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# India's medical manufacturing: Aligning with global standards

In an exclusive digital dialogue hosted by mojo4industry titled "From Local to Global: Aligning Indian Medical Manufacturing with International Standards," industry experts gathered to discuss India's journey towards becoming a global hub for medical device manufacturing. The event focused on the importance of aligning Indian practices with international standards, ensuring both global competitiveness and enhanced patient safety.

Dr. Jitendra Sharma, Managing Director & Founder CEO of Andhra Pradesh MedTech Zone (AMTZ) - which is the world's largest medical devices research and manufacturing park. He kicked off the session by emphasizing the critical role of AMTZ in bridging the gap between India's domestic medical device production and international requirements. He outlined how AMTZ, established in 2018, has evolved into a consolidated space for medical device production, providing infrastructure and services like validation centers, testing labs, and logistics facilities. "AMTZ is a unique cluster that integrates all elements needed for medical technology production, ensuring that Indian-made devices meet both national and international standards," he stated. Dr. Sharma highlighted three key steps to enhance India's global standing: the need for mutually accepted certification systems, careful consideration of trade agreements, and building a robust pool of qualified auditors to ensure compliance.

Rajiv Nath, Managing Director of Hindustan Syringes & Medical Devices Ltd. and Forum Coordinator of the Association of Indian Medical Device Industry (AiMeD) - an umbrella association of Indian manufacturers covering all types of medical devices including consumables, disposables, equipment, instruments, implants, electronics and diagnostics with over 400 members nationwide. He shared his perspective on India's role in the global medical device market. Mr. Nath discussed the evolution of regulatory standards and how India's certification frameworks, like the Indian Certification for Medical Devices (ICMED) and the Zero Defect, Zero Effect (ZED) certification, are positioning Indian manufacturers to meet global demands. He emphasized that quality standards need to go beyond the minimum regulatory requirements and must be demonstrated through third-party audits to build confidence with international buyers. "To truly compete globally, we need to move from quality control to quality assurance and demonstrate our competence through certifications recognized worldwide," he added.

Manoj K. Sundaram, Head of Business Development at Carl Zeiss India, offered insights into how quality and metrology play a crucial role in medical device manufacturing. Mr. Manoj pointed out that, as India rapidly emerges as a global player in medical device manufacturing, ensuring top-notch quality is more important than ever. "Our focus must be on precision and reliability at every stage of production," he said. "Quality cannot be an afterthought—it has to be ingrained in the entire manufacturing process, from the initial stages of design to the final product."

Dr Jitendra Sharma

Manoj K Sundaram

Rajiv Nath

During the discussion, Mr. Manoj also highlighted the importance of aligning Indian certification systems with international norms. "For India to truly establish itself as a global leader in medical device manufacturing, it is crucial to adopt globally recognized certification systems. This will not only enhance the credibility of Indian-made devices but also open up more export opportunities," he emphasized.

As the medical device sector in India continues to grow, the need for collaboration between industry and regulatory bodies becomes even more important. Mr. Sundaram added, "There has to be a continuous dialogue between manufacturers, industry associations, and government agencies to ensure that the certification and quality systems in place are robust and aligned with global standards."

**Watch the video here:**
https://bit.ly/medicalstandards

# IN NATIONAL INTEREST

India needs a "tit-for-tat" policy to ensure that its manufacturers can compete on a level playing field, writes **Rajiv Nath**, Forum Coordinator, Association of Indian Medical Devices Industry (AiMeD)

As India and the European Union (EU) engage in negotiations for a Free Trade Agreement (FTA), there is growing concern over the potential inclusion of medical devices in the final deal of permitting duty-free access to European Medical Devices to the large and rapidly growing Indian Healthcare Market. This issue calls for immediate and thoughtful consideration. At the heart of this debate is the question of India's healthcare security (which was recently challenged in Covid times when international supply chains disrupted and country was forced to go into lockdown) and the future of its domestic medical devices industry, both of which are at risk if the import of medical devices is further liberalized under the FTA.

In the last four years, the import of medical devices into India has skyrocketed by 68%, and around 70% of medical devices used in the country are imported currently. This huge over-dependency has already raised serious concerns. And India's experience with previous FTAs only amplifies these concerns. Take the Japan-India Comprehensive Economic Partnership Agreement (JICEPA) for example, where medical equipment imports from Japan rose by 19% between FY20 and FY24.

Rajiv Nath

> The Indian government must insist on similar inspections and compliance checks for EU-made medical devices

Germany and the Netherlands, both EU countries, are already among the top five exporters of Medical Devices to India.

While India allows the imports of these devices with minimal regulatory hurdles and no factory inspections, Indian manufacturers face stringent requirements to sell their products in the EU. The CE Certification process, mandatory for Indian medical devices entering Europe, is both extremely expensive and highly time-consuming. Moreover, EU regulators get Indian factories rigorously inspected, while Indian manufacturers face no such reciprocal benefits.

India needs a "tit-for-tat" policy to ensure that its manufacturers can compete on a level playing field. The Indian government must insist on similar inspections and compliance checks for EU-made medical devices, ensuring that they adhere to Indian Medical Device Rules (MDR) and provide evidence of domestic value addition.

The EU's regulatory framework allows companies to label themselves as a 'Legal Manufacturer' without necessarily being involved in the actual manufacturing process. This has enabled pseudo-manufacturing to inadvertently thrive in the EU, creating a loophole where the true country of origin is not always clear to consumers as not required to be mentioned on the packaging. This lack of transparency is in stark contrast to the requirements in India and the United States, where medical devices must be clearly labelled with their country of origin based on domestic value addition requirements. There's a huge risk of 3rd country exports to India via the potential zero duty access route as a purported EU origin product though that Medical Device may not be made in Europe. Without physical factory inspection and verification of value addition how will Indian customs distinguish what's made in EU to what's imported via EU?

The Indian government has the opportunity to protect its domestic manufacturers and ensure long-term medical security by excluding medical devices from the India-EU FTA.

**Read the article here:**
https://bit.ly/rajivnath

# Is India ready for electric highways?

Abhijeet Sinha, Program Director, Ease of Doing Business and Project Director, NHEV, shares insights

On the sidelines of REI 2024, mojo4industry had a fireside chat with Abhijeet Sinha, Program Director - Ease of Doing Business and Project Director- NHEV. Mr. Sinha has been instrumental in advancing India's transition to electric mobility, with recent tech trials marking a significant step forward. In this conversation, we explored the implications of these trials and their impact on the future of electric mobility in India.

**Could you share the key objectives of the third tech trial in Tamil Nadu for upgrading highways into e-highways? How does this trial differ from the previous successful trials in Delhi, Jaipur, and Agra?**

The third tech trial in Tamil Nadu is pivotal in advancing the concept of electric highways, primarily focusing on public transportation vehicles such as buses, intercity cars, and SUVs. Unlike the previous trials in Delhi, Jaipur, and Agra, which were more focused on personal vehicles and electric trucks, this trial introduces a broader scope for public transport systems. In the current landscape of electric mobility, it is imperative to understand how larger vehicles, like buses, can operate efficiently on electric highways. This shift will not only cater to individual mobility needs but also address mass transportation requirements, making electric mobility more accessible and sustainable on a larger scale.

In terms of data collection, this trial emphasizes gathering extensive data on how public transportation can be electrified, which includes operational insights, cost efficiency, and route optimization for electric buses and SUVs. The collected data is crucial not only for refining electric mobility but also for future infrastructure development, asset management, and policy planning.



**After the success of these pilot projects, what are the next steps in scaling the National Highways for Electric Vehicles initiative across India? How will this contribute to the broader goals of sustainable transportation and renewable energy integration?**

Following the successful trials, the next logical step is to scale the National Highways for Electric Vehicles (NHEV) initiative across the country. This third trial is part of a broader series designed to gather data, not just on personal vehicles, but also on public transportation options like buses and trucks. As we move forward, scaling the NHEV initiative will require comprehensive efforts to optimize the network, including the deployment of fast-charging stations, integration of renewable energy sources, and the creation of electric vehicle (EV)-friendly infrastructure across the highways.

Abhijeet Sinha

One of the major goals is to develop a comparative analysis that helps us understand the operational costs, break-even points, and environmental impacts of different vehicle types—electric, diesel, and LNG. With this data, we can identify the most cost-effective and sustainable transportation options for long-distance travel, particularly in the context of India's unique geographical and economic landscape. The transition from diesel to electric transportation will not only help reduce carbon emissions but also support the government's broader agenda of integrating renewable energy sources, such as solar and wind power, into the transportation grid. This initiative will contribute to achieving the national goals for reducing dependency on fossil fuels and meeting global climate commitments.

**There's been significant investment in electric trucks and infrastructure. How is this funding being sourced and deployed? Who will benefit from these financial resources?**

The electric truck sector is inherently capital-intensive, requiring substantial investment not just in vehicle technology but also in the development of supporting infrastructure, including charging stations, power backup systems, and high-speed charging networks. The government has recognized the importance of these investments and is deploying financial resources through various funding mechanisms, including long-term loans and blended financing options. These financial instruments are crucial for addressing the viability gap in the electric truck ecosystem, ensuring that both private sector players and public enterprises have access to the necessary capital to build the required infrastructure.

One notable initiative includes the government matching Rs 500 crore in private funding with an equal amount from public funds, thereby creating a strong financial foundation for the deployment of electric trucks. This blended financing approach ensures that the benefits of these investments reach a wide range of stakeholders, including fleet operators, logistics companies, and large-scale transportation networks. The infrastructure built today will serve as the backbone for the future of India's electric truck industry, ensuring that both large corporations and smaller businesses can transition to electric transportation. By facilitating this shift, the government is not only driving the adoption of electric vehicles but also ensuring that the economic benefits of this transition are shared across various sectors.

**Watch the video here:**
https://bit.ly/nhev

# LIVGUARD introduces high-frequency solar inverters at REI expo



Livguard, under the SAR Group, launched their new line of High-Frequency Solar Inverters exclusively at the recently concluded 17th Renewable Energy India Expo (REI) 2024. Alankar Mittal, President Business Unit Head, Solar & Exports, Livguard unveiled these new products.

The newly launched Hybrid Series and Off-Grid Series inverters are designed for higher efficiency with transformer-less technology, making them more reliable and compact, the company claims. Compatible with Lead Acid and Lithium Batteries, they also feature built-in Wi-Fi for easy smartphone performance tracking. The brand also launched cutting-edge lithium-based ESS, high-efficiency Bi-facial panels, and high-efficiency DCR Panels.

These products complement Livguard's wide range of solar solutions catering to residential and small business needs. The brand facilitates consumer finance for solar starting from Rs. 1 lakh to Rs. 2 crore. The Company is also providing interest-free loans on their off-grid & hybrid solutions for 6 months. Livguard's wide range of solar solutions like Off Grid solutions, On Grid Solutions, Hybrid solutions, and Lithium ESS offer multiple mode operation for battery and grid preference, higher ROI, and uninterrupted use of solar energy for savings and backup respectively. With Livguard's Livmonitor 360 app, you can monitor solar generation through an easy one-click step! With a 1000+ PAN India service team and on-call solar expert assistance, Livguard continues to set the standard in installation quality and customer satisfaction.

Alankar Mittal, President Business Unit Head, Solar & International Business. Said, "The REI Expo provided the perfect platform to showcase our cutting-edge solutions, reaffirming our commitment to a greener future. We are thrilled with the response to the exclusive launch of our High-Frequency Solar inverters that are compact and lightweight, RMS enabled, allow for quick changeover, and have low noise. We see immense potential in India's renewable energy sector and we will continue to be at the forefront of developing innovative products and services that drive sustainable energy solutions in India."

**Read the news here:**
https://bit.ly/livguard-mojo