Vol.32 No. 1 Jan. - Feb. 2024

Our 32nd Year of Publication

MEDICAL PLASTICS DATA SERVICE

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A TECHNO-ECONOMIC NEWS MAGAZINE FOR MEDICAL PLASTICS, MEDICAL DEVICES, DIAGNOSTICS AND PHARMA INDUSTRY

Medical Device Manufacturing

- Medical Device Manufacturing: Importance of Supply Chain
- Medical Device Sterilization
- US FDA :
  - Harmonization & Modernization of Regulations
  - Disposable Syringes : Quality Failures

Materials

- PVC Vs. Other Polymers In Medical Devices
- EU Report On Essential Role of PVC in Healthcare
- Adhesives For Medical Device Applications

Peru Medical Devices Market

Mr. Manoj Bhardwaj
Managing Director, SMC Ltd., Bangalore
Key Requirements of Contract Manufacturers

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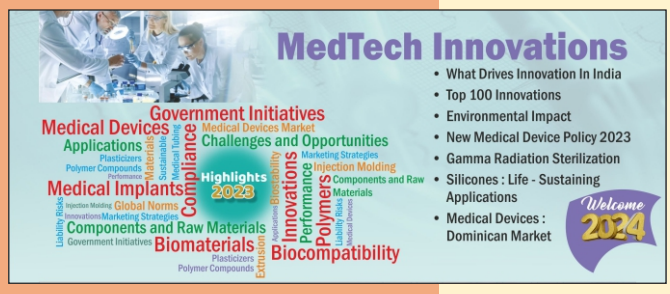

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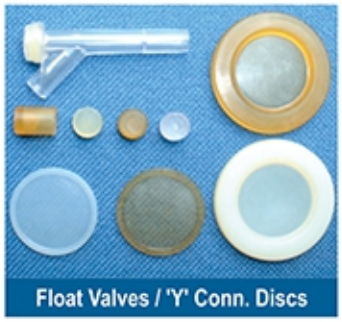
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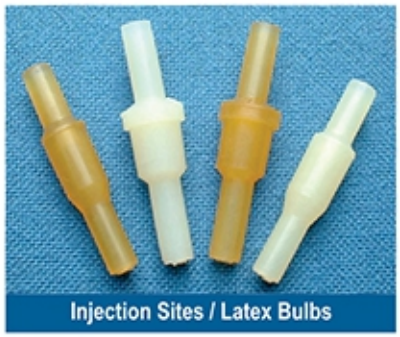
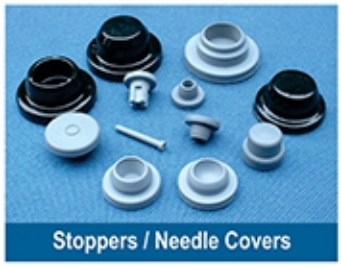

Injection Sites / Latex Bulbs


Syringe Gaskets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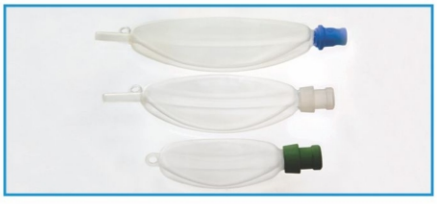
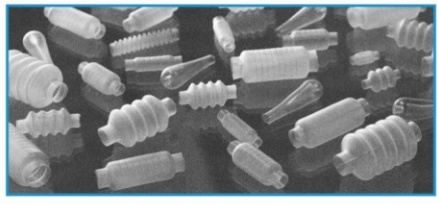


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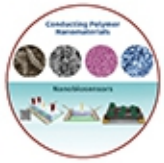

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Flashback

MEDICAL PLASTICS DATA SERVICE

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July 2020 to Sept. 2020

Did You Know ?

About US FDA Alert Regarding China Made Plastic Syringes Quality Failures

As per recent safety communication issued by the U.S. Food and Drug Administration (FDA) for consumers, health care providers, and health care facilities, FDA is evaluating the potential for device failures (such as leaks, breakage, and other problems) with plastic syringes manufactured in China.

Generally, a syringe is used to inject fluid into, or withdraw fluid from, the body and can be used in a variety of clinical and home health settings. Some syringes may also be used with infusion pumps to deliver fluids into the body in a controlled manner.

This alert was for Syringes used for injecting fluids into, or withdrawing fluids from, the body and not glass syringes, pre-filled syringes, or syringes used for oral or topical purposes.

FDA is aware of quality issues from recent syringe recalls, Medical Device Reports (MDRs), and additional complaints about syringes made at various manufacturing sites in China.

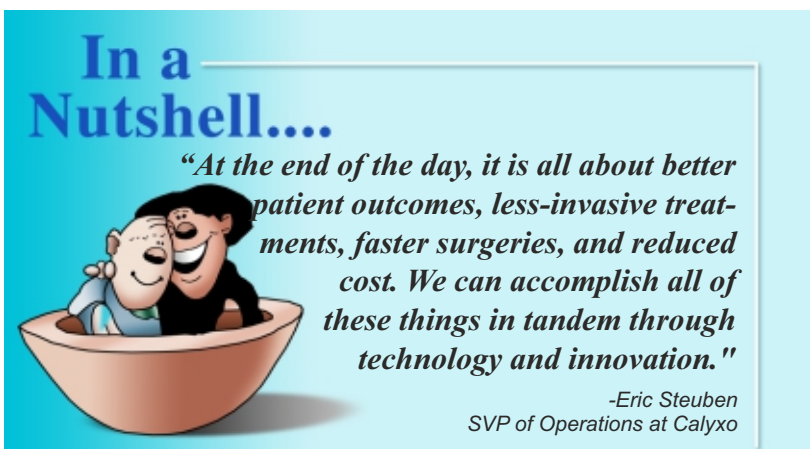
Quality issues reported have included leaks, breakage, and other problems after manufacturers made changes to the syringe dimensions. These quality issues may affect the performance and safety of the syringes .

The differing dimensions reportedly affected their use with syringe pumps, potentially resulting in pump performance issues like overdose, underdose, delay in therapy, and delays in occlusion alarms.

In one of the recalls by a leading US Company, it was found that the Single Use Sterile Syringes had the potential to leak blood or heparin back or from the syringe. There were also reports of an unknown black material inside the syringe. Use of the syringes, according to FDA, could cause serious adverse health consequences including sepsis and blood loss due to leakage, or risks like incorrect heparin dosage.

The FDA is working with federal partners to further test syringes manufactured in China and may prevent syringes made in China from entering the United States.

(Ref : https://www.fda.gov/medical-devices/safety-communications/evaluating-plastic-syringes-made-china-potential-device-failures-fda-safety-communication)



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EDITOR
D.L.PANDYA, B.E.(Chem), M.I.E.

ASST. EDITOR
KAVISHA R. CHOKSHI, B.A. (Mass Comm.)

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From the Editor's Desk

"MEDICAL PLASTICS DATA SERVICE" : NOW IN THE 32nd YEAR OF PUBLICATION.

It is a matter of immense satisfaction and pleasure that with this issue, our magazine is now in the 32nd year of publication.

As always, we remain grateful to numerous Industry leaders and professionals for their kind support, continued co-operation and guidance. Also their generous contribution by way of articles sharing their insight and vision about current and future scenarios.

Along with the magazine, through our other activities namely Conferences, Technology Show Exhibitions, Information Portals, Training Programs etc, our mission is to create a knowledge sharing platform for Medical Device Industry through interaction with materials / machinery / technology, services providers as well as academic and research organizations.

Our successful completion of 31 years' service to the Medical Plastics / Medical Devices sector has been possible because of generous support from all the stakeholders.

Medical Device Manufacturing: Importance of Supply Chain
The supply chain plays a vital role for the growth of Medical Device Industry in India. A well-managed supply chain is the key to quality, efficiency, innovation, availability and affordability. The cover story gives overview on supply chain challenges that can impact operations and overall success of Medical Device Companies. Contract manufacturing is an important component of supply chain. In an article titled, "Medical Device Manufacturing For Mature Markets", Mr Manoj Bhardwaj, Managing Director, SMC Ltd , shares his knowledge and long experience regarding supply chain management and the key requirements of contract manufacturers.

"Medical Devices : Quality System Regulation Amendment" by US FDA
US FDA has recently amended Quality Management System Regulation to harmonize with requirements used by other regulatory authorities including ISO 13485. As summarized by Mr Bhupesh Soon, CEO, SEC GLOBAL in his article, this will result in not only cost saving for Medical Device Industry, but result in " quicker access to newly developed medical device to patients leading to improved quality of life of the consumers."

This issue also introduces Vaporized Hydrogen Peroxide (VHP) as the latest Medical Device Sterilization alternative.

Safe Production and Essential Role of PVC in Healthcare
PVC is the single most used polymer in Medical Devices with global market share of 26 % . As per a recent report by ECHA made for PVCMed Alliance, no alternative material has been identified that can replace PVC in all its medical applications and there is no Life Cycle Assessment (LCA) data to substantiate the claim that alternatives are environmentally preferable to PVC. Along the major applications, facts & figures regarding market share of PVC vs Other Polymers used in Medical Devices are given in this issue.

This issue includes our regular features including Industry & Regulatory News, Global Trends & Markets, Product Gallery and more …

D L Pandya

Medical Device Manufacturing: Importance of Supply Chain

The supply chain in medical device manufacturing is like the backbone of ensuring that the medical devices we use are top-notch in quality and safety - incredibly important. Starting right from sourcing reliable raw materials and components, supply chain plays a vital role more important so in emergencies.

Shortage of semi-conductor & components disrupted the entire supply chain globally during the COVID times. It created shortage of life saving medical devices such ventilators, oxygen concentrator etc. and impacted the human lives.

Recent research from the McKinsey Global Institute (MGI) reports lengthy disruptions from a shock (two months or longer) are frequent, occurring every 3.7 years. The same research also found that within a ten-year period, shocks could cause some medtech companies to lose approximately 38 percent of one year's earnings.

Today's supply chain issues are often crosscutting, involving shortages of raw materials that impact multiple manufacturers and devices, according to Tammy Beckham, associate director for the Resilient Supply Chain Program at the US Food and Drug Administration's Center for Devices and Radiological Health (CDRH).

These factors have impacted a variety of device materials and components including resin, silicone, paper, cotton and semiconductors, she said. (RELATED: Study: COVID pandemic triggered spike in device shortages, Regulatory Focus 08 December 2022)

A well-managed supply chain is the key to quality, efficiency, innovation, availability and more affordable. With a smooth and efficient supply chain, we can get those life-saving medical devices to patients who need them without any delays.

Supply Chain Challenges that can impact operations and overall success of Medical Device Companies .

• Vendor Management

Finding reliable and qualified vendors who meet the necessary quality standards and delivery timelines can be a challenge. Ensuring a stable supply of raw materials and components is crucial for uninterrupted manufacturing.

• Regulatory Compliance

Medical devices are subject to strict regulations and certifications to ensure patient safety. Complying with regulatory requirements, such as FDA regulations in the United States or CE marking in Europe, can be complex and time-consuming.

• Quality Control

Maintaining consistent product quality is vital in the medical device industry. Ensuring that all components and processes meet stringent quality standards requires robust quality control measures and continuous monitoring.

• Demand Forecasting

Accurate demand forecasting is crucial for managing inventory levels and production schedules. Inaccurate forecasts can result in excess inventory, tying up capital, or stockouts, leading to delayed shipments and dissatisfied customers.

• Supply Chain Visibility

Lack of visibility across the supply chain can make it challenging to track inventory levels, monitor supplier performance, and identify potential bottlenecks or disruptions. Real-time visibility is crucial for proactive decision-making.

• Global Supply Chain

Many medical device manufacturers operate globally, which introduces additional complexities such as managing multiple suppliers across different regions, dealing with varying regulatory requirements, and navigating customs and import/export processes.

• Counterfeit Components

The risk of counterfeit components poses a significant challenge. Substandard or cloned parts can compromise the safety and performance of medical devices, leading to product failures and potential harm to patients.

• Cost Management

Balancing cost-effectiveness with quality and compliance is a constant challenge. Fluctuating raw material prices, transportation costs, and regulatory expenses can impact the profitability of medical device manufacturers.

• Continuity Planning

Unexpected events, such as natural disasters, pandemics, or geopolitical disruptions, can significantly impact the supply chain. Developing robust continuity plans to mitigate risks and ensure business continuity is essential.

• Collaboration and Communication

Effective collaboration and communication between manufacturers, suppliers, and distributors are critical for streamlining the supply chain. Lack of collaboration can lead to delays, misaligned expectations, and suboptimal outcomes.

Addressing these challenges requires strategic planning, effective supplier relationships, robust quality management systems, advanced data analytics, and proactive risk mitigation strategies. Medical device manufacturers must continuously evaluate and optimize their supply chain processes to ensure efficiency, compliance, and customer satisfaction.

Medical Device Manufacturing For Mature Markets

Mr. Manoj Bhardwaj,
Managing Director, SMC Ltd., Bangalore

The Indian medical device and pharma manufacturers are striving hard to grow their complex and high-risk medical device product portfolios in particular for the lucrative but hard to penetrate mature markets like U.S., Europe and Japan.

One of the key challenges is difficulty in complying with regulations and expectations of regulators of these markets. To overcome this challenge, a few medical device and pharma manufacturers have partnered with medical, diagnostic and drug delivery device contract manufacturers that have the systems, resources, execution capability and proven track record of meeting both quality and regulatory requirements of mature markets.

The key requirements of such contract manufacturers are as follows:

- Robust quality management system, certifications and registrations that comply with regulations of mature markets
- Best-in-class manufacturing practices
- State-of-the-art facility with sophisticated equipment for manufacturing and testing
- Highly skilled and well-trained resource base
- Program management, speed to market and strength in execution during development, validation and manufacturing phases
- Supply chain management experience including capability to source and procure exotic materials and components from across the globe, even in small quantities

SMC is uniquely positioned in this space as a medical, diagnostic and drug delivery device contract manufacturer headquartered in U.S. and having a world class manufacturing facility (E.O.U.) in Bangalore. SMC has design and manufacturing facilities in U.S.A., U.K., Costa Rica and India. With 1 million square feet dedicated to medical manufacturing, SMC provides full services from initial concept through final packaged device including program management, design and development, validation, product manufacturing, clinical manufacturing, electronics integration, kitting and packing, sterilization management as well as global sourcing and supply chain management. In 2016, SMC acquired Oval Medical Technologies, a cutting-edge parenteral technology company based in Cambridge U.K.

SMC's manufacturing facility in Bangalore makes complex medical device components, assemblies and finished devices for domestic, emerging and mature markets. SMC's capabilities include device design rationalization, component design, tooling,

process development and validation, injection molding, finished device manufacturing, manual / automated assembly, parts adhesion, ultrasonic welding, printing, coating, labelling, kitting, packaging, custom / inline device testing, sterilization management and global distribution. SMC also designs and manufactures custom inline manufacturing, inspection and testing equipment.

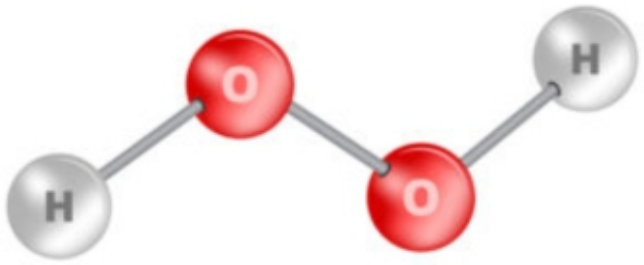
SMC's value proposition is as follows:

- SMC owned and operated 35,000 sq. ft. manufacturing facility at Bangalore
- ISO 13485 certification, US FDA registration, MedAccred certification, ISO 14001 certification and Japan health ministry accreditation
- Mature global quality management system
- Best in class new product development, engineering, validation, automation and sterilization services
- Tool design and build, injection molding and device assembly, kitting and packaging
- Manufacturing environment: ISO Class 7 and Class 8 clean rooms, air-conditioned and white rooms
- Global sourcing and supply chain management capability
- Exports to mature markets from over a decade

For more information, please visit www.smcltd.com or email manoj.bhardwaj@smcltd.com

Vaporized Hydrogen Peroxide For Medical Device Sterilization

Vaporized hydrogen peroxide (VHP) is the latest **medical device sterilization alternative to ethylene oxide (EtO)** as the industry seeks to **limit potential harm from EtO** and increase total sterilization capacity.



A molecular model of hydrogen peroxide (H2O2) [Illustration by petrroudny via Adobe Stock]

Vaporized hydrogen peroxide (also referred to as VH_2O_2) is the **FDA's newest addition to its list of Established Category A sterilization methods for medical devices.** Other Category A sterilization methods include EtO, dry heat, moist heat and radiation.

Like the aqueous form of hydrogen peroxide (H O), VHP (also referred to as VH O) kills infection-causing bacteria, viruses and all other microbial life by oxidizing amino acids and proteins.

VHP has a similar effectiveness as EtO, which is the most commonly used method for medical device sterilization. Like EtO, VHP can permeate many materials used for medical devices and packaging without causing damage or leaving harmful residue. And VHP can similarly be used to sterilize medical devices in bulk.

But unlike EtO, VHP is not flammable or explosive and is not considered by the EPA to be a cancer risk when inhaled. VHP also sterilizes at lower temperatures than EtO, which reduces the risk of heat damage to device components or materials.

Which medical devices can be sterilized with vaporized hydrogen peroxide?

VHP is an effective sterilization alternative to EtO for many medical devices, including single-use and reusable surgical instruments, endoscopes, implants and devices with electronics, temperature-sensitive devices, combination delivery devices, single-packaged complex devices, and complete assemblies or devices with loose components.

VHP can also be used for pharmaceutical sterilization, including containers, pre-filled syringes and other parenteral drug delivery systems.

VHP is "a safe and effective alternative" to EtO sterilization, Stryker's Sustainability Solutions division said in a **2021 white paper** as the world's largest orthopedic developer explained its migration from EtO to VHP. That Stryker white paper — authored by Sterilization & Microbiology Global Director Erick Gustin — explored VHP's use for medical device sterilization, covering efficacy, temperature, processing cycles, emissions and materials compatibility.

"Vaporized hydrogen peroxide provides a safe alternate to ethylene oxide sterilization of medical devices when specific limitations of the technology are appropriately addressed during process development," Gustin wrote.

Vaporized hydrogen peroxide sterilization processing

VHP can permeate most materials — including seams, joints and plastic membranes — and is an effective sterilant at low concentrations. "Following established ISO guidelines, the VHP process shows consistent repeatability and reproducibility for medical device sterilization," Gustin wrote.

VHP can sterilize at lower temperatures than heat sterilization or EtO, with typical processing cycles in the range of 75-100°F, Gustin said. He reported efficient VHP sterilization at temperatures as low as 39°F to minimize the risk of damage to heat-sensitive materials.

Like EtO, VHP is applied in a vacuum chamber, but VHP has relatively short sterilization cycles, with less or no need for extended product residual outgassing like EtO. VHP also has low toxicity. Water and oxygen are the byproducts of VHP sterilization, eliminating the toxic emission risks of EtO. This all yields faster turn times and increased chamber availability to maximize sterilization throughput.

Vaporized hydrogen peroxide materials compatibility

Medtech industry testing has found VHP is compatible with most materials used to make medical devices, including a wide range of metals (such as stainless steel, aluminum, and titanium), plastics (including polycarbonate, polyethylene and polypropylene), silicones, glass, adhesives and electronics.

However, VHP may react with certain uncoated reactive metals like copper and brass, causing material degradation and/or discoloration.

"During design and development of VHP sterile processing cycles, devices are inspected both from a cosmetic and functional aspect post exposure," Gustin wrote. "Any materials or devices that are found to not pass stringent requirements for functionality and cosmetic appearance are not adopted into the VHP processing cycles."

Another notable exception for VHP materials compatibility is cellulosic material like the paper or cardboard that's commonly used in medical device packaging and shipping. That's a big disadvantage compared to EtO, which can be used to sterilize pallets worth of devices in cardboard packaging because the gas permeates the packaging to sterilize the contents within.

"Stryker's Sustainability Solutions division addresses this limitation by processing devices only in their primary sterile barrier that is VHP compatible and composed of non-cellulosic materials (Tyvek, Mylar, various plastic polymers)," Gustin wrote. "Following VHP processing, products are packaged in secondary and shipping containers for distribution."

Stryker also warned of adsorption and condensation difficulties with long lumen devices and densely packed exposure loads.

"Poor cycle development which does not consider potential dew point changes, gas concentration and saturation levels and exposure environment temperature will exhibit these processing non-conformances," Gustin wrote. "Stryker Sterilization Engineers account for these conditions and parameters during the developmental process of a VHP cycle. Devices are seeded with appropriate biological challenges to challenge the process and achieve the desired sterility assurance levels to avoid these anomalies."

https://www.medicaldesignandoutsourcing.com/vaporized-hydrogen-peroxide-vhp-sterilization-medical-devices/

PVC vs. Other Polymers In Medical Devices :

PVC is the single most used polymer in medical devices. PVC has a market share of 27% in Europe and 26% globally. It is estimated that PVC will retain its market position in the years to come.

PVC uses in medical devices and medical equipment

PVC is used in wide variety of medical applications – from blood bags over oxygen tubing and catheters to mattress covers. The largest share goes into medical bags, including blood bags, IV bags, dialysis bags and urine bags. The second largest segment is masks, including oxygen masks and anaesthetic masks, followed by tubing, gloves and kits. The remaining 70% is used for catheters, drip chambers, transfusion sets, diagnostic equipment and many other applications.

Medical Tubing

PVC is the single most used polymer for medical tubing in Europe with a market share of 31%

Medical Bags

PVC is the single most used polymer for medical Bags in Europe with a market share of 82%

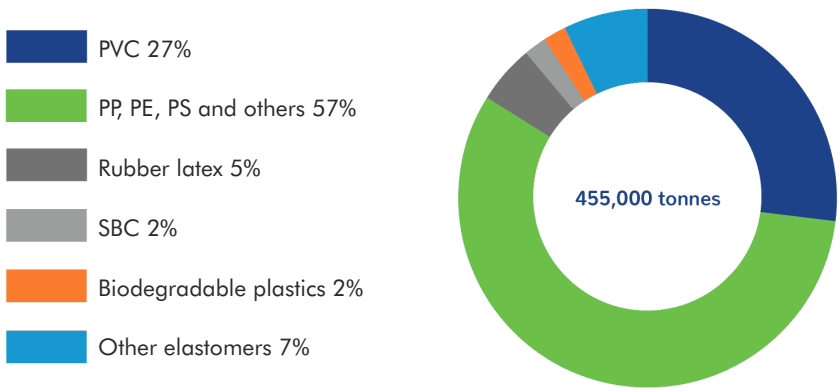
Pharmaceutical Packaging

PVC is the material of choice for medical blister packaging

PVC used in Hospitals

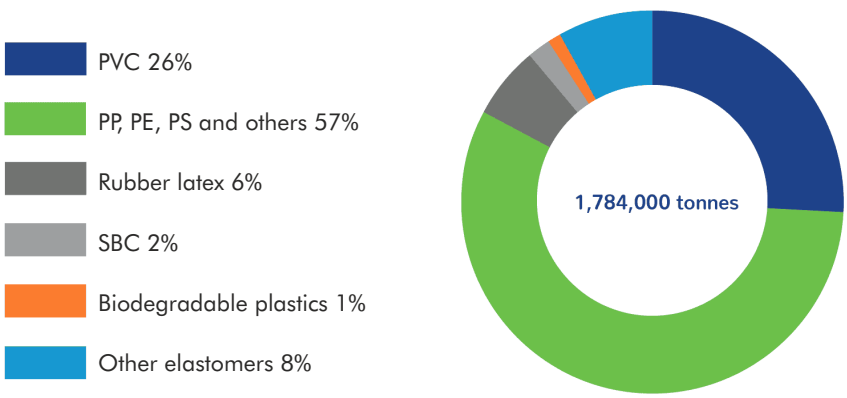
Facts And Figures

Medical devices in Europe - PVC vs. other polymers



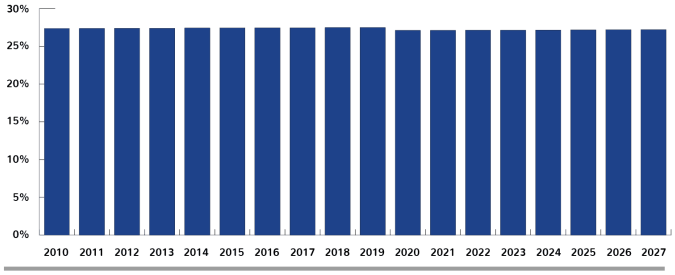
Note: Shares calculate based on volumes of unformulated polymers

Medical devices globally - PVC vs. other polymers

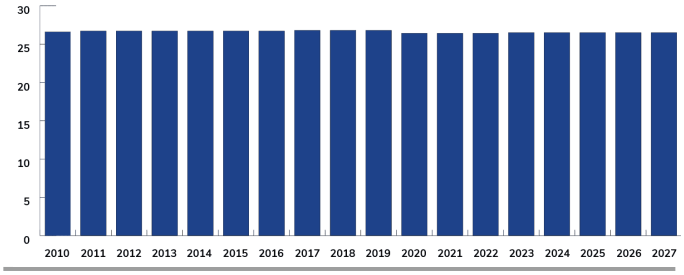


Note: Shares calculated based on volumes of unformulated polymers

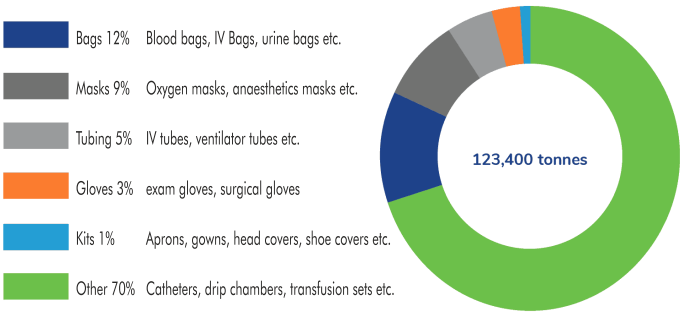
Medical devices in Europe - PVC volume share 2010-2017



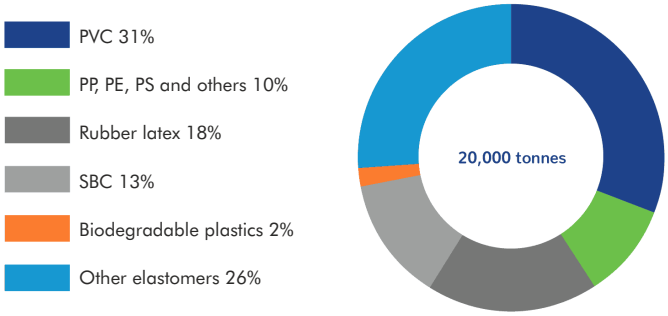
Medical devices in Europe - PVC volume share 2010-207



PVC uses in medical devices and equipment, Europe



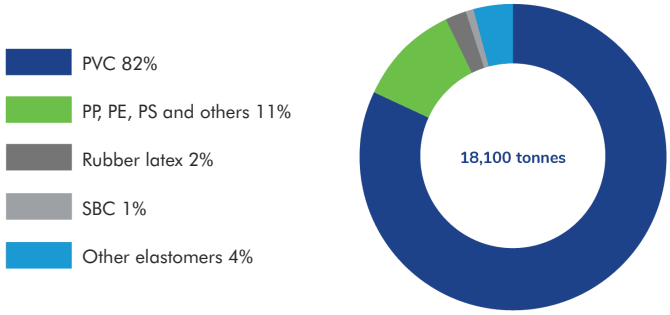
Medical tubing in Europe - PVC vs. other polymers



Source: Europe Medical Polymer Market Report, Global Market Insights, 2021

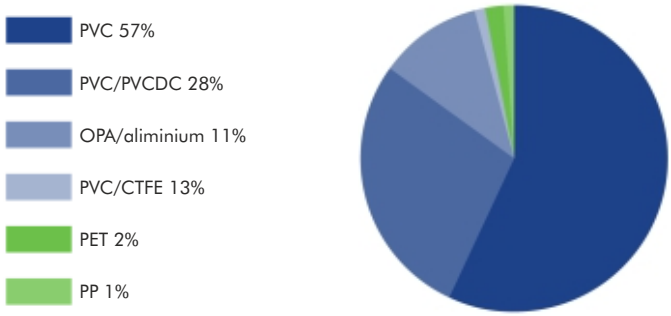
Ref. : http://pvcmed.org/healthcare/facts-figures/

Medical bags in Europe - PVC vs. other polymers



Pharmaceutical packaging

Market share distribution for medical blister packaging materials



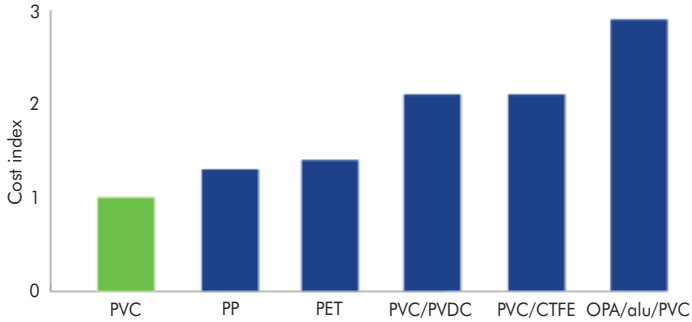
Source : Llano Martinez, G. (2012). Environmental impact of the pharmaceutical packaging (Master's thesis, Lund University). Lund University Publications. http://lip.lub.lu.se/student-papers/record/3044827

PVC is the material of choice for medical blister packaging

97% of all medical blister packaging utilises PVC

Source : Llano Martinez, G. (2012). Environmental impact of the pharmaceutical packaging (Master's thesis, Lund University). Lund University Publications. http://lip.lub.lu.se/student-papers/record/3044827

Cost comparison of blister packaging materials



Source : Llano Martinez, G. (2012). Environmental impact of the pharmaceutical packaging (Master's thesis, Lund University). Lund University Publications. http://lip.lub.lu.se/student-papers/record/3044827

Henkel Introduces Instant Adhesives For Medical Device Applications

As a manufacturer of advanced adhesive solutions for the medical industry, Henkel has introduced two next-generation medical grade, cyanoacrylates-based instant adhesives that are designed to offer improved safety and performance.

Operational excellence concept. Productivity with excellence process. Industrial management in efficiency and efficient process. Lean cost and productivity growth. Process of continuous improvement.

The new products are formulated without CMR (Carcinogenic, Mutagenic or Reproductively hazardous) ingredients and are designed to offer increased strength during and after heat cycling. Loctite 4011S and Loctite 4061S are designed to meet the specifications of Loctite 4011 and 4061 for easier validation in existing medical applications.

Both new products have been tested to ISO 10993 biocompatibility standards. The adhesives aim to develop handling strength in seconds on most substrates and aim to provide high bond strength on a range of materials including plastics, rubbers, and metals. After 1000 hours of exposure to 120°C (248°F) heat, these next generation adhesives offer approximately 100% greater shear strength on steel than other instant adhesive formulations.

Henkel's new, heat-resistant instant adhesives are "excellent candidates" for bonding various types of catheters, as well as tube sets, surgical robots, and other medical housings.

“Henkel is committed to medical quality systems and good manufacturing practices as a pioneer for sustainable solutions,” said Philipp Loosen, vice president and head of industrials EIMEA and global key accounts medical at Henkel. “The launch of these new, next generation instant adhesives are formulated to meet the highest safety standards, addressing the need for safe and effective medical device assemblies, and demonstrating our longstanding commitment to the medical industry.”

For more information about Loctite 4011S and Loctite 4061S, Henkel will be at MD&M West from 6-8th February in Anaheim, CA, at booth #2326.

https://www.medicalplasticsnews.com/news/latest-medical-plastics-news/henkel-introduces-next-gen-instant-adhesives-for-medical-dev/

www.medicalplasticsindia.com
www.medisourceasia.com

MEDICAL PLASTICS DATA SERVICE

SINCE 1994

A TECHNO-ECONOMIC NEWS MAGAZINE FOR MEDICAL PLASTICS, MEDICAL DEVICES, DIAGNOSTICS AND PHARMA INDUSTRY

Target Readers

All who are involved or interested in Medical Plastics user industries ranging from Medical Plastic Devices / Equipments Manufacturers / Marketing Companies, Diagnostic & Pharmaceuticals industries, Hospitals, Doctors, Medical & Pharmacy Collages, Research Institutes.

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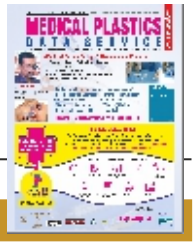

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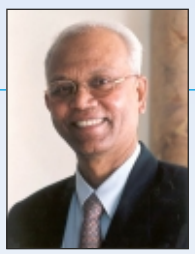

Forward (1st Edition)

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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US FDA QSR Amendments : Relevance to Medical Device Component Manufacturers

Mr. Bhupesh Sood
CEO, SEC Global, Ahmedabad

Excerpts of Medical Devices; Quality System Regulation Amendments – Special reference to component manufacturers. The following points must be considered for future compliance requirements:-

1. The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation to harmonize and modernize the regulation.
2. DATES - This rule is effective February 2, 2026.
3. FDA is revising its medical device CGMP requirements as set forth in the QS regulation, codified in part 820 (21 CFR part 820). FDA is accomplishing this primarily by incorporating by reference the 2016 edition of ISO 13485 (ISO 13485). Through this rulemaking, FDA is harmonizing quality management system requirements for medical devices with requirements used by other regulatory authorities.
4. FDA has not undertaken a significant revision of part 820

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 4 and 820
[Docket No. FDA–2021–N–0507]
RIN 0910–AH99
Medical Devices; Quality System Regulation Amendments
AGENCY: Food and Drug Administration, HHS.
ACTION: Final rule.

I. Executive Summary

A. Purpose of the Final Rule

FDA has historically recognized the benefits of harmonization with other regulatory authorities and, over time, has taken a number of actions to promote consistency with its regulatory counterparts. As part of such activities, FDA is revising its medical device CGMP requirements as set forth in the QS regulation, codified in part 820 (21 CFR part 820). FDA is accomplishing this primarily by incorporating by reference the 2016 edition of ISO 13485 (ISO 13485). Through this rulemaking, FDA is harmonizing quality management system requirements for medical devices with requirements used by other regulatory authorities.

B. Summary of the Major Provisions of the Final Rule

We are amending part 820, primarily through incorporating by reference the quality management system requirements of ISO 13485.1 We have determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act). As such, we are retaining the scope of the QS regulation, and amending many of the provisions. We are also amending the title of the regulation and establishing additional requirements and provisions that clarify certain expectations and certain concepts used in ISO 13485. These additions ensure that the incorporation by reference of ISO 13485 does not create inconsistencies with other applicable FDA requirements. This revised part 820 is referred to as the Quality Management System Regulation (QMSR). FDA has made conforming edits to part 4 (21 CFR part 4) to clarify the device Quality Management System (QMS) requirements for combination products. These edits do not impact the CGMP requirements for combination products.

C. Legal Authority

We are issuing this rule under the same authority that FDA initially invoked to issue the QS regulation and combination product regulations, as well as the general administrative provisions of the FD&C Act: 21 U.S.C. 351, 352, 353, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

D. Costs and Benefits

We estimate that the QMSR will result in an annualized net cost savings (benefits) of approximately $532 million at a 7 percent discount rate (cost savings: $540M, costs: $8.2M) and approximately $554 million in annualized net cost savings at a 3 percent discount rate (cost savings: $561M, costs: $7.29M). In addition to the cost savings to the medical device industry, the qualitative benefits of the rule include quicker access to newly developed medical devices for patients leading to improved quality of life of the consumers. The rule will also align part 820 with other related programs potentially contributing to additional cost savings.

(Ref: https://www.govinfo.gov/content/pkg/FR-2024-02-02/html/2024-01709.htm)

since the 1996 Final Rule.

5. We are amending part 820, primarily to incorporate by reference ISO 13485, Medical Devices—Quality Management System Requirements for Regulatory Purposes. This resulting regulation is referred to as the QMSR.
6. Scope - FDA has chosen, in this regulation, not to require components and parts to comply with the requirements of this rule making. FDA's determination not to extend this regulation to manufacturers of components and parts does not preclude any contract between manufacturers that requires compliance with this rulemaking and is consistent with Clause 0.1 of ISO 13485.
7. FDA agrees that manufacturers of components or parts of finished devices are not subject to the QMSR. We also note that, although the scope of the QMSR remains unchanged, FDA has the legal authority to inspect component manufacturers under the FD&C Act should the need arise.
8. FDA encourages manufacturers to consider provisions of this regulation as appropriate. FDA declines to specify in this rulemaking the specific provisions "appropriate for" manufacturers of components or parts of finished device.
9. Voluntary compliance with the QMSR will provide manufacturers of components or parts of finished devices a framework for achieving quality throughout the organization.
10. FDA notes that because ISO 13485 clarifies the term "as appropriate" in section 0.2, "Clarification of concepts," in the manner requested by the commenter, we do not need to add such a definition to this rule.
11. FDA confirms that compliance only with ISO 13485 does not fully satisfy the QMSR. With the incorporation of ISO 13485 in the QMSR, the requirements of ISO 13485 become the foundational requirements for device CGMPs. FDA has added limited additional requirements to the QMSR where appropriate, and thus device manufacturers must meet those additional QMSR requirements in addition to those set forth in ISO 13485.
12. This final rule incorporates the entire introduction from ISO 13485, which sets forth important concepts. FDA confirms that the QMSR incorporates ISO 13485:2016 by reference, including Clauses 0.1 (General), 0.2 (Clarification of Concepts), and 0.4 (Relationship with ISO 9001) of the Introduction of the standard.

EU Report Confirms Safe Production and Essential Role of PVC in Healthcare

The PVCMed Alliance acknowledges ECHA's recent investigation report on PVC and PVC additives which provides, among many other topics, a comprehensive analysis of PVC's role in medical devices and packaging. The report confirms that the production of PVC in Europe adheres to the highest safety standards, effectively managing risks associated with its production, particularly concerning worker safety and environmental impact.

The ECHA investigation highlights the significant advancements in the European PVC industry through the VinylPlus® Commitment to sustainable development. Through VinylPlus, the industry has voluntarily enforced its own continuously updated charters, which supersede regulatory requirements.

The ECHA report emphasises that no single alternative material has been identified that can replace PVC in all its medical applications, underscoring the polymer's irreplaceable role in healthcare. Simultaneously, the report concludes that there is no Life Cycle Assessment (LCA) data to substantiate the claim that alternatives are environmentally preferable to PVC.

However, the ECHA report omits PVC's increasing role in the circular healthcare economy, namely the scheme VinylPlus® Med scheme that helps hospitals turn their DEHP-free PVC medical device waste into useful products for the healthcare sector, such was vinyl wall covering. A new comparative LCA documents that recycling cuts greenhouse gas emissions by 25% compared to incineration. Ongoing research commissioned by PVCMed Alliance is investigating how many times medical PVC can be recycling without loss of functional properties. So far, four cycles have been completed with success.

Ole Grøndahl Hansen, Project Leader at PVCMed Alliance, commented on the report: "It is heartening to see ECHA's findings align with our understanding of how PVC is produced today. We are also happy about the nuanced approach to PVC's role in healthcare from a high-level European authority. We hope the report will contribute to more evidence-based procurement decisions among European hospitals and consider PVC's potential carbon savings through recycling."

Additionally, the ECHA report acknowledges the advancements in developing new plasticisers, which address health concerns related to low molecular weight phthalates such as DEHP.

The ECHA's investigation further reviews PVC in medical packaging, particularly in blister packs, where PVC's versatility and cost/performance ratio are unrivalled.

The ECHA report addresses the often-discussed topic of PVC in waste incineration, providing clarity and reassurance. It concludes that the formation of dioxins is not directly linked to the amount of chlorine present in the waste, challenging a common misconception. Instead, dioxin production is mainly influenced by the management of the incineration process. In addition, chlorine from other sources, such as salty foods, are always present in the waste. ECHA also acknowledges that current European waste incineration capacity is adequate to safely process waste containing up to 2% PVC.

In conclusion, the ECHA report provides impartial evidence of safe PVC production in Europe and PVC's crucial role in healthcare. PVCMed Alliance continues to support the responsible production, use, and end-of-life of PVC in the medical sector.

(Ref : https://pvcmed.org/echa-investigation-report/)

Peru Medical Devices Market

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

Country Profile

Motivated to write about Peru since the author had also spent quite some time in Peru, a South American country, during his recent visit to the region.

Peru is a fairly large country in the region. The population of the country is 34 million (compared to 11 mn in DR and 17.5 mn in Guatemala). This extreme western country in South America (please see the map) has thick jungles, beautiful Andean mountains, and also the world-famous Machu Picchu, "the lost city of the Incas", in these mountains. The capital city is Lima. This country's official language is Spanish.

The economy of Peru is the forty-seventh largest economy in the world based on total GDP. The country also has a high Human Development Index. Post-Covid, the economy was projected to grow at a rate of more than 9%!! Peru is the third largest economy in the region of South America (after Brazil, and Argentina). Interestingly, Peru boasts one of the highest average life expectancies in the region (77 years).

Like most of the other South American countries, Peru has signed several free trade agreements, including the one with China (China–Peru Free Trade Agreement), besides agreements with the United States, Japan, and the European Union. Readers know that these treaties cover almost all the countries that are the major players in the medical devices sector. One interesting and important point is that Peru imports more than 97 percent of its medical devices. This point adds to the attractiveness of the market.

Regulatory Framework and Product Classification

DIGEMID is the regulatory agency for Peru and their website (all contents in Spanish) iswww.digemid.minsa.gob.pe/webDigemid/. This webpage has a facility for auto-translation and readers are encouraged to visit and study the webpage for more clarity. Law 29459 (Law of Pharmaceutical Products, Medical Devices, and Health Products) covers the regulatory framework. This Law 29459 describes the document requirements, application evaluation timelines, and surveillance obligations to apply for sanitary registration.

It is generally observed that in a geographical region, medical devices product classifications are almost similar. So, like DR and Guatemala, Peru also has four classes for medical devices –

- Class I : Low risk (and need general controls).
- Class II : Moderate risk (requiring controls during the manufacturing).
- Class III : High risk (and call for controls in design and manufacturing), and
- Class IV : Critical in terms of risk, and special controls in the design and throughout the manufacturing process.

An overseas manufacturer needs to obtain a sanitary registration for the importation, marketing, and distribution of medical equipment and devices in Peru.

Peru Highlights

- Very high import dependence for medical devices
- Regulatory Framework almost like the other counties
- A large Indian population involved in the healthcare market
- Larger market with better realization

Registration certificate is always issued in the name of a local importer or distribution partner since the rules do not allow foreign manufacturers to be the owners of product registrations. A clear legal contract/documentation between the parties is, therefore, recommended.

Peru Medical Devices Market

Different estimates by different market research agencies give the market size between 400 mn to 500 mn USD. The growth rate is estimated at about 6% per year. The readers will immediately realize that the market size is very high on a per-capita basis if compared with other countries in the region (as well as with India). Dependence on imports is very heavy, as stated in the beginning.

For medical devices, the Peruvian market has five buyer segments-

1. Public hospitals which serve 60% of the population. These hospitals fall under MINSA (local health ministry). Mostly, their buying is through open tenders
2. The national social security agency (El Salud). They attend to the rest of the 40% population.
3. The military
4. The police department
5. The private sector

The private sector is growing mainly because of the growing middle class with more disposable income. Because of longer life expectancy, the elderly population is also seen increasing. Such factors make the last segment attractive. Typically, a large distributor has teams that take care of each of these segments. However, the first two are quite important, though highly cost sensitive. The type of products also decides the segment selection for an exporter.

Opportunities and Challenges

A larger market size comparatively, because of the factors listed above, longer life expectancy resulting in the larger elderly population and increasing private market offer a good opportunity. Prioritization for digitization and telemedicine also provides a newer segment opportunity.

The registration process and steps are almost like that in the other counties in the region. An Indian exporter can prepare documents common for more than one country of the region. Like other countries, here also, the challenges could be language and distance.

A very large population of Indians residing in the country (mainly in Lima) can be a good support system. In the healthcare profession, there are many Indian operators. The author had an opportunity to meet many of them during a function of the recent festive season, and their enthusiasm as well as local contacts were found to be quite impressive. These people can be effective and reliable partners and can solve many challenges.

Medical Devices Sector Applauds Budget Announcements On Healthcare Sector

The Medical Devices industry has welcomed the interim Union Budget 2024 lauding the measures announced in connection with the healthcare sector, but expressed hope that their demands including on customs duty would have been addressed.

Association of Indian Medical Device Industry (AiMeD), the umbrella association of Indian manufacturers of medical devices covering all types of medical devices, praised the interim Union Budget 2024 as a comprehensive continuity of the earlier roadmap for India's 'Atmanirbhar Bharat'.

But it also pointed out, "we await the fine print to study if Department of Pharmaceuticals' recommendations have been addressed as seemingly the budget has fallen short of expectations for addressing the rising import graph of medical devices and soaring import bills worth over Rs 63,200 crore ($8 billion)". The Association has requested an increase in custom duty to 10-15 percent and a predictable tariff policy to support the domestic industry.

Medical Technology Association of India (MTaI), which represents leading research-based medical technology companies with a large footprint in manufacturing and training in India, on the other hand appreciating the measures announced, said that a reduced customs duty could have helped the growth of FDI in the medical technology sector.

Rajiv Nath, Forum Coordinator, AiMeD applauded the government's announcements including those regarding the establishment of medical colleges and the expansion of preventive vaccination and Ayushman Bharat to ASHA and Aganwadi workers. He also welcomed the port connectivity corridors and high traffic density corridors through PM Gati Shakti and the focus on Northeastern states as it will improve supply chain management and infrastructure.

The domestic medical technology industry may benefit from the budget's focus on green growth, youth and women empowerment, and farmer centricity, which are aligned with Vision 2047, and the principle of reform, perform, and transform will ensure that India has a modular economic structure for all sections of business and society during the Kartavya Kal, enabling India to address global challenges and sustain development. The AiMeD was expecting an increase in Custom Duty to a nominal 10%-15% Duty and a predictable tariff policy, correction of Inverted Duty by levying Health Cess of 5% custom duty on balance Medical Devices (this was not earlier applied to all HS Codes), trade margin capping by monitoring MRP of Imports (if over 10 - 20 times of CIF) and income tax benefits for project investments in Medical Devices Manufacturing.

"We can only be hopeful that the fine print of the Union Budget would possibly act upon our recommendations," said Nath. "We do hope to see in the fine print action on the assurances from various government departments to implement the National Medical Devices Policy 2023 and make it attractive and profitable to make in India rather than import into India," he added.

Pavan Choudary, Chairman, Medical Technology Association of India (MTaI) & Managing Director, Vygon India said, “The schemes for maternal and child care which are currently in place are disparate and sometimes deficient. Bringing them under one common, standardized platform would help deliver optimal and comprehensive care throughout India".

“While the customs duty has not gone down which was our expectation, and remains at the same level, this itself will take FDI in MedTech to a never-before high this financial year. However, if the government had reduced the customs duties, the FDI in MedTech could have taken a meteoric trajectory”, he added.

MTaI has requested the government to reduce the high customs duties to 2.5% on medical devices, remove the 5% health cess, removal of undue complications in the tax provisions and put healthcare services under zero rated Goods and Services Tax (GST) for hospitals to avail GST credit on inputs, among others. Since the custom duty regime on most of the medical devices in many neighboring countries is lower than in India, the difference in duties created could lead to the smuggling of the low-bulk-high-value devices. The result will not only be loss of revenue for the government but also the patient will be beset with products which are not backed by adequate legal and service guarantees, it said.

https://www.pharmabiz.com/NewsDetails.aspx?aid=166132&sid=1

DoP Invites Applications Under AMD-CF Scheme

The Department of Pharmaceuticals (DoP) has invited applications from eligible candidates under the scheme for Assistance to Medical Device Clusters for Common Facilities (AMD-CF), fixing the last date of filing the applications as February 10, 2024.

The Department has come out with the guidelines for the scheme with a proposed financial outlay of Rs. 300 crore, on May 9, 2023, to offer financial assistance to strengthen the existing and new medical device clusters through creation of common infrastructure facilities. It has also announced procedures to select a Project Management Agency (PMA) for the scheme.

The eligible applicants may apply through online mode only, after going through the detailed guidelines published by the Department, informed a Department official.

The industry organisations have also applauded the DoP’s move to set up the scheme, stating that this will play an important role in attracting foreign and domestic investments in the MedTech space.

The Scheme, with two sub-schemes, is expected to help in boosting the domestic manufacturing capacity and improving the quality of clusters for sustainable growth of the medical devices sector.

The scheme further intends to support central or state governments, institutions, or organisations to establish or strengthen the testing laboratories for medical devices to meet the needs arising due to the roll out of the licensing regime of the Medical Devices Rules (MDR), 2017.

The Scheme has two components or sub schemes - Assistance for Common Facilities (CF) and Assistance for Testing Facilities (TF) - and would be running for three years from 2023-24 to 2025-26. The tenure of the scheme is from the financial year 2023-24 to the financial year 2026-27.

Both the sub-schemes are designed to set up 12 common facilities and 12 testing laboratories, under which the common facilities will be supported with a financial assistance of Rs. 240 crore (Rs. 48 crore in the first year, Rs. 128 crore in the second and Rs. 64 crore in the third year) for the common facilities and Rs. 60 crore (Rs. 18 crore for the first, Rs. 30 crore for the second and Rs. 12 crore for the third year) for the testing facilities.

For Common Infrastructure Facilities for medical device clusters, the limit of support will be 70 per cent of the approved project cost or Rs. 20 crore, whichever is less, as per the approval of the Scheme Steering Committee (SSC). In the case of Himalayan States and States in the NorthEast Region, the grant-in-aid would be Rs. 20 crore per Cluster or 90 per cent of the project cost of the CIF, whichever is less. The grant will be released in instalments, with 30 per cent each released in the first, second and third instalment while the rest of the 10 percent will be released at the fourth stage where the SPV has mobilised and spent its 100 per cent share in proportion of the first three grants.

The sub scheme is expected to have benefits including improvement in quality of medical devices, regulatory compliance specified for medical devices, increased availability of trained personnel for the clusters, increased competitiveness of units in the cluster and reduction in the manufacturing cost of the devices.

The sub scheme on assistance for testing facilities is aimed at strengthening availability of more medical device testing laboratories in order to boost manufacturing of quality medical devices, and national or state level government of private institutions interested to establish or strengthen testing facilities for medical devices to test Class A, B, C and D medical devices including in vitro diagnostic medical devices under MDR, 2017 can apply for the assistance. Other legal entities which open a separate account for the funds to be utilised for the project assistance under the sub-scheme can also apply for the grant.

January 15, 2024

https://www.pharmabiz.com/NewsDetails.aspx?aid=165760&sid=1

New Portal For Medical Devices Registration In India (NSWS)

On January 01, 2024, India's medical device regulator, Central Drugs Standard Control Organization (CDSCO) issued a notice that applications for certain medical device related regulatory approvals will not be accepted on the current medical devices CDSCO portal (CDSCO MD-Online portal) after January 15, 2024. Instead, they will be accepted through the National Single Window System (NSWS) portal only.

This transition is being implemented in stages. In the first phase, medical device related regulatory applications which are described below in this article will be accepted through NSWS portal. In future all medical device related regulatory applications will be accepted and filed through the NSWS portal only.

What is NSWS portal?

The NSWS portal is a digital platform established by the Indian Government with the aim to act as a single window for all the approvals. The portal enables the investors (manufacturers, importers, traders etc.) to obtain registrations and approvals according to their business requirements.

Which medical devices approvals could have been obtained through NSWS portal prior to January 01, 2024?

Importers and manufacturers of medical devices were previously able to use NSWS portal to make application for legal metrology registration, wireless planning and coordination wing's (WPC) equipment type approval (ETA), import export code (IEC), etc.

Going forward, which medical devices related regulatory applications will be accepted through NSWS portal only?

From January 15, 2024, the list of medical device applications which will be accepted through NSWS portal are as follows:

- Application for license to import medical devices for the purposes of clinical investigations or test or evaluation or demonstration or training (Form MD-16).
- Application for license to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration, or training (Form MD-12).
- Application for grant of certificate of registration of a Notified Body (Form MD-01).

Is there any guidance for the filing of applications for approvals on NSWS?

There is a user manual for the submission of the applications through the NSWS portal which has been made available by the Indian Government.

What happens to the applications that have been filed before January 01, 2024?

The medical device regulatory applications which were filed before January 01, 2024, through CDSCO MD-Online portal will be processed on the same portal. The medical device regulatory applications that are identified above should not have been filed after January 01, 2024, on CDSCO MD-Online portal. Importers and manufacturers of medical devices will not be able to use CDSCO MD-Online portal for filing regulatory application identified above after January 15, 2024.

Which medical device regulatory applications will be accepted through CDSCO MD- Online portal?

All applications excepting those described above, including applications for import and manufacture of medical devices will be accepted through CDSCO MD-Online portal until further notice.

January 15 2024

https://www.lexology.com/library/detail.aspx?g=af79a9a4-ef50-4763-9951-6de3cd0f60a3

Kerala Makes Cut In Medical Device Manufacturing

Kerala is slowly emerging as a manufacturing hub for medical devices, thanks to a clutch of local entrepreneurs who have made the state their base for this highly advanced industry.

KOCHI: Kerala is slowly emerging as a manufacturing hub for medical devices, thanks to a clutch of local entrepreneurs who have made the state their base for this highly advanced industry, which requires expertise in plastics and precision engineering, besides qualified engineers.

Industry insiders reckon Kerala is home to around 20 established medtech players with around Rs 7,350 crore in annual turnover. If small and medium enterprises (SMEs) are also considered, Kerala has nearly 60 registered medical device manufacturers — of the total 900 in the country — that contribute 20-25% of the total production in the country.

Some of the companies are leading players in their segments. Consider this: Thiruvananthapuram-based Terumo Penpol is India's largest blood-bag manufacturer; Dentcare Dental Lab in Muvattupuzha is Asia's largest producer of dental products; Kochi-based Agappe Diagnostics is India's leading in vitro diagnostics company; NeST, also Kochi-based, is the original equipment maker (OEM) for many multinational corporations, including GE and Philips.

'State can become medtech hub in one or two years with policy changes, autonomy'

Based in the state capital, central PSU HLL Lifecare, which specialises in blood transfusion and neo-natal care equipment, contraceptives, and surgical and healthcare products, reported a turnover of `500 crore in 2022-23.

Industries Minister P Rajeeve said Kerala accounts for around 20% of the medical device manufacturing in the country. The government aims to make it 50%. "The Thonnakkal Life Science Park and the expansion of medical device manufacturing companies in the state have benefited us. We also ensure support to the sector. The industrial policy outlines our aim to make the state a medical device manufacturing hub," he said.

According to Thomas John, the MD of Agappe Diagnostics, Kerala contributes significantly to the Indian market. "The state has around 20 established companies in medtech sector. Highly skilled employees, technology and other factors make the state conducive for setting up the firms," he said.

Balagopal Chandrashekar, the founder of Terumo Penpol, said there are several states with potential in the sector. "With just 7% of the total registered companies, Kerala accounts for around 20-25% of total output. The majority of the companies are small and medium enterprises with turnover in the range of Rs 50 crore to Rs 200 crore," he said, adding that the numbers show that there is a flourishing medical device manufacturing sector in Kerala.

C Padmakumar, the special officer of the Kerala Medical Technology Consortium (KMTC), said companies can benefit from the experience and expertise of institutions like the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) and other universities which are directly or indirectly involved in research in the field. "It helps in reducing imports and raising the quality of products," he said.

Kerala has other facilities that can help manufacturing units flourish, says Balagopal. "Testing facilities, research institutions and the strong base of higher education institutions that do research in the field, besides the presence of manufacturing units are key to establishing medical devices manufacturing units. Also, the geographical character, topography, pattern of land colonisation, and the distributed and dispersed urbanisation patterns of Kerala can help," emphasises Balagopal.

The government, too, has a role to play. "The establishment of KMTC with people from the medical devices manufacturing sector was a good move on the part of the government. However, there's much more the government must do," he added.

Various departments should come together to ensure the growth of the sector, stresses Padmakumar. "By making use of existing infrastructure, enabling collaboration between universities, industries, hospitals, and startups, and connecting them to global leaders, we can make the state a hub for medical devices manufacturing. KMTC is working towards realising the goal," he said.

"Medical device industrial parks with ancillary units and supporting systems are required. It will help if manufacturers are provided land at cheaper rates with extended period for making payments and support for capital expenditure, such as long-term interest-free or low-interest loans, common warehousing facilities, and subsidies for power and water," said Thomas.

"Policy changes, along with the efficient functioning of KMTC, with a certain amount of autonomy, will allow the state to become a hub within one or two years," added Balagopal.

29 Jan 2024

https://www.newindianexpress.com/states/kerala/2024/Jan/29/kerala-makes-cut-in-medical-device-manufacturing

Revolutionising Pharma-MedTech: India Allocates Rs 5,000 Crore To Propel Research And Innovation

In a move towards advancing research and innovation in the pharmaceutical and medical technology (Pharma-MedTech) sector, the Ministry of Finance announced the "Promotion of Research and Innovation in Pharma-MedTech" (#PRIP) initiative.

New Delhi: In a move towards advancing research and innovation in the pharmaceutical and medical technology (Pharma-MedTech) sector, the Ministry of Finance announced the "Promotion of Research and Innovation in Pharma-MedTech"

The Ministry of Finance posted on X, "Promotion of Research and Innovation in Pharma-MedTech #PRIP was announced as a long-term scheme to help strengthen pharmaceutical #infrastructure and boost research in six moon-shot areas. #PromisesDelivered"

This long-term scheme aims to fortify pharmaceutical infrastructure and propel research across six transformative areas. The announcement, made through the ministry's official handle on X, showcased the government's commitment to fostering advancements in the healthcare industry.

Under the banner of the Department of Pharmaceuticals, the PRIP initiative has made substantial progress since its inception in the fiscal year 2023-24. The scheme, with a budgetary allocation of Rs 5,000 crore, received approval from the Cabinet and was officially notified on August 17, 2023.

The first component focuses on enhancing research infrastructure through the establishment of seven Centres of Excellence (CoEs) at National Institute of Pharmaceutical Education and Research (NIPER) institutes. These CoEs, strategically located in pre-identified areas, are allocated a financial outlay of Rs 700 crore.

Industry News

The second component of PRIP is dedicated to promoting research in the pharmaceutical sector across six moon-shot areas.

The areas of focus include new chemical entities, complex generics (including biosimilars), medical devices, stem cell therapy, orphan drugs, and anti-microbial resistance.

A financial assistance of Rs 4,250 crore will be extended to companies collaborating with government institutes and conducting in-house research and development (R&D) in these priority areas.

By establishing Centres of Excellence and providing financial support for groundbreaking research, the government aims to bolster India's position in pharmaceutical advancements globally. As part of the PRIP initiative, the government will actively encourage industry players to invest in research and development, focusing on specific priority areas outlined in the scheme.

This collaborative approach between the government and private entities is expected to drive innovation, address critical healthcare challenges, and contribute to the overall growth of the pharma-medtech sector in India.

The PRIP scheme stands as a testament to the government's commitment to fostering a robust ecosystem for research and innovation, aligning with the broader vision of building a self-reliant and cutting-edge pharmaceutical industry in the country. With a clear focus on transformative areas, PRIP is poised to shape the future trajectory of the pharma-medtech sector in India.

https://health.economictimes.indiatimes.com/news/pharma/pharma-industry/revolutionising-pharma-medtech-india-allocates-rs-5000-crore-to-propel-research-and-innovation/107012681

Qosina Introduces RondelO™ Stopcock Manifolds

Ronkonkoma, NY, USA, September 21, 2023—Qosina, a global supplier of OEM single-use components to the medical and pharmaceutical industries, is pleased to introduce the RondelO™ stopcock manifold. The RondelO modernizes drug infusion protocols through an innovative, patented design.

The RondelO is the world's first medical stopcock manifold that provides a serial sequence of incompatible drugs and enables flushing fluid in between. These stopcock manifolds are available through Qosina in 2-, 4-, or 6-luer inlet ports with a through line for flushing fluid. Each luer port is ISO 80369-7 compliant.

The unique features of the RondelO are:

- Flushing fluid is available in all stopcock positions
- No other stopcock currently has this design or capability
- No need for a back check valve on secondary lines
- Any air can be expelled through a secondary line
- Automatic flushing when the stopcock remains in the same position
- Easy to back prime all infusion lines

RondelO can be used in the bioprocess industry for easy sampling, either manually or automatically from a bioreactor. Additional luer-to-barb connectors may be needed to attach tubing to the RondelO. The automation aspect streamlines the sampling process using only one motor turn with the RondelO handle. It also enables easy sampling from a bioreactor when a new sampling port can be used every time. By simply turning the handle to a position in between each sampling port, the internal volume can be rinsed prior to and/or after each sampling.

Qosina is a one-stop source for single-use medical device and bioprocess components, with low minimum order quantities, a liberal sampling policy and bill of material kitting, all supported by regulatory documentation and backed by Qosina's assurance of supply.

Learn more about Qosina's new line of RondelO stopcock manifolds.

Founded in 1980, Qosina is a leading global supplier of OEM single-use components to the medical and pharmaceutical industries. Qosina's philosophy is to address its customers' need to reduce time to market by providing thousands of stock components. The company's vast catalog features more than 5,000 products shown in full-scale illustrations on a one centimeter grid. Qosina offers free samples of most items, low minimum order requirements, just-in-time delivery, modification of existing molds, and new product design and development. Qosina is ISO 13485, ISO 9001, ISO 22301, ISO 45001 and ISO 14001 certified, and operates in a 95,000 square-foot facility with an ISO-8 Class 100,000 Cleanroom. To learn about Qosina's full component offering, which includes the newest products,visit www.qosina.com or call +1 (631) 242-3000. Visit Qosmedix, Qosina's cosmetics division, at www.qosmedix.com. Qosmedix is a certified global supplier of beauty tools and accessories to the cosmetic, skincare, spa and salon industries.

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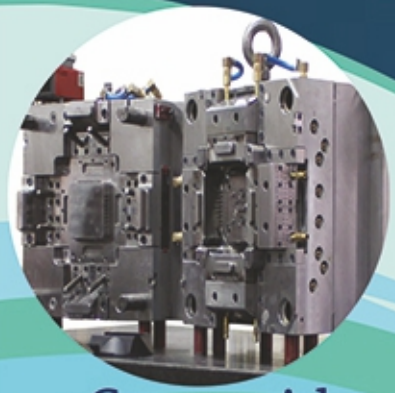

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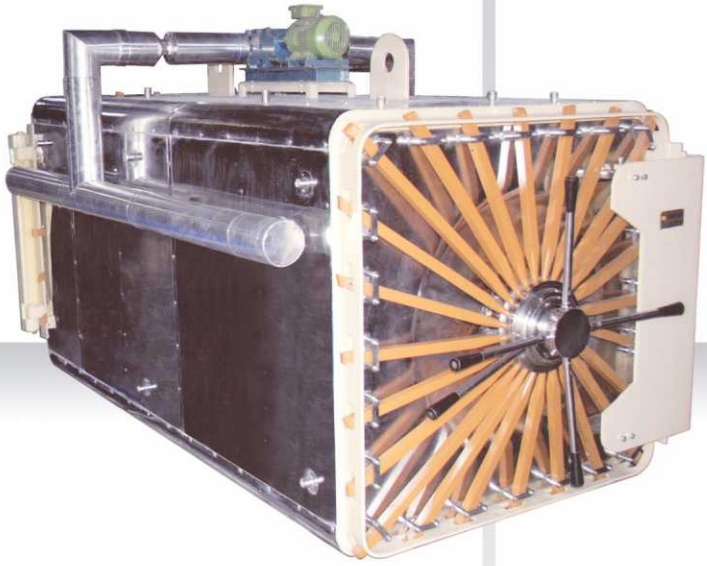

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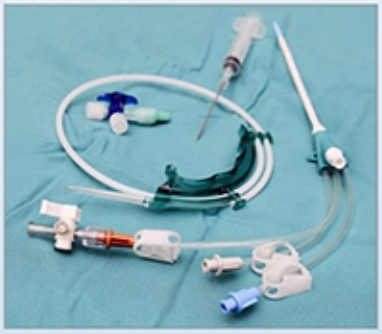

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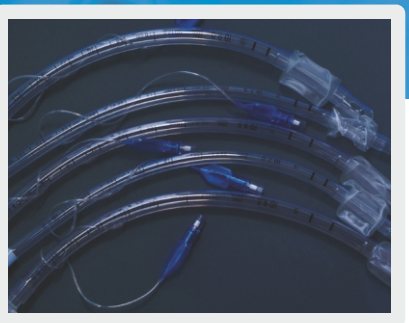

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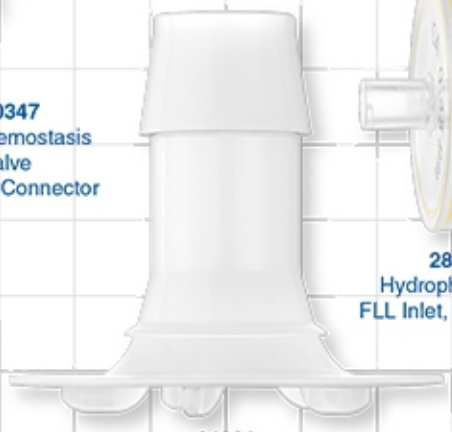

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