GCCRA
REGULATORY AFFAIRS
PHARMA SUMMIT 2025
A Decade of Excellence

10th Edition

Exclusive Interview with our Networking Partner

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RAPS
REGULATORY AFFAIRS PROFESSIONALS SOCIETY

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- **What initiatives does RAPS support to help regulatory professionals in the GCC region navigate the complexities of diverse local and regional requirements?**

The Regulatory Affairs Professionals Society (RAPS) is the largest global organization of professionals involved with regulatory and quality for healthcare products, including medical devices, pharmaceuticals and biologics, diagnostics, and digital health.

Founded in 1976 as a neutral, nonprofit organization, RAPS supports and elevates the regulatory profession with education and training, professional standards, publications, research, networking, career development, and other valuable resources. RAPS serves as a forum where a diverse group of stakeholders from health authorities, academia, and industry can interact and come to common understanding together. The Society seeks to increase the increase the capabilities and competency of all of those working in healthcare regulatory affairs.

Additionally, RAPS is home to the Regulatory Affairs Certification (RAC), the only post-academic professional credential to recognize regulatory excellence.
The Society is headquartered in suburban Washington, D.C., with chapters and affiliates worldwide. RAPS is headquartered in the U.S. with an operations center in Brussels, and chapters and affiliates worldwide.

- **How does RAPS contribute to the professional development of regulatory affairs specialists in the GCC, particularly in adopting global best practices and digital innovations?**

RAPS is highly committed to supporting global regulatory affairs professionals throughout their entire career. Everything we do is created by (and for) the global regulatory community and helping them stay abreast of evolving regulations is one our most critical priorities.

In addition to *Regulatory Focus*—which provides timely, quality news, information and analysis fully dedicated to covering regulatory issues associated with healthcare products and the regulatory profession—RAPS has an extensive portfolio of programs, online courses, resources and events that keep the global regulatory profession up-to-date and connected. We try to meet our members and the regulatory community at-large where they are (hence, our new support of the AfriSummit and GCC Summits), and we try to make membership and professional development accessible to all. In fact, we have reduced "emerging market" rates on membership and many education programs/products available to regulatory professionals living in countries classified as upper-middle, lower-middle, or low-income by the World Bank.

RAPS provides opportunities for the community to engage directly with global regulators at RAPS Convergence, RAPS Euro Convergence and our conferences. In fact, we are excited to be partnering with Mecomed to produce our first event in the region which further supports our commitment to professionals in the Middle East and Africa (2025 MEA MedTech Regulatory Summit, 30 January 2025 in Dubai www.meamedtech.org).

Other ways we keep the community connected include Regulatory Exchange (our members-only online forum) where professionals can get questions answered from peers. Our research, workshops, webcasts and publications offered throughout the year also focus on the most current issues and developments across regulatory.

Finally, RAPS also produces the Regulatory Competency Framework (RCF), which details essential elements of what is required of regulatory professionals at four key career and professional levels. Each of RAPS' programs and initiatives are mapped to the stages of the Regulatory Competency Framework so we can ensure that we are meeting the demands and needs of professionals at all times.

- What strategies does RAPS recommend to bridge gaps between regulatory frameworks in the GCC and international markets, ensuring smoother pathways for pharmaceutical product approvals?

There are many strategies to bridge gaps between regulatory frameworks in the GCC countries and international markets for pharmaceutical product approvals. A few key approaches include:

1. **A Focus on Harmonization and Reliance Pathways:** When GCC regulations are aligned with international standards, including those set by ICH, this can reduce and streamline the approval process timeline.

2. **Capacity Building:** A core aspect of RAPS's mission is to ensure that regulatory professionals globally are as capable and confident in their position as possible. RAPS suggests investing in training and development consistently and continually. Globally, regulatory professionals engage in (on average) 80 hours of professional development per year. This is due to the evolving nature and interpretation of healthcare product regulations. Enhanced expertise can lead to more efficient regulatory processes and better understanding of international requirements.

3. **Collaboration and Communication:** A reason why RAPS convenes meetings and conferences is under the belief that fostering dialogue between regulatory authorities and other stakeholders can help address regulatory clarity. Regular workshops and conferences can facilitate knowledge sharing and best practices which will lead to common understanding.

4. **Stakeholder Engagement:** Involving all stakeholders—including industry representatives, healthcare professionals, health authorities, and patient groups—in the regulatory process ensures that diverse perspectives are considered and can facilitate smoother approvals.

Implementation of these approaches can allow stakeholders to work towards a more cohesive regulatory environment that benefits both the pharmaceutical industry and public health in the GCC region.