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GLOBAL REGULATORY
SOLUTIONS & SERVICES
AN ISO 9001 & 27001 COMPANY

VOL 6 ISSUE 1
2018

# CONNECT

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## LEAD STORY

REGULATORY LABELING:
A GLOBAL PERSPECTIVE

# WHAT'S INSIDE ?

## Regulatory Stories



## Freyr 360°



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# FOREWORD

**Dear Patrons,**

Welcome to Freyr CONNECT Vol 6, Issue 1.

WOW! What a great start, it has been!!! Fueling the season with utmost positivity, Freyr has been in the limelight for being a key market player in the Regulatory arena. Freyr has received prestigious awards from:

Gamechangers 2018

- International Niche Technology Company of the Year
- International Regulatory Solutions Provider of the Year (Pharma & Lifesciences)
- International Gamechanger of the Year – Suren Dheenadayalan

IAE 2018

- Best Pharma Contract Services Company

In addition, Freyr witnessed remarkable growth in terms of its clients that rose to 250+ and the team that crossed the threshold of 550+ Regulatory experts. Indeed, a sign of our swift growth; isn't it!

This edition of Freyr CONNECT commences with a thorough investigation of Labeling regulations worldwide, which are specifically targeted towards protecting patient safety. Progressing further, it offers market and Regulatory analysis of Pharmaceuticals and Medical Devices in the Philippines, the importance of quality assurance in Artwork and Packaging, updates and additions made in TGA's latest eCTD version and FDA's Medical Device Reporting (MDR) and other Regulatory updates.

This edition will also give you an opportunity to go through an exciting amalgamation of fun and business at Freyr.

Thanking everyone who diligently contributed to this chapter of Freyr CONNECT, we hope this edition will enlighten your day.

**HAPPY READING!**

**Suren Dheenandayalan**
CEO

Center of Excellence
**Regulatory Labeling**

# REGULATORY LABELING: A GLOBAL PERSPECTIVE

Have you ever thought that not aligning with labeling best practices can lead to non-compliance and a product recall? If we can consider the classic example of a Delaware-based Pharma company's voluntary recall of its product, we will have to say, 'Yes, not following the labeling best practices will lead to non-compliance'. In 2017, the Delaware-based Pharma company had voluntarily recalled asenapine 10 mg sublingual tablet blister packs because of a labeling error. The packs were labeled for 10 mg tablets but in the actual scenario, they contained 5 mg tablets that made the company to step back on product marketization. As a single mistake could cause misbranding, black mark on the organizational reputation, product recalls, wastage of resources and re-investment to get the things corrected, non-compliance to labeling is something any pharmaceutical marketing authorization holder (MAH) doesn't want to experience with any of their products. It affects not only company's sales, but also consumers trust, which is difficult to gain again.

Hence, pharmaceutical labeling should be treated as a responsibility than a mere Regulatory mandate. As label is the only document available to know more about the safety of a medicinal product either by healthcare professionals or by patients, preparing it in accordance with various health authority regulations may sometimes prove challenging for MAH. It is quite difficult for an MAH to have an eye on what is happening around the globe for Regulatory updates in labeling and missing them may end up in non-compliance. Let us look into various mandatory scenarios and their transition provisions for labeling across the globe.

## Australia - TGA mandate on Product Information (PI)

The major labeling update of the season is Australia's intention to realign their labeling standards on par with global regulations. To ensure that the critical clinical information is more accessible within the document, the Therapeutic Goods Administration (TGA) of Australia changed the format of the Product information (PI) document. In addition, the new format has been developed to align with the formatting requirements of other international regulators, specifically the New Zealand medicines regulator Medsafe, and the European Medicines Agency;





the European Summary of Product Characteristics (SmPC) and New Zealand Datasheet although have some key differences in the presentation of information for the Australian PI, for example, in sections 4.8 Adverse Effects and 6.7 Physicochemical Properties. The use of electronic bookmarks is strongly encouraged to facilitate navigation through the document. Important information is also provided for the required clean and annotated versions of the PI which must be submitted to support an application to revise content and reformat the PI.

### Transition provisions

The new PI format should be implemented with a 3-year transition period (i.e. December 2020) for all products that are currently marketed in Australia.

- All PIs accompanying Category 1 applications must be provided in the new format if they are submitted after January 01, 2018.
- Reformatted PIs should be submitted with any other application type related to that medicine, including minor variations, safety related requests, and applications to update medicine ingredient names.

## MHRA – Safety Features Legislation

The European Parliament and Council has approved and published a Delegated Regulation (EU2016/161) in the Official Journal of the European Union. This supplements the Falsified Medicines Directive (FMD) and introduces two mandatory safety features that will allow medicines to be verified and authenticated.

The safety features are:

- a unique identifier (a 2D data matrix code and human-readable information) which will be placed on medical products that can be scanned at fixed points all along the supply chain. The unique identifier comprises:
  - » a product code which allows the identification of at least the name of the medicine, the common name, the pharmaceutical form, the strength, the pack size, and the pack type
  - » a serial number which is a randomly generated numeric / alphanumeric sequence with a limit of 20 characters
  - » a batch number
  - » an expiry date
- tamper evident features on the pack

### Transition Provisions

The delegated regulation comes into force in 2019 in the UK. MAHs will be required to place the safety features on the packaging of medicines which fall within the delegated regulation no later than February 09, 2019.

## Vietnam- New Regulations on Pharmaceutical Product Labeling

On January 18, 2018, the Ministry of Health (MoH) of Vietnam issued Circular No. 01/2018/TT-BYT (Circular 01) on the labeling of pharmaceuticals which is tending to replace the current labeling regulation, (Circular No. 06/2016/TT-BYT).

As per this guidance the Package Insert (PI) must contain only one section which has general information for both healthcare professionals and patients, unlike the previous regulation of two separate sections one each for patients and healthcare professionals.

### Transition provisions:

1. Drugs which are granted registration numbers before June 01, 2018, may be sold with MoH-approved labels and PIs until the expiry date of the Marketing Authorization (MA) license.
2. In case of drugs for which the MA/import license dossiers were submitted to the agency before June 1, 2018, and are awaiting agency's approval, the following would apply:
   - » The applicant may submit updated labels and updated PIs for the drugs in accordance with the new circular; or
   - » If no updated documents are submitted to the agency, the applicant's label and PI may be considered by the agency under current regulations. However, within six months from the date on which an MA license is issued, the MA holder must submit updated labels and PI in the form of a variation registration to comply with Circular 01.

The Vietnamese new labeling circular is effective from June 01, 2018.

### Canada - Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products

The Plain Language Labeling (PLL) regulations impose new obligations on sponsors of non-prescription drugs, including the requirement to include a Canadian Drug Facts Table (CDFT) on the outer labels of products.

**Drug Facts**

**Active ingredient (in each 5 mL)** — **Purpose**
Guaifenesin 100mg.....Cough expectorant

**Uses** • relief of wet cough or chest congestion due to common colds • helps loosen phlegm or mucus and thin lung secretions

**Warnings**
**Do not use** with other cough and cold medications unless recommended by a doctor or pharmacist

**Ask a doctor or pharmacist before use if you have**
• trouble breathing • a persistent cough that has not gone away • asthma or other chronic lung conditions • are pregnant or breastfeeding

**Stop use and ask a doctor if** • symptoms get worse or last for more than 1-week • you have a high fever (>38°C) or headache that does not go away • you cough up thick yellow or green mucus • you develop a rash

**Keep out of the reach of children.** In case of an overdose, call a poison control centre or get medical help immediately

**Directions** • adults and children 12 years of age and older: take 10-20 mL every 6 hours • do not take more than 80mL in 24 hours

**Other information** Store at room temperature (15-30° C).

**Inactive ingredients** All inactive ingredients are listed here

**Questions?** Call 1-8xx-xxx-xxxx

### Transition Provisions

For all non-prescription drugs, any new Drug Identification Number (DIN) applications or (Supplemental) New Drug Submissions submitted on and after June 13, 2017 are required to be in compliance with the PLL Regulatory requirement which includes the existence of the CDFT on the product labels. This applies to new products, or already-marketed products.

All non-prescription drug products must be in full compliance at the retail level by June 30, 2021. Marketed products coming into compliance are not required to file a submission solely for the purpose of complying with PLL, provided there are no substantive label text changes and that labels follow the standard CDFT format.

### USA – FDA's draft guidance on Generic Drug Labeling Rule

The current FDA regulations specify that Abbreviated New Drug Application (ANDA) holders must match their label with the Reference Listed Drug (RLD) label, thus restricting the ANDA holders to update their label independently. Recent draft guidelines released by FDA encourage the ANDA holders to update their labels independently with no or minimal dependency on the RLD.

Nevertheless, ANDA holders must have strong supportive data if they want to update their label and they will have to file a supplement to notify the Agency about the labeling change. This may trigger the RLD or any other ANDA holders to update their labels. Thus, the rule clearly emphasizes the product safety responsibility is with both NDA and ANDA holders, which is not the case currently.

### Transition Provisions

The NDA and ANDA holders should note that this is based on the draft prepared by FDA and is yet to be finalized by the agency.

To conclude, health authorities (HAs) worldwide, in a view to protect patient's safety, are rapidly bringing in more amendments to existing labeling rules and/or entirely reinventing the Regulatory landscape for their region's medicinal product labeling. To be in compliance, Pharmaceutical companies and MAHs must keep abreast with the current regional labeling best practices and adhere them for timely compliance and products' market entry. Freyr's labeling experts along with the Freyr Label navigate MAHs to incorporate safety, quality or administrative changes as the opportunity arises for successful submission to HAs under the appropriate submission category. Freyr offers end-to-end labeling services and software solutions for global and regional labeling management. Our team of highly qualified medical/ scientific experts create evidence-based core safety information (CSI) and core clinical overviews (CO), prepare labels in compliance with local Regulatory requirements for HA submissions, review and suggest changes, track the status of safety data implementation across the globe.

Stay informed to be compliant.





Center of Excellence
**Publishing & Submissions**

# TGA MANDATES eCTD V3.1 MODULE 1 SPECIFICATION:

## DECODE THE DEADLINE AND SECTION-WISE UPDATES

Are you currently planning an eCTD (electronic common technical documents) submission to Australia? If you intend to, take a pause to look at these changes. Therapeutic Goods Administration (TGA) of Australia has rolled out a new mandate to use latest version 3.1 Module 1 Specification for Regulatory submissions post June 30, 2018.

TGA has initiated accepting submissions adhering to version 3.1 from the day it has come to effect i.e., January 01, 2018. And at the same time the agency has also provided transition time to align with the new version. Submissions made basing on both versions (3.0 & 3.1) will be accepted until the deadline which is on June 30, 2018, after which it will be deemed a mandate to adhere to the new version (3.1).

As the deadline to use version 3.0 Module 1 Specification is completed, moving forward, any submission which will be submitted to the agency need to be in version 3.1, with all the changes mentioned by Regulatory Authority. In this latest version, TGA has incorporated changes to existing XML directory structure and content files and made some additions which make it more accessible for reviewing and recollecting data.

### What's in the Updated Version?

The update includes specific sections marked as "updated" and "newly added" to clearly outline the difference. As per the Agency's guidance section-wise updates include:

### New sections include

- 1.3.1.3 Product information - approved
- 1.3.2.3 Consumer medicine information

### Updated sections

- 1.3.1.4 Package insert
- 1.3.3.1 Label mock-ups and specimens – clean
- 1.3.3.2 Label mock-ups and specimens – annotated
- 1.3.3.3 Label mock-ups and specimens – approved

### New sequence types

- Notification
- CN
- Extension of provisional registration
- Duplicate: Requirement inclusion for potential work sharing options
- Provisional registration – TGA initiated variation: Support MMDR recommendation implementation updated sequence types
- Product withdrawal

### Advantages of updated version

The updated version allows implementation of Medicine and Medical Device Review (MMDR)'s recommendations; including the priority, provisions and notification pathways. Further, the update also allows requesting for multiple changes in eCTD dossier. Providing greater user clarity, it also enhances the dossier quality.

The detailed nature of changes/additions must be interpreted from a Regulatory perspective which will need expertise in understanding the submissions in eCTD format. With minimal time left for transition, it is important to achieve compliance in line with the latest version

Freyr's eCTD submission solutions:

- Easy migration from paper/NeeS to eCTD
- Templates for eCTD documents
- Latest Module 1 Specification for TGA
- Migrating from older Module 1 specification to Latest Module 1 specification
- Dedicated team for gap analysis
- Quick turnaround of eCTD dossier
- Well experienced eCTD publishers for global Regulatory requirements.

Keeping abreast with global agency updates, Freyr upgrades Freyr SUBMIT – an eCTD publishing and submission tool – to suit the immediate client requirements. Considering the TGA eCTD V3.1 update,

Freyr SUBMIT is already upgraded with version 3.1 Module 1 Specification template and successfully dispatched to the existing clients to support their submissions to TGA.

**Be compliant with Zero RTRs. Integrate Freyr SUBMIT.**

Center of Excellence
**Regulatory Strategy**

# 3 THINGS TO KNOW ABOUT THE MEDICAL DEVICE MARKET IN PHILIPPINES

According to Market Research Reports, the global medical devices market is expected to reach almost $300 billion in international trade value by 2020. Advances in technology, rising healthcare expenditure, and an aging population are cited as the driving factors for the market's steady growth over the coming years. The Philippines medical device market is also expected to grow on the back of growing population, growing annual per capita income, increased spending on medical care, and growing investments in healthcare facilities.

As for emerging markets, the Philippines is considered as a lucrative market for the USA suppliers when it comes to medical equipment. With local production limited to disposables, spare parts, and prototype units, medical devices in the country are almost 100 percent imported.

If you are currently considering importation prospects or markets to access for international expansion, read on for the 3 things to know about the Philippines' medical equipment sector.

## 01 | Best Sales Prospects

According to investphilippines.org Philippines medical device market scale in 2011 was approx. US$400 Million. In 2011, diagnostic imaging products were the main items, with 35.8% market share, followed by medical devices with 21.9%, other medical devices 21.5%, auxiliary devices, dental products, and orthopedic implants accounted for 9.1%, 8.6%, and 3.2% respectively.

Ultrasound or ultrasonic scanning machines, magnetic resonance imaging (MRI) equipment, linear accelerators, and other high-tech products offer the best sales potential for suppliers. In order for Philippine hospitals (government and private) to deliver efficient healthcare services, they must keep up with new technologies and replace old equipment. High-value, low-volume products are at the top of the list of supplies that need to be upgraded for facilities to remain competitive.

This increased demand for high-tech products also ties in with the plans of the Philippines' Department of Health (DOH) for building cancer centers nationwide. A total of around PHP 9.18 billion has been allocated by the Department of Budget and Management (DBM) for upgrading equipment for cancer diagnosis and treatment in DOH hospitals and cancer centers across the country.

## 02 | Market Leaders

USA, Germany, Japan, China, and Singapore are the top countries exporting medical devices to the Philippines. The medical device market in the Philippines is dominated by the USA in particular, mostly due to buyer preference (i.e. US-trained Filipino doctors). Prominent brands include GE Medical, Medtronic, Terumo, BD Medical, 3M, Fresenius Kabi to mention a few.

Germany and Japan both enjoy 13 percent of the market, while Singapore has an 11 percent market share. Aside from offering high-quality products, suppliers are advised to offer good after-sales, flexible payment terms, and warranty services. Suppliers should also keep in mind that they need to appoint a market authorization holder if they want to sell medical devices in the Philippines.

## 03 | Market Access

The Philippines imposes tariff duty (approx. 1-3 percent) and value added tax (12 percent) on imported medical devices. Sellers can opt to pass on VAT to supply chain to recoup some of the costs.

According to the FDA, only two documents are required from a company that wishes to import medical devices to the country. The first is an LTO or license to operate, and the second is the CPR or certificate of product registration.

Again, foreign suppliers need to appoint a market authorization holder to enter the medical device market in the Philippines. Market authorization holder will represent their interests in the country and usually handle all aspects of importation, as well as license approval.

The best supply chain for your medical devices, medical consumables, equipment and in-vitro diagnostics are private and government owned hospitals, outpatient clinics and diagnostic centers. As of 2016 there were 790 DOH licensed hospitals in the Philippines, major hospitals include St. Lukes Medical Center, The Medical City, Asian Hospital and Makati Medical Center. Chain outpatient clinic is also a good option to place your medical device innovation. Major players include The Medical City Satellite clinics, Healthway Medical Clinic, Family Doc, My Health Clinic, AC Health and Delos Santos Mega Clinic.

In-vitro diagnostics such as rapid test kit has a great opportunity in diagnostic centers. As of 2016 there are 620 DOH registered diagnostic clinics in the Philippines.

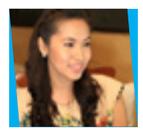
Need Advice on Accessing The Philippines' Medical Device Market?

We can help. From license approval to market launch, we can custom fit our services based on your needs. Our end-to-end solutions cover everything from importation to marketing of your healthcare products in the Philippines.

Be informed. Be compliant.

Get in touch with us at sales@freyrsolutions.com for more information.

Authored by



**Cristine Fernandez**

Center of Excellence
Regulatory Strategy

# COSMETICS MARKET TRENDS IN BRAZIL


After a cycle of economic growth of approximately two decades, by 2015 the Brazilian beauty market had reached 3rd position globally for consumer cosmetics. Since then, Brazil has gone through a serious economic recession, prolonged by rampant corruption scandals in the political scenario and by the increase in taxation over several sectors of the economy – including cosmetics. Today, Brazil is still the fourth largest market for cosmetics, behind the United States, China and Japan – and all projections point to an 8% growth during 2018.

Despite economic stagnation during the last 3 years, Brazil still demonstrates to have a dynamic economy. Almost all Brazilians in urban areas invest in beauty products to improve their self-esteem with relatively little investment. Women's products have long been leading this market's growth, but now exclusive men's products are scaling-up on market share; numbers reflect a paradigm shift in the personal and beauty care habits of the Brazilian men.

This new trend for men care can be clearly identified on the streets of large Brazilian cities where barber shops and segmented cosmetic shops pop up every day to meet this increasingly demanding consumer need. This category is expected to continue growing double-digits until 2020.

In addition to the men's products, there is a high demand for natural and organic cosmetics, offering a great opportunity for brands who would like to explore this country. The idea that "what you put on your skin should be good enough to be eaten" is provoking the local natural cosmetic formulations to achieve a whole new safety level. Customers also demand transparency in labeling and claims to natural and organic ingredients. These claims, however, are no longer acceptable if the list of ingredients shows otherwise.

If all projections stand until the end of the year, the Brazilian beauty market is sure to return to its glorious days. Those who understand these new trends and are willing to adjust to the Brazilian legal, Regulatory and taxation systems are guaranteed to achieve great results.

Authored by

**Felipe Guanaes**

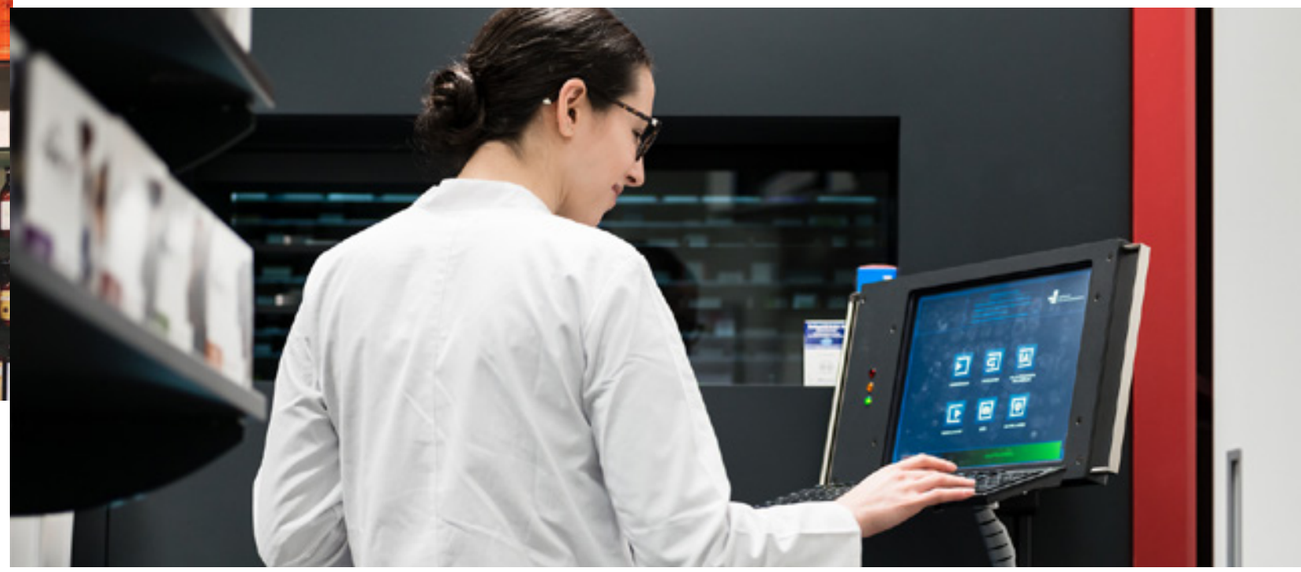




Center of Excellence
Regulatory Medical Writing

# SETTING UP A PHARMACOVIGILANCE SYSTEM

Dharmapal Sharoff, Manager, Regulatory Operations, Freyr, shares his opinion on why it is important to set up a PV System.



Pharmacovigilance is a complex process for which robust systems are essential. A strong PV system is an important part of the overall medicinal product Regulatory system. It reflects on the stringency and competence of the Regulatory bodies in regulating the market and ensuring the safety and effectiveness of the medicinal product.

Pharmacovigilance (PV) is principally concerned with the identification of Adverse Drug Reactions (ADRs) and reduction of the associated risks. Detection and reporting of ADRs can make prescription of medicinal products much safer and more effective. This is possible only if pharmaceutical companies and patients report the ADRs as and when they occur.

Before a medicinal product is marketed, its safety and efficacy exposure is limited to its use in clinical trials. Generally, clinical trials cover a limited number of patients with strict inclusion criteria, often excluding special patient groups like those with co-morbid conditions, children, elderly and pregnant women. Hence, they do not reflect the experience in bigger population and in different geographical regions. People from different geographical regions differ from one another with respect to genetics, food habits, lifestyle, clinical practices, etc. This makes it obligatory to maintain a constant vigil on the use of medicinal products during the post-marketing period.

PV is a major post-marketing tool to ensure the safety of medicinal products apart from the respective drug regulating authorities in each country, International Conference on Harmonization (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use, Pharmacovigilance.

Planning-ICH E2E and World Health Organization-Uppsala Monitoring Centre (WHO-UMC) also play key roles towards developing, enhancing and monitoring global PV system. A PV system is defined as a system used by an organization to fulfill its legal tasks and responsibilities in relation to PV that

monitors authorised medicinal products' safety and detects any change in risk-benefit balance.

After the thalidomide disaster in the year 1961, WHO worked along with its Collaborating Centre to establish a programme for International Drug Monitoring. Through this programme, WHO promoted PV at the country level. At the end of 2010, 134 countries were part of the WHO-PV Programme.

### The goals of PV are to:

- Augment patient care and patient safety with respect to the use of medicinal products
- Run public health programmes by providing reliable information for the effective assessment of the risk-benefit profile of medicinal products.

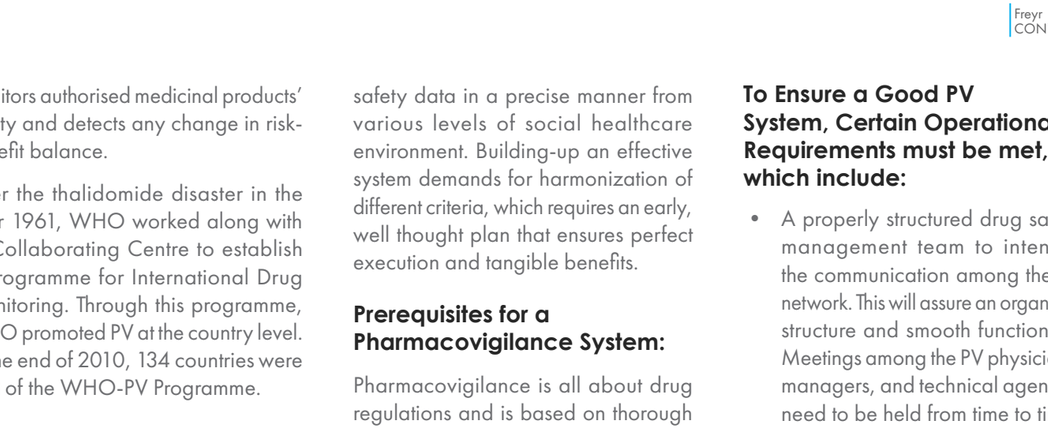
A well-structured PV system can establish safety data in a precise manner from various levels of social healthcare environment. Building-up an effective system demands for harmonization of different criteria, which requires an early, well thought plan that ensures perfect execution and tangible benefits.

### Prerequisites for a Pharmacovigilance System:

Pharmacovigilance is all about drug regulations and is based on thorough collaborative ties, coordination, communications, and public relations. The most suitable location for setting up a PV center is dictated by the political governance and its healthcare priorities, including willingness to do, law enactment, its enforcement, funding, organization, staffing, training, and development.

### To Ensure a Good PV System, Certain Operational Requirements must be met, which include:

- A properly structured drug safety management team to intensify the communication among the PV network. This will assure an organised structure and smooth functioning. Meetings among the PV physicians, managers, and technical agencies need to be held from time to time
- A countrywide database which provides provision for collating and managing ADR reports
- A national PV advisory committee
- A clear approach, to be communicated in detail, in regular situations as well as situations of crisis
- Funding to run on different grounds of a system




### Basic Steps in Setting up a PV System Include:

Developing guidelines and communications with the health authorities, a general guideline is a standard strategy to confirm that the PV system at all levels meets the national and international standards and regulations. Getting into regular communications with the health authorities, local, regional and national bodies, and professionals involved in clinical medicine, pharmacology, toxicology, epidemiology, briefing them about the importance of the project and its applicability in modern therapeutics.

- Should have adequate qualified and experienced man power to run the system - PV staff should have complete knowledge regarding data collection and verification, coding of drugs and adverse events, causality assessment, signal detection, risk management, interpreting the data obtained etc.
- Setting up of PV centers - Creating a database which is safely stored, retrievable and guarded by required degrees of confidentiality. Some of the basic technological requirements to be met by the PV center are uninterrupted electric supply and ensuring that the intercom, multi connection telephone, computer, printer, fax, internet, photocopiers are in working condition. The PV center should have adequate back up facilities so that the work is not hampered during breakdowns; anticipated or sudden.
- Continuous monitoring and improving the PV system performance - the capacity building processes include the management of the medicinal products, the system and the individual in the network, and effective monitoring of medicinal products from a safety perspective. The aim of capacity building is to create a robust system without creating changes in social structures, resources, technologies and personalities.
- Data acquisition through ADR reporting form - preparing an ADR reporting template and to make it readily available, in different hospital settings and general practitioners, based on which they can provide relevant information to the PV center.
- Creating public awareness for ADR reporting – conducting workshops and meetings in the different healthcare institutions, academic institutions, promotional events to educate patients and healthcare professionals on the importance of reporting ADR through medical journals, professional publications, and seminars, and developing printed handouts. All these are done to notify healthcare professionals and public about the definitions, goals, scope, and methodology of the PV system to create awareness about its present relevance.
- Detecting signals on the reported adverse drug events - based on the case reports, the PV center should be able to detect a signal with regards to probable ADR
- Be associated with health authorities, pharmaceutical companies, other professional associations /organizations and WHO and its collaborating bodies so that information on observed adverse reactions is shared / notified time to time which may include cases with particular interest; and take proper preventive measures whenever those are necessary.

### Funding

The PV system needs to deal with large population and the rate of reporting governs the estimation of the money needed to run the complete system. Huge investment is required in terms of collection of data from the actual source to transforming it into a Regulatory reportable format. Funding can be obtained from various parties, such as drug Regulatory authority, university departments, health insurance companies, and professional associations.

### Conclusion

PV is a complex process for which robust systems are essential. A strong PV system is an important part of the overall medicinal product Regulatory system. It reflects on the stringency and competence of the Regulatory bodies in regulating the market and ensuring the safety and effectiveness of the medicinal product. The foundation for building a robust PV system demands skilled manpower, support from healthcare professionals and pharmaceutical companies, safety awareness among the patients, information technology, and funding. The system needs to be refined with the help of PV experts in collaboration with technology. Establishing a robust PV system is a tough job; however, with thorough preparation, a practical approach, continuing zeal and motivation of the concerned staff, it can be achieved. PV ensures that future generations will not condemn the present one for its apathy, indifference, and callousness to the gravity of the situation. Without PV, modern medicine will be continued to be called as allopathy.

This article was first published by
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# STEP AHEAD FOR COMPLIANCE

## ADDRESS THE EUROPEAN POST APPROVAL CHANGES

With End-to-End LCM Support

### SAFETY REPORTS

- PBRER Preparation and Submission
- DSUR Preparation and Submission
- RMP Preparation and Submission
- Literature Monitoring
- Expertise for ICSR, Aggregate Reports, Signal Detection, QPPV
- Local Affiliation
- Response to HA Queries

### CMC DOCUMENTATION

- Change Control Evaluation
- Variation Submission Strategy Preparation
- Document Gap Analysis
- Preparation Review and Submission of Variations (Type IA, Type IAIN, Type IB, Type II and Extension Applications)
- Tracking, preparation, review and submission of MAA Renewal
- Response to HA queries

### LABELING

- CCDS/CSI/RSI Update
- EU PI (SPC, PIL & LT) Update for Referrals/Safety Article update; Variations, Renewals, QRD Changes etc. for all EU Procedures (CP, MRP/D-CP/NP)
- EU Linguistic Review Coordination and Translations for Centrally Authorized Medical Products
- PRAC/PBRER Recommendation Based PI Update
- Harmonization of PI
- Assessment of EPARS and Updating PIs
- Response to HA Queries





Center of Excellence
**Global Medical Device**
**Regulatory Services**

Freyr **What Is...?**

# WHAT IS MEDICAL DEVICE REPORTING (MDR)?

Medical Device Reporting (MDR) is one of the post-market surveillance tools that the Food and Drug Administration (FDA) uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of devices. The core purpose or the goal of MDR is to detect and address device related adverse-events in a timely manner. It enables physicians, healthcare setups, manufacturers and consumers for voluntary reporting to understand the device's post-market efficacy.

## Which Region Does It Apply In?

It is applicable to all classes of medical devices, which are either manufactured in the United States of America (USA) or imported to the USA. Medical Device manufacturers who are willing to market their devices in the USA must comply with MDR, otherwise it may lead to financial penalties. MDR is applicable in the USA including a foreign event, i.e. it is applicable to legally marketed medical devices in the United States both manufactured in the USA and foreign countries as well. Additionally, there are various cases of applicability for an MDR, such as:

- if a device is manufactured in the USA, distributed locally and to other markets
- when a device is manufactured in the USA but distributed in other markets
- when a device is manufactured in the foreign country, supplied in the USA and other markets
- when a device is manufactured in the foreign country and distributed locally and
- when a device is under investigation in the USA

## MDR Types and Timelines

There are two types of MDR: one is manual and the other is electronic (eMDR), among which the latter is preferred to be the mode of reporting in the current scenario. The FDA mandated electronic MDR (eMDR) in 2015 to identify critical issues of data quality and integrity associated with

reporting serious injuries related to all classes of medical devices.

Manufacturers can submit their eMDR through an Electronic Submissions Gateway (ESG). From the time of submission, the electronic gateway takes up to 48 hours to send an acknowledgment. If there is any error while submitting report a message will show up for making the correction(s).

### eMDR – How Is It Beneficial?

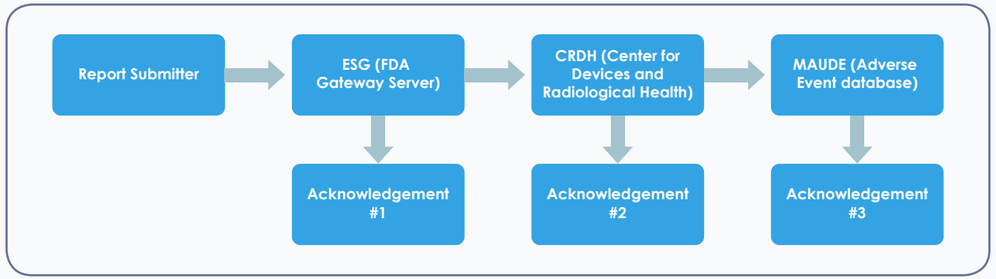
eMDR offers multiple advantages over manual reporting mechanism (i.e., MDR). Mentioned below are a few notable benefits that manufacturers / agency / patients can bank on:

- eMDR submission tool enhances better collaboration between an organization, the health agency (FDA), and patients.
- eMDR saves costs. Automation reduces the need for administrative overhead and traditional communication; it helps to speed up the process and fosters effective event reporting, resulting in immediate interaction with the FDA.
- Manual processes require a lot of paperwork and may take a long time to track and process. With eMDR submission, everything is automated and centralized. Thus, previous records can be retrieved with one click saving a lot of time while reviewing.
- eMDR enables parties to flag submission errors quickly, as opposed to manual and time-consuming correspondences with the FDA.
- eMDR acts as a single point of entry to process all electronic submissions in a highly secured environment and it is beneficial because complaints at the organization can be linked directly to the MedWatch form and integrated within the FDA's gateway.

### eMDR and The Reporting Process Flow

The eMDR regulation contains many mandatory requirements for manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA. The process flowchart details the reporting process step-by-step.

The reporting process comprises of four steps. Beginning with the second step, each step has an acknowledgment. Further, each step is provided with additional information that will help ease the process.




### Step 1

Submitting an eMDR. At the outset, to make a submission, one should have an electronic signature and should ensure submission filenames include only one period, which is used to indicate the file type extension (for example *555*.xml or *555*.pdf). However, the application delivery and processing time depend on the overall size of your submission; larger submissions take longer time to get delivered and processed.

### Step 2

When your submission reaches the ESG, you should quickly receive an acknowledgment #1 unless the ESG is down for maintenance. You are required to check the status of your MDR on the ESG web site.

### Step 3

eMDR is automatically routed from the ESG to the Center for Devices and Radiological Health (CDRH). Once it is routed, like in step 2, you should receive an acknowledgment, i.e., #2.

### Step 4

When the CDRH validates and updates the submission in the Adverse Event database (MAUDE), it is expected the submitter should receive an acknowledgment #3. It is to be noted that any errors that occur during the validation and loading are recorded.

Center of Excellence
**Regulatory Strategy**

# 4 QUICK FACTS ABOUT THE PHARMACEUTICAL MARKET IN PHILIPPINES

The Philippines' pharmaceutical market offers plenty of business opportunities for both local and foreign companies. Learn more about the country's pharma market here.

Consulting firm Global Data projects the growth of the Philippines pharmaceutical market to be around USD 4 billion by 2020. Factors that will drive the market's growth include strong patent and trademark laws, as well as the government's support of generic alternatives in both the public and private sectors.

In terms of investment opportunities, GlobalData believes the pharmaceutical market in the Philippines is ripe for the picking. Aside from the country's open economic system, it also supports a BOT or build-operate-transfer investment scheme, which allows private companies to recoup their initial investment in a reasonable amount of time.

Here are four more things to know about the pharmaceutical market in the Philippines if you are currently considering the country for investment opportunities.

## 01 | Generics Dominate the Market

The Department of Health (DOH) secretary confirmed that generics enjoy 65 percent of the total pharmaceutical market when it comes to volume sales. This is mostly due to the passing of the Cheaper Medicines Act of 2008, as well as the efforts of the current administration to promote generics use.

Local and foreign manufacturers, both have taken advantage of this fact, with the latter accounting for more than 75 percent of the Philippines' pharmaceutical market. Big players include GSK (GlaxoSmithKline), Sanofi, and Pfizer, while the largest domestic drug companies are Natrapharm, United Laboratories, Pascual Laboratories, and GC International.





## 02 | High Demand for Medicinal & Pharmaceutical Products

Population growth, increased family expenditures for drugs, and rapid increase in hospitals are some of the factors driving the demand for medicinal and pharmaceutical products in the Philippines, according to investphilippines.gov.ph.

Other market opportunities include the expiration of patents, which will open the market to generic versions of patented drugs, as well as the increase in the number of medical doctors. The latter in particular will contribute to the sales of prescription drugs, which account for 70 percent of total sales compared to OTC or over-the-counter medications.

## 03 | Business Requirements

Only a select number of foreign pharmaceutical companies do their own manufacturing in the country. Mostly they import and distribute products and outsource production to local manufacturers.

Both local and foreign manufacturers should meet GMP (Good Manufacturing Practice) standards, aside from completing requirements including but not limited to: Legal entity registration, Business permits from local Municipality, Income tax registration, Import license, Market authorization as Importer and or Distributor, Registration to Department of Labor and Employment and Product license approval prior to marketing and sale of pharmaceuticals.

Foreign manufacturers may opt to establish business partnerships with local Market authorization holder to import, distribute and obtain product license approval on their behalf to save time and operational cost for foreign manufacturers.

## 04 | Philippine Pharmaceutical Regulations

Certain commodities including pharmaceuticals are regulated or prohibited in the Philippines. The main Regulatory body for pharmaceutical regulations in the country is the FDA or Food and Drug Administration.

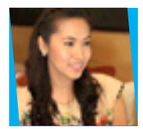
The FDA as the Regulatory authority of the Philippines responsible for implementation and enforcement of all regulations pertaining to pharmaceuticals, medical devices, cosmetics, food, household hazardous substances, and diagnostic reagents. Operation of manufacturers, importers, exports, distributors, wholesalers, and other facilities related to health products are also under the jurisdiction of the FDA.

The Food and Drug Administration requires all foreign manufacturers be subject for site inspection of their respective manufacturing facility prior to product license approval. If they pass the inspection a cGMP clearance certificate shall be issued and apply for new application of certificate of pharmaceutical product.

Phamaceutical dossier submission must be in Asean Common Technical Document format which includes administrative data & product information, quality document-study reports, nonclinical document and summary of clinical study.

For product labeling of pharmaceutical including herbal medicine, FDA strictly implements generic labeling guidelines for human use as the labeling materials are the primary source of information for consumers. Noncompliance shall be ground for appropriate administrative charges and imposition but not limited to fines, suspension, cancellation or revocation of any license, permit or registration issued by FDA.

Authored by



**Cristine Fernandez**

Center of Excellence
**Global Cosmetics Regulatory Services**

# RINSING OFF RESPONSIBILITIES?

What is the current legal situation concerning microbeads? Find out from Priyanka Malik, Solutioning Lead, Cosmetics - EU, Freyr.

One of the most noteworthy introductions into the cosmetics and body care industries was that of microbeads. The term microbeads refers to the microplastic ingredients used in cosmetics such as Polyethylene terephthalate, Polytetrafluoroethylene, Polymethyl methacrylate and Nylon. These tiny plastic pieces, with dimensions of less than one millimetre, have the ability to deep-cleanse the skin. They help remove dead cells, whiteheads and blackheads and clean pores at a micro level, thus giving the skin a smooth and feel-soft texture.

## How It All Began?

Patented in 1970s, microbeads became highly commercialized in the 1990s and 2000s and were a hit with consumers; slowly but surely more and more products started including them in their formulations, so that the usage of these ingredients increased tremendously. Consumers all over the world became used to products that contained microbeads and unknowingly let them drain into the general world water system. Because of their miniscule size, it is impossible for water treatment plants to filter them out. This leads to pollution in both fresh and marine waters, which then threatens aquatic life and causes deterioration of the marine environment.

While no European Union-wide action has yet been proposed, various country-specific regulations have been proposed, and some have already taken effect. Currently, the proposed ban applies only to rinse-off products, while make-up products and sunscreens are excluded from the list. The movement has experienced a surge, with 91 NGOs from all over the world partnering in a 'Beat the Microbead' campaign to support the cause. The 'Beat the Microbead Campaign' aims at banning these tiny plastic substances from products of daily use because of the detrimental effects they cause to the environment.

## The UK was the first European country to ban microbeads

The United Kingdom (UK) became the first European country to ban microbeads in personal care products. The government has pledged to ban manufacturing of all cosmetics and personal care products containing microbeads as of September 2016. The ban came into full effect on January 10, 2018. It prohibits all manufacturing companies in the UK from including microbeads in their formulations. However, selling these products is allowed until July 2018. The French government published a decree '2017-291' on March 06, 2017, aiming to impose a ban on the use of microbeads in rinse-off exfoliating and cleansing cosmetics as of January 01, 2018. Sweden announced a ban on the sale of cosmetics containing microplastics at the United Nations Ocean Conference at the beginning of June 2017. The ban will come into effect in 2020. Countries such as Finland, Iceland, Ireland, Luxembourg and Norway have also joined the initiative.

## Campaign shifts responsibility to companies

To achieve a fully comprehensive ban, the campaign Beat the Microbead has shifted the responsibility to the companies by asking producers to include a statement that their cosmetics are completely free of microplastic ingredients. Companies that make this statement publicly are allowed to use the **Look for the Zero** logo. Such a statement might look like the following: "We as a producer declare that all of our products of brand [...] are 100% microplastic free". While many still debate whether the ban should be extended to other products, it is safe to say that the movement for environmentally friendly products is on the rise.

Given the bans that have been imposed, are the personal care product manufacturers living up to their own responsibilities? Will they be able to label their products with the **Look for the Zero** logo? Let's hope that we won't rinse off our responsibilities; let's just be compliant.

**This article was first published by**
COSSMA
www.cossma.org

**References**

Look for the Zero - http://www.beatthemicrobead.org/look-for-the-zero/

Center of Excellence
**Artwork Pack Management**

# ARTWORK, PACKAGING AND THE NEED FOR QUALITY CONTROL AND ASSURANCE

Each aspect of the Life Sciences industry is very important as they deal with many safety aspects once the product reaches the market. As the industry goes through multiple stages of research, clinical trials, and product development, until the product is approved, each step is crucial to maintain, validate and attain quality, and to ensure safety of the end user. Enroute, artwork and packaging function plays a significant role as it represents the end product in the minds of consumers with mandated safety information, which should possess high-quality standards and must be intelligible. Thus, there should be no scope for error. Quality in artwork is crucial to retain the brand value, assure safety/trust to end users, to reduce product recalls, for quick market-access, for structured reporting, and to be cost-effective. Major drawbacks that impact quality in artwork include:

- Improper tool/workflow used during review/approval process
- Lack of compliance to changes
- Frequent Regulatory and manufacturing updates
- Knowledge gaps which can be due to improper training or employees not being competent enough
- Lack of process centralization
- Multiple contributors
- Expecting approvals with fast TAT
- Lack of version control of procedures
- Roles and responsibilities not clearly defined
- Lack of understanding of the customer's expectation or instructions
- Noisy environment
- Unclear annotations

How can we validate the quality? A streamlined system is required to control, monitor and validate any activity involved in the process to make sure the quality is maintained.

### Industry Standards and Best Practices to attain quality

- Identify risk in current quality process
  - » Identify repetitive errors
  - » Categorize current errors
  - » Identify count/percentage of each type of error in type of component/artwork/region/market
  - » Assess knowledge of the quality lead
  - » Test team member's knowledge
  - » Test consistency of work amongst different team members
  - » Identify the measuring method, process and quality audits
- **Industry Benchmarking**
  - » Compare the practices, ways of working and the observations within the company and team/department - Six Sigma methodology called Measurement System Analysis (MSA) is performed by two or more team members by doing random sampling and the observations are compared to that of a senior quality lead. This methodology helps to analyze the knowledge gaps amongst team and training can be scheduled to resolve those gaps. This helps to understand the exact status and can be performed on a periodic basis to check the progress
  - » Compare the company's practices with other companies/regions who deliver high quality artworks and try to implement the same in your organization
- **Recruitment Process**
  - » Stringent methodology needs to be followed to bring in the right talent - Test packs which cover all the critical /Regulatory requirements need to be conducted for every individual for different type of components
  - » Color blindness test need to be performed
  - » Eye for detail test packs are to be cleared before recruiting the right candidate
  - » All the resources once recruited need to undergo training in well-designed artwork program to expect optimal performance. Sample artwork tests of different components are given to every member on a daily basis. Feedback and evaluation is done on a daily basis throughout the training period. Similarly, market/site/region-specific guidelines along with checklists are to be trained and tested before onboarding and performing any live task. A peer reviewer performs second level QC of every task until the second level QC identifies no observations
  - » Team leads should facilitate and participate/liaise in artwork brief meetings and for any updates/clarifications with related stakeholders to understand expectations
- Documentation: SOPs, Work Instructions, updated training documents, Region/site/market specific checklists, workflows, flowcharts, supporting artifacts etc. must be followed by a QC every time
- Technical and compliance QC components are constantly updated based on ongoing market specific Regulatory requirements from the knowledge bank
  - » Regulatory requirements including Regulatory text, font, font Size adherence as per Health Authority requirements, Braille and Registration requirements including DIN, NDC number, MAH address, special instructions, directions to use
  - » Packaging technical specifications including die-line dimensions, text/text free area, barcode inspections, registration marks, Braille, barcode area, trim marks etc.
  - » Printing and readability requirements including color separations, minimum-printing font size adherence, varnish, print margins, pre-print and over-print areas etc.
  - » Product and company branding requirements including product logo, product-specific color and graphics, company logo, company address, manufacturer address, distributor address
  - » Legal and copyright requirements including patent information, copy right statement, registered symbols, and trademark symbols
  - » Safety requirements like tamper evident labels and statements, storage conditions, precautionary statements
  - » Formatting related checks such as line/paragraph/page breaks, alignment, widow/orphan lines, alignment, indentation etc. must be done
- Critical High-Risk QC components need to be checked for consistency within and across all the packaging components (Labels, Cartons, Foil

and Leaflet) of the product in every stage of QC and by everyone involved in the review and approval process. Those checks include but are not limited to product name, brand name, active ingredients, strength/dosage, unit of measure, quantity/content of the pack, storage conditions, shelf-life, and method or route of administration

- Quality Control: Quality control can be done by regularly monitoring the results/feedbacks and by analyzing/detecting if the team/individual comply with relevant quality standards that are mandatory requirements and identify ways to eliminate causes of errors or poor-quality. This can be achieved through some of the tools listed below and the outcome is usually to make changes to current process, update checklists etc.
  - » Inspection through multi-level QC (peer review and sampling) is performed during operational delivery for every artwork that is completed
  - » Pareto analysis: Recurring feedbacks, observations are noted and the defects which contribute to opportunities of error are noted. Extra precautions are taken like updating the checklists, or identifying if there is any gap in the system or individual or process to eliminate those errors completely. It is to be noted that most of the times, 20% of errors contribute to 80% of repetitive errors
  - » Fishbone analysis is another mechanism that is performed by brainstorming sessions to identify the root causes using 5 whys or questioning if there are any issues in people, policies, procedures or system
  - » Measurement System Analysis (MSA) is a tool to determine the variation within the team/process that contribute to overall process variability. Stability, repeatability and reproducibility are the parameters used to perform MSA
  - » Corrective and Preventive Action (CAPA) has all the info of problem with solution, so that the errors are prevented much before occurring
- Quality Assurance: Quality assurance is a process-based approach that should be in place to prevent defects in the approved artwork and to avoid rework in future. This can be achieved through audits at the commencement of the task to understand the requirements and to create a plan. Auditing is also done at periodic intervals after commencing the task, to identify the gaps in requirements and expectations. The findings should be well documented and a time frame should be set and followed up that all the gaps are identified are rectified
- Quality deviation reports, need to be created whenever there is a deviation in the process. Who did the deviation, why did they do that, what was the outcome, what and who was affected, what are the corrective and preventive actions that must be documented and implemented immediately. The resolution and ways to work moving forward along with complete documentation of the report should be signed by all employees involved in the training and by those who approve live tasks. An awareness session should be conducted for the entire team whenever the incident occurs
- A quiet and noise free atmosphere need to be created for concentration and employees should be made sure that they take regular breaks to sustain concentration
- Well-defined metrics should be in place to increase the RFT% to eliminate reworks and to minimize errors in artwork, which can be achieved through checklists
- Structured Reporting is very important to know the exact status of present-day quality %, factors affecting quality and will help the leads to see the trend and create/alter quality management plan

To conclude, quality in artwork is important, but maintaining it will require ample amount of time and resources to be invested. To ease out the process, it is required that organizations should consult a proven partner who has established processes and approaches that ensure the quality.

Freyr's Artwork and Labeling CoE (Center of Excellence) employs a comprehensive approach in excelling the industry needs for a high-quality artwork by following the above-mentioned industry standards. Freyr is certified with ISO/IEC: 9001:2008 for Quality Management System and ISO/IEC: 27001:2013 for Information Security Management. The scope of the certifications includes "Software Development" and "Global Labeling Management" from among various departments covered under the scope. Freyr has an independent "Compliance and Validation" department responsible for implementing Integrated Regulatory Management System. The department interacts with customers for monitoring adherence with respect to Quality and Information Security agreements.



CASE STUDY

# Time-critical QMS Remediation and Audit Services

Center of Excellence
**Compliance, Audit and Validation**

**CLIENT**
Fast growing Medical Devices Company

**GEOGRAPHY / LOCATION(S)**
South-East Asia

**FUNCTION(S)**
Compliance and Audit Function

**SERVICE(S) / SOLUTION(S)**
13485:2016; 21 CFR 820, STED

**THERAPEUTIC AREA(S) / INDICATION(S)**
Haemostatic Dressings

**PRODUCT(S)**
Wound Dressings

**BENEFIT HIGHLIGHTS**
- Quick turnaround - QMS remediation and audit completion in 2 weeks

## Business Imperatives
Client required Audit to be conducted for their
- Manufacturing facility
- QMS remediation and SOP rationalization

## Challenges
- The Company is ISO 13485:2003 certified, which is currently obsolete and needed an upgrade to ISO 13485:2016 Standard
- Wants to market in the USA and the EU (So, 21 CFR 820 and CE are applicable). The facility and QMS remediation should be upgraded in this regard
- Customer understanding on difference between QMS remediation, audit, and labeling requirements

## Freyr Solutions & Services
- Freyr proposed a multidisciplinary team of auditors (3) with expertise in GMP, medical devices and facility audit
- The QMS documentation gap analysis and facility audit were separated to speed up the process
- Draft of gap analysis report was generated within 1 week for QMS remediation (around 1000 audit findings were identified)
- Audit findings, remediations and closure
- Prioritization in terms of documentation that affect 510(k) submission
- Implementation and facility audit were conducted after 3 months

## Client Benefits
- Quick turnaround with planning, execution and report completed in 2 weeks
- Expert team produced high quality Audit with recommendations as per the latest Agency standards
- Audit readiness

CASE STUDY

# Regulatory Strategy and 510(k) Submission Services

Center of Excellence
**Global Medical Device Regulatory Services**

### CLIENT
Mid-size Medical Device Company

### GEOGRAPHY / LOCATION(S)
India

### FUNCTION(S)
Regulatory Submissions

### SERVICE(S) / SOLUTION(S)
Regulatory Strategy Development and Implementation [ 510(k) compilation]

### THERAPEUTIC AREA(S) / INDICATION(S)
Wound Dressing: Stops moderate to severe bleeding

### PRODUCT(S)
Medical Device

### BENEFIT HIGHLIGHTS
- Timely compilation and submission of 510(k)
- 100% quality for compliance

## Business Imperatives
- The client has an advanced class of wound dressing products that stops severe bleeding quickly and provides an active mechanical barrier to the wound site
- These products have various variants – Emergency, Vascular, Military and Dental
- The client had planned for product launch in the 3rd quarter of 2017 and reached out to Freyr for development of strategy and successful registration of 510(k) with the US FDA

## Challenges
- The product had two prescription indication for wound healing
- Client has changed the indication in the middle of the project, which in turn needed rework for the deliverables
- Biocompatibility testing data was not sufficient to prove substantial equivalence data between client product and predicate device
- Raw material had no GRAS number approved by the US FDA
- Vendor for sterilizer was not registered under "device establishment" requirements
- SOPs were not inline with 510(k) submission requirements
- Packaging labels were not updated in-line with the US FDA packaging requirements.

## Freyr Solutions & Services
- Assisted client for understanding the Regulatory strategy for submission of two indications together in one 510(k) as a bundle submission
- Provided awareness on getting vendor registered and raw material supplier registered parallelly as it is important while importing the product post 510(k) clearance.
- Performed in-depth gap analysis on the requirement of 510(k) submission to the US FDA against the data availability
- Based on the available information and gaps identified, aligned with the client and suggested to perform additional testing
- Regulatory templates prepared to include the Regulatory submission information related to 510(k)
- Compiled, written and reviewed all technical documents for usability in 510(k)
- Assisted client to identify gaps on present content on carton, label and IFU and updated the label in-line with guideline and in comparison to predicate device
- Listed all SOPs required for 510(k) clearance. Created templates and wrote missing SOPs/ updated available SOPs

## Client Benefits
- Timely Regulatory strategy for guiding the product registration process
- 100% quality compliance of technical documents required for 510(k)
- Timely compilation and submission of 510(k) with minimum queries from the Agency



CASE STUDY

# EU Market Authorization (DCP) in eCTD Format

Center of Excellence
**Publishing & Submissions**

### CLIENT
Top 3, Fortune 50, $40+ Billion Pharma / Consumer Company

### GEOGRAPHY / LOCATION(S)
United Kingdom, EU

### FUNCTION(S)
Regulatory Operations – Consumer and Pharma

### SERVICE(S) / SOLUTION(S)
Regulatory Publishing & Submissions

### THERAPEUTIC AREA(S) / INDICATION(S)
Analgesic/Pain

### PRODUCT(S)
OTC

### Technology Environment
Documentum, Lorenz DocuBridge, EURS Validator, Lorenz Validator

### BENEFIT HIGHLIGHTS
- Timely compilation and submission of 510(k)
- 100% quality for compliance

## Business Imperatives
- Freyr was associated with the client's Regulatory services that included eCTD, NeeS, CSR and other Regulatory solutions
- The Project was a DCP eCTD submission spanning ten countries including UK
- Freyr supported client in submitting sequences starting from 0003 (160 day response)

## Challenges
- Received the submission documents from DMS and uploaded into client's documentum using appropriate metadata
- Created the LCM tracker for the previous sequences to understand the life cycle attributes
- Created tracking table document and included the same in the submission
- Built the submission using 2 resources in a short span of 5 days

## Freyr Solutions & Services
- Prior communication with the client for the missing documents for the submission
- Check for the PDF properties like bookmarks, hyperlinks, inherit zoom and optimization and making the documents submission ready
- Careful understanding of the metadata shared by the client and assigning while uploading the documents
- Rigorous quality check performed at every step of the process, following the QC check list
- Validating the submission by using different validators using EURS and Lorenz validator

## Client Benefits
- Provided required work instruction to be followed by the publisher while building the sequences
- Provided valid submission, compliant to the agency requirement with zero errors
- Made the documents submission-ready; converted scanned and legacy documents into text searchable
- Coordinated with the various departments to enhance efficiencies of data work flow
- Followed a well-defined process to identify the gaps, and to document the issues

Leadership Story

# SARANDHA KUMAR – DECODED.

## INSPIRING. POSITIVE. TRANSFORMATIVE.

With the capability to understand high degree of complexities from multiple perspectives, Sarandha has been an integral part of Freyr's growth and success and has helmed many key roles in the Regulatory leader's transformational journey. Having been known for her efforts in building passionate teams, acquiring new customers whilst innovating new delivery models, Sarandha is currently leading the Beauty, Wellness and Household line of business at Freyr and she deserves all the credit for building business from scratch. How could she manage it? Let's decode it in her own words.

**As we spoke to her....**

**At the outset, most of us, especially the new lot, at Freyr, don't know much about Sarandha apart from her title. May we ask you to introduce Sarandha, the backbone of Cosmetics Regulatory Affairs at Freyr?**

It's always difficult to describe yourself accurately because what you think of yourself versus how others actually see you versus what you actually are, are all quite different! But let me try – I have worn multiple hats at Freyr and this by far is my favorite role – I have a fabulous team that energizes me, I work on some fun products, I get to make a difference, and I am enjoying every bit of it. I guess that pretty much sums up who I am right now at work.



**From a Mathematician to an Engineer to a RA professional. Where it all began? And how it all synced? Is it the complex nature of all the subjects been a cause for your switchover?**

You missed out the Banker bit and that I think was by far the most complicated role!

Ya, I have dabbled in multiple disciplines and I guess that also is a reflection of who I am, I like to try out different things, and one of the reasons I enjoy being at Freyr is because of the sheer variety of roles you can rapidly take on within this one organization. I think the common thread in all the various roles I have played is the fact that you are always picking some universal skills that come in handy at various points of time – be it conflict management, time management, team management or even the very critical but often overlooked self-management. And so, I see these not as distinct roles but rather a natural progression as a constantly evolving professional.

**We know the equations for Cosmetics are changing rapidly in the global market. Going forward, as an organization, where and what should be our focus to cater to the Industry needs?**

As consumers get more demanding cosmetics are getting more complex, be it discovering more effective ingredients, innovative packaging and applicators, personalized cosmetics or technological advances like the use of AI for predicting skincare needs or augmented reality for testing products. I believe the cosmetics of the future will be a combination of devices/software/products and we should be prepared to offer integrated services that cater to this rapidly evolving hybrid domain.

**What is that most interesting thing that hooks you to Freyr if it tends to be your last stop?**

Complete ownership and accountability for what you do and the freedom to do it the way you like.

**Whomever we interacted with so far, to inquire about you, the common word we've encountered is that Sarandha is amicable and Positive. What's your strength to pick so much of positivity?**

I feel people perform best when there is the right combination of a challenge as well as positive energy to tackle that challenge and I try to bring about that balance in myself as well as others in my team. And anyway I guess life is just too short for negativity.

**What approach do you employ among your team to achieve harmony at work?**

I strongly believe that each of us comes in to work everyday with an honest intention to perform our job well, to the best of our ability and understanding. Sometimes things go wrong, but more often than not, it is a consequence of misaligned objectives and priorities rather than lack of intent. I try to deal with situations with this core underlying belief, and it usually helps me find reasonable solutions and maintain harmony, and I encourage my team to do the same.

**If you were to quote someone on leadership/anything, who would it be and what would be the quote? Why?**

I don't know if it's a quote from someone but I came across this philosophy early on in my career – A leader's role is to Envision, Enable, Empower and Energize and I think this rings true even today.

**May we expect to see Sarandha in this year's Festronix?**

Yes, looking forward.

**A hot cup of coffee on the Swiss Alps or a challenging RA project? Which one excites you the most?**

A hot cup of coffee on the Swiss Alps after completing a challenging RA project sounds just perfect to me.

**We know you like to explore places. You like to travel. Tell us a bit more about your tryst with visiting neighborhood villages?**

I love hiking by the river to discover tiny tea shops in nearby villages, and then relax with a cup of tea and scones, topped off with clotted cream and raspberry jam. And then hike back to burn off the calories.

**Sarandha off the work, is ...?**

Excited about life in general and the endless possibilities.

**Passionate about...?**

Dancing, travel and experimenting with world cuisines.





Freyr CONNECT

# BASK IN THE GLORY OF PONDICHERRY

## Admire the Tranquillity, History and Fun

India is full of admirable treasures. Be it the ancient monuments and historical sites from our glorious past, or the mesmerising scenic beauty, right from snow-capped mountains to pristine beaches; India has it all!

I was always more inclined towards the invincible belt of North India, but hardly had a chance to visit South India. Awestruck and hypnotized by the impression of the South - from placidity of the forests to the glitterati of sizzling beaches, from forlorn kingdoms to the breeze of a hill station – it was my first choice to book the tickets for the famous weekend getaway- Pondicherry, the largest city of the Indian union territory of Puducherry.

June, as we soon learned, is one of the most favorable time to visit Pondicherry. The early showers of monsoon are infrequent enough, to not lash out your day-wise plan. They ensure to temper the humidity, which was extremely unbearable even a few weeks ago.

And to our bliss, the summer vacations were at an end, that thankfully means, no bickering families, lesser tourists, and most importantly - cheaper accommodation. Do keep in mind this window, if you wish to plan a trip to Pondy - The French colony of India.

Thou beauty! Where do I begin to describe you! Perhaps from the bus-stop itself?

Finally, we reached Koyambedu bus terminal, the last stop for private buses in Chennai, as we had to board a bus to Puducherry, which, we were assured, was less than 3 hours away by a beautiful sea-side pathway. It's indeed! Admiring the sea reflex through the coconut grooves, we landed in Pondy, finally.

We boarded an auto to search our hotel – Le Mirage. Yes!

company/freyr-solutions

They still have the old French names. Navigating through narrow lanes, in an alien city, driven by a man who couldn't understand us, and who seemed to be harboring a personal grudge against Google Maps, we somehow reached our destination.


Those immaculate lanes, lined with trees, old villas, and the smell of freshly-baked bread hovering in the air made me realize that Pondicherry's charm is one of a kind, where beauty meets history.

The city was unique in many ways and proved to be a throwback for us, to its beautiful French colonies and war memorials, which are intact till date. One of the good things about Pondicherry is that all the places that one needs to wander are dotted in the close-by distance. One can literally circle the entire city walking, if exaggeration is permitted. As I recollect my memories, here are few sites of Pondi about which I would love to share with you all:

## 1. The Rock Beach

Pondi, being the Indian abode of French style, has boulevards and palm trees all around. The seafront is magnetizing when visited during the sunrise. Also known as Promenade beach, it is accentuated by the fashion of rocks sitting against the roaring waves. Walking along the Promenade for the first time was special. A walk to remember indeed, accompanied by light monsoon shower, the feeling just got augmented!

Whether you're looking for a no-filter selfie with the beautiful sunrise or just a pleasant beach walk with your loved one while the splashing waters drench your feet, Rock beach will be a treat to your soul (and camera too).

Do not forget to try the tea or coffee from the stalls by the beach. To cherish the aura and mist of sea breeze, block a stone to enjoy the picturesque beauty while sipping a hot cup of coffee.

## 2. Matri-Mandir Auroville

Rent any two-wheeler or hop on the bus and witness

something extraordinary. Located in utmost silence, we could only hear the cool breeze singing with the trees and our own breath. This truly ineffable place left us relaxed and composed.

Matri-mandir, also known as the Auroville Ashram, is a beautiful embodiment of community living. Renowned as "the soul of the city", it is a peaceful and harmonic home to people from different cultures, nationalities, traditions, and religions. Auroville is the best spiritual escape if you are done with sightseeing in Pondicherry and still have room for a unique experience.

I was shopping open-mouthed in Auroville, which added more colors to my day, where my eyes were glued to an exotic collection of handcrafted clothes, jewelery, cute candles, organic food products, essential oils, and incense too. I felt so accomplished, as this was one of the feelings, that every woman can relate to!

You'll feel like exploring the realness of South India, when you find yourself surrounded with vibrant penthouses, palm trees, and the nature that adds to its beauty in all.

## 3. Paradise Beach

It was the best decision we made. Words may fall short to describe the magnificence of Paradise Beach; however hard I try. Naming it 'paradise' is lazy, but it was truly named like a one for a reason.

Adorned with its glittering golden sand and splendid backwaters, this pristine white beach is also known as the Plage Paradiso. Situated in Chunnambar, the island town close to Pondicherry city, you will have to take a boat journey to get to this island beach. Surrounded by mangrove forests,



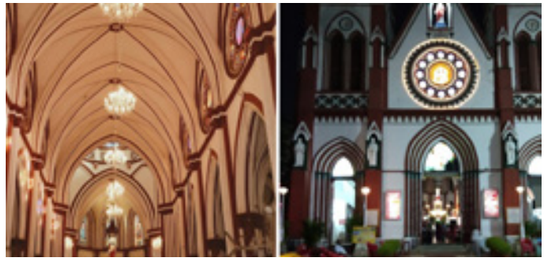


its peaceful and serene ambiance makes it a haven for avid photographers and nature lovers.

It is a captivating hub of fine sand and crystal-clear water, which makes it joyful and safe for children to play. The delectable street food, banana rides and chilling on shacks, will make you feel on a trip to one of the finest beaches across the world.

## 4. Basilica of the Sacred Heart of Jesus

A quick glance was not enough to experience the charisma of this wonderful church. Also known as the parent church, Basilica of The Sacred Heart of Jesus is located at the south boulevard. It's magnificent semblance and sacredness is the one, I could give away my sins for. It was the most remedying effect, which I encountered as I walk around this grandeur and meditated in the splendor of this Basilica's abode.



## 5. Hub to Water Sports

Pondicherry waves go as high as 12 ft., which makes it most sought-after surfing destinations in India. While active surfers rode on the rising waves, the tourists and locales on the Serenity beach watched them with awe. Among all the things we did in Pondicherry, surfing was the most exciting activity, as I just adore the moving waves and tryst with the peaceful wind.

Believe it or not, Pondicherry is one of the best scuba diving destinations in India. You can dive through the Eastern coast and discover the enthralling beauty of the marine life. Organized by PADI certified drivers, who will give time for an underwater break, this adventure sport is not something you should miss!

## 6. Baker's Street

I wouldn't have left Pondy without visiting this place, I could have paid heavily to my taste-buds, if I missed this out. Situated in the main town, this café offered a massive range of French delicacy, which could cross my mind in that sweet memoir croissants, Danish, brioche, pizzas, lasagna, cinnamon rolls, burgers, sandwiches and don't even get us started on the bakery! Baker's Street had a variety of desserts such as lemon and fruit tart which were already making me slobber over them, until my husband offered me one.

Baker's Street is a heaven for Bakery lovers. I would recommend leaving a little early for this sugar-coated hotspot, or you may find yourselves hoarded among the sweet meat lovers.

For me, Pondy is a reinvention, an ultimate rejuvenation therapy, which not only soothed us from our sedentary lifestyle, but also helped in reconnecting us with our inner being, with those silent drizzles kissing the serene beaches, it seemed infinite. It is a peaceful coastal beauty with unique calm waters but what makes it a youngster's favorite hideout is the numerous water sporting options, along its golden sandy beaches. Isn't it a true delight to travellers who love to have an off-beat experience?

Bask in the glory of Pondicherry.

Authored by

**Surbhi Bhatnagar**

# FREYR IN LIMELIGHT 2018

## Freyr Wins the Best Pharma Contract Services Award At the 2018 International Awards of Excellence (IAE)

The IAE awards initiated the industry voting to choose the best of International Pharmaceutical and Biotechnology Companies, Scientists, Auditors, C-Level Executives, Pharma Leaders and Solution Providers with proven State of Excellence. Basing on the industry's choice, the platform, then, recognized the winners for their exceptional contribution.

We are thankful to all our well-wishers both inside and outside the industry for choosing Freyr as the Best of Pharma Contract Services Company, in the 2018 IAE Awards.



## Freyr Receives ACQ5 Gamechangers 2018 Awards In Three Niche Categories

ACQ5 acknowledges Freyr as winner in three categories of Gamechanger Healthcare / Pharmaceutical / Biotech and Medtech Awards 2018.

| | | |
|---|---|---|
| Technology Company of The Year (Pharma and Lifesciences) | Regulatory Solutions Provider of The Year (Pharma and Lifesciences) | Gamechanger Of the Year, Suren Dheenadayalan |

Freyr

# CLIENT WINS

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A US based, global Clinical Research Organization

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IND AR Submission

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A Philippines based personal care Company

**Project Details:**
Cosmetic product registration in Japan market

The Customer:
A Chile based Nutraceutical company

**Project Details:**
Regulatory information in UAE and Nigeria to register their product

The Customer:
An India based pharmaceutical excipients manufacturer

**Project Details:**
Freyr SUBMIT software

The Customer:
A New Zealand based medical device manufacturer

**Project Details:**
Regulatory support for clarification of their products in India



The Customer:
A South Korea based, global pharmaceutical company

**Project Details:**
Local agent support and services in Ukraine

The Customer:
A UK based, Medical devices manufacturer

**Project Details:**
Medical Device registration support in Mexico

The Customer:
An Australian based, cosmetic product supplier

**Project Details:**
Cosmetic Product Safety Report in the EU market

The Customer:
A USA based, leading precision medicine company

**Project Details:**
Product clarification in Europe (CE marking services)

The Customer:
A USA based, medical devices manufacturer

**Project Details:**
Ad-hoc Regulatory consulting for their products in ME




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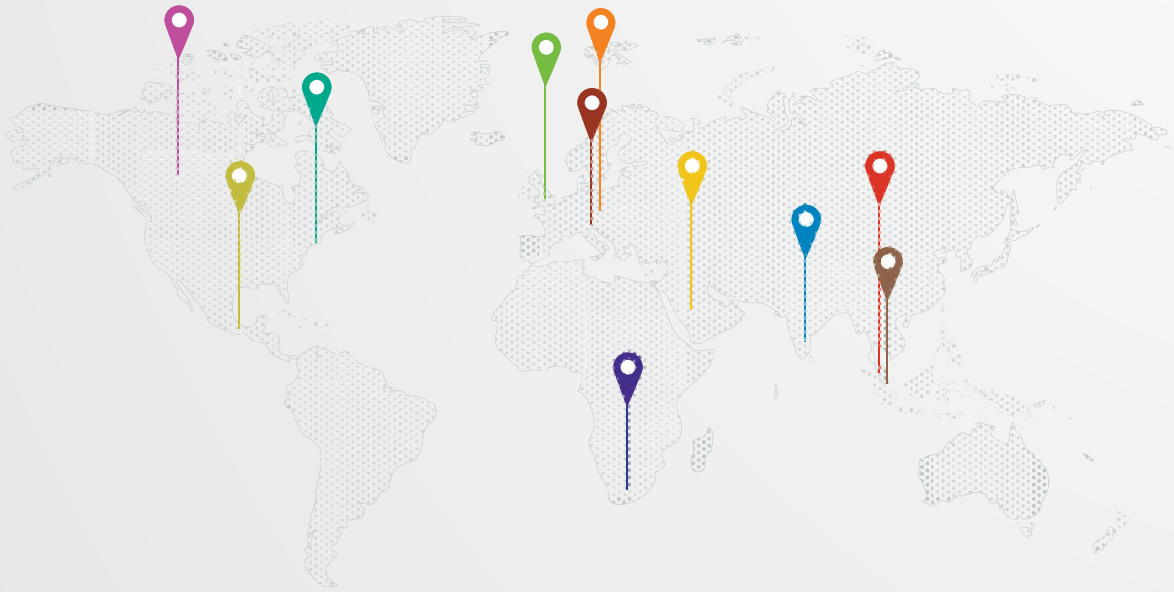

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