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Our 34th Year of Publication

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- ISO 10993-14: Identification and quantification of degradation products from ceramics
- ISO 10993-15: Identification and quantification of degradation products from metals and alloys
- ISO 10993-17: Toxicological Risk Assessment (TRA) of medical devices, packaging materials and CCS
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Upcoming Webinar

Accelerated Ageing and Stability Testing for Pharma & Medical Device Packaging

25th June | 2:30 PM | Online

KEY HIGHLIGHTS:

- Accelerated ageing principles and testing methodologies
- Correlation with real-time aging studies
- Seal integrity and material compatibility assessments
- Regulatory expectations aligned with ISO 11607
- TÜV Rheinland testing and certification support

SPEAKER

Harish Kumar Kannepalli
Medical Devices & Packaging Testing Expert

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Smart Textile For Healthcare Applications Dr. Ketan Vadodaria, National Institute of Design (NID), Ahmedabad Smart textiles are engineered using materials and textile structures to meet specific functionalities. They have a wide range of applications that span various industries. In healthcare, they have the potential to revolutionize patient monitoring, enabling continuous health tracking, early detection of health issues, and remote healthcare. (May-June 2023)

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SINGAPORE : MEDICAL DEVICES MARKET Mr. Amit Dave, M. Pharm, MBA, Former CEO – Brazil Operations / Vice President Export - Zydus Cadila /Claris Lifesciences Singapore is an entry point for the whole southeast Asia market. A stable political and economic environment adds to the attractiveness of this market. Singapore's strong base for research and innovation can help med tech companies in framing collaboration models in healthcare. (May-June 2023)

AiMeD & REGULATORY UPDATES
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- AiMeD Applauds Health Minister Mansukh Mandaviya for launching 3 major Medical Device Policy & Scheme
- Health ministry notifies MDR amendment to enable state govts to establish medical devices testing laboratories. (May-June 2023)

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- IIT Madras launches Department of Medical Sciences & Technology
- Husky Installs First-of-Its-Kind Medical Molding System in India
- ICMR issues list of technologies supported under ICMR- MDMS to foster indigenous manufacturing of medical devices. (May-June 2023)

Did You Know?

About Recycling Solution for Lab Plastics: Successful Feasibility Study By BD & Envetec

A recent successful pilot study by Becton, Dickinson & Company in collaboration with Envetec Sustainable Technologies indicate that following effective disinfection and processing, several polymers, including polystyrene, polyester (PET), polypropylene and polyethylene, can be reintroduced into the manufacturing supply chain. These materials are widely used in medical devices.

This pilot project, led by BD's Sustainable Medical Technologies Institute, is an important step toward developing circular economy solutions for widely used healthcare products made from plastics, such as blood collection tubes, syringes and packaging materials. Widely used laboratory plastics can be safely recycled and reintroduced into the manufacturing process without compromising quality.

As part of the study, unused BD BBL prepared plated media were processed using Envetec's GENERATIONS technology, a low-energy chemical disinfection process that converts regulated waste into clean, recyclable polymer flakes. These flakes were then processed into polystyrene pellets and used to create new Petri dish prototypes. Testing confirmed that the recycled material met required performance standards and could be successfully molded. Envetec's GENERATIONS technology is currently being implemented across health care & life science settings in United States and Europe.

Plastic consumables, particularly pipette tips and plates, are a significant source of waste in laboratories. Broader studies estimate that the production of a single 96-rack of polypropylene pipette tips releases approximately 0.304 kilograms of CO2 equivalent (CO_2e) and requires about 6.6 liters of water. With laboratories using these consumables regularly, the cumulative effect on carbon emissions and water usage is staggering. As per Precedence Research, the sustainable laboratory plasticware market is anticipated to be valued at $970.97 million in 2026 and is expected to witness a CAGR of 19.2% through 2035.

(https://www.nasdaq.com/articles/bd-envetec-showcase-closed-loop-recycling-solution-lab-plastics)

In a Nutshell....

"Precision in medical device manufacturing isn't just about technology. It's about having proven expertise across multiple quality standards and certifications".

- Michael Freeman, JD Ocutrxtech

MEDICAL PLASTICS
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From the Editor's Desk

Biocompatibility of Polymers & Factors affecting Biocompatibility

A medical device must be adequately designed to be safe for its intended use. With more and more applications for minimally invasive devices and implants getting developed, polymers used come in temporary or long-term contact with human skin, blood, body organs or tissues should be biocompatible and be evaluated and tested for biocompatibility.

It is also important to take care of the **impact of various manufacturing processes on the biocompatibility**. One such aspect as discussed under Cover Story is about impact of Sterilization Methods on Polymer Biocompatibility.

Sterilization of medical polymers often alters their physical, chemical, and structural properties, significantly affecting biocompatibility and in vivo performance. Proper sterilization must balance microbial elimination with maintaining material structural integrity, surface morphology, and minimizing cytotoxic, leachable by-products. The cover story elaborates on the **"Key Effects of various Sterilization Methods on Polymer Biocompatibility."**

Enhancing biocompatibility can also be achieved through Coatings on Polymers and Medical Devices which can improve device performance, reduce immune response and prevent infections, thereby improving patient outcomes. Under "Global Trends" column in this issue, it is explained how global biocompatibility coating practices is witnessing fast growth. It also elaborates on the key types of Biocompatible Coatings and their benefits.

An article by Dr T S Kumaravel and Dr S S Murugan on **"The Strategic and Regulatory Implications of Cost-Based Selection of Testing Services" explains** a very important relationship between laboratory costing structures and quality. It evaluates the regulatory risks associated with low-cost service models. As explained , for the lifesaving industry like medical device manufacturing, while cost containment remains a legitimate operational objective, disproportionate emphasis on low pricing may introduce systemic vulnerabilities including long term regulatory, economic, and reputational risk.

This issue also covers a case study on Autoinjectors. The article on, **"High-Performing Pens and Autoinjectors in India: What Today's Market Demands from Manufacturers",** Mr. Rajen Kasi, Director & General Manager, Husky Injection Molding Systems Pvts Ltd, explains why manufacturers must deliver precision, consistency and scalability – without compromising cost or timeliness.

Under "Regulatory" column by Mr. Sanjay Shah, a very important development regarding recent proposals for changes in the EU's Medical Device Regulation (MDR) as well as IVDR are discussed. The proposed changes are aimed at streamlining regulatory processes, reducing administrative burden and enhancing predictability, while maintaining patient safety and public health.

Recycling of Laboratory Plastics: Plastic consumables, particularly pipette tips and plates, are a significant source of waste in laboratories. The "Did You Know" column gives details about a recent successful pilot study shows that following effective disinfection and processing, several polymers can be recycled.

This issue also our regular features of "Global Markets" as well as Industry News and more.

D L Pandya

Impact of Sterilization Methods on Polymer Biocompatibility

Sterilization of medical polymers often alters their physical, chemical, and structural properties, significantly affecting biocompatibility and in vivo performance. Common methods—autoclaving, gamma radiation, ethylene oxide (EtO), and H_2O_2 plasma—can cause chain scission, crosslinking, polymer degradation, or surface toxicity. Proper sterilization must balance microbial elimination with maintaining material structural integrity, surface morphology, and minimizing cytotoxic, leachable byproducts.

Sterilization methods can significantly impact the biocompatibility of medical devices, as outlined in ISO 10993. Techniques like ethylene oxide sterilization, gamma irradiation, or steam autoclaving may alter the chemical composition, physical properties, or surface characteristics of device materials, potentially leading to adverse biological responses. ISO 10993 emphasizes evaluating the effects of sterilization processes as part of the overall biological assessment, ensuring that they do not compromise the safety and functionality of the device. This includes testing for residual sterilants, degradation products, and material changes that could affect cytotoxicity, sensitization, or irritation. By integrating sterilization evaluation into the biocompatibility framework, manufacturers can ensure their devices meet both safety and performance standards.

Biocompatibility is a broad expression describing a material's fitness for use within the body. Implantable devices nearly always cause inflammatory or immune responses. For a biocompatible material, these responses do not rise to the level of being harmful. Testing for biocompatibility of materials is mainly centered on guidelines put forth by ISO 10993, the FDA (United States), Regulations (EU) 2017/745-6 (European Union), and the USP. The USP classification system for plastics groups them into Classes I – VI defined by compliance testing and approval criteria. Fluoropolymer plastics, for example, fall under USP Class VI. For material evaluation specifically, testing includes chemical, mechanical, and thermal analyses. An additional and crucial step in biocompatibility assessment is the effect of sterilization on the material. Many plastic device components must tolerate repeated sterilizations.

Key Effects of Sterilization Methods on Polymer Biocompatibility:

- **Gamma Radiation:** High-energy radiation can cause polymer chains to break (scission) or crosslink, decreasing molecular weight, causing discoloration, and sometimes increasing brittleness. It can lead to the formation of free radicals, resulting in cytotoxic effects.
- **Autoclaving (Steam):** Ideal for non-degradable, high-temperature stable polymers (e.g., polyurethanes). However, high temperatures and humidity can cause structural deformation, hydrolysis, and degradation in biodegradable polymers like polylactides (PLA).
- **Ethylene Oxide (EtO):** A common low-temperature method. However, it can leave behind toxic residues, necessitating long aeration times to ensure patient safety. It is effective for devices that cannot withstand heat or radiation.
- **H_2O_2 Plasma:** A highly effective low-temperature process that, while effective at killing bacteria, can be quite corrosive, modifying surface chemistry and decreasing surface strength, which may affect cell adhesion and biocompatibility.
- **Degradable Polymers:** These are highly sensitive to radiation and heat, which can speed up biodegradation rates and alter drug release kinetics.

Biocompatibility and Material Selection Considerations:

- **Degradation Rates:** Sterilization-induced cleavage of chains in biodegradable polymers like PLA or PGA can drastically change their in vivo behavior.
- **Surface Changes:** Sterilization can alter surface hydrophilicity and roughness, directly affecting how cells interact with the material.
- **Regulatory Requirement:** Any changes in sterilization methods require careful evaluation, as they may impact the biocompatibility profile.
- **Optimal Methods:** Choosing the right sterilization method depends on the polymer's thermal and chemical stability to avoid altering its surface morphology and mechanical strength. [1, 2.

Fluoropolymers and Biocompatibility

As a group, fluoropolymers have many attractive qualities for biocompatibility including near-inertness for chemical reactivity in the body, high lubricity, and broad temperature tolerance. Despite these properties and the multiple banks of testing necessary to attest to biocompatibility, absolute conclusive judgment regarding safety is not realistic. Biocompatibility instead is characterization based on current knowledge and the best judgment of accepted experts.

Sterilization Technology and Regulations

Sterilization technology and regulations are both complex and extensive. Despite the diversity in methodology, conventional terminal sterilization methods originally developed for metallic, ceramic, and chemically stable polymeric implants present barriers to sterilizing labile degradable functional polymers and tissue grafts for regenerative medicine applications. To preserve the chemical, structural and mechanical integrity of the polymer-based implant and its surgical handling and in vivo degradation/drug release profiles, a salient choice of terminal sterilization modality should be made based on an understanding of both the unique nature of the polymer and the pros/cons of each sterilization method and associated regulatory classification .

General polymeric formulation/scaffold considerations include chemical compositions (e.g., presence of labile linkages sensitive to cleavage during sterilization or functional groups that may react with a chemical sterilant), unique thermomechanical behavior (e.g., transition temperature compatibility with the sterilization temperature implemented), and dimensional stability/porosity (e.g., whether irreversible swelling may occur by steam autoclave or scCO2). Once incompatible terminal sterilization modalities are excluded (e.g., autoclave for thermal sensitive materials; scCO2 for porous polymers that swell/plasticize extensively; EtO for polymers with nucleophilic

functional groups), priority should be given to methods with Class A or Class B designations. In the case of macroporous, thermal-sensitive, degradable shape memory polymer scaffolds, multiple established modalities may all present challenges. In such a case, different methods may need to be evaluated to identify the one resulting in minimal or acceptable levels of alterations to key materials properties and implemented consistently for all preclinical in vitro and animal studies.

As highlighted in this review, infrastructure, capital, time, compliance protocols, and burden of proof are but a few areas affected by regulatory classifications. Furthermore, these implications may not be confined solely to the approval processes but may extend throughout the product's lifetime. Managing this process is undoubtedly complex and calls for interdisciplinary collaboration. Identifying a terminal sterilization modality/condition that sufficiently satisfies regulatory requirements while preserving product functionality could be a substantial challenge. Indeed, many novel biomaterials have a hard time transitioning from research laboratories to the market due to either belated findings of incompatibility with conventional Class A/B sterilization methods or the tremendous regulatory burdens associated with the novel sterilization modalities implemented during laboratory research or the aseptic processing alternative. Deliberate integration of the regulatory considerations discussed in this review early in the material design/innovation may prove critical to streamlining ultimate clinical translations. Interdisciplinary collaboration between research and development, regulatory, and leadership teams is likely required to thoroughly evaluate options and tackle the challenge.

(https://pmc.ncbi.nlm.nih.gov/articles/PMC9691608/)

A Medical Device Must Be Adequately Designed to be Safe for Its Intended End Use, After Sterilisation

Radiation Effect on Polymer Materials Commonly Used in Medical Devices

Description

Industrial sterilization is primarily used for medical and healthcare products including a wide range of single-use medical products and devices. Historically, sterilization is mostly done using gamma sources. However, recently we observe a transition to accelerator-based sterilization, specifically uses of e-beam and X-ray. Lack of the knowledge of radiation effects on polymers for e-beam and X-ray is one of the reasons to impede the spreading use of these technologies. Therefore, the purpose of this proposal is to expand our understanding of radiation effects on polymer materials commonly used in medical devices by comparing gamma, e-beam, and X-ray irradiation. The increased access to accelerator-based sterilization, in addition to other sterilization methods, will have a collateral benefit aligned to UN Sustainable Development Goals, specifically SDG 3 (good health and well-being), SDG 9 (industry, innovation and infrastructure), and SDG 12 (responsible consumption and production).

Many polymers used in medical devices show varying degrees of degradation and change with radiation that may create toxic by-products or leachables. Technological advance has done much to improve a material's resistance to radiation with the use of stabilisers additives, antioxidants, etc. These stabilisers, additives or antioxidants to improve a material's radiation compatibly may in turn be toxic. The range of biological and physico-chemical hazards is wide (e.g., silicone, latex), and medical procedures and drugs are becoming increasingly sophisticated. The evaluation and subsequent comparison of biocompatibility of materials require test methods that are meaningful and appropriate.

The evaluation of biological responses (biocompatibility) of materials is subject to limitations, inconsistencies and opportunities for misapplication and/or misinterpretation. The challenge of biocompatibility and material safety is to create and use knowledge to reduce the amount of unknowns and to help make the best possible decisions and predictions. This is a simplified approach on how to address and assess the materials and tests for device(s), for their biological and physico-chemical responses as part of the overall evaluation and development of irradiated materials and devices. Like other normative work on this subject, this guideline does not fully address the determination of the effects of devices and materials on tissues and end use but advances what approaches to take, when to test, and how to start evaluating the biocompatibility and material safety of materials of medical devices used and irradiated by device manufacturers.

Ref :
01 'Sterilisation of Polymer Healthcare Products" By Wayne Rogers
02 Internet source :
- https://pmc.ncbi.nlm.nih.gov/articles/PMC9691608/

Ultra-high Molecular Weight Polyethylene (UHMWPE) Used in Orthopaedic Prosthesis

Ultra-high molecular weight polyethylene (UHMWPE) is a biomaterial widely used as part of prostheses that require articulating surfaces, such as knee endoprostheses, for its excellent mechanical qualities.

The Ultra-High Molecular Weight Polyethylene (UHMWPE) market for knee implants is experiencing robust growth, driven by an aging population, increased joint replacement surgeries, and demand for durable, wear-resistant materials. The market is dominated by implant-grade, cross-linked UHMWPE, which offers superior wear resistance and longevity in total knee replacements (TKR).

Market Dynamics

- **Market Growth & Size:** The medical-grade UHMWPE market is experiencing constant growth, with the overall medical-grade UHMWPE market expected to reach over USD 4 billion by 2030.
- **Key Drivers:** Rising orthopedic disorder cases, younger patients receiving knee replacements, and superior longevity of modern implants (specifically cross-linked UHMWPE) are key factors.
- **Regional Dominance:** The Asia Pacific region is expected to be the fastest-growing market due to continuous medical sector investments and increased joint replacements.
- **Challenges:** High production costs, energy-intensive processing, and competition from alternative materials (e.g., PEEK) pose challenges to market growth. [1, 2, 3, 4, 5, 6]

Key Trends and Innovations

- **Cross-Linked UHMWPE:** The industry has moved toward high-performance cross-linked UHMWPE to reduce wear.
- **Antioxidant Stabilization:** The inclusion of vitamin E (antioxidant-stabilized) in UHMWPE formulations is enhancing material resistance to oxidation and increasing implant lifespan.
- **Advanced Formulation:** Modern orthopedic implants are adopting 21st-century formulations that enhance toughness and fatigue resistance.

Factors Limiting Life of UHMWPE Prosthesis

Two major problems limit the life of UHMWPE prosthesis - wear and delamination, with both phenomena being mainly the result of chemical oxidation of polymer. Polyethylene wear debris formation continues to be a primary factor in the reduced longevity of total knee replacements.

Wearing causes the release of generated particulate matter that triggers a macrophage reaction leading to chronic inflammation and osteolysis, while delamination, due to the mechanical stress, macroscopically alters the surfaces.

It is well known in the field of biomaterials that the surface chemistry plays an important role in the interaction of cells, specifically those cells involved in the inflammatory response. And hence it is also important for the applications of UHMWPE.

Oxidized UHMWPE is an inherent state that exists in UHMWPE components used in total joint replacements.

It has also been well established that these UHMWPE components are susceptible to oxidative degradation through consolidation of the resin at high temperatures and pressures, sterilization by gamma irradiation, storage of the irradiated UHMWPE components and the implantation environment. The oxidation of UHMWPE components has been linked to changes in the mechanical properties of the material, such as decreased fatigue strength and the production of wear particles around the site of the implant.

Ref :
Internet Sources :
-https://pmc.ncbi.nlm.nih.gov/articles/PMC5445701/#:~:text=The%20oxidation%20of%20UHMWPE%20components,site%20of%20the%20implant%20%5B4%5D.
-AI source

EVENT REPORT

Two-Day Workshop on Medical Device Development

Venue: Biomedical Technology Wing, SCTIMST, Satelmond Palace Campus, Poojappura, Trivandrum

March 12 & 13, 2026.

Organised By:

Industry Institute Partnership Cell, Biomedical Technology Wing, SCTIMST Trivandrum

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) Trivandrum

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A two-day Workshop on **Medical Device Development** has been conducted during **12–13 March 2026** at the **Biomedical Technology Wing, Poojappura,** organized by the Industry-Institute Partnership Cell (IIPC) of the Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, SCTIMST, Trivandrum. This event was co-organised by Society of Plastic Engineers (SPE), India. The prime sponsor was M/s.Freudenberg Medical.

The objective of the workshop is to provide participants a comprehensive understanding of the stages involved in the development, testing, evaluation, and regulatory aspects of medical devices. The workshop brought together experts dealing with different aspects of device development. The speakers shared their knowledge on biomaterials, safety evaluation, clinical studies, and emerging trends in medical technology. The series of lectures spread in 2 days covered the entire lifecycle of a medical device, from concept to commercialization, mainly related to regulatory and safety (medical device classification, ISO 10993 biological safety, risk assessment, and clinical evaluation), technical analysis (materials characterization, biocompatibility, and various testing methods in the aspects of chemical, thermal, mechanical, and morphological) and product development modalities (product release studies, pre-clinical efficacy, and emerging innovations). A total of 25 participants enrolled in this program, from academia as well as from industry, spread across various parts of the country.

On Day 1, 12th March 2026, the program began with an introductory and welcome address by the co-ordinator and felicitation session from 9:15 am to 10:00 am. Dr.H.K.Varma, Head, BMT Wing, SCTIMST and Shri.D.L.Pandya, Vice President, SPE India Medical Plastics Division, gave felicitation speeches on behalf of the organisors. Mr.Falgun Jani from Freudenberg Medical, delivered a short presentation on the activities of the Company.

The first session, conducted by Ms. Amrutha C., focused on Biomaterials and Medical Devices. She explained the definition and classification of medical devices and discussed how biomaterials are selected based on their intended medical applications and regulatory classifications.

The second session was delivered by Dr. Anil Kumar P.R. on the Principles of Biocompatibility. He explained the fundamental concepts of biocompatibility and risk management, highlighting how materials must be tested to ensure that they do not cause harmful biological responses when used in the human body.

In the afternoon, Dr. Remya N.S. conducted a session on Laboratory Testing for Biological Safety. She discussed the importance of toxicological profiling and explained how biological safety assessments are performed according to ISO 10993 standards. This session emphasized the need for thorough biological evaluation before medical devices are approved for clinical use.

The next session was handled by Dr. Roy Joseph, who spoke about Material Characterization. He described physico-chemical characterization tests and chemical risk assessment methods used to analyze the composition, stability, and safety of biomaterials.

The final session of the first day was delivered by Dr. A. Maya Nandkumar on Product Release Studies. She explained the processes involved in sterilization, cleanliness testing, and packaging of medical devices before they are released to the market. These procedures are essential to maintain product safety and prevent contamination. The day concluded with laboratory visits, giving participants further exposure to practical biomedical testing techniques.

On Day 2, 13th March 2026 the sessions focused more on pre-clinical and clinical evaluation of medical devices. The first session was conducted by Dr. A. Sabareeswaran, who discussed Implantation Tests for Biological Safety. He explained how implantation studies and histopathological analysis are used to evaluate tissue responses to implanted medical materials. The following session was led by Dr. Renjith S., who spoke about Material Properties Evaluation. He explained various thermal, mechanical, and morphological tests that help determine the structural integrity and performance of biomaterials used in medical devices.

Dr. Sachin Shenoy delivered a session on Pre-Clinical Efficacy Evaluation. He discussed the use of animal models and different experimental methods used to evaluate the safety and effectiveness of medical devices before they proceed to human clinical trials. Participants were again given the opportunity to visit the laboratories to observe testing facilities and equipment used for biomedical research.

In the afternoon session, Dr. Vivek Pillai discussed Clinical Evaluation and Documentation. He explained the importance of clinical evidence, regulatory documentation, and post-market surveillance in ensuring that medical devices remain safe and effective after they are introduced into the market. The final session was conducted by Dr. Manoj Komath, who spoke about Emerging Trends and Innovations in MedTech. He highlighted recent advancements in medical device technology and discussed future opportunities and challenges in the field.

The workshop concluded with a feedback session and closing remarks. Overall, the workshop provided valuable insights into the entire process of medical device development, from material selection and laboratory testing to clinical evaluation and regulatory approval. The combination of expert lectures and laboratory visits made the program highly informative and beneficial for participants interested in biomedical research and medical device innovation.

The Strategic and Regulatory Implications of Cost-Based Selection of Contract Laboratories in Regulated Industries

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Abstract

In regulated industries such as medical devices, pharmaceuticals, and biologics, non-clinical laboratory studies form the evidentiary foundation for regulatory decision-making. Although cost considerations influence outsourcing decisions, disproportionate emphasis on low pricing may compromise scientific rigor, regulatory compliance, and long-term economic outcomes. This article examines the relationship between laboratory costing structures and study quality, evaluates the regulatory risks associated with low-cost service models, and argues that reasonable costing is intrinsically linked to compliance infrastructure, scientific robustness, and data defensibility. The analysis highlights how investment in quality systems, documentation integrity, and post-submission engagement ultimately mitigates regulatory risk and supports sustainable product development.

Introduction

Outsourcing of regulatory laboratory studies has become standard practice across the medical device and pharmaceutical sectors. Sponsors routinely engage contract laboratories to conduct biocompatibility, toxicology, microbiology, analytical chemistry, and other preclinical evaluations required for regulatory submissions. In this competitive environment, laboratory selection is frequently influenced by budgetary constraints.

However, laboratory studies conducted under frameworks such as Good Laboratory Practice (GLP), international ISO standards, and national regulatory expectations are highly structured scientific processes. These processes require robust quality systems, trained personnel, validated methodologies, and controlled environments. The economic model underpinning such infrastructure inevitably influences the quality and reliability of generated data.

This paper examines whether selection based predominantly on low cost aligns with regulatory science principles and evaluates the broader implications of cost-driven outsourcing decisions.

Regulatory Compliance as a Systems-Level Investment

Regulatory authorities evaluate not only study outcomes but also the integrity of the systems within which those outcomes are produced. GLP principles, ISO standards, and OECD guidelines collectively emphasize traceability, reproducibility, documentation control, personnel qualification, equipment calibration, and data integrity.

Compliance with these frameworks requires:

- Comprehensive standard operating procedures
- Independent quality assurance oversight
- Document control and archival systems
- Environmental monitoring
- Periodic internal and external audits
- Continuous training programs

These elements represent recurring operational investments rather than one-time expenditures. Laboratories offering significantly lower pricing structures may face economic pressures that limit allocation of resources toward quality management, training, or infrastructure maintenance. Such constraints can increase the probability of deviations, documentation inconsistencies, or audit observations.

Regulatory agencies increasingly scrutinize data integrity and laboratory compliance histories. Deficiencies identified during inspections may affect the credibility of submitted studies and, in severe cases, necessitate repetition of testing. Thus, reasonable costing is directly associated with the sustainability of compliance systems.

Scientific Rigor and Study Design Integrity

Methodological rigor is central to regulatory acceptability. Appropriate endpoint selection, statistically justified sample sizes, validated analytical methods, and scientifically defensible interpretation are critical determinants of study credibility.

Scientific planning requires multidisciplinary expertise, including toxicology, biostatistics, materials science, microbiology, and regulatory affairs. Inadequate investment in protocol development or statistical consultation may lead to design limitations that become apparent during regulatory review. For example, insufficient power calculations, inappropriate control selection, or incomplete method validation can undermine confidence in study conclusions.

A cost-minimization approach may incentivize standardized protocols with limited customization or abbreviated internal review processes. Although such approaches may reduce upfront expenditure, they increase the risk of regulatory queries or requests for supplementary data.

Reasonable costing structures allow laboratories to dedicate adequate time to protocol refinement, internal scientific peer review, and risk-based evaluation aligned with contemporary regulatory guidance. The resulting data are more likely to withstand scrutiny and achieve acceptance without extensive clarification cycles.

Documentation Quality and Data Defensibility

Regulatory submissions rely on comprehensive study reports that integrate methodology, results, statistical analysis, and interpretation within a coherent scientific framework. Authorities assess not only the data but also the clarity and completeness of documentation.

Weak documentation practices—such as incomplete method descriptions, insufficient statistical justification, or ambiguous conclusions—may prompt deficiency letters or additional information requests. Each cycle of clarification extends review timelines and increases administrative burden.

High-quality reporting requires structured technical writing, layered quality review, and regulatory alignment assessment. These processes involve personnel specialization and time investment that cannot be sustained under extreme pricing compression.

From a regulatory perspective, defensible documentation is a risk-mitigation mechanism. Laboratories that allocate adequate resources to reporting integrity contribute directly to smoother regulatory evaluation.

Operational Stability and Turnaround Time

Timeliness is a strategic consideration in product development. However, accelerated timelines must not compromise methodological integrity. Operational stability—defined by adequate staffing, equipment redundancy, workflow management, and quality oversight—is essential to balancing efficiency with reliability.

Low-cost operational models may function with limited personnel reserves or constrained infrastructure capacity. Under peak demand conditions, such limitations can result in scheduling delays, incomplete quality review, or prolonged report finalization.

Reasonable costing enables laboratories to maintain balanced workloads, invest in preventive maintenance, and sustain project management systems. Predictable turnaround times enhance sponsor planning and reduce downstream scheduling uncertainty.

Post-Submission Technical Engagement

The regulatory review process frequently includes requests for clarification or additional scientific explanation. Effective responses require access to original study personnel, detailed methodological knowledge, and supporting documentation.

When laboratories disengage after report issuance - particularly in low-cost service models—sponsors may encounter difficulty addressing regulatory questions comprehensively. This gap can ead to prolonged review periods or inconsistent responses.

Sustained technical engagement represents an extension of laboratory accountability. Incorporating post-submission support into costing structures reflects recognition that regulatory evaluation is iterative rather than transactional.

Economic Analysis: Short-Term Savings Versus Long-Term Risk

An economic comparison of laboratory selection models must account for indirect and downstream costs. While lower quotations reduce immediate project expenditure, the potential costs of study repetition, regulatory delay, lost market opportunity, and reputational impact may substantially exceed initial savings.

Repeat testing involves not only laboratory fees but also additional material procurement, internal coordination, regulatory resubmission preparation, and delayed revenue generation. In competitive markets, delayed entry can diminish market share and investor confidence.

Thus, cost evaluation should incorporate risk-adjusted analysis rather than simple invoice comparison. Reasonable costing functions as a form of risk insurance, reducing the probability of costly regulatory setbacks.

Reputational and Regulatory Confidence Considerations

Regulatory authorities develop familiarity with laboratories and their inspection histories. Data originating from facilities with consistent compliance records may be reviewed with greater confidence. Conversely, laboratories associated with prior deficiencies may encounter heightened scrutiny.

For sponsors operating in global markets, alignment with laboratories demonstrating established compliance cultures strengthens overall regulatory positioning. Laboratory selection therefore carries reputational implications extending beyond individual studies.

Conclusion

In regulated product development, laboratory studies constitute critical evidence supporting safety and performance claims. The integrity of this evidence depends on compliance infrastructure, scientific rigor, documentation quality, and sustained technical engagement.

While cost containment remains a legitimate operational objective, disproportionate emphasis on low pricing may introduce systemic vulnerabilities. Short-term financial savings can translate into long-term regulatory, economic, and reputational risk.

Reasonable costing should be viewed as proportional investment aligned with regulatory complexity and scientific accountability. Organizations that integrate cost evaluation with quality and compliance assessment are better positioned to achieve timely regulatory acceptance, maintain credibility, and ensure sustainable market success.

FAST FACTS

"Under the Health Infrastructure Mission, we have allotted Rs 64000 crores for filling the gaps between primary and secondary Healthcare"

Shri J.P. Nadda, Union Health and Family Welfare Minister

High-performing Pens and Autoinjectors in India: What Today's Market Demands from Manufacturers

Mr. Rajen Kasi
Director & General Manager
Husky Injection Molding Systems Pvt. Ltd.

As biologics become more accessible across India and patients increasingly shift toward at-home care, demand for pens and autoinjectors is accelerating rapidly. The rise of biosimilars, increasing diabetes prevalence, and the introduction of GLP-1 therapies are pushing device programs from thousands to millions—and soon, into the billions.

India presents a unique dynamic. Growth is not constrained by regulation, but by manufacturing readiness. In many cases, acquiring the right manufacturing technology is the primary bottleneck—not regulatory approval.

This shift has redefined what the market expects from manufacturers. It is no longer enough to produce precise components—manufacturers must now deliver that precision consistently, at high volume, at competitive cost, and within aggressive timelines.

Balancing Cost, Scale, and Speed

India's autoinjector market is shaped by four key pressures: demand, cost, time to market, and manufacturing capability.

The rapid growth of biosimilars and generics means manufacturers must operate at lower margins, while still meeting global quality standards. At the same time, being first to market is critical—particularly as patents expire and competition increases.

This creates a challenging balance:
- Deliver high-quality, precision components
- Scale production quickly and reliably
- Maintain cost competitiveness

Success depends on manufacturing systems that can achieve all three simultaneously.

Rising Expectations in Device Performance

As India moves toward more advanced drug delivery devices, expectations around performance are increasing. Manufacturers must now meet tighter requirements for dimensional accuracy, material consistency, and functional reliability.

Small variations can have significant consequences. A slight dimensional shift can affect dose accuracy, while inconsistencies in part geometry can compromise device integrity. At higher volumes, these issues scale quickly. Therefore, process stability essential from the outset.

Why Manufacturing Capability Is the Differentiator

Autoinjectors are complex, multi-component devices that require precise processing of materials such as PP, PC, POM, and PBT. Many of these materials have narrow processing windows, where even small variations in temperature or flow can introduce defects.

In India, this challenge is amplified by cost sensitivity and the need to scale rapidly. Manufacturers must minimize scrap, reduce variability, and maintain consistent quality across high-volume production.

Hot runner performance plays a critical role here. When systems are not aligned, manufacturers often face longer validation timelines, higher reject rates, and increased operational costs.

Husky addresses this by integrating hot runner design directly into mold development, ensuring systems are engineered together for the specific application. This enables manufacturers to begin validation from a stable, well-understood baseline—reducing variability and accelerating time to market.

Scaling Production with Confidence

As production volumes increase, maintaining consistency becomes the defining challenge. High cavitation amplifies even small process variations, making control and repeatability essential.

Husky draws on experience from more than 1,000 autoinjector-specific systems globally, embedding this knowledge into technologies such as UltraMelt, UltraSync E, Ultra Helix, UltraShot, and the New Altanium 6 Series controller platform.

These solutions are designed to:

- Improve part consistency across cavities
- Stabilize processing of sensitive materials
- Reduce scrap and rework
- Support reliable, high-volume production

In a cost-driven market like India, these efficiencies directly impact competitiveness.

The Power of FIVE: Expert Hot Runner Support Throughout Your Journey

In a market where manufacturing capability is a key bottleneck, access to expertise is just as important as access to technology. Husky's Power of FIVE model ensures expertise is embedded throughout the lifecycle:

- **Solution recommendation:** Product Development Engineers design systems optimized for your specific device application
- **Optimization:** Application Engineers fine-tune performance for maximum efficiency and part quality
- **Engineering:** Project Engineers ensure seamless implementation and integration
- **Start-up:** Technical Sales Leaders guide successful launch and validation processes
- **Field support:** Field Service Experts provide ongoing assistance throughout your system's lifecycle

Supported by global infrastructure, validation documentation, and proactive monitoring, this approach enables early issue identification—before it impacts uptime.

Conclusion

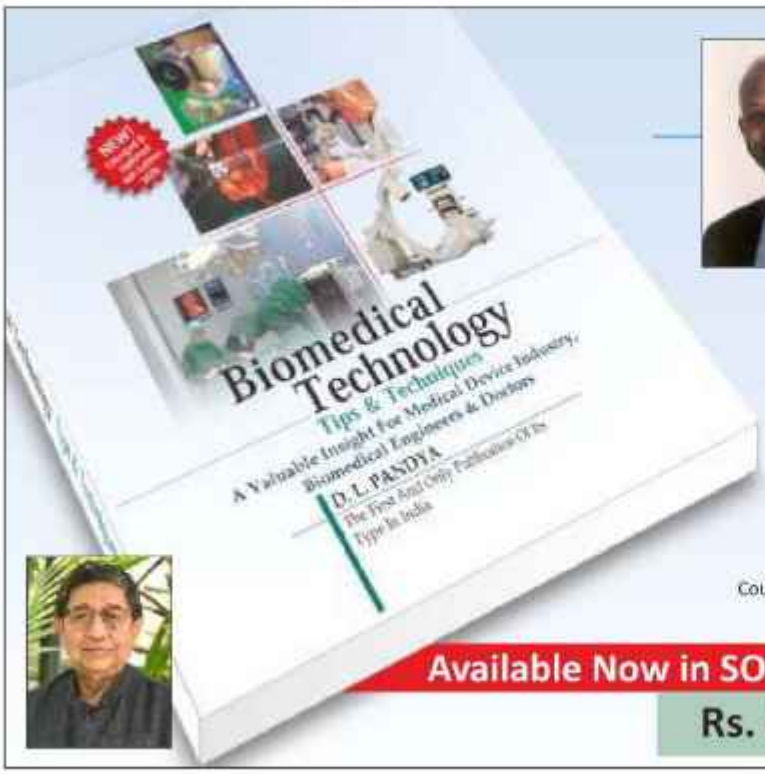
India's autoinjector market is defined by rapid growth, cost pressure, and increasing expectations for quality and speed.

Manufacturers must now deliver precision, consistency, and scalability—without compromising cost or timelines.

Achieving this requires more than capable equipment. It requires integrated systems, proven validation approaches, and ongoing technical expertise.

Husky enables Indian manufacturers to meet these demands with confidence—supporting the delivery of high-performing, accessible drug delivery devices at scale.

Contact you're a Husky representative to start your pen and auto injector journey! https://www.husky.co/en/contact/



Forward

Biomedical Technology sector positions itself in a high value market place, but one where errors can be very expensive. Products are highly regulated and subjected to extensive quality controls.

I find here a treasure of tips and techniques put together in a very simplified and user friendly manner. Whether one is a teacher or a student of Biomedical Engineering / Technology or a manufacturer / marketer of medical devices or a medical professional using the technology day in and day out, dipping into this collection will give one valuable insight.

Dr. R. A. Mashelkar
Former Director General
Council of Scientific & Industrial Research & Secretary, Government of India
Department of Science and Technology, New Delhi

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The EU Medical Device Proposed Changes And Their Interpretation

Sanjay Shah
CEO, Unikal Consultants

EU Medical Device and IVD Devices are regulated under MDR & IVDR. After substantial changes from MDD 93/42 there has been continuous changes, updating and manufacturer / user implementation has been difficult, to say the least. Under the more regulated atmosphere, issues of non-availability and high cost have been a constant issue, but better regulated products for the patients have been debated. And for which EU regulators have been working to balance the sides.

At the same time, it has been a constant endeavor for the EU medical devices regulatory framework to evolve continuously in tune with the times. This is done with significant legislative and policy reforms.

For companies bringing medical devices and in vitro diagnostics (IVDs) to the EU market, the landscape remains complex and resource intensive, but meaningful changes are now on the horizon.

Although the EU's Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), which came into force in 2021 and 2022 respectively, introduced stricter requirements compared to the previous Directives, such as on clinical evidence, post market surveillance, and economic operator requirements, their implementation has been challenging, to say the least.

The absence of grandfathering for legacy devices, limited notified body capacity, and strict rules without clear guidance have created backlogs, increased production and regulatory compliance cost, slowed innovation, and increased the risk of supply disruption.

These pressures have prompted sustained criticism and repeated calls for reform. For non-EU manufacturers, the stakes are even higher. They needed to appoint a competent EU Authorized Representative, registering in EUDAMED, and ensuring compliance with EU-specific labelling and language requirements.

Failure to plan early for notified body engagement and certificate renewals had their consequences. Having single EU-ARep, changing their services, changing NB was very difficult and time consuming as well as costly. The complexity and cost of compliance had made many companies to reconsider EU launches altogether, underscoring the importance of proactive strategy and resource allocation.

They say quality has no cost; but it is not infinite.

Proposed Changes to MDR and IVDR

Towards the end of 2024, the European Commission launched a public consultation on the MDR and IVDR, framed as a "targeted evaluation" to identify problems with the legal framework. This was launched in part due to the European Parliament adopting a resolution on the urgent need to revise the MDR and the IVDR. Since then, on September 8, 2025, the European Commission published a call for evidence on "the targeted revision" of the regime, with the aim of identifying methods to tackle critical issues experienced throughout the industry caused by the regulations.

The European Commission published a significant legislative proposal on 16 December 2025 (COM (2025) 1023 final). Often referred to as MDR 2.0 and IVDR 2.0, these amendments aim to simplify regulatory procedures, reduce administrative burdens, and prevent device shortages while maintaining high safety standards.

The proposals provide an overhaul of current requirements under the MDR and IVDR, aimed at streamlining regulatory processes, reducing administrative burden, and enhancing predictability, while maintaining patient safety and public health. For manufacturers, healthcare institutions, innovators, and industry stakeholders, the proposals signal a shift toward a more proportionate, risk-based system that supports timely access to critical technologies without compromising quality.

Key Proposed Changes

The proposal is structured around eight main themes aimed at making the system more proportionate and predictable:

- **Certification & Validity:** The current maximum 5-year validity period for certificates would be abolished, allowing for indefinite certificate validity supported by risk-based periodic reviews instead of full recertification.
- **Risk Reclassification:** Several devices are slated for reclassification to lower risk classes, including reusable surgical instruments (to Class I), certain software categories, and accessories for active implantable devices.
- **Clinical Evidence:** Manufacturers may rely on a broader range of clinical data, including scientific literature and non-clinical data like in silico testing or computational modelling, especially for legacy or well-established technology (WET) devices.
- **Administrative Relief:**

Reporting Timelines: The deadline for reporting serious incidents (not involving death or serious public health threats) would be extended from 15 to 30 days.

PSUR Updates: The frequency for Periodic Safety Update Reports (PSUR) would be reduced to every two years for high-

risk devices, and only "when necessary" for Class IIa devices.

PRRC Requirements: Qualification requirements for the Person Responsible for Regulatory Compliance (PRRC) would be simplified, particularly for SMEs.

Innovation & Access:

- **Breakthrough & Orphan Devices:** New formal definitions and priority review pathways (rolling reviews) would be introduced for these critical devices.
- **Regulatory Sandboxes:** Controlled environments would allow for testing innovative technologies with temporary waivers of certain requirements under strict supervision.
- **Digitalization:** The proposal mandates electronic submissions and allows for digital EU Declarations of Conformity and digital labeling/instructions for use (eIFU) in certain contexts.
- **Governance & Support:** National authorities would act as an "ombudsperson" to resolve disputes between manufacturers and Notified Bodies within 90 days.

Current Timeline and Next Steps

- **Legislative Process:** The proposal is currently undergoing review by the European Parliament and the Council of the EU.
- **Feedback Period:** A public feedback period concluded on 30 March 2026.
- **Expected Adoption:** Full implementation and adoption by co-legislators are anticipated around Q2 2027, with most simplifications applying six months after entry into force.

A Definitive Treatise on Medical Device Clinical Research in the Era of Medical Technology

Dr. Ashish Indani
Medical Device Clinical Research Expert

In an age defined by rapid innovation in Medical Technology and the global proliferation of advanced Medical Devices, the need for a rigorous, structured, and comprehensive understanding of Medical Device Clinical Research has never been more urgent. Addressing this critical gap with remarkable clarity and depth, Essentials of Medical Device Clinical Research by Dr Ashish Indani emerges as a seminal contribution to the evolving body of knowledge in Medical Technology Clinical Research.

This multi-volume work distinguishes itself not merely as a technical manual, but as an intellectual framework that systematically integrates foundational principles with advanced methodologies. Unlike conventional texts in Clinical Research, which are predominantly oriented toward pharmaceutical interventions, this book is meticulously crafted to address the unique scientific, regulatory, and operational dimensions of Medical Devices and Medical Equipment.

At its core, the text offers an end-to-end exploration of the lifecycle of Medical Device Clinical Research. It begins with a lucid exposition of fundamental concepts—rendered in a manner accessible even to those newly initiated into Clinical Research—before advancing into the intricate paradigms that govern Clinical Evaluation, regulatory compliance, and post-market surveillance. This pedagogical progression ensures that the reader is not merely informed but intellectually equipped to navigate the complexities inherent in Medical Technology Clinical Research.

One of the most compelling attributes of this work lies in its nuanced treatment of Clinical Evaluation. Recognizing that Medical Devices operate at the intersection of engineering, biology, and patient care, the author adeptly elucidates the methodological divergences between drug trials and device-based investigations. The discussion extends beyond theoretical constructs, offering pragmatic insights into trial design, risk stratification, and performance assessment—elements that are indispensable for robust Medical Device Clinical Research.

Furthermore, the book engages deeply with the regulatory architectures that shape the global landscape of Medical Technology. By examining frameworks across major jurisdictions, it provides readers with a comparative perspective that is both academically enriching and professionally actionable. This global orientation is particularly valuable in an era where Medical Equipment and devices are developed, tested, and deployed across transnational ecosystems.

Another noteworthy dimension is the integration of emerging technological paradigms within the discourse of Medical Technology Clinical Research. The author acknowledges the transformative impact of digital health, artificial intelligence, and data-driven methodologies, situating them within the broader context of Clinical Research and innovation. This forward-looking perspective ensures that the text remains not only relevant but anticipatory of future developments in Medical Devices and Medical Equipment.

From a structural standpoint, the multi-volume format enables an expansive and detailed treatment of subjects that are often relegated to cursory discussion in other works. While this depth necessitates a certain degree of intellectual commitment, it simultaneously elevates the book to the status of a reference compendium—one that can be revisited across different stages of professional growth in Medical Device Clinical Research.

Importantly, the accessibility of the narrative should not be underestimated. Despite its scholarly rigor, the language remains coherent and systematically organized, allowing readers from diverse backgrounds—be they students, clinicians, engineers, or regulatory professionals—to engage meaningfully with the material. This inclusivity reinforces the book's utility as both an academic text and a practical guide within the domain of Medical Technology Clinical Research.

In evaluating its broader impact, it becomes evident that Essentials of Medical Device Clinical Research fulfils a dual function. It not only consolidates existing knowledge in Clinical Research and Medical Devices but also contributes to the standardization and maturation of Medical Device Clinical Research as a distinct discipline. Such contributions are indispensable in ensuring the safety, efficacy, and ethical deployment of Medical Equipment in contemporary healthcare systems.

In summary, this work stands as a definitive and authoritative resource in the field of Medical Technology. Through its comprehensive scope, methodological precision, and forward-thinking insights, it offers unparalleled value to anyone engaged in or aspiring toward excellence in Medical Device Clinical Research. For scholars and practitioners alike, it is not merely a book, but a foundational text that redefines the contours of Medical Technology Clinical Research in the modern era.

Biocompatible Coatings for Polymeric and Other Medical Devices: Global Trends

Biocompatible coatings for medical devices enhance tissue integration, prevent thrombosis, and minimize immune reactions by tailoring the surface chemistry of implants and instruments. Common materials include polymers (like Parylene), ceramics (like hydroxyapatite), and metals (like Titanium dioxide), often applied through PVD techniques for improved performance.

Key Types of Biocompatible Coatings

- **Hydrophilic/Hydrogel Coatings:** These reduce friction, which is critical for catheters and guidewires, often improving patient comfort.
- **Osseointegration Coatings:** Hydroxyapatite (HA) is commonly used on orthopedic implants to promote strong bone-implant bonding.
- **Antimicrobial Coatings:** Incorporating silver or copper nanoparticles, or titania (\(TiO_{2}\)), to minimize the risk of infection in surgical tools and implants.
- **Hemocompatible Coatings:** Phosphorylcholine (PC) or drug -eluting polymers used on blood-contacting devices (stents, heart valves) to prevent blood clots. [1, 2, 3, 4, 5]

Benefits of Biocompatible Coatings

- **Increased Lifespan:** Improved wear resistance and reduced corrosion in implants.
- **Reduced Rejection:** Minimizes inflammation and adverse foreign body reactions.
- **Improved Functionality**: Tailored surface roughness and porosity encourage cell adhesion and tissue healing

Biocompatible Coating Market to Reach $41.4 Billion, Globally, by 2033 at 12% CAGR: Allied Market Research

The global biocompatible coating market is witnessing growth as rising demand for medical implants, technological innovations, stringent regulatory standards, and increasing collaborative research initiatives drive the development and adoption of advanced biocompatible coatings across healthcare and biomedical applications.

According to a recent the report by "Allied Market Research", the biocompatible coating market was valued at $13.4 billion in 2023, and is estimated to reach $41.4 billion by 2033, growing at a CAGR of 12% from 2024 to 2033.

Prime Determinants of Growth

Biocompatible coating market leverages advanced materials and surface modification techniques to improve the compatibility of medical devices and implants with human tissues. These coatings enhance device performance, reduce immune response, and prevent infections, thereby improving patient outcomes. The rising adoption of implantable medical devices, increasing prevalence of chronic diseases, and growing demand for minimally invasive surgeries are driving the growth of the biocompatible coating market.

Biocompatible coatings are widely applied in orthopedics, cardiovascular devices, dental implants, and drug delivery systems. The market growth is further fueled by technological advancements in nanocoatings, polymeric coatings, and bioactive coatings that improve the longevity and functionality of medical devices. Increasing healthcare expenditure, rising awareness about patient safety, and demand for high-performance biomaterials are key factors supporting market expansion.

However, challenges such as high manufacturing costs, stringent regulatory requirements, and compatibility issues with diverse medical devices may restrict adoption in certain regions. Ongoing investments by governments and private organizations in research & development, as well as advancements in coating technologies, are expected to create significant opportunities in the global market.

Drivers

Rising demand for implantable medical devices and minimally invasive surgeries

Advancements in polymeric, nanocoating, and bioactive coating technologies

Increasing focus on patient safety and improved device longevity

Opportunities

Growth potential in emerging economies with expanding healthcare infrastructure

Innovation in personalized and precision medical devices requiring tailored coatings

Increasing R&D investments in advanced biocompatible materials

Segment Highlights

Rising Adoption of Advanced Biocompatible Coatings

The biocompatible coating market is witnessing increasing adoption due to its ability to enhance medical device performance, improve patient safety, and reduce post-implantation complications. Antimicrobial coatings, for instance, are increasingly applied to prevent infections on implantable devices, while hydrophilic coatings improve device integration with human tissue. These coatings enable medical device manufacturers to improve device longevity and functionality, driving adoption across healthcare and medical device segments. Moreover, advanced coatings help in minimizing immune responses and improving healing, supporting better clinical outcomes

Growth Across Material Segments

Material innovation is a key growth driver in the biocompatible coating market. Polymeric coatings are widely used due to their flexibility, durability, and compatibility with various medical devices. Ceramic coatings offer excellent wear resistance and biocompatibility, making them suitable for orthopedic and dental implants. Metal-based coatings, such as titanium and its alloys, are preferred for their mechanical strength and corrosion resistance. Ongoing R&D in nanocoatings and bioactive materials is further expanding the material portfolio, providing tailored solutions for complex medical applications.

End-User Adoption Driving Market Expansion

Healthcare providers and medical device manufacturers are increasingly prioritizing biocompatible coatings to enhance patient safety and device efficacy. In hospitals and surgical centers, coated implants reduce complications such as infections and implant rejection. For medical device companies, integrating biocompatible coatings into their products supports regulatory compliance, product differentiation, and extended device lifespan. The growing demand for minimally invasive procedures and implantable devices further fuels market adoption across the healthcare and medical device segments.

Role of Digital Technologies and Manufacturing Innovations

Digital technologies and advanced manufacturing processes play a pivotal role in improving biocompatible coatings. Techniques such as plasma deposition, chemical vapor deposition, and 3D printing enable precise coating applications, uniform thickness, and tailored surface properties. Additionally, digital process monitoring and simulation tools optimize coating performance and ensure consistent quality. These technologies allow manufacturers to scale production efficiently, reduce material waste, and meet the stringent quality standards required in the medical industry.

Regional Outlook

North America held the largest market share in 2023 and is expected to maintain dominance through 2033. The region benefits from well-established healthcare infrastructure, high adoption of advanced medical devices, strong R&D investments, and favorable regulatory frameworks. Europe follows closely, supported by technological innovations and increasing healthcare expenditure. The Asia-Pacific region is expected to register significant growth due to rising healthcare investments, increasing medical device manufacturing, and growing awareness of advanced coating solutions. LAMEA is also witnessing gradual adoption driven by expanding healthcare infrastructure and government initiatives to enhance medical device safety.

Ref : https://www.alliedmarketresearch.com/purchase-enquiry/A323973
(https://www.marketwatch.com/press-release/biocompatible-coating-market-to-reach-41-4-billion-globally-by-2033-at-12-cagr-allied-market-research-2adc4999, PR Newswire February 18, 2026)

FAST FACTS

The Asia Pacific is expected to be the fastest-growing market for medical plastics, as the global plastics market size is expected to reach $44.66b by 2032, according to Verified Market Research.

The market size is projected to gain a 6.60% Compound Annual Growth Rate (CAGR) over the forecast period, it added.

Cambodia and Laos Medical Devices Market

Mr. Amit Dave
M. Pharm, MBA
Former CEO – Brazil operations/ Vice President Export - Zydus Cadila Claris Lifesciences

Today, we will cover two smaller countries – Cambodia and Laos. Generally, the strategy and planning consider these two countries together, probably because they are adjacent to each other and probably because they are comparatively smaller individually.

After this article, we will move to the African subcontinent.

CAMBODIA

Country Profile

The Indian civilisation had influenced Cambodia for almost 2000 years. The 12th-century temple of Angkor Wat, a massive structure, is an example of this. In the later years, many areas of Cambodia became part of Thailand, Laos and Vietnam. Cambodia later became a French colony, and saw the turmoil of war and instability, followed by massive devastation by the Khmer Rouge, the communist guerrilla movement, with the death of about 15 Lakh people.

The population of Cambodia is about 1.70 crore. The capital of the country is Phnom Penh. Cambodians (The Khmer) make up a vast majority of the population (96%). Other minorities are Chinese, Vietnamese, Malays and indigenous people. Again, a vast majority is Buddhist (97%). Urbanisation is just 39%, unlike many neighbours, while 61% population is rural. The male-female ratio is 0.95 males/females, and more than 90% population is below 60 years of age. Despite high corruption, a very successful vaccination campaign had saved the country during the COVID period, it must be noted.

Medical Device Registration in Cambodia

Prakas No. 1258 (Prakas means official legislation/gazette) covers the process for registration of Medical Devices. Accordingly, DDF (Department of Drugs and Food), which is under the Ministry of Health, is the main authority for the regulations. This Prakas states the four categories of the device classes (in line with the classification in most other countries)–

- Class A: Low-risk devices
- Class B: Moderate risk devices
- Class C: High-risk devices
- Class D: Very high-risk devices

AMDD (ASEAN Medical Device Directive), the regulation for harmonised standards for medical devices in ASEAN countries, also needs to be considered while registering the products. A local representative is to be appointed by an overseas manufacturer to deal with the DDF on behalf of the manufacturer. Once the application submitted for registration is evaluated, the party is informed to pay the government a registration fee of approximately USD $100. The registration approval takes about 15 to 18 months. The labelling is to be in the local Khmer or English language.

Cambodia Medical Devices Market

Broad scenario:

The market is growing, mainly due to improved healthcare infrastructure, rising healthcare awareness, and an increase in the country's healthcare spending. Diagnostics and monitoring devices are growing very fast. Enhanced healthcare accessibility, mainly in rural areas, is the focus of policymakers, leading to more hospitals in rural peripheries and increasing demand for diagnostic imaging equipment, surgical instruments, and patient monitoring systems. Chronic diseases like diabetes and cardiovascular conditions are on the rise, again fuelling the demand. Regulatory and import bottlenecks are the main constraints. The local production of medical devices is missing, and so, there is a very heavy dependence on imported devices in the country. Very limited market data is available, but between 2008 and 2018, imports of medical instruments grew by about 57%.

Highlights of Cambodia

- Very large medical devices imports
- Smaller market size
- Product approval takes longer

Highlights of Laos

- A smaller market
- An opportunity, just opening up

Market in numbers:

Medical devices market size – USD 132 mn
Medical devices market growth rate – 7.4%
Number of hospitals – 34 national and 54 private hospitals
Hospital beds – 0.9 / 1000 populations
Medical devices import – very high, more than 90%

Opportunities and Challenges

Heavy reliance on imports and high growth make the market attractive. The size, however, is smaller. Long approval time, corruption and complex regulatory processes are the constraints. This may be considered as an incremental market rather than a focus market.

Laos Country Profile

The reason for including this country in our exploration journey, despite its very small size, is twofold- the country depends 100 % on imports of medical devices, and a manufacturer can also directly apply and import the products for selling.

Laos is a landlocked country and depends heavily on its neighbouring countries. Laos is a small country with a population of only 75 L people. Its capital is Vientiane, and the major religion is Buddhism. Between the 14th and 16th centuries, the country was very influential in Southeast Asia, but a decline followed, and Myanmar, Thailand and Cambodia influenced the country a lot. The influence of the Hindu culture is also visible here. Unlike Cambodia, there are many minority groups in the country. Laos is a communist country. Laos has strong ties with Vietnam and China (both communist countries), and these two have strong political and economic influence on Laos. An example is 70% of the funding by China for a 6 bn USD railway line between the two countries (and 30% through a loan from China). Laos still remains one of Asia's poorest countries despite consistent economic growth.

Medical Device Registration in Laos

In 2024, through a Notification (No. 9606 and Decision No. 1470), a new and simpler regulatory process became applicable. This new, simpler process started with class C and D devices, and from January 1, 2025, class A and B devices are also covered in this new law.

The Classification of devices is the same as that of Cambodia (and most other countries)–

- Class A
- Class B
- Class C
- Class D

A small but very pertinent presentation on the regulatory process for Laos, done by the Director General, MoH, Lao PDR, is available on the website mentioned below- https://ahwp.info/sites/default/files/Annex%2017%20Laos%20PDR.pdf

Laos Medical Devices Market

Broad scenario:

Laos depends totally on imports for medical devices, though recently, small PPE kit manufacturing has started in the country. In line with its smaller population, the market size is smaller. MoH is the main health service provider as per a WHO report. This coverage is limited, however, but is growing. The market size numbers below may look small, but they may indicate an opportunity for the future.

Market in numbers:

Market size for medical devices – 25 mn USD (tiny, not even small)
Device market growth – 7 %
Social healthcare coverage – about 27%

Opportunities and Challenges

The major challenge is the smaller market size of this market, but the opportunity is in the form of a possible future market.

QOSINA

Thousands of Stock Components

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Qosina has been a trusted partner to medical device engineers, providing thousands of in-stock components and innovative solutions to meet the industry's evolving needs. Qosina delivers high-quality components and practical support.

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Whether you're in the design or development phase, Qosina is here to support you with practical, reliable solutions at every step.

Log on to **qosina.com** today to see our full product offering.

India's Medical Device Sector Gets Its First Standardised Testing Fee Framework

India is overhauling the regulatory framework for its $12 billion medical devices sector, introducing the country's first standardised fee structure for testing and certification — a move that promises greater compliance predictability but has drawn mixed reactions from the industry.

The Ministry of Health and Family Welfare has proposed amendments to the Medical Devices Rules, 2017, capping testing fees at government facilities between ₹150 and ₹5,000, replacing the existing market-driven pricing model where costs varied significantly across laboratories. Fees will rise automatically by 5% annually. The government is seeking public comments within a 30-day window before finalising the rules.

The proposed framework also extends recognition to European Union standards for device registration, streamlining market access for EU-certified products — though devices will still require clearance from Indian licensing authorities. Quality Management System requirements will be incorporated into testing lab norms, and government testing facilities will be renamed Government Medical Device Testing Laboratories to clarify their official status. Low-risk devices — including stethoscopes, wheelchairs and alcohol swabs — are proposed for exemption from licensing, replaced by a simpler online registration process.

Industry response is divided. Himanshu Baid, Managing Director of Poly Medicure, welcomed the reform, noting that standardised fees and enhanced traceability norms would strengthen trust across the value chain and free up resources for innovation. However, Rajiv Nath of the Association of Indian Manufacturers of Medical Devices (AiMeD) flagged a significant concern — the new mandate requiring sterilisation subcontractor licence numbers on product labels could delay exports by three to four weeks during subcontractor downtime, adding friction to an already complex supply chain.

The government has not yet responded to queries on the proposed amendments.

https://medicalbuyer.co.in/indias-medical-device-sector-gets-its-first-standardised-testing-fee-framework/?utm_source=Netcore&utm_campaign=MB+DN+13+Apr+2026+%408%3A17am-MB+Weekly+11+Apr+2026&utm_medium=%7BCHANNEL%7D, April 13, 2026

AiMeD's Remarks on GoI Draft Notification on Testing Fees & Labelling

On capping testing fees:

Unilateral implementation without consulting NABL-accredited labs (BIS/ISO standards) risks unsustainable models for quality testing. With 6,000+ devices in scope, controls must be risk-proportionate—rigorous for high/moderate high-risk. Focus efficiency on high-risk devices, not overburden low/moderate low-risk segments. Draft absent from CDSCO website limits participation; urge consultations.

On sterilization subcontractor labelling

Mandating license numbers on product labels creates a "significant barrier," delaying exports by 3-4 weeks during downtime at Gamma Radiation subcontractor. Recommend limiting to shipping cartons/batch records for traceability and supply chain flexibility—no global regulator imposes such restrictions. Clarify equitable applicability to Indian vs. overseas manufacturers/imports. Shift focus from low-risk to high-risk devices.

Panel recommends decentralisation of approval of all medical devices

The Parliamentary Panel on Health and Family Welfare has recommended various significant regulatory changes in the regulation of medical devices, including decentralisation of approval for all medical devices with the State Drug Authorities, self-financing of the drug control authority using the substantial revenues generated from medical device licensing, and an immediate overhaul of the Central drug regulator's medical devices (MD) online portal to reduce the bottlenecks in approvals.

The Department Related Parliamentary Standing Committee on Health and Family Welfare, in its 172nd report on the Demands for Grants for 2026-27 for the Department of Health and Family Welfare, observed that that present decentralized framework is under which the State Authorities regulate drugs and Class A/B devices, while the Central Drugs Standard Control Organisation (CDSCO) oversee imports and Class C and D devices.

However, it recommended a decentralized framework for imports and Class C/D devices.

"The Committee strongly recommends that CDSCO approval for imports be completely decentralized to the State Authorities. Centralization with the DGCI at the Central level has created major bottlenecks and is the biggest hurdle in India being at the forefront of medical devices manufacturing," said the Panel headed by Member of Parliament Prof. Ram Gopal Yadav.

"The Committee recommends for decentralization of approval for all Medical Devices with the State Drug Authorities to reduce pendency. In this current phase when we are competing with China, Vietnam, Malaysia giving CDSCO approvals for even already approved devices/technologies beyond a period of 45 days resulting in India losing its competitive edge," said the Panel.

It noted with concern that significant administrative bottlenecks hindering the swift clearance of medical devices, particularly the Class C and Class D categories regulated by the CDSCO.

Out of 2,999 manufacturing and import applications processed, approximately 62% were subjected to queries more than twice, and 253 import applications, even those possessing US FDA/CE certifications, have been pending for over 90 days, (most of these import applications are pending at the applicants end for submission of requisite documents as per MDR-2017).

Repetitive query cycles indicate a systemic lack of clarity in the initial submission guidelines and point toward an inefficient, iterative assessment process, it opined.

The Panel recommended that the Department immediately

overhaul the 'MD Online' portal to include a mandatory, AI assisted pre-submission validation checklist to ensure applications are complete before formal submission.

"The Committee is of the view that CDSCO must adopt a 'single comprehensive query' policy, wherein all deficiencies in an application are identified and communicated to the applicant in a single instance, rather than in piece-meal fashion," it added.

Besides, it recommended establishment of a dedicated facilitation cell within CDSCO to assist domestic manufacturers in navigating the Medical Device Rules (MDR) 2017, thereby reducing the delays currently attributed to pending applicant responses.

The CDSCO has generated substantial revenue of around Rs. 87.18 crore and Rs. 118.69 crore annually over the last three financial years from medical devices licensing. Therefore, the revenue earned from the activity should be used for self-financing of the institution.

A designated percentage of the revenue collected by CDSCO be ring-fenced and directly reinvested into upgrading the digital and technical infrastructure of both the Central and state regulatory bodies, it recommended.

"The Committee is of the view that the Department must utilize these funds to develop a unified, real-time National Regulatory Dashboard that seamlessly integrates CDSCO's 'MD Online' portal with State-level licensing databases," it added.

This will ensure that intelligence regarding non-compliant manufacturers, suspended licenses, and spurious drug trails is instantly shared across jurisdictions, leveraging both Central and state expertise to guarantee uniform enforcement of the Drugs and Cosmetics Act nationwide, averred the Panel.

https://www.pharmabiz.com/NewsDetails.aspx?aid=185069&sid=1 , April 2, 2026

Product Gallery

Plastic Drying as a Medical Device Imperative

Cutting Energy Costs While Maintaining Pharmaceutical-Grade Quality

In medical device manufacturing, proper moisture control directly impacts biocompatibility, sterility, and shelf-life. Yet plastic drying remains among the highest continuous energy loads—operating 24/7—making it a major controllable cost for facilities producing tubing, connectors, and surgical instruments.

Industry studies reveal widespread inefficiencies: dryers are frequently oversized, operate at unnecessarily low dew points, or regenerate desiccant beds longer than required. Traditional water-cooled systems increase both water and power consumption. Each extra degree of heat or minute of regeneration directly increases kilowatt-hours per kilogram of resin.

Advanced drying technologies address these inefficiencies. Waterless rotor-based desiccant systems eliminate cooling water dependence, achieving energy reductions up to 40%. Multi-bed desiccant systems deliver 25% savings while maintaining precise dew points (−40°C to −65°C) tailored to specific resins. Smart controls dynamically adjust temperature, airflow, and regeneration based on actual moisture load—eliminating excess blower energy.

For medical manufacturers, compliance is critical. Real-time moisture monitoring enables production traceability required for ISO 13485 and FDA oversight. Integrated sensors verify each batch meets specification before processing, with data logged for regulatory audits.

Modern systems integrate seamlessly: hopper dryers on molding machines, mould dehumidification systems preventing surface defects, centralized conveying maintaining dryness, and in-line analyzers providing verification. Implementation requires 2–3 months for complete system replacements.

As energy prices rise and sustainability targets tighten, optimized drying becomes a strategic investment—Bry-Air knows drying best in reducing costs, strengthening compliance, and supporting the reliability that patient safety demands.

MedArtha & WTC–AMTZ: Building India's First Operator-Led MedTech Ecosystem

India's medical device sector is entering a decisive decade. With rising policy support, import substitution goals, and increasing global credibility, the opportunity is clear: India can transition from a cost-driven manufacturing base to a global innovation hub. However, one structural gap has consistently limited this ambition—the absence of operator-led capital combined with execution infrastructure.

Having spent decades building and scaling a global medical device company, I have seen this gap closely. When we were growing Sahajanand Medical Technologies (SMT), awareness of Indian medical devices was minimal. Entering regulated markets like Europe required not just product quality, but deep clinical validation, regulatory navigation, and trust-building over years. Today, Indian devices are present in over 80 countries—but this journey has largely been built through isolated efforts rather than ecosystem support.

This insight led to the creation of MedArtha.

MedArtha is not a traditional investment fund. It is an operator-led platform designed to actively participate in building companies. The Indian startup ecosystem has matured significantly, but medical devices remain underrepresented in dedicated capital pools. Unlike SaaS or consumer sectors, medtech requires long development cycles, regulatory rigor, and capital-intensive validation. Financial investors alone cannot bridge this gap.

What is required is "intelligent capital"—capital combined with experience.

This is where MedArtha differentiates itself. Our approach involves working closely with founders on product-market fit, regulatory pathways, manufacturing strategy, and global commercialization. The objective is not just to fund innovation, but to reduce execution risk—something that often determines success or failure in medtech.

The partnership with Andhra Pradesh MedTech Zone (AMTZ) strengthens this model significantly. AMTZ has created one of the most advanced shared infrastructure ecosystems for medical devices globally. By providing access to high-end testing labs, prototyping facilities, and regulatory-compliant manufacturing environments, it reduces both cost and time barriers for startups.

The addition of World Trade Center (WTC) AMTZ further extends this ecosystem into global markets. It enables companies to access international trade networks, partnerships, and market entry pathways early in their lifecycle. This combination—capital, infrastructure, and global access—creates a full-stack platform for medtech company building.

Importantly, this model also addresses a fundamental industry issue: India has lacked dedicated medical device funds led by operators. Most investment decisions in healthcare have historically been driven by adjacent sectors such as pharmaceuticals or hospital services. While valuable, these perspectives often do not fully capture the nuances of device development.

Medtech is different. A delay in regulatory strategy or an incorrect clinical pathway can set a company back by years. Operator involvement helps avoid these pitfalls.

Another critical pillar of the MedArtha approach is the involvement of senior advisors. These are experienced professionals across clinical, regulatory, and commercial domains who provide strategic guidance at key decision points. Their role is not just advisory, but directional—helping startups validate assumptions, refine strategies, and accelerate credibility.

Looking ahead, India's ambition to become a global medtech leader will depend on its ability to build companies systematically. Innovation alone is not enough. Execution, scale, and global integration are equally critical.

The MedArtha–AMTZ–WTC partnership represents a step toward creating this structured ecosystem. It is designed to move beyond fragmented support models and create a cohesive platform where ideas can be translated into globally competitive businesses.

The next decade of Indian medtech will not be defined by isolated success stories, but by the strength of platforms that can consistently build them. Operator-led ecosystems will play a defining role in this transformation.

MedArtha is built with that vision—to not just participate in the industry's growth, but to help shape its future.

AMTZ Expands Additive Manufacturing CoE To Boost India's MedTech Sector

January 29, 2026 | Thursday | News

Strengthening India's journey towards self-reliance in medical device manufacturing, the Advanced Additive Manufacturing Centre of Excellence (CoE) at Andhra Pradesh MedTech Zone (AMTZ) is set to expand its advanced manufacturing capabilities across plastics, metals and silicone-based medical components.

The expansion builds on the Centre's proven success in polymer and metal additive manufacturing, CNC precision machining and pilot-scale production, positioning AMTZ as a key enabler of high-precision, export-ready MedTech manufacturing in the country.

To date, the facility has worked with over 20 startups and more than 35 industry partners, providing end-to-end support ranging from industrial design and rapid prototyping to machining, post-processing and low-volume production.

Commenting on this integrated approach, Dr Jitendra Sharma, Founder CEO and Managing Director, Andhra Pradesh Medtech Zone said, "By combining additive manufacturing with precision machining, injection-moulded plastics, silicone component manufacturing, and advanced post-processing capabilities, the Centre of Excellence at AMTZ has created a strong platform for indigenous, scalable, and globally competitive medical device component production. This integrated model reduces import dependence, shortens manufacturing cycles, and accelerates innovation and commercialisation for the MedTech sector."

Aligned with national initiatives such as Make in India and Atmanirbhar Bharat, the Centre of Excellence is playing a pivotal role in strengthening domestic manufacturing while supporting export-oriented production. Its shared-access model lowers entry barriers for innovators and manufacturers, enabling them to leverage world-class facilities without heavy capital investment, while simultaneously addressing quality, scale and compliance requirements demanded by global markets.

The Centre enabled the development of a manufacturing process for ultra-high molecular weight polyethylene (UHMWPE), a critical material used in joint replacements and orthopedic implants. This effort helped Nanoshel break a global supply duopoly and provide a domestic alternative, significantly reducing India's dependence on imports estimated at nearly Rs 2,000 crore.

Looking ahead, AMTZ plans to increase collaborations beyond current industry partners and continue building a skilled workforce in advanced manufacturing technologies. With this expansion, the Centre of Excellence is poised to play a defining role in positioning India as a global hub for medical device component manufacturing.

https://www.biospectrumindia.com/news/16/27250/amtz-expands-additive-manufacturing-coe-to-boost-indias-medtech-sector.html

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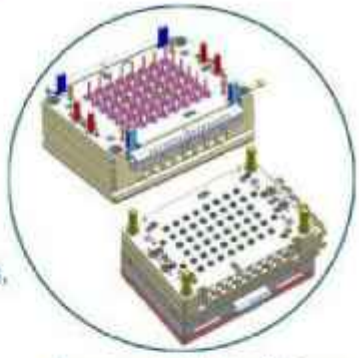

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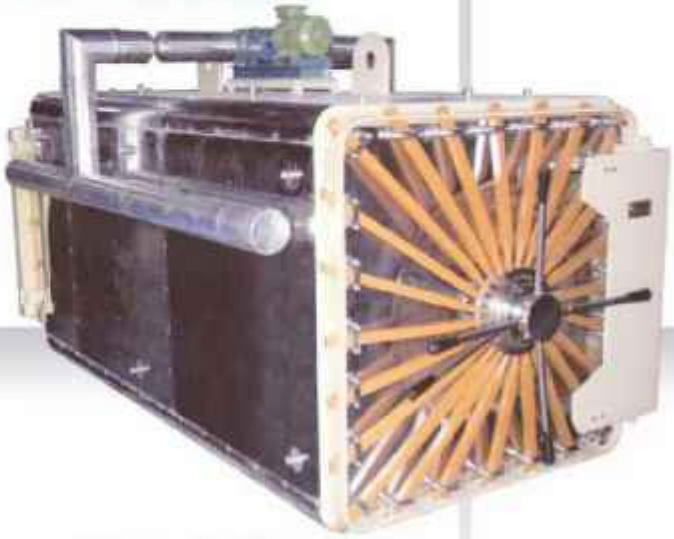
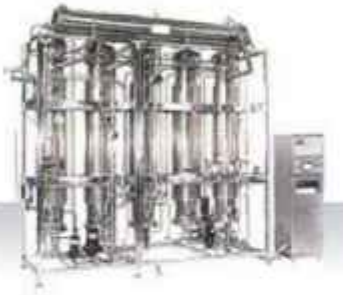


Auto - Sliding Door
Auto - Center Door
Manual Type Door



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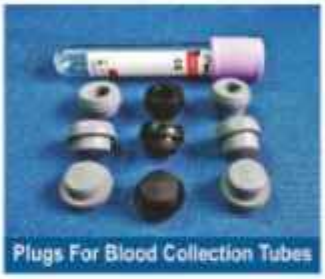
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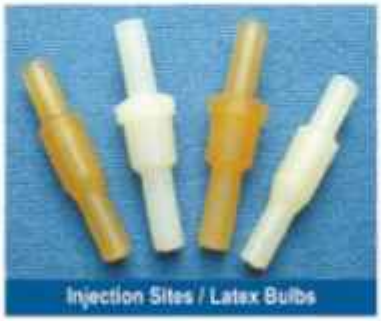
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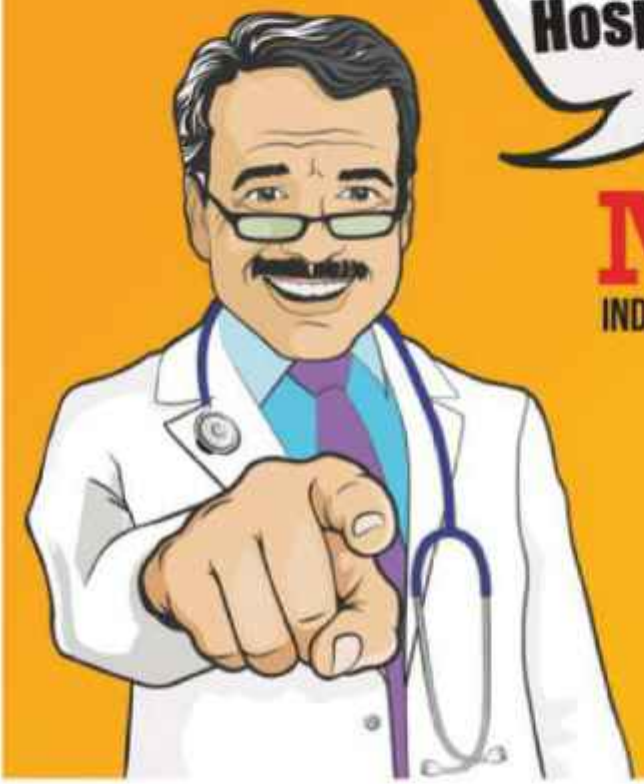

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