DIA Latin America Regulatory Conference
Session 3
Regulatory Convergence & Collaboration
14Mar22

Talking Points

Good afternoon and thank you for the invitation for the Coalition to share our perspective on convergence and collaboration for the Medical Device Sector. As most of you know, even though regulatory frameworks for Medical Devices and Pharmaceutical products, are required to consider their differences in nature, life cycle, R&D, et al., they have an essential commonality to succeed in the journey towards convergence: collaboration.

Slide 3.

From the Coalition perspective, there are many elements to ensure successful collaboration, and we would like to point our attention in this session, to these four: Legality, Capacities, Transparency and Trust.

Slide 4.

Starting with Legality, from the Good Regulatory Practices perspective, it allows for a common ground for collaboration, as all WTO members, are obliged to comply with the same legal requirements, while being signatories of the Agreement on Technical Barriers to Trade and even further for the ones being members of OECD or in the process to become such or among the ones that within bilateral or regional trade agreements include GRP obligations, such as the one between Brazil and the US or USMCA.

At a national level, as countries already have or are in the process of implementation of Quality Infrastructure Laws and / or Regulatory Improvement Laws, which provide a framework to implement Good Regulatory Practices while either developing new regulations or updating existing ones, even to the point where questioning whether the existence of such regulations is still justified.

Being International References and Standards required to be used as a base for regulations, within the Good Regulatory Practices obligations, also provides a common language to all stakeholders.

Open public consultations, both at a national and international level, for the latter, through Notifications to the WTO, not only allows for collaboration from all stakeholders but also makes it evident the co-responsibility among all relevant stakeholders to produce effective and convergent regulations.

Slide 5.
Next element is Capacities. All stakeholders, from regulators to industry, academia and research are required to develop the required capacities, not only in the technical aspects and science behind the products, but also on the GRP process.

And we must consider that capacities, also have to do with strong Quality Management Systems, again for regulators and industry that, within their Standard Operating Procedures, include all national and

international obligations on Good Regulatory Practices, to demonstrate, through and auditable system, the level of compliance.

Capacities also have to do with available resources, from personnel to systems. Collaboration can be challenged by insufficient resources, which may end up being a “Vicious Cycle”. Not sufficient resources for collaboration to advance in convergence prevent the possibility to reduce “unique requirements” or “duplicative processes”, which themselves demand significant resources.

Slide 6.

And now let’s touch on transparency. Another key element for successful collaboration as to not only allow but encourage all relevant stakeholders, national and international, to provide proper visibility on the processes and procedures, learning on the opportunities to participate in the technical committees at the relevant stages of the regulatory process. We consider that Quality Management Systems and Open Communication, provide a solid base for transparency.

Slide 7.

And last but not least, Trust, which if not in the picture, will become the greatest barrier for collaboration towards convergence. This slide shows what we consider some building pillars for Trust.

Certainty in processes and procedures, confidence on the proper implementation and operation under strong QMS and SOPs among all stakeholders, again, national and international, provide a strong base to develop Trust.

Inter-Ministerial Commitments, in our case, among Health and Trade Regulators, and representatives at the International Community to discuss and solve potential misalignments, are also key elements for Trust.

And with no doubt, all of the above, absolutely require Ethics and Compliance to be at the top of every action undertaken by each and every stakeholder. From the private sector perspective, ensuring that they stick their actions to a Code of Ethics and ideally, that they are also members of trade associations that require and monitor compliance with ethical behavior.

Slide 8.

And to close my participation, some take aways:

- Collaboration is a Key Success Factor for Convergence
    - Legality, Capacities, Transparency and Trust
- Collaboration is required to effectively implement Reliance & Recognition
- Collaboration is a co-responsibility among all relevant stakeholders