HIGHLIGHTS - TIC Council Webinar: Shaping India's Medical Devices: Global Best Practices and Priorities

On Thursday 28 October, TIC Council India began a 2-part webinar series with senior policy makers from ministries & regulatory bodies in India, Europe & the U.S. Senior industry leaders from the medical devices and the TIC industry were also present, sharing their experience, global trends and best practices towards ensuing quality and safety of medical devices.

Day One – 28 October

The panel was composed of high-level speakers, including:

- Suresh Sugavanam, Chairman, TIC Council India
- Hanane Taidi, Director General, TIC Council
- Anupam Kaul, Founder and Lead, Veriti Masters Guild
- Karthik Venkataraman, Business Manager, UL India
- Claire Dyson, Global Vice President, Dekra
- Kimberly Trautman, Medical Device, IVD and Combination Product Regulatory & Quality Expert
- Reinaldo Figueredo, ISO-CASCO Chair
- Sudhir Zutshi, Chair, Public Affairs, Sub Committee, TIC Council India

Dr. Aparna Dhawan, Executive Director of TIC Council India, kick-started the event explaining how the medical device sector is one of the key sectors which has seen an unprecedented growth, be it in India or globally. Today, India has the fourth largest medical device market and is among the top 20 worldwide, which includes multinationals as well as SMEs. Furthermore, she also explained how the TIC sector and conformity assessment bodies play a key building block for India's infrastructure.

Mr. Suresh Sugavanam followed suit, welcoming all speakers and attendees, and commenting that TIC Council fully supports the drafting of a robust medical devices regulatory and policy framework which lays a strong foundation towards ensuring a robust quality and conformity ecosystem for medical devices in India.

Next, Ms. Hanane Taidi said that certification and notifying bodies play a crucial role in supporting the medical devices industry to place safe and compliant medical devices on the market. Ms. Taidi said that it is imperative that the industry understands and effectively implements the regulatory requirements in this fast paced and challenging regulatory environment. She said it is also required that the medical device supply chain implements appropriate quality measures which are compliant with the standard requirements and adapts the best global practices currently existing.

Our panel, moderated by Karthik Venkataraman, Business Manager at UL India, began with an introductory presentation from Mr. Anupam Kaul, Founder and Lead of Veriti Masters Guild. Mr. Kaul believes it is extremely topical to talk about

India's regulatory framework, as there is a lot of new regulatory oversight and thinking among governments in terms of catching up with OECD countries and developing countries, including concerns around market practice and access market issues. Mr. Kaul, who has been involved in policy frameworks for the last five years, continues to say that many policy initiatives have come up and several new regulations are coming into place, such as mandatory certification programmes.

Our second speaker was **Ms. Claire Dyson, Global Vice President at Dekra**, who presented the new UK Conformity Assessment (UKCA) product marking, which came into effect in January 2021 following the United Kingdom's departure from the European Union, used for placing goods on the market in Great Britain and covering most goods where CE is required. Ms. Dyson carefully explained that, due to geographical challenges, manufacturers in Great Britain cannot export their UKCA-marked product over to Northern Ireland which is still part of the United Kingdom, as it shares a border with the Republic of Ireland, which in turn is still a member of the EU. As a result, the CE/UKNI marking was brought into place so that goods that are dispatched from Great Britain can then be placed on the market in Northern Ireland as well.

Our third speaker, **Mr. Reinaldo Figueredo, Chair of ISO-CASCO**, presented the use of CASCO's standards to harmonise the medical device regulatory framework, further explaining what ISO is, their vision, and future goals, including their strategy for 2030. Mr. Figueredo explained the role of CASCO as the ISO Policy Development Committee on Conformity Assessment, that is, to study means of assessing the conformity assessment of a product/process/service/Management System/person to standards and other technical specifications, to prepare international standards relating to practice of conformity assessment, and to promote mutual recognition and acceptance of national, regional and international conformity assessment systems.

Lastly, **Ms. Kimberly Trautman, expert in Medical Device, IVD and Combination Product Regulatory & Quality,** presented the medical device single audit programme and its key learnings. She explained that one of the things that is most confusing with the medical devices single audit programme is that there is a specific consortium. The International Medical Devices Regulations Forum (IMDRF) recognised the value in developing a global approach to auditing and monitoring the manufacturing of medical devices to ensure safe medical devices. At its inaugural meeting in Singapore in 2012, the IMDRF identified a working group to develop specific documents for advancing the concept of the Medical Devices Single Audit Programme (MDSAP) which includes the use of third-party auditors as well as regulatory inspectorates, to allow greater coverage in auditing manufacturers around the globe. She also discussed the FDA upcoming rulemaking to harmonise with ISO 13485:2016 and how the FDA might use additional aspects of MDSAP, and finally to understand the recent changes in the EU and UK global regulatory authority schemes utilisation of MDSAP.

If you wish to know more, you can access the recording and the full presentation of the webinar.

Check our list of webinars to find about more about TIC Council's work in providing thought-provoking presentations on the current market trends and legislative developments around conformity assessment.

Editor's Note About TIC Council

TIC Council is the global trade federation representing the independent third-party Testing, Inspection and Certification (TIC) industry which brings together more than 90-member companies and organizations from around the world to speak with one voice. Its members provide services across a wide range of sectors: consumer products, medical devices, petroleum, mining and metals, food, and agriculture among others. Through provision of these services, TIC Council members assure that not only regulatory requirements are met, but also that reliability, economic value, and sustainability are enhanced. TIC Council's members are present in more than 160 countries and employ more than 300,000 people across the globe.

The Value of TIC Report

To learn more about TIC Council and its member's activities, the landmark report on the Value of the TIC sector, developed jointly by the international law firm Steptoe and the London-based consultancy Europe Economics is now available to read. This report illustrates, by using data and case studies, how the TIC sector benefits a variety of stakeholders and industries around the world. You can find the study here, and we welcome you to share it with anyone who might be interested.