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MEDICAL PLASTICS DATA SERVICE

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

Biological Evaluation

Dr. T S Kumaravel
Founder Chairman
GLR Laboratories, UK

- **Drug Device Combination Medical Devices**
  - Development
  - Regulatory Landscapes in EU & USA
  - Global Markets
  - Plastic Materials & Components Used

Developing from Concept to commissioning

Dr. Atul Sardana
Chairman, Alfa Corpuscles Pvt. Ltd.,
New Delhi.

- **Biological Evaluation of Medical Devices**
- **Medical Device Sector : Comparing with Pharmaceuticals**
- **Book Reviews**
  - Applications of Polyurethanes in Medical Devices
  - Plastics For Cardiovascular Applications

Regulatory Landscapes

Anil Chaudhari
Founder
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A Tribute to Prof. M S Valiathan
The Pioneer of Medical Devices Development in India

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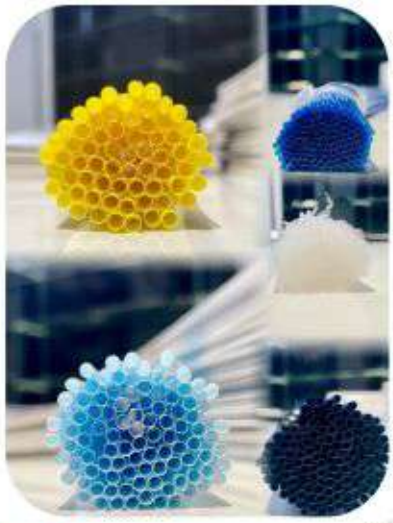
Precision Micro-catheter Extrusion Line



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MEDICA	Dusseldorf	11-14th Nov	Hall/Stand: 8B/P31

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- Hemocompatibility Tests (ISO 10993-4)
- Carcinogenicity Test (ISO 10993-11)
- Reproductive / Developmental Toxicology (ISO 10993-11)
- Degradation Testing (ISO 10993-9, ISO 10993-13, ISO 10993-14 & ISO 10993-15) Toxicokinetic study of Degradation Products (ISO 10993-16)
- In-vitro Skin Irritation Test (ISO 10993-23)
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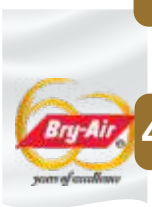

Flashback

MEDICAL PLASTICS
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Did You Know ?

Medical Devices That Use Breathing Gas Pathways, Like Oxygen Masks, Can Pose Risks To Patients?

Air from the device and its parts can enter the patient's breathing passageways, exposing internal tissues to chemical emissions and condensates. Patients receiving supplemental oxygen can expose others to exhaled air, especially if they cough. Patients with respiratory infections or COVID-19 who require oxygen therapy can spread viral particles through the air.

If the gas pathway of a medical device can reach 100 percent saturation with water causing condensation to form, and that condensate can then reach the patient, there could be a considerable risk to patient safety. This is typically associated with medical devices which deliver humidified gas to patients.

Traditionally, toxicologists and biocompatibility experts considered the materials in breathing gas pathways as external communicating devices and evaluated these materials according to the ISO 10993 series of international standards.

In March 2017, ISO 18562 (Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications) was published which is a four-part standard aimed at providing the general framework required to adequately determine the acceptability of medical devices that contain breathing gas pathways.

ISO 18562 is comprised of four parts:
1. Evaluation and testing within a risk management process,
2. Tests for emissions of particulate matter,
3. Tests for emissions of volatile organic compounds (VOCs), and
4. Tests for leachables in condensate.

The scope of ISO 18562 covers the gas pathways of every medical device, device parts, or device accessories that are intended to provide respiratory care or supply substances via the respiratory tract to patients. Therefore, not only does the facemask of a breathing device need to be tested, but also any connectors, filters, and tubing that may come into contact with the gas being delivered to the patient.

Medical devices, parts or accessories containing gas pathways that are addressed by this document include, but are not limited to, ventilators, anaesthesia workstations (including gas mixers), breathing systems, oxygen conserving equipment, oxygen concentrators, nebulizers, low-pressure hose assemblies, humidifiers, heat and moisture exchangers, respiratory gas monitors, respiration monitors, masks, medical respiratory personal protective equipment, mouth pieces, resuscitators, breathing tubes, breathing system filters and Y-pieces as well as any breathing accessories intended to be used with such medical devices. The enclosed chamber of an incubator, including the mattress, and the inner surface of an oxygen hood are considered to be gas pathways and are also addressed by this document.

MEDICAL PLASTICS
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MEDICAL PLASTICS
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From the Editor's Desk

Drug Device Combination Medical Devices

As per US FDA, Combination Products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products.

The maturity of combination products as a market category has led to 3 key global trends: expanding adoption of medical devices for drug delivery, increasing complexity and growing awareness of product experience and risk. Integrated product risk management enables robust product development and manufacturing strategies as well as efficient regulatory pathways.

Drug-device combination products (DDCs) can include a variety of plastics, including those used for packaging and other components.

Complex combination of polymers and plastics materials with APIs can often be achieved only by overcoming a variety of technological challenges associated with determining drug-elution rates, preventing mechanical stresses, and avoiding excessive heat. Solving these issues requires not only expertise in unifying materials and drugs but also the active collaboration of materials experts and medical device manufacturers.

This issue of "Medical Plastics Data Service" focuses on various techno-commercial aspects relevant to Drug Device Combination Medical Devices.

It starts with introducing essential aspects about **"Plastic Materials, Components & Packaging"** used for these products while giving basic comparison between Medical Devices & Pharmaceuticals.

A very comprehensive article by Dr Atul Sardana, Chairman, Alfa Corpuscles Pvt Ltd gives overview on **"Developing Drug Device Combination Products : Concept to Commissioning".** It covers Unmet Need Identification, Design Development, Classification of Drug/Device combinations in the currently prevailing law in India, Regulatory Approvals such as EU MDR-, Legal and Intellectual Property Right Issues and more.

A very well researched article by Dr T S Kumarvel, Chairman, GLR Laboratories along with other experts elaborates on **"Biological Evaluation of Medical Devices"** which is crucial for ensuring patients safety and regulatory compliance.

An article by Mr Anil Chaudhary, Founder, Operon Strategist discusses **"Regulatory Requirements for EU and US markets".**

A Tribute To Prof. M S Valiathan, The Pioneer of Medical Devices Development in India.

On behalf of Indian Medical Device Industry, we pray our tributes to Dr Valiathan on his recent demise and Pray The ALMIGHTY For His Soul To Rest In Peace.

As founder Director of Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Trivandrum, he identified the need and took unprecedented efforts to develop high quality medical devices and implants meeting international standards. He had a vision of establishing a world class Biomedical Technology Wing campus in the country along with a hospital.

Under Book Review column, for the Indian Medical Device Industry we introduce to very important technical publications on **"Applications of Polyurethanes in Medical Devices" and "Plastics in Medical Devices for Cardiovascular Applications" by Dr Dr Ajay Padsalgikar.**

The "Did You Know" column describes why **Medical Devices that use breathing Gas Pathways like Oxygen Masks, can pose risks to patients.**

As always, this issue includes Association, Regulatory & Industry News, Global Markets, Product Gallery etc.

D L Pandya

About Plastic Materials, Components & Packaging Used For Drug Device Combination Medical Devices

Combination products are becoming increasingly important and are predicted to become market leaders in the future with the growing trends towards home healthcare and self-care. It is to improve patient outcomes, reduce length of hospital stays, reduce procedure times and promote recovery. It is believed to reduce practitioner errors.

As per US FDA, Combination Products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products.

An array of combination products fall into various categories including Cardiovascular, Non-Cardiovascular, Urological, Bone Treatment, Antimicrobial Treatment, Cancer Treatment, Ophthalmic Treatment, and Diabetes Treatment and more. Some of commonly used products include prefilled syringes, pen injectors, inhalers, drug-eluting stents, orthopaedic products, infusion pumps, wound care products, transdermal patches, and more.

The maturity of combination products as a market category has led to 3 key global trends: expanding adoption of medical devices for drug delivery, increasing complexity and growing awareness of product experience and risk. Integrated product risk management enables robust product development and manufacturing strategies as well as efficient regulatory pathways.

Complex generic drug-device combination products are typically difficult to develop, which means that many of these products face less competition than non-complex products, and therefore can be more expensive and less accessible to the patients who need them.

Combination products are developed using plastics raw materials to which active pharmaceutical ingredients (APIs) are added during the manufacturing process.

The complex combination of polymers and plastics materials with APIs can often be achieved only by overcoming a variety of technological challenges associated with determining drug-elution rates, preventing mechanical stresses, and avoiding excessive heat.

Solving these issues requires not only expertise in unifying materials and drugs but also the active collaboration of materials experts and medical device manufacturers.

The addition of a drug to a medical device can greatly enhance the safety and efficacy of products, providing differentiated product performance. Drugs have allowed devices to last longer in the body, perform therapeutic actions more effectively, and mitigate unwanted effects. As long as drugs continue to improve the safety and efficacy of both existing and novel medical devices, combination products will remain an area of significant growth.

Since combination products involve components requiring different types of regulatory authorities, they raise challenging regulatory, policy, and review management challenges. Differences in regulatory pathways for each component can impact the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications.

Plastics Materials & Components Used In Drug Device Combination Products

Drug-device combination products (DDCs) can include a variety of plastics, including those used for packaging and other components.

Plastic parts used in these products are made up of multiple components, combine multiple products, or may only use a specific separate drug or device.

Medical device manufacturers and design engineers can greatly narrow the field of polymer alternatives by carefully arriving at end-use requirements and matching performance requirements with polymer capabilities. This helps them to focus on other critical aspects of bringing a device to market.

Apart from performance properties including disinfection or sterilization requirements, the most important material consideration is biocompatibility (ISO 10993 test results). The selection of materials also depends on on the level and duration of body contact. Raw materials suppliers are not required to submit Master Access Files, but many have done so to help bolster their customer's confidence in using their materials for medical device applications.

It is important to consider the potential interaction (desired or undesired) between the device and the drug/biological constituents. For example, it may be required to conduct studies to evaluate the potential for the following:

- Leachables/extractables of the device materials including plastics into the drug/biologic substance or final combination product;
- Changes in stability of the drug constituent when delivered by the device or when used as a coating on the device;
- Drug adhesion/absorption to the device materials that could change the delivered dose;
- Presence of inactive breakdown products or manufacturing residues from device manufacture that may affect safety, or device actions that could change the drug performance characteristics at the time of use; or
- Changes in the stability or activity of a drug constituent when used together with an energy emitting device.

Likewise, similar consideration should be given to the effects a drug or biological product may have on the device constituent. For example, the plastic material properties of a delivery catheter may be adversely affected by some drug/biologic products but not others.

Partnering with the manufacturer during the design process, or working with a device development company that truly understands manufacturing, ensures early concepts aren't reliant on component features that can't be produced in higher volumes. When making a single, or a low volume of components, smaller tolerances can often be achieved. However, in higher volumes, more variation is inserted into the manufacturing process. Plastic materials used in products like Drug-eluting stents, implantable drug delivery devices and the packaging needs of Drug-Device Combination products are discussed below.

Drug-eluting stents

These stents are coated with a thin, non-degradable polymer, such as poly-isobutylene or polymethacrylate, to control the release of a drug. More biodegradable polymers, like poly-lactic acid or polylactide-co-glycolide, are also being developed.

Implantable drug delivery devices

These devices can use biocompatible, biostable thermoplastic polyurethanes (TPUs) like Lubrizol's Pathway TPU. TPUs have flexible chemistry and adaptable mechanical properties that allow them to be compatible with a wide range of drugs

Packaging

Plastics used in Combination medical devices / pharmaceutical packaging systems include polyethylene, polypropylene, polyolefin and polyvinyl chloride. These plastics can be used for bags, bottles, vials, cartridges, metered-dose inhalers, prefilled syringes, pouches, and closures for capsules and tablets. The packaging system also includes other components like gaskets, rubber stoppers, and tubing. When choosing plastics for packaging, the sterilization method is important, as secondary packaging can sometimes serve as a sterile barrier.

As per FDA Guidance for Industry-Container Closure Systems (CCS) for Packaging Human Drugs and Biologics, "A container closure system refers to the sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the drug product." This critical distinction is important as the vials, ampules, bottles, or moulded components a company uses to house a drug must be tested with the drug and be considered a "whole" throughout the product development process.

Drug product integrity and effectiveness are additional aspects for why CCSs need to be thoroughly tested against edge-of-failure conditions. Any potential breach of a CCS for a sterile product, parenteral, or injectable could introduce byproducts, toxins, impurities, or other foreign materials that could impact the drug product stability profile; the drug product could be less effective for the targeted disease state, adverse reactions could manifest due to the foreign materials or degraded product, or a combination of these two could happen. The CCS must allow for the product's integrity throughout the supply chain until the end of expiration.

Packaging's Role

The Medical Packaging Community needs to track the growth of the combination products market,

The packaging for combination products can be just as complex as the products themselves. It is important to identify specific product and user requirements for both primary and secondary packaging. And not only must packaging serve the traditional roles of maintaining product integrity, efficacy, and perhaps even sterility, it may also need to be patient friendly by promoting user convenience, safety, and compliance. Package design should therefore be built around both product and end-user needs.

Following are some of the important aspects to be kept in mind

- Risk analysis of a product and the applicable standards. e.g. Syringes : With regards to vials and syringes, [designers must] protect liquids from any contaminants, visible or nonvisible, as well as [promote safe] handling both by the nurse and the patient, Considerations therefore include "usability, biocompatibility, extractables and leachables, and potential sterilization of the content. Also easy processability.

  Inhaler canisters and cartridges for pens need to be easy to handle for patients of varying age and capabilities (a very special consideration that rarely applies to a primary package of a mere medical device).
- Immediate plastic packaging for drug products requires different levels of documentation, depending on whether they are for oral or topical products, for inhalation, or for parenteral or ophthalmic administration.and there is further differentiation on whether it concerns a solid or a non-solid dosage form.
- The requirements for plastics that are in direct contact with a drug are higher in terms of documentation of chemical interaction, extraction, and toxicological information than compared with a mere medical device.
- Primary packaging of a combination device requires more -sophisticated packaging design and validation than that of a typical medical device.
- For product like an intravascular catheter, adding a drug functionality will require different packaging development. The different standards for medical devices and medicinal products need to be consolidated, and this results also in different solutions and total costs of packaging.
- Particles and particle burden is of high interest, especially to those manufacturers who handle non-solid drugs. This is less of a concern for a majority of medical devices.
- For combination products that are required to use a sterile barrier system, the sterilization method drives packaging materials selection and design. In some cases, the secondary packaging serves as the sterile barrier.
- For pharmaceutical products as well as for products to be used in the operating room, secondary packaging can serve as 'dust' protection to allow for moving product from the grey to the white

zone.

- For protection of a product such as a prefilled syringe for use in an ophthalmic surgery, which needs to be sterile on the outside for immediate use.
- For combination products , consideration should also be given to human factors for increased acceptability of the product by patients as well as treatment compliance for better clinical outcomes.

Using Bioegradable Polymers for Drug Delivery Systems

Utilizing biodegradable polymers fror drug delivery systems is expected to have enormous potential. The primary goal of targeted drug delivery system is transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effect, while reducing undesired side effects as much as possible. This is by bringing the required amount of drug into the body to the region, where the effect is required.

Biodegradable polymers will disintegrate and eventually vanish when implanted into the human body. Many medical devices are used as implant , serving as drug delivery system, intended to continuously administrating a drug without any need for repeating intake of medicines. This ossers diverse benefits. Drugs may be delivered continuously right at the desired location within the human body, bypassing the digestive system and liver. Moreover, convenience of the patient is increased as he is released from remembering when and how to intake drugs, or any additional surgical intervention to remove the implant.

Currently the following five major groups of biodegradable plastic materials are commercially available.

01 Polyglycolic Acid (PGA)
- Wide application for absorbable suture.

02 Polylactic Acid (PLA)
- Used for implants such as anchors , mesheas, pins, rods, and screws

03 Polycaprolactone (PCL)
- Utilized for implants such as adhesion barriers, suture, or drug delivery.

04 Polyanhydrides
- Material of choice for drug delivery

05 Polylactic-Co-Glycolic Acid (PLGA)
- Utilized for implants such as grafts, sutures , surgical films and nanoparticles.

Moreover, by combining these materials by means of copolymerization of compounding, an enormous variety of materials may be obtained.

A well-estabilised medical application is absorbant surgical suture materials that were introduced in the early 1960s.

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Medical Device Sector, VUCA & Comparison with Pharma

- *VUCA denotes Volatility, Uncertainty, Complexity and Ambiguity, a perfect cocktail prevailing in the medical devices sector in India*
- *Entrepreneurs always thrive in such a testing time, and the same is happening in India*
- *The entrepreneurial model of developing an imported product indigenously with better quality and better price is working well and is the answer to the over-dependence of India on imports for the medical device sector*

The term VUCA was coined by the US defence in 1987. This popular management term VUCA also has its connection with military strategists. The term VUCA was used for Volatile, Uncertain, Complex and Ambiguous situations arising from the collapse of the USSR. The Cold War era meant a clearly identifiable enemy, the USSR. However, once the Soviet Union disintegrated, a situation was created where the enemies were not clearly identifiable and could be anybody, coming from anywhere. The US Army in this situation may become disoriented, and the term VUCA was used to highlight this multilateral world order. Bennett & James in the Harward Business Review magazine explain the VUCA situation as below-

- **Volatility** – characterized by a challenge which is unexpected, unstable and of unknown duration. However, knowledge about the situation is not difficult to obtain.
- **Uncertainty** – A large part of information is lacking but the cause and effect of the change are known.
- **Complexity** – As the word means, the situation is not simple. There are many variables and interconnected components in a situation.
- **Ambiguity** – There are many "unknown unknowns". Cause–effect relationships are not clear, and are ambiguous.

The situation in the medical devices sector has many of these characteristics. Unexpected challenges, though known to an extent, represent Volatility; missing information pieces – typical of Uncertainty; a situation not-so-straightforward – means Complexity, and; many "unknowns", driving Ambiguity.

A quick study of any definition given for medical devices by any authority or researchers will indicate that the function of a medical device is like that of a medicine. However, a careful eye will immediately catch the difference. That difference is that a device does not achieve its primary intended action by pharmacological or metabolic means, in or on the human body, but which "may be assisted in its intended function by such means". These last words make the fundamental bases of a drug-device combination. A medical device may very well be supported by a pharmacological product (meaning medicines) in its intended function. Not only this but in today's VUCA moment, medicines can even provide an answer to the puzzle of medical devices for growth. How? Please read further.

Though very detailed information about the differences between medical devices and pharmaceuticals is provided in this issue of Medical Plastic Data Service by other experts in many articles, a summary given in the table here will not be out of place. More relevant points are covered in detail below, even at the cost of repetition.

Budget constraint: The R&D budget of the top five device companies in the world is more than double the medical device sector size (11 b USD) in India! Competing on R&D spend with such players is too big a call, especially when 95% of the Indian medical device companies have less than 12 mn USD (100 cr INR) turnover per year.

Constraint on Reward of research: Patent protection in pharma is solid. An inventor company can milk its research efforts for 15 years out of 20 years of patent protection (since the remaining time may be lost in regulatory approvals, etc). New research is thus rewarded in Pharma. In the medical device sector, such protections are loose & vulnerable and so, big research investment is not that rewarding.

Brand value creation: Pharma is a branded business while (almost) all the devices are generic, despite efforts of branding (except Umbrella brands like BD). Individual pharma brands have intrinsic value which generic devices do not have. Today in India, there are 388 pharma brands with more than 100 cr sales. 25 out of these have sales above ₹500 crore and 79 fetch above ₹250 crore sale. Remember, we are talking of individual brands, not molecules. This is also a constraint for devices.

User training cost as a constraint: A user is important for a new device. Training for a user is, therefore, required. This training is a patient job and is costly too. To calculate a budget and factor this training cost for new product development is not always possible, which ideally should be done.

The conservatism of users: There is a big inherent difference between the switch-over to a new medicine and a new medical device despite training investment. For example, after Cimetidine, the next congener Ranitidine is readily and quickly accepted, if slightly better. But for the use of a device, conservatism always (maybe rightly) prevails. The doctors stick to the old patterns of usage. Assuming that a new device is developed by an Indian player, its acceptance is not guaranteed, which again is a constraint.

The answer to all these constraints is in the pharma R&D model. Many smart entrepreneurs in the medical devices sector have already "discovered" this model and have already started implementing this model.

As the readers know, India is a net exporter of the Pharma sector but is a net importer of medical devices. In pharma, the success *मंत्र* was (and is) **reverse engineering** for APIs. A research molecule invented by a foreign company and which was under patent (having a high profit margin), was synthesised in India through reverse engineering. Often, the Indian companies were the first to launch a generic version of these off-patent products in the USA and EU. The US pharma market is the largest in the world, as the readers know, making up close to 50 % of the world's pharma market. Generic versions are often launched with

70 to 80% lower prices in comparison to a leader brand and even after this, an Indian player makes a good profit. Dr. Reddy's was the first to successfully use this strategy. Now many companies have followed suit.

The safest, quickest and sure-shot R&D model in this VUCA situation is to follow the footsteps of the pharma model, and the *मंत्र* is **reverse engineering -**

- Select a large volume imported product
- Do reverse-engineering and develop the same in India at a lower cost
- If required, import components and assemble them here
- Ensure the same/better quality

…and go ahead.

A survey was done recently with entrepreneurial medical device manufacturers. This survey revealed that this strategy is being implemented successfully by some players and they have found it to be very effective for the Indian market.

The proof of a pudding is in eating, isn't it?

Differences between Medical Devices and Pharmaceuticals

	Medical Devices	Pharmaceuticals
	Definition	
1	Effect without undergoing change themselves	A medicine gets metabolized while acting
2	Do not "act" inside a cell	Effect inside a living cell
	New Product development	
1	Problem identification by users is the starting point for development.	New product development starts from understanding biochemical pathways.
2	New product development is much complex, involving multiple technologies (a "horizontal" process).	Biochemistry and chemistry are the bases for product development (a "vertical" process)
3	Basic principle of a device is patentable	A molecule is patentable
4	Patent protection very loose and vague	Patent protection for a long time
5	Copies can come to the market in 5 years	Effective life "under patent" for 10- 15 years
6	Life cycle is 2 to 3 years	Life cycle is 12 to 18 years
7	Product design/ Ergonomics is important.	Product design is not an important factor.
8	Professional training is needed for new products	Specialized training for use is not needed.
9	New product acceptance by doctors is slow.	Switch-over is very fast for a new molecule.
	Regulatory and QA aspects	
1	Regulatory authorities may have less knowledge	Regulatory frameworks are very clear
2	Regulatory classification is risk-based.	Regulatory classification is form-based.
3	Stability study is much less critical/not needed.	Stability is important due to internal usage, and is part of the regulatory guidelines..
4	Post-launch surveillance is not critical.	Post-launch pharmacovigilence is necessary.
5	The evaluation here is on performance and engineering parameters.	Evaluation of drugs is on the parameters of efficacy and quality.
6	Device QA tests are often complex, needs special needs.	Quality assurance tests are practicle
7	Trials through bench studies, not human studies	Large scale clinical trials are possible
8	Use depends on the user, and comparisons are not always easy.	Action and side effects are easy to compare
	Market, Commercials and distribution	
1	Market size is smaller comparatively.	Market size is 3/4 times of that of devices for a region.
2	Most of the usage in a clinical set-up.	Maximum usage is by a patient himself.
3	Distribution channels are shorter.	Long distribution channels are involved, going upto a retailer.
4	Most of them are generic products.	Branding practice is common and brands have intrinsic value.
5	Prices change (drop) very fast.	Prices are steady for a long time.
6	A user is important, and influences the use.	Method of "use" is generally very simple.
7	Cost-effectiveness evaluations are not easy.	Cost-effectiveness comparisons are easy.
8	Cost of training is difficult to factor.	Training cost is not an issue here.

Developing Drug / Device Combination Products : Concept to Commissioning

Dr. Atul Sardana, Chairman,
Alfa Corpuscles Pvt. Ltd., New Delhi.

Definition of Drug/ Device Combination

- A Drug Device combination is a product comprising of active pharmaceutical ingredient(s) and a medical device that are physically or chemically combined to produce a single product.
- Such combination products are emerging as innovative medical products due to their contribution in advancing medical care and are thus expected have an impact in the coming years.
- These offer several advantages including reduced adverse/side effects, improved patient compliance, controlled release of drugs and targeted drug delivery, overall reduction in healthcare expenses and augmented performance.

Classification of Drug/ Device Combination

- "Single Entity" or "Integral" product comprises of two or more different regulated components (drug/device) that are physically, chemically, or otherwise combined or mixed.
- "Co-packaged" or "Kitted" unit in a single package comprising of drug(s) and device(s).
- "Cross-Labelled" comprise of drug(s) or device(s) packaged separately that according to its investigational plan or proposed labelling is intended for use only with another individually and where both are required to achieve the intended use, indication, or effect.

Examples of Drug/ Device Combinations

"Single Entity" or "Integral"

- **Prefilled Drug Delivery Systems**
  - Prefilled syringes
  - Prefilled autoinjectors
  - Prefilled pen injectors
  - Prefilled on-body delivery systems
  - Dry-powder inhalers
  - Metered dose inhalers
  - Prefilled nasal sprayers
  - Transdermal patches
  - Oral Vaccine Delivery Devices

- **Medicated Devices**
  - Drug-coated stents
  - Drug-coated catheters
  - Drug-coated pacemaker leads
  - Antimicrobial surgical scrubs
  - Antimicrobial wound dressings
  - Antimicrobial Sutures
  - Drug impregnated surgical mesh
  - Antibiotic bone cements
  - Spermicidal condoms

Examples of Drug/ Device Combination "Co-packaged" or "Kitted"

- **Convenience kits**
  - Surgical trays with anaesthetic and/or surgical scrub
  - Vial and syringe packs
  - Injector pen with user-loaded prefilled cartridge
  - Liquid medication with dose- dispenser

- **Other**
  - Collagen sponge with bone morphogenic protein

"Cross-Labelled"

- Companion diagnostics
- Photodynamic therapy (laser activated drug)
- Contrast agent and diagnostic imaging
- Iontophoretic delivery systems

The Development of Drug/ Device Combination entails the following steps :

1. Unmet Need Identification

- A Device may require a drug to
- Improve its Safety especially over long term implantation or when being placed in pathological conditions or challenging environments within the body.
- To augment the function of the device by providing synergy
- To enhance the efficacy of the device by suitably modifying the local or systemic conditions

To reduce device associated co-morbidities and complications.

- A Drug may need a Device in order to :
- Ensure or regulate proper dosing
- To provide a constant rate of drug elution and sustained release
- To monitor drug release and concentration levels as in a loop feedback
- Improve patient compliance
- To ease administration and make self administration possible.
- To enhance the shelf life of the drug
- To reduce filling and administration losses and drug contamination
- To improve drug safety
- To provide targeted drug delivery

2. Design Development

Design development of a drug device combination needs in depth understanding and critical analysis of the following :

- Understanding the drug device Interphase with the body
- Understanding the interactions between the drug and the device throughout the product life cycle

Raw Material Selection for the device is based on the following criterion that need to be evaluated in all phases of the product development and use.

- Leachable interaction with the body and the drug
- Extractable interaction with the body and the drug
- Additives and Coatings to be used on the device and their interactions with the drug.
- Barrier Properties of the Material and effects of oxygen, moisture and other gases on the drug.
- Stability Testing of Drugs in the drug device combination
- The effect on drug(s) on Polymer(s) properties and function
- DMPK (Drug Metabolism and Phamacokinetics) Study
- Shelf life study and accelerated ageing of the drug device combination
- Method of sterilization to be used for the combination with respect to drug stability.
- Prototyping challenges for drug device combination usually preclude 3D printing as the combination needs to be tested with actual polymer proposed. Though it may be used for mechanical and dimensional validation.
- A thorough understanding by the devices manufacturer is required with regards to the drug filling lines and due consideration should be given to the environmental challenges of the aseptic conditions to be maintained.

The Current Challenges faced During the Development and Marketing of Drug / Device Combination can be summarized as below :

1. During Manufacturing of the Drug Device combination the following challenges may be encountered

- Large Scale Manufacturing
- Device Filling in Aseptic Lines with Drugs
- Replication of the Drug Impregnation / Coating process on commercial scale
- Combipack Development
- Integration of Automation
- From Production to Filling/ Coating
- Validation Protocols to be used
- Clinical Trials requirements for Novel Devices
- Packaging Requirements (Intermediate and Final)
- Filling Lines
- Sterility of Ready to Fill Systems in Aseptic Lines
- Labeling for Regulators and Users
- Choice of Sterilization Methods
- Standardization of Exchange of Data amongst Device and Drug Manufacturers

2. Affixing Responsibility

- Post Market Clinical Feedback
- Post Market Surveillance
- Vigilance and Incident Reporting
- Complaints
- Corrective and Preventive Actions

Dr. Atul Sardana (MBBS, MS, FIAGES) is a minimal access surgeon with a knack for applying technology to conventional surgical principals which benefits patients. Dr. Atul Sardana has been working in the health care sector since 1990 starting as a social worker in one of Delhi's large government hospital. He graduated from the University of Rajasthan in 1998 and served in the rural sector in there. He then did his masters in surgery in 2002 and has since been working extensively in minimal access surgery as a consultant surgeon in various hospitals of repute including Sir Ganga Ram, Kolmet and Apollo Spectra Hospital. He has over 30 national and international clinical publication and presentations and is a honorary member of the World Association of Laparoscopic Surgeons, member of the Indian Association of Gastrointestinal and Endoscopic Surgeons and the BIS Technical Committee on Surgical Instruments (MHD01). He was also member of the steering committee for Good Clinical Practices formed by the GOI.

Dr. Atul Sardana has been invited at various forums and conferences as a key speaker on Medical Device Innovation and Medical Device Plastics and as a panelist on talk pertaining to the fund raising in the Healthcare sector with particular focus on Innovative Medical Device Companies in India. He has been on the committee for Medical Devices constituted by the Principal Scientific Advisor, GOI and also as panelist on innovation ecosystem in Gujarat organized by GSBTM. He has also been invited to deliver guest lectures at IIT-Delhi on medical applications of textiles and has conducted workshops at IIT-Delhi, IIT-Rourkee and IIT-Mumbai for FTT, TIDES and SINE incubates on Medical Device Regulations. He serves as an expert in various panels for evaluation of novel and innovative technologies for grants and funding by BIRAC, FITT, IKP, BREC, C-CAMP, Bill & Melinda Gates Foundation and the Pfizer Trust. His work has been covered both press and media on several occasions. He was awarded the fellowship of Indian Association of Gastrointestinal and Endoscopic Surgeons in 2007. He was actively involved in training of surgeons in the field of Advanced Solid Organ Laparoscopic Surgery, Endo stapling Principles and Techniques, and Laparoscopic Hernia Surgery at Ethicon Institute of Surgical Education, New Delhi and is a faculty for the conduct of the fellowship of Indian Association of Gastrointestinal and Endoscopic Surgeons. He is a certified internal auditor of quality management systems for medical device manufacturing as per ISO 13485:2003 from TUV-SUD. He was the Vice Chairman of the Indian Industries Association (IIA-Delhi), a chamber of commerce and advocates policy change to encourage the development MSME sector at the Government level. He served as the head of Technical operations at Biosurge Technologies, Mumbai and later was the founder chairman at Alfa Corpuscles Private Limited where he currently serves at the Head for Research and Product Development. He has four national patents and three PCT's filed for his invention of the "Laparoscopic Trocar", "Safety Syringe", "Coated Hernia Mesh" and "Oral Vaccine Reconstitution & Delivery Device". His efforts on the safety syringe have been acknowledged by the "Wellcome Trust, UK" and the invention has been awarded the Silver Prize at the Seoul International Invention Fair 2012. He also has the distinction of being honoured twice at the Rashtrarapati Bhawan, during the display of his innovative technologies at the exhibition on "Innovations in Medical Science and Biotechnology" in 2015 and 2017

3. ***Classification of Drug/Device combinations in the currently prevailing law in India (Medical Device Rules 2017)***

   states that all Medical devices incorporating medicinal products shall be assigned to Class D, if it incorporates as an integral part a substance which, — (1) if used separately, may be considered to be a medicinal product; and (2) is liable to act on a human body with an action ancillary to that of the medical device until and unless if the incorporated substance is a medicinal product exempted from the licensing requirements of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder, in which case it will be assigned to Class B,.

4. ***Regulatory Approvals such as EU MDR- Combination products have undergone a substantial change under the EU MDR 2017/745 and new regulatory challenges are at the horizon.***

   Rule 14 for device classification according to the EU MDR states that all devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III. The main regulatory challenge is related to article 117 of EU MDR, that introduces a new concept for combination products (typically drug-device combinations).

5. ***Legal and Intellectual Property Right Issues amongst the parties involved in collaborative development (drug manufacturer and device manufacturer)***

Alfa Corpuscles

Offers Pilot Facility for Medical Device Development and Contract Manufacturing

Alfa Corpuscles is one of the fastest growing innovative medical device company, offering very high quality, Disposable Skin Staplers and Removers, Disposable Laparoscopy Access Devices and Implantable Hernia Repair Solutions. The company has been able to establish itself as one of the preferred supplier to leading medical institutions in a very short span of time due to its focus on delivering quality products that exceed the expectations of doctor's and paramedical staff. These technologically advanced and innovative medical devices conform to all international standards.

Alfa Corpuscles also offers contract research and manufacturing services to select clients and has developed test and commercial supplies for products such as Stem cell fractionation device, Continent Stoma Devices, Chemoport, PRP tubes, Spine Gels, Single Use Pharmaceutical Couplers and Customised Filling Lines and Surgical Connector and Filter Tubing's.

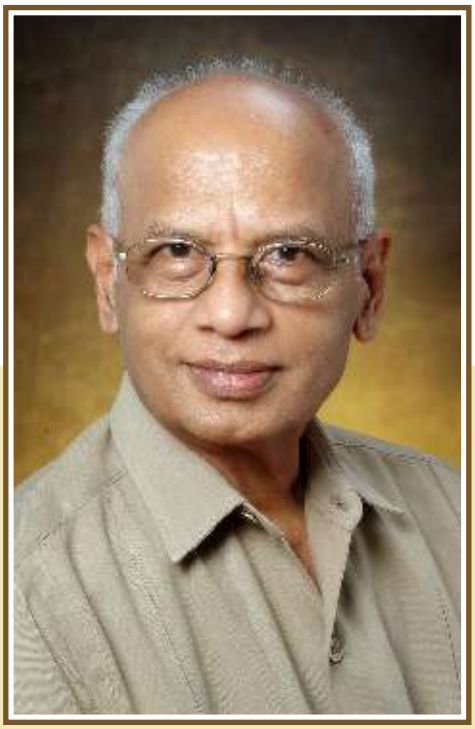
Alfa Corpuscles, has a state-of-the-art clean room manufacturing facility situated in the National Capital region of Delhi, at a 60 Min Drive from the airport and covers a total 6500 Sqft as Plant Area. All the Manufacturing Processes are done in Clean Room Environment of 3800 Sqft which is designed as Per cGMP norms and meets to ISO 14644 standards, with Class 100,000 Injection Molding, Silicon Molding, Pack Development and Component Forming and Class 10,000 and Class 100 Assembly and Packing Zones. It has an in-house product design centre, EO sterilization and physical, chemical and microbiological Testing facility for its products. The work floor has a myriad of processing capabilities including plastic molding, knitting, metal forming, laser cutting, ultrasonic welding, thermoforming, vacuum drying and packing surface activation using low temperature plasma, electrospinning and Electrospray coating and product printing to name a few. The company has deployed state of the art, all Electric, Low Energy Consumption Machines with a Robotic Interface and a Very High Level of process Automation to reduce human handling and error. The QA and QC departments ensure that quality products are delivered consistently to the clients, with strict Quality Controls at all levels of processing to ensure World Class products.

Alfa Corpuscles also offers a wide range of Device Testing and Analytical services including, metrological analysis, complex force testing, burst strength and elongation profiles, hardness and surface characterization, shelf life and stability studies using real time and accelerated ageing, microbiology and sterility validation to name a few

At Alfa Corpuscles innovation is not just a goal; it's a way of life. The in-house R&D facility has achieved major recognitions from various agencies worldwide and has many patents in the field of medical devices to its credit. It boasts of a 1200 Sqft of Dedicated R&D Facility with an Array of Specialized Equipment and Highly Qualified Technical Resources.

1500 Sqft is dedicated to Warehousing Space with High Levels of Housekeeping. There is an In House Testing Labs for Plastics, Metals, Silicon and Host of Other Raw Material and Packing Material. The in-house EO Sterilization Facility comes with a Complete Microbiology Labs including Class II Biosafety Lab for Validation

The company is ISO 9001:2008 and ISO 13485:2003 certified. The company has the drug regulatory approval for manufacture and sale of its devices in India. Alfa Corpuscles offers OEM/OBL services for product development, Test and Manufacturing Licences as per CDSCO and a full range of Technical Documentation and Regulatory Support Services.



A Tribute To Prof. M S Valiathan

The Pioneer Of Medical Devices Development In India

(Courtesy : Balram Sankaran, Scientist,
Sree Chitra Tirunal Institute for Medical Sciences
& Technology, Trivandrum)

- As founder Director of Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Trivandrum, he identified the need and took unprecedented efforts to develop high quality medical devices and implants meeting international standards.
- Had a vision of establishing a world class Biomedical Technology Wing campus in the country along with a hospital (SCTIMST).
- Eventhough trained as a cardiac surgeon, he had the mind of an inquisitive scientist, practical wisdom of an engineer and enthusiasm of an entrepreneur.
- As a cardiac surgeon, his dream was to develop an artificial heart valve prosthesis to replace diseased valves and make it affordable to his large number of patients.
- He had the foresight to set up a Technology Transfer Cell in house to protect the intellectual property (IPR) and file patents for the inventions made in the Institute.
- Committed to ensure that the results of the research reached the patients in the form of commercially available and competitive devices and implants.
- Indian medical devices industry will always gratefully remember his contributions to the growth of indigenous medical device development in the country.

Professor Marthanda Varma Sankaran Valiathan (24 May 1934–17 July 2024), was a **distinguished cardiac surgeon who is considered as the pioneer of medical devices development in the country.** As early as the 1970s, he identified the need and took unprecedented efforts to develop high quality medical devices and implants meeting international standards. He was founder Director of Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Trivandrum, a unique Institution in the country that combines a medical hospital with a biomedical technology wing. The Institute was strategically placed under the Department of Science and Technology, Government of India through an Act of Parliament in 1980, to support his vision of establishing a world class Biomedical Technology Wing campus in the country along with a hospital. The hospital wing set up by him, stood out for excellence as a tertiary care cardiac and neuro hospital and became synonymous with high quality patient care.

As a cardiac surgeon, his dream was to develop an artificial heart valve prosthesis to replace diseased valves and make it affordable to his large number of patients. As he embarked on this mission, he realised that developing biomedical devices, especially high risk implants requires a multi disciplinary approach and dedicated infrastructure for both research as well as testing which was lacking in the country. He therefore took upon himself, the task of setting up a multidisciplinary team of engineers, polymer scientists, biologists, toxicologists and veterinery surgeons to work on biomedical projects. Under his leadership, engineering laboratories for design, development & testing, precision tool room for fabrication and polymer processing labs were soon set up with best of facilities.

A polymer analysis lab which was much advanced for the time, with equipment such as DSC, TGA, FTIR, HPLC, UV Vis spectrophotometers and UTM was set up with expert faculty for screening and characterisation of biomaterials. For the first time in the country, a laboratory to study blood material interaction and conduct thrombosis research was set up in SCTIMST. A toxicology division was established to assess material safety and identify biocompatible materials as per ISO standards. An animal facility for breeding and care of experimental animals comprising rabbits, mice and guinea pigs was also established as a logical step to facilitate smooth conduct of toxicological evaluations.

To cap it all, a large animal evaluation facility consisting of a modern operation theatre, pre and post operative care for animals such as sheep, pig and dogs was established. An unmatched facility and expertise for conducting surgical procedures in large animals was established within the Biomedical Technology wing campus which played a crucial role in subsequent product development. All these facilities were conceived and implemented with deep thought that even after four decades, they still remain relevant, functional and continue to be part of safety and performance evaluation of a large number of devices and implants. These facilities have also been utilised by several medtech industries on a chargeable basis. In addition to these, a gamma radiation facility for sterilisation of medical devices was set up in the campus with the help of Bhabha Atomic Research Centre.

Much before it became mandatory, he set up an Institutional Ethics committee which was chaired by a retired high court judge to review

proposals for human clinical trials. A library with huge repository of books and journals provided access to latest research information at that time. Under his guidance, a nation wide market survey to estimate the market demand and identify the medical devices to be developed was carried out.

He encouraged international collaborations and many faculty of Institute were given an opportunity to get trained abroad. Under an active Indo-UK program, several visits of experts from leading biomedical institutions in UK to Institute and vice versa took place.

Prof. Valiathan was committed to ensure that the results of the research reached the patients in the form of commercially available and competitive devices and implants. He had the foresight to set up a Technology Transfer Cell in house to protect the intellectual property (IPR) and file patents for the inventions made in the Institute. He was actively involved in scouting for appropriate industry partners to license the know-hows and IPR developed by the institute. He constituted a Technology Transfer committee with experts from academia and industry to develop policies and guidelines to facilitate transfer of technology from Institute to industry. It became evident to him that the technologies developed in the laboratory needed to be scaled up for mass production to be commercially successful. To facilitate a scale up of production and to ensure a smooth technology transfer to industry, a unique Technoprove facility was established in the Institute. This facility, in which the industry and institute personnel jointly worked towards solving the problems in scaling up and producing a large number of clinically usable devices became a catalyst for successful transfer of technology and commercialisation. The clinically usable devices were utilised for the conduct of unicentric or multicentric clinical trials as well as market seeding.

The tilting disc mechanical heart valve prosthesis launched as TTK Chitra Heart valve with M/s TTK Pharma (now TTK Healthcare) as the industry partner became a blockbuster success and is a testimony of the tireless efforts and comittment of Prof. Valiathan in overcoming the various scientific and technical challenges that came in the way. From selecting appropriate materials to its sourcing and processing, from design to testing and manufacturing, each step had several challenges as a heart valve has to beat over 40 million times in an year without any minute wear and tear inside the body. The heart valve finally launched was after a decade of sustained research and development efforts. It is implanted in over 200,000 patients successfully without any failures and continues to be the most affordable mechanical heart valve and widely used. **The blood transfusion bags developed by the Institute was transferred to Peninsula Polymers (now Terumo Penpol) in the 1980s and subsequently to Hindustan Latex Ltd (now HLL Lifecare) both of which even today produce over 50 million bags annually and are extensively used for blood transfusion all over the world.** The blood oxygenator and cardiotomy reservoir was commercialised as SPICTRA brand through South India Drugs and Devices Pvt Ltd (SIDD). Several disposables such as chest drainage system, urinary bags, custom packs, humidifiers etc were developed as spin off projects. Development of hydrocephalus shunt system, dental materials, embolisation materials, vascular graft etc were taken up during his tenure, some of which were later commercialised.

Eventhough trained as a cardiac surgeon, he had the mind of an inquisitive scientist, practical wisdom of an engineer and enthusiasm of an entrepreneur. It is no wonder then, that the high risk medical devices that he undertook to develop, achieved highest standard in performance and commercial success. Apart from medical device development, his contributions in patient care, medical and higher education, public health research, scientific administration, ayurveda etc were equally significant. Professor Valiathan received many coveted honours and was bestowed with the prestigious Padma Vibhushan.

The generations to come associated with the Indian medical devices industry in the country will always gratefully remember his contributions to the growth of indigenous medical device development in the country.

Ensuring Patient Safety: A Comprehensive Guide to the Biological Evaluation of Medical Devices

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GLR Laboratories Pvt. Ltd.

INTORODUCTION

The biological evaluation of medical devices is a crucial part of the regulatory framework aimed at ensuring patient safety. Experts with the necessary knowledge and experience should conduct this evaluation. According to Section B.3.1.4 of ISO 10993-1, "It is critical for the integrity of a biological risk evaluation that it should be conducted by assessors with the necessary knowledge and expertise to determine the appropriate strategy for the evaluation and ability to make a rigorous assessment of the available data and to make sound judgments on the requirements for any additional testing" [1].

Successful biological evaluation depends on collaboration among various stakeholders [Figure 1]. The medical device manufacturer provides essential information about components and materials, including details on manufacturing and cleaning additives. The material supplier offers comprehensive data on composition, including MSDS and CoA. The biomedical engineer selects suitable materials for device construction and designs devices to minimize biological risks. The toxicologist performs toxicological risk assessments, evaluates data from biological tests, and recommends strategies for risk mitigation. The analytical chemist identifies the extraction strategy, selects appropriate solvents, and conducts chemical characterization studies to report extractables. Additionally, the toxicologist, veterinarian, and pathologist carry out standard biocompatibility tests, analyze and report results, and provide scientific interpretations.

Two essential documents in the biological evaluation process are the **Biological Evaluation Plan (BEP)** and the **Biological Evaluation Report (BER).** These documents offer a systematic approach to assessing and documenting the biocompatibility of medical devices, ensuring that all potential biological risks are identified, evaluated, and mitigated [Figure 2]. The overall biological evaluation process should be seen as an ongoing cycle of improvement. Post-market surveillance data, feedback from clinical use, and new scientific findings should be continuously integrated into the BEP and BER. This iterative approach helps maintain the relevance and accuracy of the biological evaluation, ensuring the long-term safety and efficacy of the medical device.

BIOLOGICAL EVALUATION PLAN

A biological evaluation plan (BEP) is a strategic document that outlines the approach and rationale for assessing the biological safety or biocompatibility of a medical device. This plan is based on ISO 10993 1, which provides guidelines for the biological evaluation of medical devices within a risk management process. The BEP identifies the necessary tests and evaluations to determine the potential biological risks posed by the device. It considers the materials used in the device, its intended use, and existing data to prescribe a risk-based approach to evaluating device safety. By understanding these factors, the plan identifies potential biological risks and outlines the necessary steps to address them. Leveraging existing data, including historical data and previous studies, helps reduce redundancy in testing. This strategic approach ensures compliance with regulatory standards and promotes efficiency and resource optimization in the evaluation process.

ISO 10993-1 mandates that the biological evaluation of any medical device intended for human use must be part of a structured biological evaluation plan within a risk management process, in accordance with ISO 14971. The BEP is also instrumental in demonstrating that medical devices comply with FDA and EU regulations. The FDA recognizes ISO 10993-1 as a consensus standard that manufacturers should follow when assessing medical device biocompatibility. This recognition ensures that the BEP aligns with the FDA's stringent requirements for medical devices, thereby facilitating smoother regulatory approval processes. The FDA's guidance document on use of ISO 10993-1 further underscores the necessity of developing a BEP to address any knowledge gaps through biocompatibility testing or other evaluations [2]. This approach ensures that all potential risks are adequately assessed and mitigated.

While the Biological Evaluation Plan is not explicitly mentioned in the EU Medical Device Regulation (MDR), the regulation obligates manufacturers to provide detailed information on their devices' biocompatibility and the methods used to evaluate it [3]. This requirement ensures that all medical devices meet the necessary safety and performance standards before being marketed in the EU.

Key components of the BEP

A holistic approach to the BEP involves not only evaluating individual components but also considering the overall design and intended use of the device. This includes understanding the clinical context in which the device will be used, the duration of contact with the body, and the specific tissues and organs that may be affected. This broader perspective helps identify potential

risks that might not be apparent when focusing solely on individual components. The plan starts with a comprehensive review of the device's materials, design, and intended use. By understanding these factors, the BEP identifies potential biological risks and outlines steps to address them, leveraging existing data to reduce redundant testing [4]. Thus, the BEP should include details on the following:

Device description: A comprehensive device description is essential for the biological evaluation plan. This section should provide detailed information about the device, including its materials, manufacturing processes, and intended use. It should also include a description of the medical device family, if applicable and the materials of construction. This information forms the foundation for understanding the potential biological interactions and risks associated with the device.

Intended use: The intended use section outlines the clinical context in which the device will be used. This includes specifying the duration of contact with the body and identifying the specific tissues or organs that will be affected. Understanding the intended use is crucial for selecting the appropriate biocompatibility tests and ensuring that the device is safe for its designated application.

Device categorization: Device categorization involves classifying the device based on several factors, including frequency and duration of contact with the human body. The frequency of contact can be categorized as single use, repeated use, or continuous use. The duration of contact can be classified into limited exposure (less than or equal to 1 day), prolonged exposure (more than 1 day but not more than 30 days) and long-term exposure (more than 30 days). This categorization helps in determining the specific biocompatibility tests required for evaluating the device's safety.

Reasonably foreseeable misuse: Reasonably foreseeable misuse refers to the use of a medical device in a manner not intended by the manufacturer, but which can result from readily predictable human behaviour. This section addresses potential misuse scenarios to ensure that the device remains safe and effective even when used incorrectly.

Risk assessment: Risk assessment is a crucial component of the biological evaluation plan. It involves identifying potential biological risks based on the device's materials and intended use. This process includes leveraging existing data to reduce redundant testing, utilizing historical data and previous studies to inform the evaluation. By systematically identifying and assessing risks, the plan ensures that all potential hazards are addressed and mitigated.

Testing strategy: The testing strategy section outlines the selection of appropriate biocompatibility tests to evaluate the device's safety. This includes tests for cytotoxicity, sensitization, irritation, systemic toxicity, genotoxicity, implantation and hemocompatibility. Additionally, chemical characterization is performed to identify potential hazards associated with the device's materials. This comprehensive testing approach ensures that all potential biological risks are thoroughly evaluated, providing a robust assessment of the device's biocompatibility.

Chemical characterization: BEP includes chemical characterization to identify potential hazards associated with the device's materials. This step is crucial for understanding the material composition and identifying potential leachable and extractable substances. By thoroughly analyzing the chemical makeup of the device, the evaluation can pinpoint any substances that might pose a risk to patient safety. This detailed chemical characterization helps ensure that all potential hazards are recognized and addressed early in the evaluation process.

Gap Analysis and Regulatory Compliance: The BEP demonstrates compliance with ISO 10993-1, FDA guidelines, and other relevant regulatory requirements. It includes a thorough gap analysis of any existing reports to ensure they meet current updated standards. By leveraging existing data and historical studies, the BEP reduces redundant testing, making the evaluation process more efficient. This strategic approach not only saves resources but also aligns the evaluation with best practices and regulatory expectations, ensuring that the device meets all necessary safety and performance standards.

BIOLOGICAL EVALUATION REPORT

The biological evaluation report (BER) is a comprehensive document that summarizes the findings from the biological evaluation of a medical device. It provides a detailed account of the tests conducted, the results obtained, and the conclusions drawn about the device's biocompatibility. The BER is crucial for demonstrating compliance with regulatory requirements and for supporting the safety and efficacy of the medical device. The BER is vital for regulatory submissions as it provides evidence that the device meets the necessary biocompatibility standards. Regulatory bodies, such as the FDA and other international agencies, require a thorough BER to ensure that the device does not pose any biological risks to patients.

Key Components of the BER

Summary of the BEP: The Biological Evaluation Report (BER) recaps the rationale behind the selected tests and assessments, providing a clear overview of the strategic approach taken for the device's evaluation. It sets the context for understanding why certain tests were chosen and how they align with regulatory requirements and the device's intended use.

Test descriptions and results: The report then details the biocompatibility tests performed, including comprehensive details of the test methods employed and results obtained. This includes an explanation of the chemical characterization process and the extraction strategy used to identify potential hazards associated with the device's materials. This result analysis highlights any observed adverse effects or unexpected findings, providing a clear picture of the device's biocompatibility. The presentation of these results is critical for understanding the device's safety profile.

Risk assessment: In the risk assessment section, the test results are interpreted in the context of the device's intended use and potential risks. This evaluation considers both the test results and existing data to assess the overall biocompatibility of the device. It provides a thorough analysis of potential biological risks, ensuring that all aspects of the device's safety are considered.

Conclusions and recommendations: The conclusions and recommendations section summarize the findings of the BER, outlining their implications for the device's safety and efficacy. It provides recommendations for any additional testing or risk mitigation strategies if necessary. This section ensures that any remaining uncertainties are addressed, and appropriate actions are taken to ensure the device's safety.

CONCLUSION

The biological evaluation of medical devices is crucial for ensuring patient safety and regulatory compliance, guided by standards like ISO 10993-1. The Biological Evaluation Plan (BEP) and the Biological Evaluation Report (BER) serve as the two key documents for biological evaluation. The BEP outlines the evaluation strategy, including test selection and risk assessment, to address potential biological risks and ensure compliance. The BER documents the evaluation outcomes, summarizing test results and making recommendations for

ISO 10993
BIOLOGICAL EVALUATION OF MEDICAL DEVICES

further action if needed. Together, the BEP and BER form a continuous cycle of improvement in the biological evaluation process. They ensure that medical devices are assessed rigorously and that any emerging risks are managed effectively. By integrating post-market surveillance data and new scientific findings, the biological evaluation process remains relevant and accurate, safeguarding patient health and maintaining high standards of medical device safety.

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[3] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

[4] ISO/DIS 10993-1:2024. Biological evaluation of medical devices. Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process.

FIGURES

Figure 1: Biological Evaluation Plan is collaborative effort

Figure 2: Overview of Biocompatibility Evaluation

Navigating Regulatory Landscapes: Drug-Device Combination Products In The EU And USA?

Anil Chaudhari, Founder
Operon Strategist

What are combination products?

Combination product is a product composed of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device, and a biological product.

These products can be composed of two or more components, each of which would typically be classified as a drug, a device, or a biological product individually. These products combine therapeutic agents with medical devices to improve patient outcomes and treatment adherence. The combination of these components into one single product is intended to provide a more effective treatment or diagnostic tool than if each component were used separately. Examples include prefilled drug syringes, Dose Inhalers, drug-eluting stents, insulin pumps and certain diagnostic test kits that include reagents and instruments.

In this article we will discuss what are challenges manufacturers of combination product may face when seeking regulatory approval for their integral combination product and what are requirements for EU and US markets.

Regulatory Framework for Market Access and Commercialization in Europe and US

Combination products are regulated by health authorities such as United States (FDA) and European Union (EMA) under specific regulatory frameworks that address the unique challenges and requirements posed by their combined nature.

EU regulations for Drug-device combination products

Obtaining a Notified Body Opinion (NBOp) will require a significant investment of time and regulatory knowledge and resources. If it is not addressed correctly, the process may directly impact the costs and time to approval. Manufacturers of Drug Device combinations have to opt for Notified Body Opinion (NBOp) to get their regulatory approvals for device components.

What is Notified Body Opinion?

According to Article 117 of MDR, Integral drug-device combination products DDCs regulated as a medicinal product and NB Opinion (NBOp), is required for those products to obtain marketing authorization for a medicinal product which forms a single integral product with an any medical device. The Marketing Authorization Holder is, if a NBOp is applicable, required to submit the NBOp in conjunction with the Marketing Authorization Application (or variation application) to the Drug Competent Authority.

NBOp Technical file of integral Drug-Device Combination (DDC) products need to follow stringent regulatory requirements and technical documentation.

What should be included in NBOp submission file?

Manufacturers needs to identify all the relevant and applicable GSPRs for their combination product with sufficient level of evidence to meet requirements. A significant amount of documentation for device components are required for an NBOp which shall be prepared and maintained by manufacturer.

- Documentation shall focus on General description device and components making direct or indirect contact with the human body, Mode of Action, Key Functional Elements. Description of variants and configurations, Accessories, Technical specifications, features, dimensions and performance attributes
- Comprehensive Design History File, user instructions, product inserts, and packaging details provide essential guidance for safe application. Harmonized standards and common specifications backed by documents offering robust evidence of conformity.
- Manufacturer shall not only focus on the device part, but also on the device part´s **interoperability and compatibility with other devices,** products or substances, Threshold analysis Report and bench testing data with RLD.
- A thorough GSPR checklist identifies and justifies applicable regulatory requirements, while methods to demonstrate conformity include comprehensive summaries of results, supported by raw data and original test report. Technical documentation shall also be supported by detailed clinical

evaluation or clinical investigation (If applicable) inconsideration to device type and risk category.

What is Role of Notified body?

Notified Body sets the assessment based on Article 117 (Regulation (EU) 2017/745 on medical devices (MDR)), and Issues and opinion on the conformity of the device as apart of drug device combination.

Points to be considered for selecting a Notified Body to issue your NBOp

- Does the NB provide services specifically for your device class?
- Do they have experience with providing NBOps?
- Any existing relationships between NB and manufacturer?
- How much charges to provide the NBOp, and is it within your budget?
- What are the NBs' proposed timelines for complete process?

Post market requirements for Drug device combination products.

Drug device combination (integral) regulated as a medicinal product, device vigilance requirements for MDR are not applicable but is recommended that manufacturer has the technical knowledge and processes built into their Quality Management System (QMS) for handling, evaluating and investigating, where necessary, all device-related complaints. Manufacturers should review their pharmacovigilance agreements with suppliers to ensure that they take into consideration additional data that may need to be collected and communicated, such as device malfunctions and device-related events.

Labelling and Unique Device Identification (UDI)

As integral Drug device combinations regulated as medicinal products, the labelling and UDI requirements under MDR are not applicable. When labelling, the integral DDC manufacturer should follow the labelling requirements for a medicinal product.

US regulations for Drug-device combination Products

Background

A provision in the 21st Century Cures Act enacted in December 2016 (PL 114-255) amends section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 USC 353(g)), which addresses combination products (21 USC 353). The amendments aim to enhance clarity, efficiency, predictability, and consistency in premarket regulatory expectations for combination products. This ensures that the FDA's components and staff coordinate appropriately on premarket review of the combination products and that the agency's stakeholders are in harmony in conducting these reviews.

What is role of OCP for Combination products?

OCP assigns the lead Center (CBER, CDER or CDRH) that will have primary jurisdiction for the premarket review and regulation of a combination. In addition, OCP is available as a resource to industry and agency reviewers to help facilitate the review process.

Principle Regulatory pathways

The guidance released by the FDA offers high-level information on principles of premarket pathways:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-premarket-pathways-combination-products

A combination product is assigned to an agency centre that maintains primary jurisdiction (i.e., the lead) for that product's regulation. A combination product is assigned to a lead centre based on which component delivers its Primary Mode of Action (PMOA) in accordance with section 503(g)(1). In the event that the PMOA is attributed to the biological product of a device-biological product combination, then the centre in charge of such a product's premarket assessment will retain primary jurisdiction over that combination product. To ensure that regulations are effective and consistent, the agency with the main authority collaborates with other centres.

https://www.fda.gov/combination-products/guidance-regulatory-information/acts-rules-and-regulations

Principles of premarket pathways

1)For Device-led Combination Products
2)For Biologic-led Combination Products
3) For Drug-led Combination Products

For Drug-led Combination Products

New Drug Application (NDA): Section 505(b)(1) and 505(b)(2) applications are both submitted and accepted under the FD&C Act's section 505(c). For a drug-led combination product, an NDA must demonstrate, among other things, the safety and efficacy of the product for the prescribed conditions recommended or suggested in the labelling.

Abbreviated New Drug Application (ANDA): The ANDA pathway is used for drug-led combination products that contain the same active ingredients, dosage form, strength, route of administration, and conditions of use and (with certain permitted differences) labeling as a product already approved under section 505(c) of the FD&C Act (i.e., a reference listed drug (RLD)). ANDA applicants are not required to provide independent evidence to support the safety and efficacy of their proposed product, instead, an ANDA relies on the FDA's evaluation that the RLD is safe and effective.

For Device-led Combination Products

Under the single application pathway, the device submission content is reviewed by the US Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) through an intercenter consulting process.

Single-entity combination products such as prefilled syringes, autoinjectors, and on-body injectors are probably the most common combination products being developed by the pharmaceutical industry. The device development submission content for these products is commonly presented in Sections 3.2.P.2 and/or 3.2.R3 of Module 3 in the eCTD submission structure, per CDRH expectations, because the content pertains to development of the device constituent part of the combination products (Table 1)

Table 1. Device development information commonly presented in Section 3.2.P.2 and/or 3.2.R3

Section	Description
Device description	Provide a description of the device constituent design and novel features and/or functionalities and include drawings, diagrams, device components, principles of operation and intended use, and materials.
Relevant standards	Describe the applicable standards used.
Design and development (design controls)	Describe the design input specification, necessary preconditioning as recommended be respective device standards and/or FDA guidance documents, sample sizes and justifications, test methods, acceptance criteria, design verification test results, and conclusions. Test protocols and reports may be provided, as applicable (e.g., when the methods do not conform to FDA-recognized consensus standards). Describe the device aging parameters (accelerated and/or real-time), and provide results to support the claimed shelf life of the combination product. Describe biocompatibility evaluation and human factors validation results.
21 CFR Part 46 (Current GMP requirement for combination products)	Describe the quality system compliance approach. Include a discussion of each prespecified quality system provision.
Manufacturing and controls	Provide a high-level summary of the manufacturing, assembly, and packaging flow. Justify the overall device control strategy.
Risk Management	Describe the risk management processes, activities, and the conclusion.

FDA, Food and Drug Administration (US): GMP. good manufacturing practice

Similarly, the CDRH expects device submission content for copackaged combination products (e.g., vials and needles). However, the extent of the content varies greatly, depending on whether the device constituent has a marketing approval or clearance and, if it does, whether the device will be used according to its intended use. The device submission sections described in Table 1 can generally be adapted.

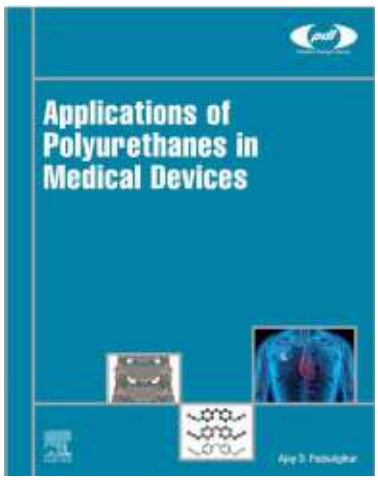
As per the US regulatory Framework, a single application can be used for both the drug/biologic and the device when doing the submission for a combination product,the FDA has provided a basic structure for the incorporation of device and the combination product in the specific data needs to provide in the eCTD.

What types of marketing applications are required for a combination product?

Combination products are typically marketed under a marketing authorization type associated with the constituent part that provides the primary mode of action (PMOA) for the combination product (i.e., a new drug application (NDA) or abbreviated new drug application (ANDA) if it has a drug PMOA, a biologic license application (BLA) if it has a biologic PMOA, or a premarket approval application (PMA), de novo classification, or premarket notification ("510(k)") if it has a device PMOA). A single marketing application is generally sufficient for combination product. In some cases, however, a sponsor may wish to submit separate marketing applications for different constituent parts of a combination product, and FDA may consider this permissible.

Consultation

In today's dynamic regulatory landscape, navigating the complexities of bringing combination products to various market requires expert guidance and consultation. Operon Strategist specializes in the regulatory approvals of drug-device combinations, navigating their unique regulatory challenges with expertise in combination product regulatory affairs pathways for seamless EU and FDA approval. We facilitate clear and efficient communications, deep industry knowledge to empower pharmaceutical companies for timely market entry and regulatory success.



Applications of Polyurethanes in Medical Devices

1st Edition - February 1, 2017
Author: Ajay Padsalgikar
Language: English
Hardback ISBN: 9780323358859
9 7 8 - 0 - 3 2 3 - 3 5 8 8 5 - 9
eBook ISBN: 9780323371223

Plastics in Medical Devices for Cardiovascular Applications enables designers of new cardiovascular medical devices to make decisions about the kind of plastics that can go into the manufacture of their device by explaining the property requirements of various applications in this area, including artificial valves, lead insulation, balloons, vascular grafts, and more.

Key features

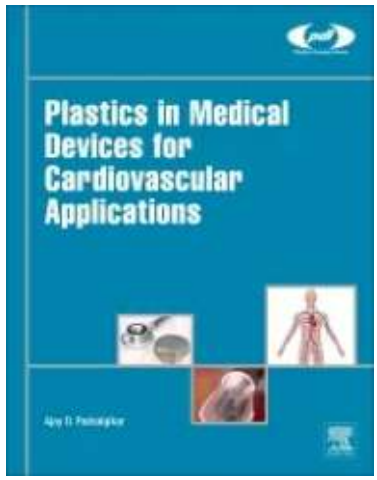
Enables designers to improve device performance and remain compliant with regulations by selecting the best material for each application

Presents a range of applications, including artificial valves, stents, and vascular grafts

Explains which materials can be used for each application, and why each is appropriate, thus assisting in the design of better tools and processes

Readership

Engineers and materials scientists in medical device companies. Plastics Material manufacturers, specifically chemists and scientists within these companies. Academic courses in plastics engineering, polymer science or biomedical engineering



Plastics in Medical Devices for Cardiovascular Applications

1st Edition - May 19, 2022
Author: Ajay Padsalgikar
Language: English
Hardback ISBN: 9780128196731
9 7 8 - 0 - 1 2 - 8 1 9 6 7 3 - 1
eBook ISBN: 9780128231685

Applications of Polyurethanes in Medical Devices provides detailed coverage of polyurethane (PU) chemistry, processing and preparation for performant medical devices. Polyurethanes have found many uses in medical applications, due to their biocompatibility, biostability, physical properties, surface polarity, and the ability to suit the field of application. This book enables the reader to understand polyurethane and how this valuable material can be used in medical devices. Sections cover the chemistry, structure, and properties of polyurethane, with in-depth sections examining raw materials, reaction chemistry, synthesis techniques, reaction kinetics, material microstructure, and structure-property relationships.

Subsequent chapters demonstrate how polyurethane can be utilized in medical device applications, examining biological properties, rheology and processing before methodical coverage explains how polyurethane may be used for each category of medical device. Finally, future directions, and safety and environmental aspects, are covered.

Key Features of the book

Bridges the gap between polyurethane chemistry, processing and preparation for cutting-edge medical device applications Includes in-depth coverage of polyurethane, covering raw materials, chemistry, synthesis techniques, reaction kinetics, properties and microstructural analysis

Takes a valuable and practical approach, addressing manufacturing issues and using testing and modeling to solve problems encountered in processing

Biography of Ajay D Padsalgikar

Ajay graduated with a degree in Polymer Engineering from the University of Poona, India in 1990. He then completed a PhD from Clemson University, SC, USA in 1996. Ajay has worked different companies, Huntsman Polyurethanes in Belgium, AorTech Biomaterials in Australia and Abbott in Minnesota, DSM Biomedical, Pennsylvania.. He has been involved with different aspects of polyurethane chemistry, morphology and processing of polyurethanes for medical devices.

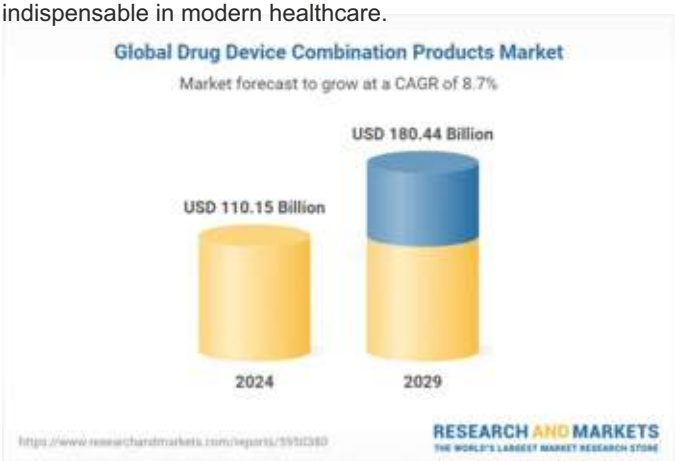
Ajay joined Biolinq Inc. in July 2022 as a Technical Director, where he is working on a range of material solutions for biosensors.

Ajay has more than 30 published scientific papers and 10 patents. He has also authored two books, 'Plastics in Medical devices for Cardiovascular Applications' was published by Elsevier. 'Applications of Polyurethanes in Medical Devices' was published in June 2022 also by Elsevier.

Drug Device Combination Products Market Worth Over $180 Billion by 2029

As the healthcare industry undergoes a transformative change, the Global Drug Device Combination Products Market stands at the cusp of revolutionary growth, with a forecast of a robust 8.74% CAGR through 2029. This sector, valued at USD 110.15 billion in 2023, is a testament to the synergy between drugs, biologics, and medical devices, providing targeted therapeutic effects. Enhanced by technological advancements and driven by the increasing burden of chronic diseases, these products are setting new standards for efficient, patient-focused treatment modalities.

Advancements in medical technology have significantly influenced the market, ushering in an era of smart, connected combination products. They improve therapeutic outcomes and facilitate patient compliance by delivering medication more efficiently. As chronic conditions rise globally, the demand for these advanced therapeutic strategies is experiencing an upward trajectory. Drug-device combination products are proving crucial for chronic disease management, making them indispensable in modern healthcare.



Market Challenges: Navigating Regulatory Landscapes and Liability Concerns

Amidst the growth, the market confronts certain challenges, including complex regulatory pathways and product liability risks. The dual nature of these products, combining drugs and devices, necessitates stringent compliance with multifaceted regulations, which can impede speed to market and elevate costs. Moreover, the intricacies of these combination products elevate the risk of product liability, potentially leading to financial and reputational setbacks for manufacturers. The industry is thus poised to manage these risks diligently to maintain market expansion and consumer trust.

Market Trends: The Future Shaped by Connectivity and Personalization

Digital integration and smart devices are charting a new course for the market, capitalizing on the digital health wave. Smart drug-device combinations provide real-time patient monitoring and insightful data analytics for personalized treatment. Simultaneously, biologics and personalized medicine are gaining momentum, fostering treatments tailored to individual patient profiles. These trends portend a dynamic market environment ripe with opportunities for industry players.

Segmental Insights and Regional Dominance

Transdermal patches are showcasing substantial segment growth, offering non-invasive and controlled medication delivery.

The cardiovascular application continues to dominate, answering to the critical demand set by a high prevalence of cardiac ailments. Moreover, North America has maintained its position as a market leader, benefiting from a robust healthcare infrastructure and a culture of innovation that supports market advancements.

Competitive Landscape Emerging in Global Market

The competitive landscape of the Global Drug Device Combination Products Market is characterized by the presence of key industry players, each contributing to the market's diverse offerings. The industry as a whole has positioned itself as a driving force for the future of healthcare, blending drugs and medical devices for optimal patient care.

https://finance.yahoo.com/news/drug-device-combination-products-market-090600529.html

Colombia Medical Devices Market

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

Country Profile

Colombia saw armed conflicts and political violence in the 1960s, and in the next three decades, such instability increased. Since the beginning years of the 20th century, the situation has improved significantly. Law and order situation was established with stability and better security after this. This followed dramatic economic growth also. Colombia is one of the most stable economies in Latin America. A strong financial institutional set-up, a fairly disciplined fiscal framework, a relatively flexible foreign exchange rate, and a clear eye on inflation monitoring have been the strong pillars of this country. Gaps in infrastructure and education curriculum systems still need attention as per the World Bank. The capital city is Bogota. It needs to be noted that Colombia has social and territorial inequalities. Post-pandemic recovery of the economy is also not as desired (where India has done fairly well in this regard).

Colombia has the highest level of biodiversity per square mile in the whole world, with diversity covering Amazon rainforests, highlands, deserts and grasslands. With a 52.7 mn population, Colombia is the third most populous country in LATAM, after Mexico and Brazil. With a per capita GDP of 19,770 USD, and a well-established healthcare system, the country offers a decent opportunity in the healthcare sector. Now Colombia is considered to have a very decent healthcare system with the best standards in the whole of Latin America, an important point from a market perspective.

Like many other countries of LATAM (and unlike Brazil), here also, the official and prevailing language is Spanish.

Regulatory Framework Outline and Product Classification

INVIMA (The National Institute for Food and Drug Surveillance) is the regulatory agency for Colombia (https://www.invima.gov.co). (The webpage is in Spanish. However, after clicking English/Translation, English matter appears.). Like in all the LATAM markets, here also, the role of a local representative partner becomes important. In general, the local partners in the surgical field are good and well-conversed with the local authorities. Unlike some other LATAM countries, the corruption level is almost nil, and the agency works with diligence. Pre-registration consultation directly with INVIMA through their website is also possible for some issues if needed.

Classification of medical devices –

- Class I (low risk)
- Class IIa (moderate risk)
- Class IIb (implantable devices)
- Class III (high risk)

This is fairly aligned with the international guidelines or IMDRF framework.

Approval for medical devices in general takes about 6 months if the set of documents is correct. The partner's Regulatory person generally scrutinizes these documents and thereby, the process may become faster (4 months). Post-approval amendments are easy and may take only 2 months.

Colombia Highlights

- A fairly large and stable market
- A decent and growing economy
- More than 80% of devices requirements are imported
- Regulatory mechanism very clear and clean
- Very competitive pricing dynamics

A few important points in this regard are - 1. There needs to be a legal representative for registration in this country (a distributor or a regulatory consultant agency). 2. Labelling requirements (label in Spanish) are also crucial for Colombia for devices. 3. For Class III (high-risk) devices, the authorities may need clinical trial data also. 4. The most important point is product approval in the USA or EU approval. This will facilitate the approval here. Testing by foreign INVIMA-listed labs is acceptable.

In LATAM, Colombia approvals are considered the fastest and most predictable.

Colombia Medical Devices Market

Colombia is the third largest medical devices market in the LATAM region, in line with the population rank. The market size estimates are about 1.5 bn USD with a growth rate of 5.7% pa. Rising emphasis on health by the Government is the main factor which may drive this growth. However, some experts predict that the growth rate may go down to 2.5% due to economic factors. In Colombia also, both public and private healthcare sub-sectors prevail. Health is a fundamental right provided in the constitution, and so, while the public healthcare system is entirely funded by the government (based on the guidelines under SISBEN, a social program), the private sector is funded by employees and employers. Probably Colombia is the only country in LATAM with GCP (Good Clinical Practice) certification for the clinics ensuring their high standards.

Cardiac devices are the largest segment followed by Diagnostics and then Ortho products. More than 80 % (82% as per one estimate) of the medical devices are imported!! Local production is mainly for lower-end products. Colombia has a free trade agreement with the EU and Canada making imports from there easier.

The market is competitive and the major part is by the Government seeking the lowest price through tenders, many times through open negotiable tenders, pushing the prices lower. There is an agreement with the USA also (US-Colombia Trade Promotion Agreement, or CTPA) adding to the competition from the American companies.

Opportunities and Challenges

Large size, with a predictable registration framework and strong economy, make the market attractive. More than 80% of the supplies of devices are through imports. A stable and predictable market with a volume suggests taking the market seriously for the future.

Price competition from the EU, the USA and Canada may act as a major challenge.

Government Working On A Scheme To Strengthen Indian Medical Device Sector: Pharma Secretary

Dr Arunish Chawla, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Govt of India said that the PLI schemes for medical devices sector have succeeded, and the government is now looking at the post PLI framework.

The government approved the Medical Devices policy a few months ago, and this new scheme is being designed to support the industry and reduce our import dependence going forward beyond the PLI, he added.

The proposed scheme, he stated will be based on 5 key components including Common Facilities for medical devices clusters; Capacity building and Skill Development; Marginal Investment Scheme for reducing import dependence; focus on clinical trial support and medical device promotion scheme.

He stated we need to bring the policy stack together in a manner that enables India to achieve the vision of Viksit Bharat by 2047. Dr Chawla further urged the industry to invest more in clinical trials. Highlighting the importance of skilled manpower required in the medical devices sector, Dr Chawla said, Across the industry, there is a shortage of technical manpower, particularly medical engineers.

To address this gap, we have partnered with the relevant skill development council in the industry to support both the training and development of technicians and medical engineers.

(https://www.business-standard.com) Aug 22 2024

CDSCO Mandates GMP Compliance For Sterile Equipment Manufacturers

This move marks a significant shift, as GMP compliance was previously required only for drug manufacturers.

The Central Drugs Standard Control Organization (CDSCO) has directed manufacturers of sterile equipment to adhere to Schedule M of the Drugs and Cosmetics Rules, aligning with Good Manufacturing Practices (GMP) standards as outlined by the World Health Organization (WHO). This move marks a significant shift, as GMP compliance was previously required only for drug manufacturers.

The inclusion of sterile equipment under GMP guidelines is crucial given the expanding Indian market for these products. The new regulations aim to ensure higher quality standards for various sterile items, including surgical instruments, forceps, biopsy tools, eye equipment, and injectables.

“The revised GMP notification published last December covers all pharmaceutical items and specifies requirements for different product types, such as sterile products, biologicals, and ophthalmic solutions,” an official explained.

In addition to general requirements, companies must now follow WHO guidelines, regularly conducting self-assessments and addressing compliance gaps to meet international standards.

The government had previously revised Schedule M of the Drugs and Cosmetics Rules in December 2023 to tighten GMP norms, particularly impacting micro, small, and medium enterprises (MSMEs). According to the guidelines announced in July 2023, companies with annual turnovers exceeding Rs 2.5 billion must comply within six months, while those with lower turnovers have a 12-month period.

This update follows a government inspection revealing significant GMP lapses, including infrastructural issues and poor documentation. This action is partly in response to incidents involving Indian cough syrups linked to child deaths in Gambia and Uzbekistan.

(https://ipfonline.com/news/detail/articles) Aug 14,24

DoP To Launch Scheme For Common Facilities In State-Supported Medical Device Parks: DoP Secretary

In a significant development, the Department of Pharmaceuticals (DoP) is planning to introduce a new scheme aimed at providing common facilities for medical device parks or clusters that have been exclusively established with the financial support of respective state governments, according to Dr. Arunish Chawla, DoP secretary.

This initiative coincides with the Government of Gujarat's recent allocation of Rs. 250 crore for a state-of-the-art medical device park at Nagalpar, near Rajkot. Spread across 336 acres, this park is distinguished as India’s first medical device park funded solely by a state budget, without relying on the central government's financial grant of Rs. 250 crore. The park is expected to commence operations by the end of 2025.

Conceived as a commercially and economically viable project, the Nagalpar medical device park is projected to attract an investment of USD 100-150 million over the next three years.

"The park is estimated to host around 400 medical device companies. The land has been allocated, and the first phase of construction has begun. Nagalpar, being an engineering hub, offers a strategic location for the park, promising good returns on investment. It will facilitate R&D, testing, manufacturing, training, and incubation for medical device companies," stated Dr H G Koshia, commissioner of the Gujarat Food and Drug Control Administration (FDCA).

The Gujarat Industrial Development Corporation (GIDC) has started the process of setting up the medical device park at Nagalpar to boost medical device manufacturing in the state.

To reduce import dependence and encourage domestic manufacturing of drugs and medical devices, the Indian government has implemented various measures. Under the “Promotion of Medical Devices Parks” scheme, financial

Continued on page 45

FDI Inflow Into Hospitals & Diagnostic Centres Grows 89 Per Cent in 2023-24

The Foreign Direct Investment (FDI) equity inflow into the hospital and diagnostic centres sector in the country has witnessed a growth of around 89 per cent during the fiscal year 2023-24, while the foreign equity infusion into the medical and surgical appliances sector grew 21.6 per cent during the financial year compared to the previous year.

The hospital and diagnostic centres in the country have attracted a foreign equity fund infusion of $1.53 billion during April, 2023 to March 2024, as compared to $809.6 million during the previous year, according to data from the ministry of commerce and industry.

The infusion into the sector has registered 86.7 per cent growth during the quarter ended March, 2024, at $446.39 million as compared to $239.09 million fund inflow in the same quarter of last year.

The growth during the fiscal year was the highest at least in the last five years, and crossed the $1 billion mark after fiscal year 2018-19 when the FDI inflow was reported at $1.04 billion. The year 2022-23 witnessed a growth of 16.07 per cent to $809.6 million, from $697.5 million in the fiscal year 2021-22. The fiscal year 2021-22 was a growth of 39.2 per cent from $501.16 million in the previous year, according to the data.

Cumulative fund infusion into the segment from the year April, 2000 to March, 2024 stood at $10.27 billion, growing from $8.74 billion till March, 2023.

The medical and surgical appliances sector registered a growth of 21.56 per cent in FDI equity infusion during the period from April, 2023 to March, 2024, at $482.83 million as compared to $397.2 million during the previous fiscal year. The quarter ended March, 2024 reported an FDI inflow of $20.41 million, as compared to $39.57 million reported during the same period of previous fiscal year, showing a decline in fund inflow.

The growth of FDI inflow was one of the lowest for the segment during the fiscal year 2023-24 in the last three fiscal years, with the year 2022-23 reporting a growth of around 91 per cent, and almost three fold growth in the year before that, at $208.05 million FDI inflow in 2021-22.

The cumulative FDI infusion into the sector from April, 2000 to March, 2024, according to the data from the ministry of commerce and industry, is at $3.29 billion, as compared to $2.80 billion reported from April, 2000 to March, 2023.

(https://www.pharmabiz.com/NewsDetails.aspx?aid=169783&sid=1#:~:text=The%20Foreign%20Direct%20Investment%20(FDI,cent%20during%20the%20financial%20year)
June 18, 2024,

Medical Device Import Grows In Last One Year In India

In 2023–24, the fiscal year's import of medical devices was Rs. 68,885 crore, while the previous fiscal year's imports were Rs. 61,179 crore. It should be mentioned that compared to the Rs. 63,276 crore reported in the previous fiscal year, imports during 2022–2023 decreased by 3.31%.

New Delhi: During the last fiscal year, the import of medical devices in India has increased around 13 per cent with disposables accounting for nearly 17.6% of the growth in comparison to the previous year, according to data from Association of Indian Medical Device Industry (AiMeD), the umbrella association of Indian manufacturers of medical devices.

In 2023–24, the fiscal year's import of medical devices was Rs. 68,885 crore, while the previous fiscal year's imports were Rs. 61,179 crore. It should be mentioned that compared to the Rs. 63,276 crore reported in the previous fiscal year, imports during 2022–2023 decreased by 3.31%. Based on data, imports increased by over 65% in five years, from Rs. 41,709 crore recorded in 2019–20.

Of the six medical device category groups, disposables saw the largest increase in imports during the fiscal year, rising 17.63% to Rs. 4,090 crore from Rs. 3,477 crore in 2022–2023. Compared to the previous year's imports of Rs. 38,540 crore, the country's imports of electronics equipment increased by 14.5% to Rs. 44,132 crore this year.

From Rs. 4,580 crore in the previous fiscal year to Rs. 5,087 crore in 2023–24, the import of implants increased by 11%. During the fiscal year, the sector's imports of consumables increased by 8.37 percent to Rs. 7,430 crore from Rs. 6,856 crore the year before. IVD reagent imports increased by 7% to Rs. 6,477 crore in 2023–24 from Rs. 6,053 crore in the previous year. Surgical tool imports saw a little decrease, nevertheless, to Rs. 1,670 crore from Rs. 1,674 crore the year before.

The industry association stated that the nation's exports totaled Rs. 31,673 crore, with the electronics and equipment segment reporting the highest exports at Rs. 12,120 crore. This was followed by consumables at Rs. 9,978 crore, disposables at Rs. 5,128 crore, implants at Rs. 2,096 crore, IVD reagent at Rs. 1,694 crore, and surgical instruments at Rs. 657 crore.

In order to assist the expansion of domestic manufacturing, the Association has asked Finance Minister Nirmala Sitharaman to boost custom duty, right the inverted duty structure, and curb trade margins in the next Union Budget 2024–2025.

Earlier this year, former Union Health Minister Mansukh Mandaviya had said that India has moved on to become a major exporter of bulk drugs and medical devices, Union Health Minister, Mansukh Mandaviya. He claimed that India was working on strategies and schemes to reduce the risk in its supply chain from the whims of the world and reliance on one nation for the procurement of APIs needed to make bulk medications.

(https://www.livemint.com/industry/manufacturing/medical-device-import-grows-in-last-one-year-in-india-11721302959252.html)
18 Jul 2024,

"AiMeD" Continued

assistance of Rs. 100 crore each has been approved for Uttar Pradesh, Tamil Nadu, Madhya Pradesh, and Himachal Pradesh to establish common facilities in their medical device parks.

The production linked incentive (PLI) scheme, with a financial outlay of Rs. 3,420 crore, aims to boost domestic manufacturing of medical devices. Running from FY 2020-21 to FY 2027-28, this scheme offers financial incentives to selected companies at the rate of 5 per cent of incremental sales of medical devices made in India, covering four target segments, for a period of five years.

(https://www.pharmabiz.com) July 3, 2024,

Ensuring Safe and Healthy Medical Plastics with Bry-Air Dryers

(Courtsey: Bry-Air (Asia) Pvt. Ltd.)

Bry-Air, a leader in drying technology, offers two premier products for medical plastic drying: the Wonder Dryer (Bry-Dry 80X Series) and the Nano Desiccant Dryer. These dryers ensure precise, efficient drying, crucial for maintaining the quality and safety of medical plastics.

Wonder Dryer (Bry-Dry 80X Series)

The Wonder Dryer is an advanced waterless drying solution designed for large-scale medical applications. It utilizes desiccant technology to deliver consistent drying at low dew points, which is essential for processing medical-grade plastics.

- **Waterless Drying:** Eliminates the need for water, enhancing efficiency and reducing maintenance.
- **Energy Efficiency:** Delivers optimal drying with minimal energy consumption.
- **User-Friendly Interface:** Equipped with an easy-to-operate control panel and maintenance alerts.
- **Versatility:** Suitable for various medical plastic applications, ensuring product quality and safety.

Nano Desiccant Dryer

The Nano Dryer is a compact, high-precision dryer ideal for small-scale or specialized applications. It operates at a dew point of -40°C, ensuring thorough drying of sensitive medical plastics such as Nylon and ABS.

- **Compact Design:** Saves space and integrates easily into existing setups.
- **High Precision:** Perfect for small batch production and specialized medical components.
- **Waterless Operation:** Enhances the mechanical properties of plastics without the need for water connections.

Both dryers are designed to meet the stringent requirements of medical plastic processing, ensuring that products are free from moisture-induced defects, thereby maintaining their
integrity and safety.

Bry-Air: The best in drying technology, ensuring the highest standards in medical plastic manufacturing.

Contact Information: Bry-Air (Asia) Pvt. Ltd. 21C, Sector-18, Gurugram - 122015, Haryana, India. Email: bryairmarketing@pahwa.com, Website: www.bryair.com

FAST FACTS

Desirable Design Practices for Healthcare Plastics

- Designing with mono-material whenever possible.
- Using polyolefin seals or gaskets on polypropylene bottles.
- Combining chemically compatible or jointly processable plastics, if multiple materials are required.
- Using materials that are easily separated during automated recycling processes, if multiple materials are required.
- Using breathable plastics as an alternative to paper.
- Minimizing paper labels and components.
- Using water-based adhesives.
- Allowing for bottles and bags to be fully drained with ease before disposal
- Providing information on contents that allows for easy identification of residual liquids.
- Minimizing pigments.

Less Desirable Design Practices for Healthcare Plastics

- Using a rubber seal on a polypropylene bottle.
- Combining incompatible bioplastics and petroleum-based plastics into one product.
- Welding, gluing or molding two components of unlike plastics.
- Combining plastic film with paper in packaging.
- Using metalized plastics, metals screws, grommets in plastic.
- Using lead.
- Using PVC.

(Ref : https://www.hprc.org/for-manufacturers/)

Qosina Welcomes New Representative in Germany and Benelux Region

Ronkonkoma, NY, USA, June 20, 2024—Qosina, a global supplier of OEM single-use components to the medical and pharmaceutical industries, is pleased to welcome Thomas Kapke as the new representative for the German and Benelux market.

With an impressive career spanning over three decades in the plastics processing, development and sales of customized technology and medical technology industries, Thomas brings a wealth of experience, dedication and customer-centric expertise to Qosina. A strong advocate of teamwork, Thomas believes in the power of collaboration, including customers as integral team members. He is dedicated to being a reliable partner, ensuring mutual success.

"We're thrilled to welcome Thomas to the Qosina team," said Giampaolo Meana, General Manager at Qosina Europe. "His extensive experience and passion for customer success will be invaluable as we continue to grow and expand our presence in the German and Benelux markets."

Qosina is a one-stop source for single-use bioprocess components, with low minimum orders, a liberal sampling policy and bill of material kitting, all supported by regulatory documentation and backed by Qosina's assurance of supply. For more information about Qosina, please visit www.qosina.com.

About Qosina

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.

QOSINA

1cm

Thousands of Stock Components

Qosina is a leading global supplier of more than 5,000 OEM single-use components to the medical and pharmaceutical industries. We offer free samples, 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 and ISO 14001 certified, and operates in a 95,000 square-foot, climate-controlled facility that includes an ISO Class 8 Clean Room.

Our Extensive Component Inventory

- Applicators, Swabs & Brushes
- Bags
- Caps
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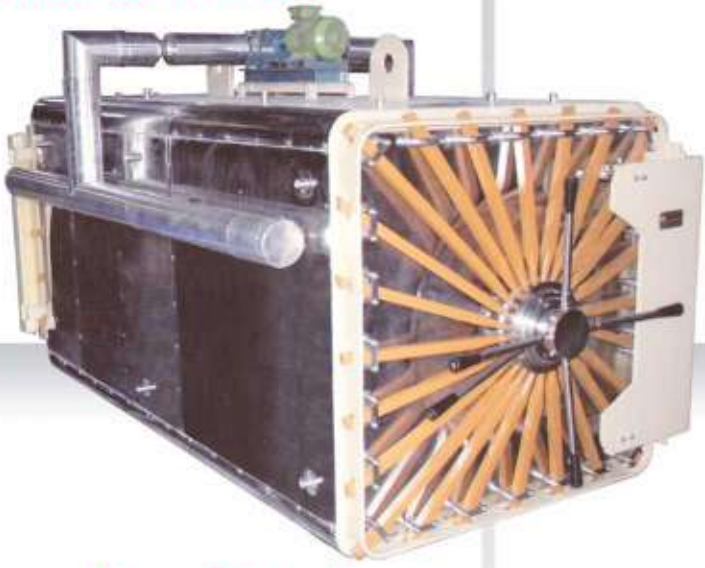

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