AdvaMed
Advanced Medical Technology Association

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The voice of MedTech

POSITION PAPER

Development of Product Standards for Medical Devices by Bureau of Indian Standards - An Industry Perspective

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Transforming Healthcare
Saving Lives

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Introduction

The role of standards for regulatory purposes has always been a matter of debate and discussion and continues to be a point of contention. In 2008, understanding the uniqueness of the medical device industry, the then Global Harmonization Task Force (GHTF) prepared a guidance document on the "Role of Standards in the Assessment of Medical Devices" to encourage and support global convergence of regulatory systems in establishing a consistent approach to regulate medical devices in the interest of public health.

The 2008 GHTF document describes standards as the building blocks for harmonized regulatory processes to assure the safety, quality and performance of medical devices but at the same time emphasizes the importance of compliance to "Essential Principles of Safety and Performance of Medical Devices" as the primary responsibility of the manufacturer. The use of standards is voluntary and manufacturers shall have the option to select applicable national or international standards or alternative solutions, thereby leaving the decision around utilization or non-utilization of standards to the manufacturers, to demonstrate compliance of their medical devices to Essential Principles. The guidance document further underlines the cardinal role of the regulatory authorities to encourage, support and adopt international standards, wherever possible, and to endorse the use of a regulatory reliance model.

In 2018, the International Medical Device Regulators Forum (IMDRF), the successor organization to GHTF, issued the document "Optimizing Standards for Regulatory Use." That 2018 document expanded upon, but did not eliminate, the prior GHTF guidance. This recent IMDRF guidance reinforces the value of standards, including "as a means to streamline and harmonize regulatory processes around the world." The 2018 document adds that commitment to Essential Principles (EPs) is a key expectation of such a standard, including identification within the standard for how conformance with the standard is consistent with Essential Principles. Appropriate use of standards will promote efficiencies and innovation while facilitating objective assessment of device safety and performance. Also in 2018, IMDRF issued an updated Essential Principles document. The updated document includes an appendix regarding use of standards to meet EPs that underscores that standards are voluntary and may represent one, but not the only, way to meet EPs.

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Appropriate Use of Standards – Area of Focus

In view of the rapid innovation in the medical device industry, a prescriptive standard can stifle innovation, and therefore standards should only focus on the necessary functional characteristics and not on the design characteristics to demonstrate compliance to Essential Principles. Accordingly, even though stringent regulators have identified the consensus standards or recognized standards, the standards are still voluntary. The use of consensus standards or recognized standards is not mandatory. Manufacturers should be free to select alternative solutions to demonstrate their medical device meets the relevant Essential Principle. Manufacturers may use "non-recognized" or "non-consensus" standards, in whole or in part, or manufacturers own specification. **To achieve harmonized regulatory processes ensuring safety, quality and performance of medical devices, the following principles are essential:**

- Recognize and adopt international standards to demonstrate compliance with Essential Principles of safety and performance of medical devices
- Demonstrate compliance to essential principles rather than burdening the manufacturer with standards compliance thereby fostering innovation in the healthcare sector
- Utilize standards to reflect existing applicable technology while not discouraging the development or use of new technologies
- **Refrain from mandatory standards that may stifle rapid innovation and emerging technologies**

In addition to compliance to essential principles, a robust post market surveillance system should be in place to understand the performance of the device in the field both at the manufacturers end and the regulators end and concerns on any signals on the performance of the device should be analyzed and if found to represent an issue, rectified.

However, since medical technology regulations are in the evolutionary stages of implementation in India, the reliance on local testing and compliance to specification is being pursued which is contrary to the regulatory processes followed by other global regulators. In other countries, compliance testing to international standards is done once during the development of a medical device by certified organizations. The reports and/or certificates are then used by the manufacturer as evidence to support their claims of conformity as part of the medical device submission process in their essential principle check list.

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Overview of Standard Making Bodies in Asia-Pacific: IMDRF Countries

The table below provides a summary of the current practices in various countries in relation to adherence of standards developed by standard bodies:

Standard Body	Country	Adherence to Standards by Health Authority
American National Standards Institute (ANSI)	United States	Voluntary
British Standards Institute (BSI)	United Kingdom	Voluntary
Standards Australia (SAI)	Australia	Voluntary
Standards Council of Canada (SCC)	Canada	Voluntary
Japanese Industrial Standards Committee (JISC)	Japan	Voluntary
Bureau of Indian Standard (BIS)	India	Mandatory

4 India –Are Standards Mandatory or Voluntary?

In India, when the Medical Device Rules 2017 was enacted, some of the principles of the drug rules were incorporated including those related to use of standards. Rule 7 of the Medical Devices Rules (MDR), 2017, provides that:

Product standards for medical device -

1. The medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.

2. Where no relevant Standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organization for Standardization (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopeial standards.

3. In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards.

Provided that the product specific standards are not available in BIS and in ISO, the regulators require compliance to essential principles either by following consensus international standards (per requirement) or based on manufacturers' validated specification. MDR 2017 also recognize Essential principles to be an important requirement as clearly specified in Rule 6 and the requirement to submit the essential principle checklist listed in the Fourth Schedule, part II clause (i) a 8 and clause (ii) d.

However, with the introduction of national vertical standards by BIS, the regulation requires the manufacturer to follow national standards as primary preference thereby essentially deviating from the fundamental purpose of the use of standards as a method to demonstrate compliance to essential principles for medical devices. Secondly, the predicament to follow solely national vertical standards first and then only international standards or any other standards acts as precursor to stifling the manufacturer efforts to introduce and launch new technologies in the market. On the other hand, with the increasing globalization of markets, International Standards (as opposed to regional or national standards) have become critical to trade and ensuring that imports meet the internationally recognized levels of performance and safety

In 2018, HITES a procurement arm of the Hindustan Lifecare Limited, through Ministry of Health &Family Welfare(MoHFW) reached out to BIS to develop standards for commonly procured medical devices because they were overwhelmed with the different technologies being quoted. BIS used this outreach as an opportunity to develop product certification for medical devices. Following this request, BIS initiated the development of product specific standards, and subsequently a core group of industry was formed to develop the standards for commonly procured medical devices by MoHFW. This action sparked the creation of vertical standards and inadvertently altered the purpose of standards, from a method to demonstrate compliance to the Essential Principles to a procurement mechanism that has the capacity to stifle innovation and reduce the diversity of medical device that could better serve the Indian healthcare sector, and more importantly patients.

Here, the industry would like to exhibit an example of a developed standard in advanced stage of adoption. In the InVitro Diagnostics (IVD) subgroup of BIS Core group on Standards, there are at present six standards for IVD equipment that have been finalized and sent to the sectional committee on IVDs, MHD 19. One of the standards is for electrolyte analyzers. At present there are three types of technologies used in electrolyte analyzers, which are available in the country and being used in different laboratories; however, the initially drafted standard focused only on cell technology. Patients benefit from the availability of multiple types of electrolyte analyzers. After protests from the industry, the finalized standard clearly mentioned that it will be the manufacturer's specification for all other technologies. This reinforces the idea that product specifications should not be utilized for the development of standards as it stifles innovation and risks limiting patient access to appropriate technologies.

It was also noted, in the draft standards being developed recently, that BIS has incorporated commercial conditions as well as BIS certification requirements into the standard, a development that goes against the purpose of standards development. The following are the excerpts from the draft analyzer standard which has been recommended to the sectional committee:

7.2 BIS Certification Marking

The Electrolyte Analyzer may also be marked with a Standard Mark. The use of the Standard Mark is governed by the provisions of Bureau of Indian Standards Act, 1986 and the Rules and Regulations made thereunder. The details of conditions under which the license for the use of Standard Mark may be granted to manufacturers or producers, may be obtained from the Bureau of Indian Standards.

8. Accompanying documents

8.1 *Documentation shall comply with the requirements of IS/ISO 14971:2012 and IS/ISO 13485:2016.*

8.2 *The accompanying documents shall include the following.*

8.2.1 *List of accessories*

8.2.2 *Instructions for use*

8.2.3 *Instructions for maintenance.*

8.2.4 *A two-year replacement warranty in the event of any failure arising from defective design, materials or workmanship.*

This example illustrates that the effort has led to the development of product standards (vertical standards)that are intended for tender specifications. Moreover, such standards do not support the aspirations of the government to become Atma Nirbhar in medical devices and our dream to be the medical device manufacturing hub of the world.

Globally there are many techniques used to procure medical devices though tenders such as the 'Value-based Procurement', which includes creating a pool of clinicians who issues cores based on a matrix involving various applicable parameters. In the case of a spilt opinion from clinicians, there is an option to use Health Technology Assessment (HTA) to determine the value of the product. These are some of the tools that the industry recommends using in India for procurement purposes, rather than creation of product standard as a means to procure medical technology

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Conclusion

In conclusion, international standards are one of the multiple tools for harmonizing regulatory processes across international markets to assure the safety, quality, and performance of medical devices. Hence, in the interest of the development of the MedTech sector and to make the latest technologies available in the country, APACMed and AdvaMed recommend the following:

1. CDSCO to amend the Medical Device Rules relating to the use of standards and clearly specify that BIS/ISO/IEC/ASTM/Pharmacopeia/ manufacturers validated specifications be used to demonstrate compliance to Essential Principles, so that India will be able to innovate newer technologies and cater to the changing needs of the patients.

2. The manufacturer should retain the ability to provide documentation to demonstrate that the device conforms to the Essential Principles through application of a selected standard or alternative means (e.g. local or international compliance testing reports and/or certificates).

3. BIS should refrain from developing India-unique standards and instead rely upon international consensus standards. If needed, BIS should develop standards that will assist manufacturers to develop specifications for their innovative products.

4. To ensure that BIS standards are in line with international standards, the commercial tender specifications and the BIS marking clause should not be included in any of the BIS standards being developed.

5. Regulatory Authorities should develop a procedure for the "recognition" of voluntary standards and public notification of such recognition as consensus standards.

With the increasing global interdependence, International Standards (as opposed to regional or national standards) have become critical to trade and ensuring that imports/exports meet the internationally recognized levels of performance and safety. The ultimate goal of standardization is to achieve international accord on all technical matters relating to the exchange of goods and services between nations.

About Asia Pacific Medical Technology Association (APACMed)

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed) is the only regional association to provide a unified voice for the medical technology industry in Asia Pacific, representing both multinational corporations as well as small and medium enterprises, together with several local industry associations across the region. Headquartered in Singapore, APACMed's mission is patient-centric, and we strive to continuously improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.

We are committed to working with governments and other stakeholders to facilitate patient access to innovative and life-saving medical technologies, supporting strong and thriving healthcare systems across the region, and promoting a robust and sustainable regional ecosystem that encourages investment, trade and innovation.

APACMed Corporate Members

About The Advanced Medical Technology Association (AdvaMed)

The Advanced Medical Technology Association (AdvaMed) is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world. AdvaMed's membership has reached over 400 members and more than 80 employees with a global presence in countries including Europe, India, China, Brazil, and Japan. AdvaMed's member companies range from the largest to the smallest medical technology innovators and companies. The Association acts as the common voice for companies producing medical devices, diagnostic products and digital health technologies.

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Chief Author

1. Aaditya Vats, Associate Director, Regulatory Affairs, Johnson & Johnson

Contributors

1. Jamie Wolszon, Vice President, AdvaMed
2. Gaurav Verma, Director- Regulatory Affairs & Government Affairs, Becton Dickinson India Pvt. Ltd.
3. Prashanth Prabhakar, Head - Regulatory Affairs, Boston Scientific India Pvt. Ltd.
4. Asok Kumar Raghavan Nair, Director- Global Strategic Regulatory Affairs, Abbott
5. Sushant Jaiswal, Manager - Regulatory Affairs, Roche Diagnostics India
6. Kaushik Anand, Senior Manager Regulatory Affairs, Alcon
7. Lipi Chakhaiyar, Associate Director - Regulatory Affairs, Abbott
8. Neeraj Sharma, Manager- Regulatory Affairs, Becton Dickinson
9. A Ganesh Kumar, Head - Quality/ Regulatory Affairs (India Zone), Siemens Healthineers
10. Elizabeth Freitas, Associate Director, Regulatory Affairs- Asia Pacific Japan, Illumina Inc.

Contact APACMed India

Anirudh Sen
Country Lead India &
Director Regulatory Affairs APAC
anirudh_sen@apacmed.org
+91 9810170348

Ankit Sharma
Manager, India
ankit_sharma@apacmed.org
+91 9810307528

Shreya Bansal
Research Associate, India &
Regulatory Affairs APAC
shreyab@apacmed.org
+91 8588067531

1st Floor, Tower B, Unitech Business Park, Block F, South City I, Sector 41
Gurugram, 1220002, Haryana, India

Asia Pacific Medical Technology Association (APACMed)2 Science Park Drive, Ascent
Tower A, #02-07, Science Park I, S118222, Singapore

Contact AdvaMed

Gaurav Mendiratta
AdvaMed India Advisor
gmendiratta@advamed.org

C/o DKM Online private limited, 2nd Floor, KLJ Complex - II, Police Station, 70/39b,
Opp, Najafgarh Rd, Moti Nagar, New Delhi, Delhi 110015