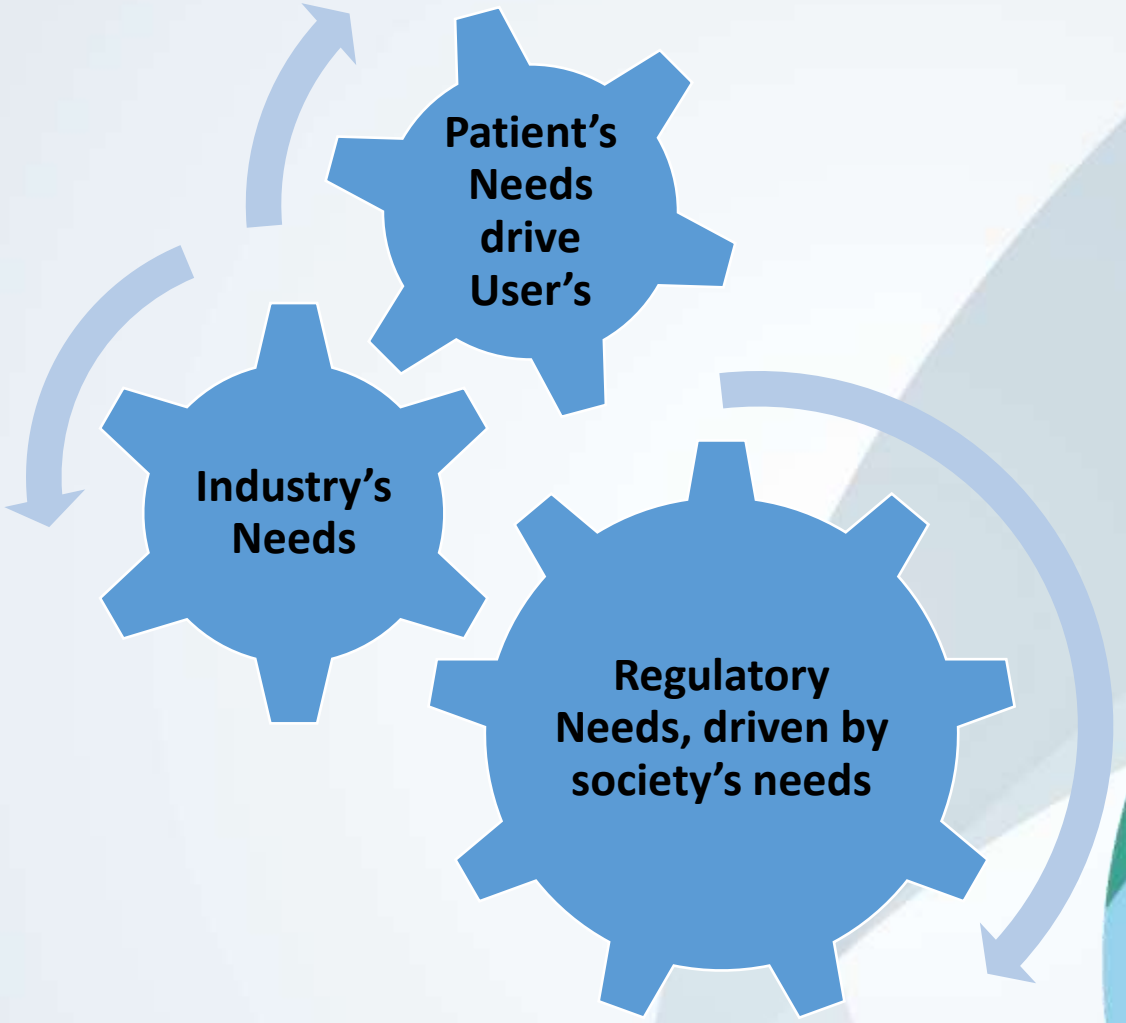
Actor's Needs

- Industry
  - Needs to provide safe and effective medical devices to users and patients, comply with regulations.
  - Must understand what the regulator wants, because it brings predictability and a healthy business environment.
  - Both industry and society need fair regulations that allow both big and small players to comply.
  - Since innovation is ever present in this industry, regulations must not prevent access to new and innovative technologies.

Actor’s Needs

- Industry (continued)
  - Due to the global nature of our industry, it is important that global regulations do not overburden companies present in multiple countries.

Cycle


Patient's Needs drive User's
Industry's Needs
Regulatory Needs, driven by society's needs

Regulatory Convergence

- Industry as a whole welcomes Regulatory Convergence, and works closely with regulators to build regulations that comply with all the actors' needs, as preconized by Good Regulatory Practices.

Industry & Regulator Partnership

- Brazilian industry associations have created mirror groups for all IMDRF working items, working closely with our regulators in building the regulations and implementing the initiatives.
  - In Brazil we have great participation of the industry in the RPS Pilot, and Anvisa has introduced revised regulations for regularization of low risk classes of medical devices and for all risk classes of IVD products, already aligned with the ToC on IMDRF RPS, with a certain deadline for implementation. When the industry realized that the time required for the implementation of the dossiers for legacy products would exceed the deadline, discussions were started with Anvisa and in the end the deadline for compliance was adjusted accordingly.

Balance Achieved

This was a great example of partnership creating balance, because legacy products in that case are guaranteed to remain compliant to regulations and accessible to users and patients.

Thank you!

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