Promixco Biomedical Research & Innovation Limited (PBRI): Advancing Medical Devices R&D in Bangladesh

Abstract

Bangladesh's healthcare sector is transforming, with an urgent need to strengthen its medical device research and development (R&D) ecosystem. This paper explores the current status, challenges, and roadmap for R&D in medical devices, while highlighting the pivotal role of Promixco Biomedical Research & Innovation Limited (PBRI) in shaping the industry's future. With a focus on sustainability, regulatory readiness, and global export opportunities, PBRI aims to bridge the gap between innovation and healthcare delivery.

1. Introduction

The medical devices sector in Bangladesh is still nascent, characterized by high import dependence, limited local manufacturing, and weak regulatory oversight. Despite growing hospital demand and public health needs, research and innovation remain underdeveloped. Promixco Biomedical Research & Innovation Limited (PBRI) emerges as a catalyst in this sector, committed to fostering innovation, ensuring compliance with global standards, and developing export-ready medical technologies.

2. Current Status of R&D in the Bangladesh Medical Devices Sector

- High reliance on imported devices.
- Local manufacturing limited to low-end consumables.
- Increasing hospital demand due to population growth.
- DGDA (Directorate General of Drug Administration) is currently drafting medical device regulations.
- Fragmented R&D ecosystem with limited university-industry collaboration.

3. Key Challenges

- Lack of dedicated biocompatibility testing labs.
- Insufficient regulatory and quality management (ISO 13485) adoption.
- Scarcity of skilled biomedical engineers and regulatory experts.
- Limited funding mechanisms and grants for MedTech startups.
- Weak intellectual property (IP) and patent generation.
- Procurement policies favor low-cost imports over local innovations.
- Absence of a structured export readiness program.

4. Steps Required (12–24 Months Roadmap)

- Establish a National MedTech Fund to support innovation.
- Create pilot and reference testing laboratories.
- Fast-track ISO 13485 adoption across the industry.
- Develop a regulatory sandbox under DGDA, IEDCR, and BSTI.
- Foster academic-industry partnerships and joint grants.
- Build prototyping hubs under PPP models.
- Launch a national medical device registry and UDI system.
- Train 500+ professionals in biomedical R&D and QMS.
- Introduce export readiness programs and incentives.

5. Recommendations

- Promote domestic innovation by prioritizing local innovators in public procurement.
- Develop a comprehensive National Medical Device R&D Policy.
- Create long-term PPP models for MedTech clusters.
- Establish regional centers of excellence for biomedical research.
- Strengthen global collaborations to ensure export readiness.
- Build capacity in ethics, safety, and sustainability.

6. Importance of Promixco Biomedical Research & Innovation Limited (PBRI)

Promixco Biomedical Research & Innovation Limited (PBRI) plays a strategic role in advancing Bangladesh's medical device sector. Its contributions include:

- Integrated innovation approach: ideation, design, verification, and small-batch manufacturing.
- Regulatory & QMS leadership: ensuring ISO 13485 and CE/FDA alignment.
- Hospital-based pilot projects to validate clinical adoption.
- Group synergies with Promixco subsidiaries for vertical integration.
- Training academy for biomedical professionals.
- Focus on ethics, safety, and sustainability in device innovation.
- Acting as an export gateway for Bangladeshi medical devices.

7. Conclusion

Bangladesh is at a crossroads in building a sustainable and globally competitive medical devices industry. The challenges of limited infrastructure, weak regulatory frameworks, and funding shortages can be overcome through structured national strategies and public-private partnerships. Promixco Biomedical Research & Innovation Limited (PBRI) stands as a cornerstone in this journey, driving innovation, compliance, and global integration. Its role is critical not only for domestic healthcare transformation but also for positioning Bangladesh as an emerging player in the global MedTech market.

References

1. World Health Organization (WHO) – Medical Device Regulations.
2. Directorate General of Drug Administration (DGDA), Bangladesh – Draft Medical Device Rules.
3. International Organization for Standardization – ISO 13485 Medical Devices.
4. Promixco Group internal strategic documents on R&D and MedTech roadmap.
5. Global MedTech Market Insights, 2025.

8. PBRI Research & Innovation Team

Promixco Biomedical Research & Innovation Limited (PBRI) is led by a multidisciplinary team of experts who combine academic knowledge, industry experience, and entrepreneurial drive. The team includes:

- **R&D Director** – Oversees medical device innovation and prototyping.
- **Regulatory Affairs Manager** – Ensures compliance with DGDA, ISO, CE, and FDA standards.
- **Biomedical Engineers** – Specialize in device design, biocompatibility testing, and prototyping.
- **Clinical Research Experts** – Conduct hospital-based pilot validation studies.
- **Quality & Safety Officers** – Maintain ISO 13485 QMS and risk management frameworks.
- **Global Affairs & Export Division** – Focused on export readiness, partnerships, and market access.
- **Training & Capacity Building Unit** – Develops future biomedical professionals in Bangladesh.

Figure 1: Current Status of the Medical Devices Sector

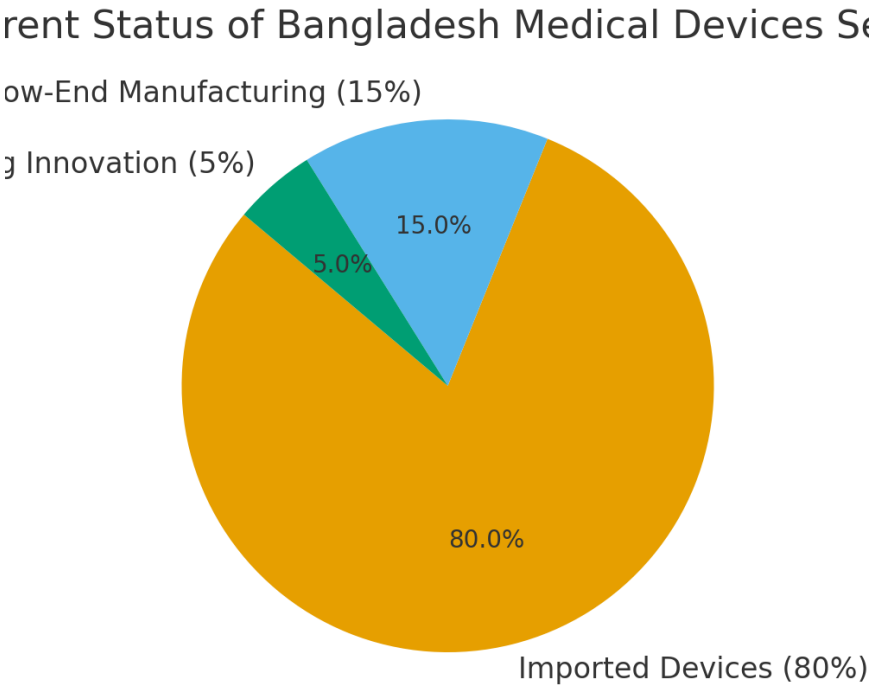

Figure 2: Key Challenges in MedTech R&D

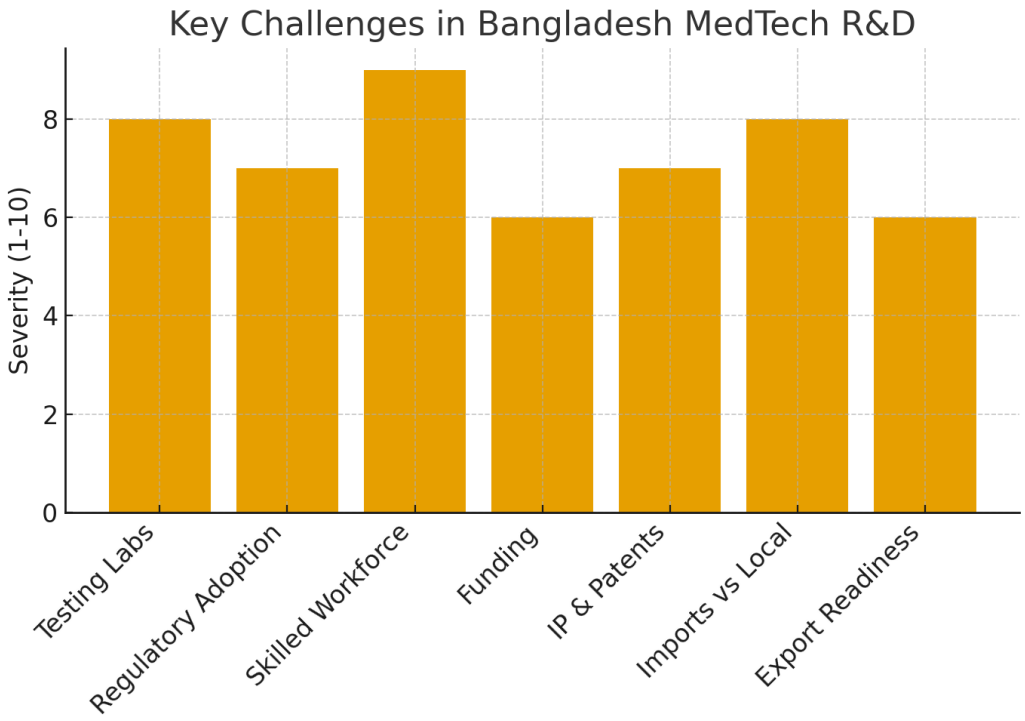

Figure 3: Roadmap Priorities for Next 24 Months