

HIGHLIGHTS - TIC Council Webinar: Shaping India's Medical Devices Regulatory Framework: 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 ensuring quality and safety of medical devices.

Day Two - 29 October

Technical Session: The Evolving Medical Device Quality & Regulatory Framework

Chair: **Dr.R.P. Singh** Secretary General, QCI

Moderator: **Dr. Shailendra Singh** TUV SUD Pvt Ltd., India

Speakers:

- **Dr. Jitendra Sharma**, Managing Director and CEO, AMTZ
- **Rajesh Maheshwari**, CEO, NABCB
- **Ravi Singh**, Member, TIC Council, Med Device WG

Dr. Jitendra Sharma illustrated the complexity of the medical devices industry, especially in the phase of testing against international harmonised standards. This complexity, however, is inevitable to bring manufactory and quality together. In order to cover the health needs of all, medical technology should be not only of quality, but also affordable and localised: for this reason, he advocated for a fruitful cooperation among all the actors involved in order to make the Indian medical devices sector independent from imports.

Rajesh Maheshwari provided an overview of the quality infrastructure in India, focusing on the audit process carried out by Notified Bodies. He explained how all these processes are intended to enhance patient safety and provide consumer protection, significantly eliminating trading of sub-standard products of doubtful origins.

Finally, **Ravi Singh** highlighted the work of the umbrella group “Competent Authorities for Medical Devices (CAMD)”, responsible for improving communication and collaborative work between competent authorities, and increasing the surveillance of medical devices on the market. He then followed with the role of notified bodies, which work closely with manufacturers to assess their compliance to regulation.

Panel Discussion: Medical Device Industry – Challenges, Solutions & Opportunities

Chair: **Girdhar Gyani**, Director General, AHPI

Moderator: **Harshit Thakkar**, Sr. Project Manager, DEKRA

Speakers:

- **Sudhakar Mairpadi** Head Quality, Regulatory and Govt Affairs, Philips India Pvt Ltd
- **Rajiv Nath**, Forum Coordinator, AiMED
- **Vibhav Garg**, Director Health Economics & Govt Affairs, Boston Scientific
- **R. Asok Kumar**, Chairman, Regulatory Sub Committee, Adva Med

In this panel discussion, moderator Harshit Thakkar invited the speakers to name, the major challenges faced by the Medical Devices industry in India. The panellists have identified the following

- Lack of regulatory framework for medical devices
- Need of an harmonised system
- High import dependency
- Lack of high-skilled manpower
- Need of mutual recognition among countries
- Need of further development and innovation on R&D

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.

TIC Council

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Formerly known as IFIA and CEOC

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.

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