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ADAPTING TO THE NEW NORMAL WITH BRAND NEW INITIATIVES

Unleashed Exclusive Web Platforms For BWH Business Line And Medical Devices Segment

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FOREWORD

Hello There,

Greetings! Welcome to the brand-new Issue of Freyr CONNECT Volume 8.

I trust that you are all coping well in the current scenario, and I am hopeful that we can adapt to the new normal in an effective way. We are, for sure, inching towards overcoming this situation very soon. On that positive note, as always, we are happy to bring you evolving global Regulatory updates with this Freyr CONNECT Volume 8, Issue 2.

Adapting to the new normal is not that easy as it sounded or as it is said. It made many organizations change the way they operate; and change the way they consume information. To be a part of the new-age procedural changes, Freyr is glad to implement many digital initiatives. Some of which include:

- Launching a new-age CoE – Freyr AiM for Ai, Automation and Machine Learning
- Spearheading the Transition of Onsite Audits to Remote/Virtual Audits
- Creating Dedicated Digital Space for our Cosmetics, Food and Food Supplements, Chemicals and Biocides, Medical Devices and Technology Business Functions

This Issue commences with discussing Freyr's digital initiatives in brief and covers various Regulatory recommendations and perspectives of global Health Authorities in relation to COVID-19 and Freyr's thought leadership on best practices to be followed for end-to-end compliance. The Issue highlights proven cases, mandatory deadlines, the information about how we have been occupied with organizing various on-demand webinars pertaining to Cosmetics, Food and Food Supplements, Medical Devices etc.

With these collated and put together, we are truly optimistic that this Issue will be a best bet for your quest of Regulatory information.

Suren Dheenadayalan

CEO

ADAPTING TO THE NEW NORMAL WITH BRAND NEW INITIATIVES

The world is gearing up for “New Normal,” but with the risk of second wave being anticipated. It certainly created a natural demand for new way of business operations. The fields of life sciences, MedTech, BioTech and Beauty and Wellness businesses, too, are not an alien to this phenomenon. They should firmly align with the new regulations and guidance documents that are being released by global Health Authorities.

To assist businesses reach out to global markets in this phase of new Normal, with the utmost safety precautions taken, Freyr is indeed happy to announce couple of brand new initiatives; these are not only to streamline clients’ business operations remotely/virtually, but also to ensure they are technically driven for disruptive innovation. Here are some of our initiatives from the last quarter...

Together in Saving Lives

In the light of recent times, the need of the hour for the Covid-19-related product manufacturers is to access and easily decode the region-specific Regulatory information to launch their products globally. With a strong intent to stand up for the current requirement and to support the cause of being together in saving lives, Freyr is glad to unleash an exclusive Covid-19 web platform that not only publishes a gamut of Covid-19 related health authority/country/product-specific information, but also deploys Covid-19 Regulatory Task Force (CRTF) to provide expert consultation.

Freyr SPL/SPM

It’s a known fact that Freyr is proven in providing exclusive line of services and platform for Structured Product Labeling (SPL). Now, aligning with the new mandate of Health Canada in relation to Structured Product Monographs (SPM), we have not only launched an exclusive SPM software, but also went ahead to be one of the few companies to compile and submit pilot SPM to Health Canada.

Exclusive Web Platforms for Cosmetics, Food and Food Supplements, Chemicals and Biocides and Medical Devices

As we look at these challenging times for manufacturers across the life sciences industry, of course, not in terms of manufacturing products, but to market them across the globe compliantly, we understand there is a dire need for effective Regulatory solutions and services to ensure product’s compliant market entry. As always, we believe that they need a dedicated approach and a clear-cut service line. Therefore, to help manufacturers comprehend Freyr’s capabilities more clearly, Freyr has come up with exclusive web platforms for the Beauty, Wellness and Health (BWH) business lines – Cosmetics, Food and Food Supplements, Chemicals & Biocides, and also for Medical Devices segment.

The new, easy-to-navigate, and user-friendly web platforms allow viewers to browse through Freyr’s vertical-wise and region-wise dedicated Regulatory capabilities.



Physical Audits to Remote/Virtual Audits

As a proven Regulatory partner for compliance practices, Freyr emphasizes to remain compliant with vendor audits, especially during emergency health crisis like COVID 19. To ensure a smooth transition from on-site physical audit to remote/virtual audit during the current pandemic, Freyr has started offering exclusive remote audit and SOP review/writing services based on a unique 3-stage, risk-based approach. These are for low-risk processes that consist of documents, forms and records that can be reviewed from a desktop.

Freyr AiM

Freyr has launched a new-age Centre of Excellence – Freyr AiM to deliver simple, smart, disruptive digital innovations for Regulatory, Safety and Clinical Operational processes.

10,000+ Freyr Brandwagons

While we are quick to adapt to the new normal with the brand-new initiative mentioned above, we are really happy to reach a milestone in the digital space. We have obtained strong and loyal team of 10,000+ followers on LinkedIn platform; we fondly call them as Freyr Brandwagons.

With these initiatives and achievements, we could say that Freyr is inching closer to the industry even during the times of COVID-19. While we are already being modernized internally, we look forward to ensuring the industry is equipped with the best possible Regulatory services for compliance. Stay connected. Stay compliant.

IMPACT OF COVID-19 ON FMCG SUPPLY CHAIN AND REGULATORY COMPLIANCE

The outbreak of COVID-19 has brought out the best and worst of businesses. From raw material availability to manufacturing to logistics to retail sales; all business segment processes are operating on limited capacity or have almost ceased operations completely.

FMCG and healthcare are among the major industries facing prominent supply chain challenges. From raw material availability to manufacturing to logistics to retail sales; all business segment processes are operating on limited capacity or have almost ceased operations completely. Same is the case with food and pharma industries. Though they were insulated as essential goods, they too had to feel the brunt of stranded scenarios. While few countries seem to be coping well with this crisis, there are still many countries that are battling against this global pandemic.

It is a well-known fact that China is the global hub for industrial chemicals and also the first country to be impacted by the novel Coronavirus. The extended factory closures in China following the pandemic outbreak caused the limited supply of several chemicals and raw materials, which certainly stand as the starting point for manufacturers across the world. According to the National Bureau of Statistics of China, the output of China's industrial enterprises dropped by 14% in the first two months of 2020, compared to the time frame a year-ago. Additionally, chemical manufacturing was among the hardest-hit sectors, with output declining by 21%. Although, the Chinese factories resumed their

operations in the months of April and May 2020, the effects of the lockdown can still be seen due to the challenges in transport, which certainly add up to the costs. For example, multiple global trade data indicates that the cost of supplies from China have increased or are likely to increase. Thus, impacting the global supply chain.

IMPACT ON GLOBAL SUPPLY CHAIN

In today's global trade ecosystem, supply chains are extremely complex with partners spread across multiple geographies. However, the present supply chain processes and infrastructure have evolved through decades of meticulous planning and strategy, which is essentially focused on availability, landed-cost, quality and optimized inventory. An additional dimension that has gained importance in the recent past is the evolving Regulatory/industry standards and consumer demand towards safe and reliable brands.

Observance and adherence to the evolving regulations and compliance enforcement are few of the key challenges in redefining the supply chain strategies and to deal with the current crisis. For business continuity, manufacturers/formulators are strategically working to include additional

suppliers to meet their present qualitative and quantitative requirements. Along with other business implications, it also triggers overhaul of supply chain compliance process, which starts from identification and qualification of new suppliers, to revisiting raw materials/products specifications and compliance assessment.

Overall, Regulatory assessment of product formula and composition with new/extended supplier base is an onerous step that adds to the overall cost and could even lead to modifications in product composition and label, which will have further Regulatory implications on product registration/notification process.



RESOLUTIONS FOR PRESENT AND FUTURE

With learnings from the present crisis, businesses should work to build smarter and robust global supply chain process and network that includes in-depth understanding of risk factors and multidimensional approaches. One among such approaches could be the principles of the 'Quality by Design' (QbD), which quickly adapts to variations and embraces the change without disrupting the normal process. Below are few steps which can help manufacturers streamline the QbD process:

- Proactive observance and adherence to industry standards and Regulatory changes of the target markets, including customer's expectations and safety issues raised by research community and Non-governmental Organizations (NGOs)
- Calibrating product and raw material specifications to accommodate wider supplier base
- Strategically designing key parameters (e.g. potential impurities, microbiology), which allows flexibility within the Regulatory limits
- Developing robust Document Management System (DMS) to collect, track and update raw material documents from the suppliers
- Embracing 'Right First Time' approach in retrieval of

- appropriate and required documents from the suppliers
- Implementing automated tools for integration of new suppliers, data gap alerts and Regulatory compliance check

Owing to large product portfolios, presence in multiple markets, various manufacturing sites and many associated suppliers, Regulatory conformity in overall supply chain matrix is very complex and there is high probability of gaps between perceived and actual compliance procedures on the ground. Segmented adoption of above measures will not only help mitigate supply chain risks and change management but will also build confidence in overall compliance structure across markets and the product range.

CONCLUSION

The outbreak of COVID-19 has created uncertainties for industries across the world. Therefore, it is only wise to prepare your business to face and overcome all the possible challenges posed by this global pandemic. Adopting global supply chain approaches, such as QbD, will not only allow manufacturers to rapidly respond to COVID-19, but will also help them manage their businesses efficiently. A Regulatory expert with in-depth experience in handling various supply chain disruptions can surely be a great asset for manufacturers in this hour of need, while adhering to all the Regulatory compliance requirements.

PROVEN CASE

The Need

Managing the processes and data related to Raw Materials (RM) can be quite challenging and time consuming, especially when the client is dealing with multiple products, manufacturing facilities and a vast distribution network. Amid these challenges, one of our clients was looking to increase efficiency and reduce costs of Regulatory compliance, as well as manage ever changing volumes of work through efficient, integrated and streamlined workflow models.

The Approach

One of the top 5 consumer goods company approached Freyr with the aim of ensuring that their top 20 brands are in full compliance with the current Regulatory requirements, supported by valid and updated documents. The scope of the project included ensuring compliance with the National, State/Provincial Regulatory requirements and industry standards for the client's product portfolio across the EU, JAPAC, Middle East, ROW and ASEAN markets.

Freyr provided end-to-end compliance support to the client, right from supplier communication, document management to product formula development and review from a compositional and Regulatory perspective.

INCI Generation

- Sort the final individual ingredients composition list based on the concentration
- Check for the INCI's from the final individual ingredients composition list, which should be the part of INCI List
- Cross check with the existing INCI List
- Create updated INCI List
- Quality check of updated INCI List
- Share INCI List with Client Project Lead

Review of Raw Materials Source Documents

- Gap analysis of received documents
- Trade name verification with supplier information
- INCI name, CAS number, composition details check
- Verify information with PCPC and other source of documents
- Impurities level review
- Raw material change analysis report creation

Update Regulatory Formulation Assessment (RFA) / INCI

- Receive feedback from Client Project Lead
- Review feedback

- Assess feedback and evaluate issues/errors, if any
- Incorporate any changes into the RFA and INCI

Regulatory Formulation Review

- Formula Oech Ration Report (FOR) review and verification
- TDS, MSDS and COA review
- Identification of other ingredients/impurities that are not the part of INCI, but still the part of composition
- FDR final review for composition/concentration
- Verification of functions of RMs
- Check for applicable restriction
- Check for concentrations of allergens and impurities in fragrance and flavor review
- Prepare the final individual ingredients composition list

The project was initiated with review/understanding of overall process and challenges faced by the client. At the outset, Raw Material Questionnaire (RMQ) was revised with Regulatory backgrounds to educate suppliers about the Regulatory context and criticality of information or documents for business continuity.

The Outcome

Key activities of the project included review of individual raw materials and the complete formulation for compliance with national requirements and collaborating with multiple stakeholders across the supply chain to obtain RM documents or obtaining clarification on these documents when the information was unclear or incomplete. The project also included indepth gap analysis followed by liaising with the global Regulatory affairs and R&D teams for gap remediation.

Stay Safe. Stay Informed.

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FDA PROPOSES INTEGRATING MASTER FILES TO NDI NOTIFICATION

Industries across the world are evolving in terms of innovation, and it is no different for the food supplements industry. The food and food supplements industry is booming and majority of its credit goes to the innovative products that are being introduced in the global markets. In most of the cases, new products are manufactured with the help of novel ingredients known as 'New Dietary Ingredients' (NDI)

What is a New Dietary Ingredient (NDI)?

An NDI is a food supplement ingredient that was not marketed in the United States (US) before October 15, 1994, according to the Dietary Supplement Health and Education Act (DSHEA). It is the responsibility of a manufacturer/distributor to determine and document whether a dietary ingredient is NDI or not. As per the DSHEA, manufacturers are required to ensure the safety and efficacy of the NDI and must submit a detailed notification for the ingredient review to the US Food and Drug Administration (FDA). However, before distributing a product with an NDI in the US market, manufacturers must ensure that the ingredient is considered as a dietary ingredient as per the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The review application for an NDI must be submitted 75-days before the product reaches the US market.

NDI Notification – Master File Component

Although the FDA asks food supplement manufacturers to notify NDI to the Agency many fail to do so for various reasons, certainly because of limited clarity on the definition of NDI. This may act as an issue for the FDA to ensure the safety of innovative products placed on the market. To overcome these issues and ensure manufacturers that the

intellectual property rights related to the NDI are protected through the notification process, the FDA has proposed to add a master file component to the pre-market process of food supplements, i.e., NDI notification. The purpose of the NDI master file (NDI-MF) is to help manufacturers protect valuable information about their NDIs, like, information related to manufacturing, safety and processing.

How will the NDI-MF work?

If a manufacturer submits an NDI-MF to the FDA for one of their food supplements, it can be referenced by another manufacturer for an NDI notification with the due permission of the NDI holder. The implementation of NDI-MFs can also streamline the notification process and reduce the paperwork burden for manufacturers as well as the agencies, as it will help multiple notification submitters to reference a single NDI-MF. In short, submitting an MDI-MF will have the following benefits:

- It can be used by other ingredient manufacturers as a reference
- The FDA will protect the intellectual property rights of the IND holders

To submit an NDI-MF, manufacturers must fulfil the following steps:

- Manufacturers must submit all the NDI-MFs along with all the necessary information through NDI notification
- Manufacturers must provide authorization to other companies, allowing them to reference the NDI by issuing a Letter of Authorization (LoA)
- If any adverse event arises, the FDA must be informed immediately
- Manufacturers must comply with the 21 CFR 111 – cGMP

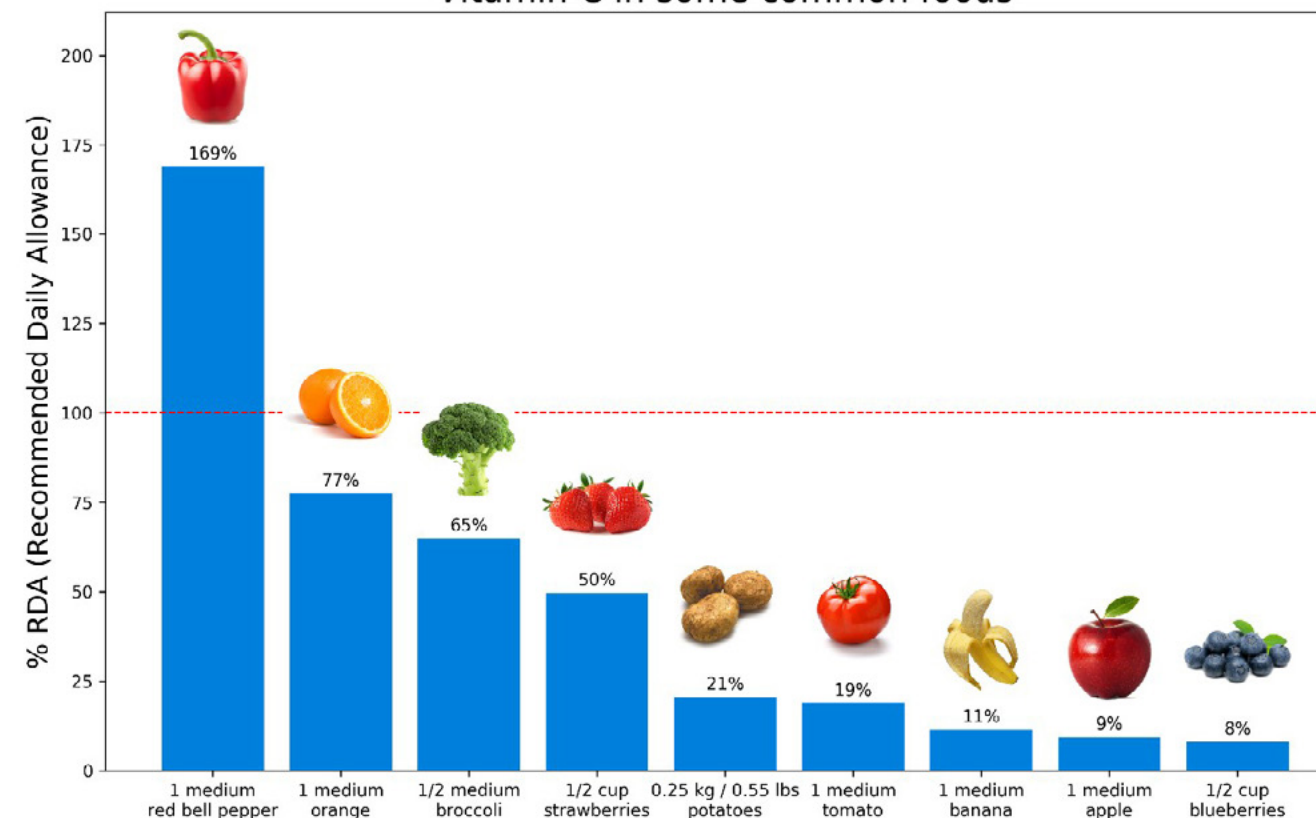
As the FDA prioritizes the safety of food products, this step of proposing an NDI-MF creates a harmonized Regulatory framework to focus on the safety of each ingredient. While the FDA is still in discussion about the proposal, it is crucial for food supplement manufacturers to keep an eye on the evolving regulations of the U.S. to ensure compliance. To do so, manufacturers are advised to consult a Regulatory expert in US food supplements for successful market-entry. Stay safe. Stay compliant.



PANDEMIC RELAXATION USING VITAMIN C

With the 2019 novel coronavirus (2019-nCoV) outbreak now spreading over the world, individuals are looking for ways to possibly protect themselves from the virus or to ease its effects once got. One such implies that is being touted on the web and in the media is Vitamin C, because of its immune function and anti-viral activity.

Vitamin C in some common foods



VITAMIN C AND IMMUNE FUNCTION

Vitamin C is known as a fundamental antioxidant and enzymatic co-factor for physiological responses, for example, hormone creation, collagen synthesis and immune potentiation. Humans cannot produce Vitamin C; hence they should obtain Vitamin C from dietary sources. It not only adds to insusceptible protection by supporting different cell elements of both the innate and adaptive immune system but also supports epithelial boundary work against pathogens and advances the oxidant scavenging movement of the skin, in this manner conceivably ensuring against environmental oxidative stress.

An eating routine that provisions 100–200 mg/day of Vitamin C should cover general prerequisites for the decrease of constant illness risk.

Vitamin C shows beneficial effects on cellular functions of both the inborn and adaptive immune system. Since it is a potent antioxidant securing the body against endogenous and exogenous oxidative difficulties, it is also active as a cofactor for various biosynthetic and gene regulatory enzymes play a key job in its immune-modulating effects. Vitamin C animates neutrophil movement to the site of disease, improves phagocytosis and oxidant generation, and microbial slaughtering.

Over the years, Vitamin C has proved to be an essential supplement for the immune system in supporting a satisfactory reaction against pathogens, while staying away from over the excessive damage to the host. Vitamin C gives off an impression of being ready to prevent and treat respiratory and systemic infections by improving different immune cell capacities. Ensuring sufficient intake of Vitamin C through diet or by means of supplementation, particularly in groups such as, the old or in individuals exposed to risk factors for Vitamin C inadequacy, is required for appropriate immune function and resistance to infections.

VITAMIN C AND THE VIRAL INFECTIONS

The common cold is a viral infectious disease of the upper respiratory tract. Colds can prompt the upper respiratory system getting less resistant to secondary bacterial infection, bringing about issues, such as, middle ear infection, pneumonia, bronchitis, sinus disease or strep throat. The body's immune system can battle the infection in the wake of delivering antibodies, yet there are right now no medications that will fix the common cold. In any case, there might be an approach to lessen the danger of getting the common cold. An ongoing Cochrane meta-investigation shows that vitamin C lessens the rate, length

and seriousness of the normal cold when ≥ 200 mg/d is taken every day.

Vitamin C is an efficient antioxidant and possesses anti-viral activity. For instance, it has been demonstrated that Vitamin C is an essential factor in the production of the anti-viral immune response during the early period of viral infection through the production of type I interferons, which up-directs NK cell and cytotoxic T-lymphocyte activity. Also, examines have shown that ascorbic acid can be utilized as an inactivating specialist for both RNA and DNA infections, influencing viral infectivity. Moreover, ascorbic acid can detoxify viral items that produce pain and inflammation.

EVIDENCE OF EFFICACY OF VITAMIN C AGAINST VIRAL INFECTIONS

High dose intravenous (IV) Vitamin C shown effective against viral infections:

- Avian virus H1N1 (Ely 2007)
- Chikungunya (Gonzalez et al. 2014)
- Zika (Gonzalez et al. 2016)
- Acute Respiratory Distress Syndrome (ARDS) (Fowler et al. 2017)
- Influenza (Gonzales et al. 2018)
- ▶ Oral supplementation Vitamin C (doses > 3g) can prevent & treat respiratory & systemic infections (Carr & Maggini 2017)

INTRAVENOUS HIGH-DOSE VITAMIN C TREATMENT FOR 2019-nCoV DISEASE

As of February 2020, a high-dose intravenous Vitamin C could be the administration of 50 mg/per kilogram body weight like clockwork for 4 days with a glucose limitation. Likewise, hydrocortisone 50 mg IV at regular intervals for 7 days must be added to battle against therapy-induced inflammation. Vitamin C when used as a parenteral agent in high doses may act pleiotropically as a prooxidant to weaken proinflammatory mediator expression, clearance, improving alveolar fluid clearance and to act as an antioxidant to improve epithelial cell functions.

Freyr extends its support to the food industry in navigating through these Regulatory challenges. Freyr provides its services across all the necessary compliances required starting from product classification and product compliance, to label and claims compliance and product registrations services in line with country specific regulations.

Freyr provides Regulatory assistance for Vitamin C Immune Boosting Supplements and we are prepared to:

- Evaluate your label or labeling information for compliance
- Review your immunity boosting claims
- Design or develop artwork for Immunity boosters
- Review or Assess the product formula to identify the product category and to check the acceptability of all the ingredients in the product in line with country specific regulations
- Suggesting mandatory, missing information and nutritional/supplemental facts or the corrections to be made on the label of the product as per the country specific regulations
- Monitor compliance with HA including advising on general labeling and advertising issues, nutrition labeling, and evaluation of permissible claims (e.g., health claims, nutrient content claims, and structure-function claims)
- Prepare and submit dossier for Notification/ registration, wherever necessary.
- Assist with devising a robust Regulatory pathway for your product

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US FDA: eSUBMISSION FORMATS FOR MEDICAL DEVICES

Reducing the complexity of Regulatory submissions, the global Regulatory Authorities transformed all the submissions from paper to electronic format. Respectively, there are several electronic submission formats proposed by country-specific Regulatory bodies.

Recently, the US FDA issued a new guidance for electronic submission for medical devices, following a draft guidance issued in September 2019. Delineating FDA's strategies, this new guidance concludes that it is not feasible to describe and implement the electronic formats that would apply to all submissions covered under the statutory requirements of section 745A(b)(3) of the FDA Reauthorization Act of 2017 (FDARA), in one guidance document. Accordingly, FDA interprets the requirements of section 745A(b)(3), which specify the following:

- Submission types must be submitted electronically
- Timetable and process for implementing the requirements
- Criteria for waivers and exemptions from the submissions

Electronic Format Submissions: Submissions solely in electronic format in accordance with section 745A(b)(3) of the FD&C Act, include:

- Pre-market notification submissions (510k submissions)
- De Novo submissions

- Pre-market Approval Applications (PMAs), including, transitional and modular PMAs
- Product development protocols
- Investigational Device Exemption (IDE) applications of all types; humanitarian device exemptions, Emergency Use Authorizations (EUAs)
- Certain Investigational New Drug (IND) applications such as, those intended for use in screening donor blood
- Biological License Applications (BLAs) regulated by CBER as biological products, regardless of whether an IND submission is required before the BLA submission
- All Q-submissions to facilitate efficient review

FDA also clarifies that all subsequent submissions to an original submission must be submitted electronically. Irrespective of a single-page submission or a multi-volume submission, all the proposed requirements are applicable for electronic submissions. Any submission that does not meet the electronic format defined in the guidance will not be filed or received, unless it has been exempted from the electronic submission requirements or if there are waivers with respect to that submission.

Exemptions from Electronic Format Submissions:

FDA claims to exempt the following types of IDE submissions:

- Expanded access compassionate use requests
- Emergency use reports
- Adverse event reports

Though there are exemptions for the above categories, FDA encourages electronic format submissions, as submission templates become available, to facilitate the review process. Also, Master Access Files (MAFs), 513(g) Requests for Information, and Clinical Laboratory Improvement Amendments of 1988 (CLIA) categorization requests and waiver applications do not require electronic submission. But FDA identifies and recommends voluntary electronic submission, as submission templates become available.

FDA intends to develop individual draft guidance documents to specify the electronic formats, subject matter, and scope of applicability for submissions under section 745A(b). To allow an eventually phased implementation, these guidance documents are released sequentially. The timelines required for electronic submissions of each submission type will be specified in the upcoming individual guidance.

Henceforth, medical device manufacturers willing to step-in the U.S. market should comply with the aforementioned new eSubmission formats, to reduce review timelines and submission evaluation process. Prepare compliant eSubmission documents with the right Regulatory expertise. Stay safe. Stay informed. Stay compliant.

COVID-19 MEDICAL DEVICES PERSONAL PROTECTIVE EQUIPMENT (PPE) US FDA REGULATIONS

PROBLEM STATEMENT

Understanding the market dynamics of PPE related to COVID-19 and the expedited Regulatory processes in place for fast track approvals of COVID-19 related medical devices.



This document has been thoughtfully created with a view to provide strategic Regulatory insights for expedited Regulatory approvals of COVID-19 related PPE and the possible steps that global PPE manufacturers may follow, during this pandemic. This document also throws light on how Freyr can help the manufacturers by devising a compliant Regulatory strategy.

Background

PPE stands for Personal Protective Equipment and helps in protecting people's health and ensures their safety. Since the onset of COVID-19, the World Health Organisation (WHO) has been continuously emphasizing the importance of appropriate use of PPE, particularly among frontline health care workers.

When used effectively, PPE can act as a barrier between infectious materials such as viral and bacterial contaminants and people. It has the potential to inhibit the transmission of contaminants from blood, body fluids, or respiratory secretions.

In the light of COVID-19, several governments and Health Agencies such as US FDA have come up with expedited

Regulatory processes for testing kits and device approvals.

1 PPE MARKET DYNAMICS

There are four major types of PPE namely Gloves, Masks, Eye Protection and Clothing. According to Reports and Data, the global healthcare personal protective equipment market was valued at USD 5 Billion in 2019 and is expected to reach USD 8 Billion by the year 2027, at a CAGR of 4.5%. Healthcare personal protective equipment is witnessing a surge in demand in the midst of COVID-19 pandemic for the safety of healthcare workers across the globe. Gloves, face protection masks or face shields, goggles and masks, gloves, gowns or coverall, head cover, and PPE boots are among some of the personal protective equipment with soaring global demand. The key factors which are expected to drive the market for the personal protective equipment includes stringent Regulatory framework, increasing awareness about the importance of healthcare safety, increasing focus on safety preparedness at healthcare facilities, and accelerating rate of COVID-19 infection cases. During 2020 to mid-2021, a short run spike is expected in the demand of PPE across the globe, where the market for healthcare applications is expected to grow at a rate of 17.2%.

2 PPE TYPES

2.1 - Gloves

There are different types of gloves made of different materials and they all come with certain advantages and

offer different levels of protection. Latex and Vinyl gloves offer the best protection against COVID-19. The below provided is a tabular comparison of different types of gloves.

Type of Gloves	Material	Benefits	Level of Protection
Latex Gloves	Natural rubber	Tactile sensitivity, fit, flexibility, and comfort	Viruses and Bacteria
Nitrile Gloves	Synthetic material	Durable and stretchable	Viruses and Chemicals
Vinyl Gloves	Synthetic material	Comfortable and cost efficient	Chemicals

2.2 - Masks

There are different types of masks available in the market and deciding on which type of mask to use as a protection against COVID-19 is not so easy. Among the ones available, N95 and medical masks offer the maximum protection and are currently in huge demand among both the people and frontline healthcare workers. The use of certified N95 Respirator masks is also being mandatory in some of the countries.

Currently, there is no standard explicitly for eye protection against biological hazards, such as COVID-19. Goggles or face shields are proposed as appropriate protection for the eyes. However, as the primary method of infection is by droplet rather than airborne transmission, closely fitted wraparound safety glasses that comply with the minimum coverage requirements for eye protectors are recommended.

Filtering Facepiece Respirators (FFR) - N95 Masks/ K95 Respirators - which are sometimes called disposable respirators and are subject to various Regulatory standards around the world. This type of mask is considered a respirator device and comes with a very close facial fit and very efficient filtration of airborne particles. The 'N95' designation means that when subjected to careful testing, the respirator blocks at least 95 percent of very small (0.3 micron) test particles.

Surgical/Medical masks - Surgical masks are regulated under 21 CFR 878.4040. Surgical masks are made in different thicknesses and they have the ability to protect from contact with liquids also. It is meant to help block large-particle droplets, splashes, sprays, or splatter that may contain germs (viruses and bacteria), keeping it from reaching your mouth and nose.

2.3 - Eye Protection

Eye Protection wear is broadly classified into four types, namely, general safety glasses, laser safety glasses, chemical splash goggles and impact goggles. However, for full face protection, using face shields is recommended.

2.4 - Clothing (includes Gowns, Aprons, Head Covering and Shoe Covers)

Clothing is also an important type of PPE and it consists of garments placed to protect the health care workers or any other persons from getting infected.

The normal standard precautions suggest wearing gloves, mask and gown as clothing requirement as a part of safety measures. However, if it is blood or airborne high infections such as COVID-19, the standard precautions are more elaborate and recommend wearing gloves, face protection, gown or coverall, goggles and mask or face shields, rubber boots and head cover.

3. EXPEDITED REGULATORY PROCESSES FOR COVID-19 RELATED MEDICAL DEVICES - US FDA

The rising concerns of COVID-19 outbreak, triggered the United States Food and Drug Administration (US FDA) to accelerate the process for quick clinical trials based on pre-IND discussions and highly expedited initial reviews. The Agency is encouraging the sponsors of investigational COVID-19 treatments to submit information and questions through the Pre-IND Consultation Program. Addressing

the unmet medical emergencies in treating serious and life threatening conditions, the US FDA has come up with multiple programs to facilitate and expedite development, review and approval of therapies, including biologics.

US FDA Programs for Expedited Approvals

Therapies treating a “serious condition” are all qualified for the four expedited review programs. They include, the diagnostic products, vaccines and products that detect, prevent and treat the effects of serious conditions.

If the therapies justify their benefits over the risks, they will be available in the market at the earliest with supportive US FDA programs like:

- **Fast Track Designation:** It expedites the review of drugs with a potential to meet the medical emergencies. Demonstrating the drug potential, the sponsors may rely on non-clinical evidences, more frequent meetings and correspondence with the US FDA and rolling review of completed sections of the marketing application.
- **Breakthrough Therapy Designation:** Potential drugs showing improvement over existing therapies are provided faster approvals through this program. As there is no existing treatment or vaccine for COVID-19 at present, this program is irrelevant at this stage.
- **Priority Review Designation:** It accelerates the US FDA’s projected approval time from ten months to six, provided the drug exhibits effective prominence to treat a serious condition in terms of safety and effectiveness. Though the review is based on clinical trials comparing an investigational drug to a marketed drug, other scientifically valid information can also be

used, where inadequate therapy currently exists.

- **Accelerated Approval Pathway:** Diseases with long courses, such as, cancers, demanding excessive time periods to measure ultimate clinical efficacy with adequate and well- controlled clinical trials are reviewed in this program.

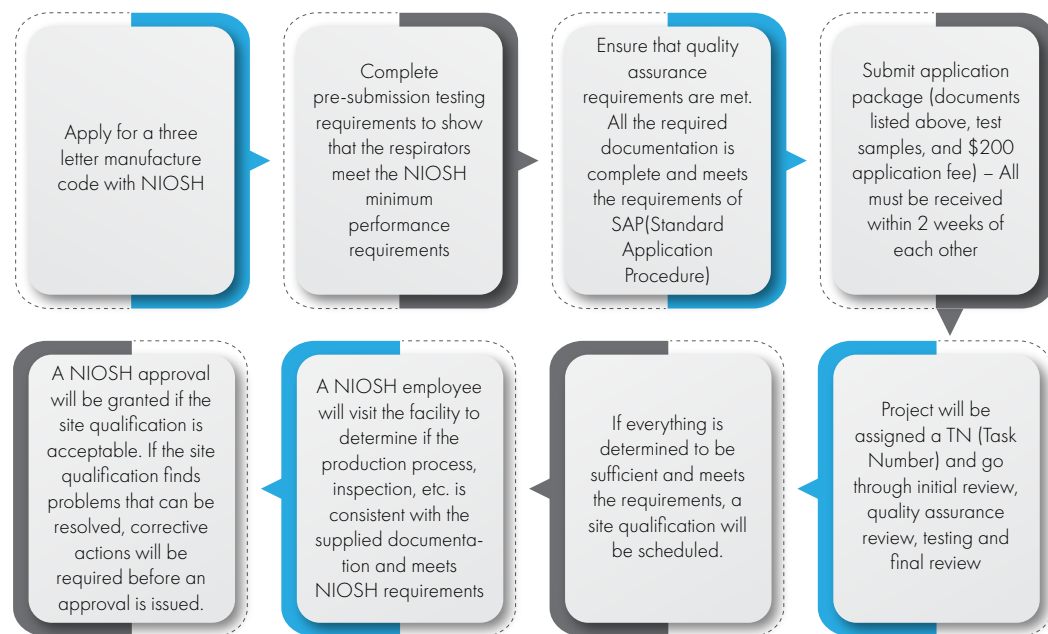
4 PPE REGULATORY PROCESSES – US FDA

As mentioned in the US FDA website, the US FDA has issued Emergency Use Authorizations (EUAs) for respirators and EUAs for systems that can decontaminate certain types of N95 respirators for reuse by health care personnel in a health care setting. One of the US FDA’s priorities in combating the COVID-19 pandemic is facilitating access to critical Personal Protective Equipment (PPE) and devices.

The US FDA is issuing this guidance to provide a policy to help expand the availability of surgical apparel for health care professionals, including gowns (togas), hoods and surgeon’s and patient examination gloves during this pandemic.

NIOSH - National Institute for Occupational Safety and Health

The US FDA concluded that, based on the totality of scientific evidence available, certain imported respirators that are not National Institute for Occupational Safety and Health (NIOSH)-approved are appropriate to protect the public health or safety. The US FDA issues an Emergency Use Authorization (EUA) for importing non-NIOSH-approved N95 respirators. The general NIOSH approval process flow is as below:



5 PROVEN CASE - NIOSH CERTIFICATION

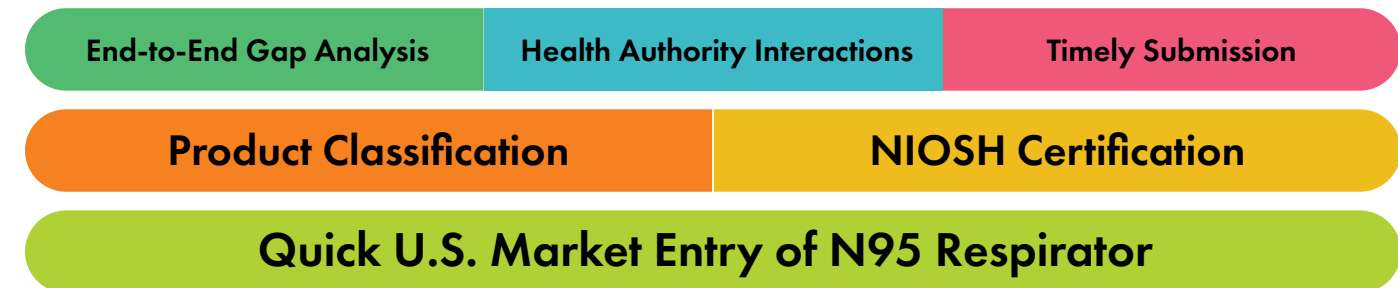
Expedited Product Classification and NIOSH Certification for N95 Respirator

Need

The most pressing need in the times of COVID-19 is making the Personal Protective Equipment (PPE) like N95 respirator available for healthcare workers. But, as you may know, the rapid spread of the pandemic in the U.S., and the shortage of such equipment has triggered more challenging scenarios. Addressing to the demanding times, one of our clients – manufacturer of novel technology based medical devices, set out to take their filtering face masks to the U.S. market.

Given the unprecedented times of COVID-19 and the US FDA’s numerous guidance documents and Emergency Use Authorizations (EUAs), the manufacturer required Regulatory support to enter the U.S. market without any compliance hurdles.

The Outcome



At Freyr, we always believe in enabling life sciences companies to reach out to the market right on the required time. What made us delighted in this scenario is not just clients’ successful market entry or NIOSH certification,

Come what may, clients’ business continuity is paramount to Freyr. Glad to share that with all proactive measures quickly taken in this scenario, Freyr has made the client enter the U.S. market with successful NIOSH certification.

The Approach

As the client had minimal knowledge on the U.S. Regulatory process for the product category, the first aspect Freyr took upon is to decode multiple US FDA guidance documents and pathways for EUAs.

The client’s product included Novel technology which has demanded us to interact with NIOSH and the US FDA to understand the classification status of the product.

With proper gap analysis, Freyr has aligned clients’ existing documentation as per the US FDA/NIOSH requirements.

Apart from assisting the client on decoding product classification and necessary requirements, Freyr has provided end-to-end support with NIOSH process, that includes the receipt of manufacturer code, compilation of the NIOSH application and submission.

CONCLUSION

While the world is tussling with the COVID-19 pandemic, there’s an emergency need for its treatments and vaccines. Though, currently, there is no US FDA approved therapy or vaccine for COVID-19, appropriate usage of PPE can help in curbing the spread of the virus effectively and the Health Agencies such as the US FDA has several programs to expedite the review and approval of COVID-19 related medical devices. Though, all the mentioned programs are not appropriate for expedited approval of COVID-19 treatments, vaccines and devices, the fast track and priority review designations may be the most pertinent pathways.

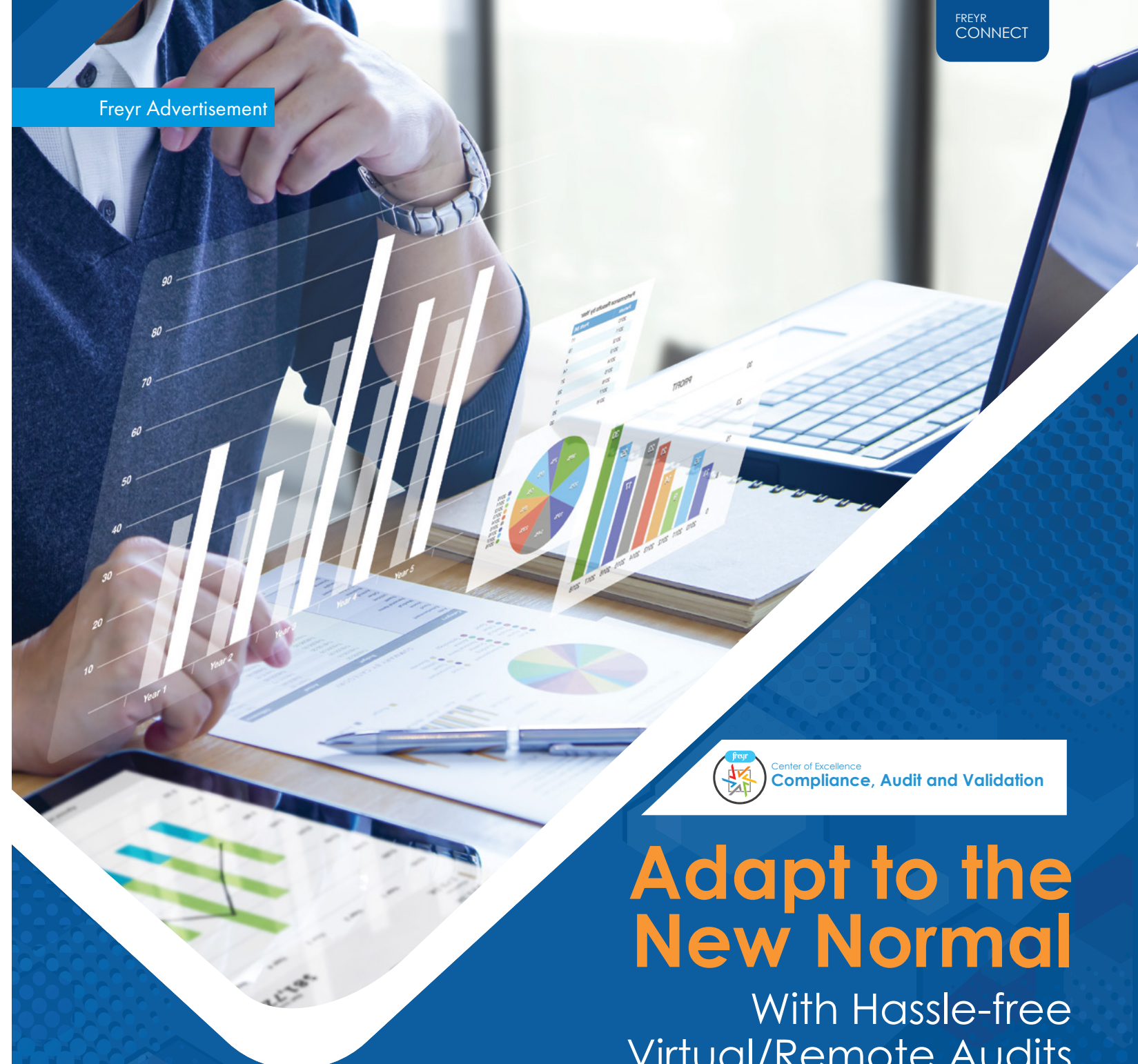
but the positive impact the N95 Respirator – our clients’ product - is going to create for many lives, especially in these extraordinary times.

As these programs don’t demand the comparison of investigational drug or diagnostic test to available therapies or tests, they stand promising for expedited approval of a device, treatment or vaccine for a fast spreading virus like COVID-19. Upon meeting the criteria specified in the respective programs, the sponsor may receive both priority review and fast track designations. Although the US FDA reviews applications for investigational devices, therapies and vaccines using its expedited programs, the Emergency Use Authorization is a potential interim measure to the approval processes for medical devices and drugs related to COVID-19.

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Freyr Advertisement



 Center of Excellence
Compliance, Audit and Validation

Adapt to the New Normal

With Hassle-free Virtual/Remote Audits

In case of no scope of on-site audits during the health crisis like COVID-19, what best options do manufacturers/regulators have to validate the safety of the drugs that are being manufactured? The answer leads to Remote/Virtual audits, unquestionably.

Ensure a Smooth Transition with a 3-stage risk-based approach.

Take Up This

Free Consultation Questionnaire

FDA'S NEW COVID-19 SPL TEMPLATES AND PRE-REQUISITES

The COVID-19 pandemic has disrupted all the industries across the world. To handle the situation carefully, certain proactive measures have already been rolled out. One among them is to properly sanitize the hands with over the counter available drugs such as Hand rubs and Hand Sanitizers. To make such products adequately available in the market, the United States Food and Drugs Administration (US FDA) has released a few new Structured product labeling (SPL) templates for speeding up the listing process of approved OTC products - hand sanitizers and hand rubs.

The purpose of introducing these templates is to speed up the SPL filing process to meet the market demand for the products. The FDA has released new SPL templates for the following products:

- Alcohol 80% - Hand Sanitizer - CoViD-19 Emergency
- Isopropyl Alcohol 75% - Hand Sanitizer - CoViD-19 Emergency
- Alcohol 80% - Hand Rub - CoViD-19 Emergency
- Isopropyl Alcohol 75% - Hand Rub - CoViD-19 Emergency

To begin SPL filing, manufacturers can load the appropriate template suitable for their product. While most of the form filing and preparing procedure is the same, some of the fields, which are common for all products, in the templates are pre-filled for the products. The forms can be reviewed or modified again, once they are duly filled.

Package Label Image Templates

Package label image templates are made available in Word Document format. Manufacturers are required to download and fill the templates in order to use them for Principle Label and Principle Display Panel section of their SPL files. The new COVID-19 SPL templates are equipped with EAN-13

bar code generators which ensure strengthened safety and efficacy of the manufacturer's supply chain.

While manufacturers of hand sanitizers and hand rubs are encouraged to use the new COVID-19 SPL templates, there are, however, certain pre-requisites for using SPL Templates, such as:

1. Manufacturers must have at least one DUNS number for each of their facilities, including the headquarter
2. Manufacturers must have a National Drug Code (NDC) – a labeler code - for each of their unique products. In case the NDC is not available, manufacturers are required to create an NDC labeler code request
3. Manufacturers are also required to create an Establishment Registration for their production facilities

Once all the requirements are filled and validated by the manufacturers in line with the new COVID-19 SPL templates, they can be submitted to the FDA for review. Kindly note that the templates are safety measures taken by the FDA to ensure that products like hand sanitizers and hand rubs are available to the general public in adequate quantity during the COVID-19 situation.

While we understand that these are challenging times, we, at Freyr, are taking all the proactive measures to ensure that the lifesciences companies reach the target market with necessary products in an expedited manner. To ensure this, with an experienced team of Regulatory experts, Freyr

supports its clients with creating compliant SPL templates as per the new guidelines. Are you looking for assistance with SPL templates? Consult Freyr's Regulatory team.

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The Time Is Now To Adapt To
Structured Product Monographs (SPM)

STREAMLINE AND AUTOMATE

WITH
Freyr
SPL/SPM

Freyr SPL/SPM is specialized in



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Right Away!

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**ECOLOGICAL
 PRODUCT**

FOOD AND FOOD SUPPLEMENTS - CLAIMS AND SUBSTANTIATION

Claims are an integral part of the packaging and labeling of any food product or a food supplement. They provide necessary information about the food product to the buyer to help them make an informed buying decision. Before moving forward to the importance of claims in food products, first let's understand what are claims? Claims are statements or phrases on a product label/ pack or advertising or promotional material to express the product performance/ its usage/ indication/ application.

**100%
 ORGANIC**

**100%
 NATURAL PRO**

**100% FRESH
 FOOD**

**ORGANIC
 NATURAL**

**ORGANIC
 PRODUCT**

**100%
 PREMIUM
 PRODU**

In case of a food product or Dietary/ Food Supplements, there are two types of claims: Health Claims and Nutrition Claims.

These claims on food product labels, promotional material, and advertising are a representation to demonstrate the connection between consumption of a food/ food supplement and its supporting health benefits, in the most effective way.

In most of the countries, there are specific regulations and scientific standards for representing claims on the labeling of a food product. These claims should be expressed accurately and must be substantiated scientifically according to the claim supporting data, by a health claims expert. The scientific requirements and substantiation of a claim can differ based on the type of claims (such as health claims, nutrient content claims, structure/functional claims, non- additional claims), type of declarations (such as sugar-free, gluten-free, low-fat), and other country-specific requirements.

However, in some countries, to obtain approval for a health claim, manufacturers are required to submit the

health claim application to the respective health authority (HA). The HA then verifies the application and supporting documents/literature in order to authorize the claim on the product label. Therefore, to ensure compliance of claims, food product manufacturers must keep the following basic principles or aspects in mind:

- A food product is not intended to diagnosis, cure, mitigate or treat any of diseases, hence, it must not make any claim of such sort
- Claims must be true, complete and not misleading, in any way
- Special assessment should be done for Drug-Food interphase products or ingredients like multivitamin and minerals, as some of them may not qualify as health claims based on their quantity in the product
- The ingredient/substance that is the subject of the health claim or any other claim for food must have a taste, aroma or supplement or nutrient value when consumed at the levels, used to justify the claim
- Claims have to be strictly defined based on the Regulatory requirement and claims guidelines of the target market
- From a consumer perspective, there are generally two

types of claims for any product: Comparative and Non-Comparative claims. These have to be carefully evaluated in terms of advertising and marketing or promotional activities and to suit the needs of the business and client consumption

Considering all the key aspects mentioned above, it is safe to say that before launching a food product or a supplement in a new market, manufacturers must decode and align with the Regulatory requirements of claims for successful market entry. Additionally, manufacturers must for supporting the claims. In such scenarios, manufacturers are advised to consult the Regulatory experts with in-depth knowledge of the possible hurdles or challenges seen in the global market, which can assist you with the preparation of the necessary scientific evidence and claim substantiation applications to the government agencies/HA.

Mandate Update

IT'S RENEWAL TIME AGAIN!!!

For the Drug Listed with the FDA
 (Oct 1, 2020 - Dec 31, 2020)

Update Your Drug Listing
 And/Or
 Submit Blanket No Certification SPL

Act Now for Compliance

Consult



TGA ARTG: STEP-BY-STEP PROCESS FOR INCLUDING THERMOMETERS

The COVID-19 pandemic urged an immediate rise in the supply and demand of thermometers. Proposedly, the sponsors and manufacturers applied to Therapeutic Goods Administration (TGA) for the inclusion of thermometers in the Australian Register of Therapeutic Goods (ARTG). Based on the significant number of applications received, the TGA devised guidelines to support the manufacturers and the sponsors both in terms of meeting the relevant Regulatory obligations and submitting the applications for a thermometer and to include them in the ARTG.

TGA Thermometer Classification

Generally, thermometers are classified as Class I (measuring) and Class IIa devices. Clinical thermometers, like, glass and mercury and not battery operated are regulated as Class I and the battery-powered digital thermometers, like, infrared/electronic are regulated as Class IIa devices.

The device classification can be determined, using an online classification tool. If the application does not hold appropriate device classification, it cannot go through the preliminary assessment. All classes of medical devices should meet the conformity assessment procedures and comply with the essential principles (device design & construction) prior to manufacturing.

Thermometer ARTG Inclusion

After meeting the above criteria, the device can be included in the ARTG and further imported or supplied within Australia. But through a certain set procedure and Regulatory obligations. Applicants can follow the below points step-by-step.

- Complete the organizational details form and submit to eBS@health.gov.au.
- Upon receiving username and password, one can submit applications for the inclusion of devices in the ARTG

- Ensure the device manufacturer has applied an appropriate conformity assessment procedure to the device, has evident documentation of device complying to essential principles, has a system for post-market monitoring & taking corrective action in place and has been audited by a conformity assessment body or comparable overseas regulator
- Log into the TGA Business Services online portal and submit a Manufacturer's Evidence application
- Post receiving the MEA acceptance notification from the TGA, log into the TGA Business Services online portal and submit an application for your device to be included in the ARTG
- Upon receiving an invoice, pay the application fee through the TGA Business Services portal. The TGA will commence processing your application after the payment.

During these times of health emergency, every sponsor and the manufacturer of thermometer should strictly adhere to the recommended regulations for expedited review and approvals. Thus, the device can be released into the market quickly supporting the requirement of healthcare professionals. Aim for the compliant market entry with on-time Regulatory assistance. Stay safe. Stay informed. Stay compliant.

WHAT ARE PMSR AND PSUR?

Post Market Surveillance Report (PMSR) and Periodic Safety Update Report (PSUR) compose critical documentation of Post Market Surveillance (PMS) of a Medical Device and an In-Vitro Diagnostic Device (IVD). Medical Device and IVD manufacturers with an intent to market the products in the European Union (EU) shall comply with Medical Device Regulation (EU MDR) 2017/745 and In-Vitro Diagnostic Regulation (EU IVDR) 2017/746.

Post Market Surveillance, commonly called as PMS, is one such compliance requirement applicable for manufacturers of all device classes and is covered under Articles 83-86 of MDR and Articles 78 – 81 of IVDR. The information, frequency and submission requirements for PMSR and PSUR vary based on the device class.

The manufacturers of Low-risk Class I Medical Devices and Class A, B In-Vitro Diagnostics (IVDs) should maintain a Post Marketing Surveillance Report (PMSR). The PMSR need not be submitted to any authority for CE Certification of the device. This report should be compiled, updated periodically and shall be readily available for submission to the competent authority upon request.

The manufacturers of moderate and high-risk Class IIa, IIb, III Medical Devices and Class C, D In-Vitro Diagnostics (IVDs) should submit Periodic Safety Update Report (PSUR). PSUR must be submitted to Competent Authority or Notified Body as a part of technical documentation. The PSUR document is evaluated as part of Conformity Assessment.

The PMSR shall contain summary of results and conclusions derived from analysis of PMS data collected as per the PMS plan. It should also describe the Preventive and Corrective

actions taken. The PSUR, on the other hand, shall summarize the results and conclusions derived from the analysis of Vigilance, PMS and PMCF data collected as per the PMS Plan. It should also describe the Preventive and Corrective actions taken. The PSUR shall include -

- The conclusions of the benefit-risk determination
- The main findings of the Medical Device Post-Market Clinical Follow-up (PMCF) or IVD's Post-Market Performance Follow-up (PMPF)
- The volume of sales of the device and an estimated evaluation of the size and other characteristics of the population using the device, and, where applicable, the usage frequency of the device

The Reports (PMSR and PSUR) are to be prepared and updated throughout the lifetime of the device. The PMSR shall be updated as and when any new changes are made to the Class I Medical Device or Class A, B IVDs in scope. The PSUR for Class IIa devices shall be updated as and when required and at the least once in every two years. PSUR for Class IIb, III Medical devices and Class C, D IVDs must be updated on annual basis.

FDA PHILIPPINES INTERIM GUIDELINES FOR IMPORTING AND MANUFACTURING PPE, VENTILATORS AND RESPIRATORS

With rapid rate of COVID-19 contagion, the Philippines FDA adopted several measures to ensure the adequate access and availability of Personal Protective Equipment (PPE – face masks (N95), shoe covers, gloves, head covers and gowns), ventilators and respirators to public.

Alongside the adequate supply of medical devices into the market, there is a rising concern on their safety and quality standards. Hence, FDA Philippines issued the following guidelines for companies and institutions importing and manufacturing PPE, ventilators and respirators, ensuring to maintain the safety and quality standards.

Licensing and Registrations

Initially, a medical device importer or manufacturer should secure a License to Operate (LTO), in order to import or manufacture PPE, ventilators and respirators. The license should be a proper pursuant to Administrative Order (AO) No. 2016-0003 entitled, "Guidelines on Unified Licensing Requirements and Procedures of the Food and Drug Administration." After securing the required LTO and prior to commercial sale and distribution of the medical devices, importers and manufacturers of PPE are advised to apply for a Certificate of Product Notification (CPN). And, the ventilators and respiratory manufacturers and importers are advised to apply for a Certificate of Product Registration (CPR) within 3 months, after lifting of the State of Public Health Emergency throughout the Philippines (Proclamation No. 922 s. 2020).

The CPN/CPR applications should comply with the requirements of AO No. 2018-0002 entitled, "Guidelines Governing the Issuance of the Authorization for a Medical Device based in ASEAN Harmonized Technical Requirements." To secure product registrations for medical devices, manufacturers will be guided by the following standards, respective to design, development, functionality/performance testing, risk management, product validation, clean room environment, sterilization, clinical trial (whichever is applicable) and other relevant considerations.

- Philippine National Standards (PNS)
- Applicable International Standards (ISO or IEC), in the absence of the PNS
- Technical requirements for registration, as provided under AO No. 2018-0002

The authorized medical devices importers and manufacturers who have started to sell and distribute their products without product notification/registration under FDA Advisory Nos. 2020-547 and 2020-449, and FDA Circular No. 2020-014 are advised to apply for a Certificate of Medical Device Notification (CMDN) or Certificate of Product Registration

(CPR) within three (3) months effective of this guidelines. All these medical devices should implement strict post-market surveillance and any non-compliance will result to proper Regulatory action. Devices holding similar terminologies and not serving the purpose of medical use will not be considered as medical devices and don't require a secure LTO or a CMDN/CPR for their products.

To enter local market for commercial use, presenting the copy of the importer's LTO shall be sufficient for compliant custom release of these medical devices. Contrary, the FDA clearance is not required for foreign donations, which include companies other than the medical device establishments with employees who use face masks in the performance of their jobs and strictly for company use. These clearance procedures prior to customs release shall be effective until otherwise lifted.

Unless revoked, replaced or rescinded, this guidance will take immediate effect and remain valid. The manufacturers and importers of these medical devices should proactively align with the proposed guidelines for a streamlined market-entry. Choose the right Regulatory approach for compliance. Stay safe. Stay informed. Stay compliant.

HEALTH CANADA STANDARDS AND AUTHORIZATION PATHWAYS FOR PPE MANUFACTURING

Worldwide, the abrupt outbreak and spread of COVID-19 has created a scarcity of Personal Protective Equipment (PPE). Proposedly, PPE demand is exceeding the available supply in Canada. To increase the global supply and availability of PPE, Health Canada responds and identifies that organizations (that do not traditionally manufacture PPE) may seek innovative manufacturing approaches to produce PPE for Canadian healthcare workers, including 3D printing.



The medical devices sold in Canada should adhere to the technical considerations, ensuring their safety, effectiveness, quality and certain Regulatory standards are met. Accordingly, the below sections detail Health Canada's PPE production standards and Regulatory authorization pathways.

Standards for Production of Face Shields and Face Masks:

As conformance to standards is voluntary for medical device manufacturers, they may choose to demonstrate conformance with a listed standard or may elect another manner to address the safety and effectiveness. Health Canada recommends face shield manufacturers to align with some or all of the following standards through the design and testing stages:

- CSA Z94.3 (2020) - Eye and Face Protectors
- ANSI/ISEA Z.87.1 (2015) - American National Standard for Occupational and Educational Personal Eye and Face Protection Devices
- CSA Z94.3.1 (2016) – Guideline for Selection, Use and Care of Eye and Face Protectors

The 3D printing of certain PPE, such as face masks, pose some technical challenges to ensure safety and effectiveness. Unlike the licensed surgical masks or N95 respirators, the 3D printed face masks are doubtful to provide the same

fluid barrier and air filtration protection, though they may provide a physical barrier. As advised by Health Canada, organizations manufacturing face masks should adhere to the following standards:

- ISO 22609 (2004) - Clothing for protection against infectious agents, medical face masks, test method for resistance against penetration by synthetic blood
- ASTM F2100 (2019) - Standard specification for performance of materials used in medical face masks
- ASTM F2101 (2019) - Standard test method for evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask materials, using a biological aerosol of *Staphylococcus aureus*
- ASTM F1862/F1862M (2017) - Standard test method for resistance of medical face masks to penetration by synthetic blood
- ASTM F2299 (2003 R2017) - Standard test method for determining the initial efficiency of materials used in medical face masks to penetration by particles using latex spheres

Including the ASTM F2100 (2019) and ASTM F2101 (2019) listed above, several relevant standards for masks, gowns, gloves and respirators are also available.

Testing Laboratories: To demonstrate that 3D printed final product complies with applicable standards, product

testing is of prime importance. The Standards Council of Canada has accredited the following laboratories and certification bodies to test the PPE standards:

Private laboratories

- Intertek Testing Services NA Inc, Intertek Cortland Laboratory
- Groupe CTT Inc. / CTT Group Inc.
- Cambridge Materials Testing Limited

Product certification bodies

- Safety Equipment Institute
- Underwriters Laboratories of Canada
- Canadian General Standards Board
- Intertek Testing Services NA Inc.
- UL LLC
- CSA Group Testing & Certification Inc.

Regulatory Authorization: If representing medical use, most PPE, including face shields are Class I medical devices. Though Health Canada specifies on Class I PPE through this communication, it acknowledges the evolvement of Class II devices, including medical exam gloves, breathing circuit components and venturi oxygen masks. And, organization manufacturing Class II medical devices or above, can email their enquires about device classification and the required Regulatory steps to hc.meddevices-instrumentsmed.sc@canada.ca. For the distribution and sale of 3D printed Class I devices, the manufacturer should hold an authorization under the two Regulatory pathways:

- An Interim Order Process
- A Valid, Medical Device Establishment Licence (MDEL)

An Interim Order was approved by the Minister of Health on March 18, 2020, to rapidly address large scale public health emergencies. To import or sell COVID-19 medical devices, the manufacturers can submit their application for authorization, under this provision. There is no submission of fees for this application and Health Canada will review all the COVID-19 submissions and applications quickly, while maintaining the standards of patient safety.

Medical Device Establishment Licence (MDEL) is for manufacturers who want to manufacture, import or sell and distribute a 3D printed Class I medical device in Canada. Any manufacturer requires a MDEL, unless they are:

- A retailer
- An Interim Order (IO) authorization holder
- A Class I manufacturer who imports or distributes solely through a MDEL holder

- A health care facility (as defined in the Medical Devices Regulations)

MDEL ensures to see that all the manufacturers, distributors and importers have distribution records and procedures in place, to handle complaints, submit mandatory problem reports and to conduct a recall. Health Canada is fast-tracking the MDEL application process and companies that need a MDEL application fast-tracked should:

- contact hc.mdel.application.leim.sc@canada.ca to obtain the MDEL Application Form (FRM-0292) or access a copy of the MDEL Application Form (FRM-0292) available on Health Canada website
- complete the form
- indicate in the subject line of the email: URGENT COVID-19 MDEL application for “-name of company”
- email the completed MDEL application form to hc.mdel.application.leim.sc@canada.ca

If access to face shields becomes limited, Health Canada looks upon improvised production. But, during urgent manufacturing scenarios of face shields in Canada, the Interim Order or MDEL requirements would be applicable along with Health Canada's minimum specifications, to be incorporated into the design and verification, to ensure safe and effective face shields. They include:

- Device must provide adequate coverage
- Device should be made of optically clear, distortion free, lightweight materials
- Device should be free of visible defects or flaws that would impede vision
- The device should allow adequate space between the wearer's face and the inner surface of the visor to allow for the use of ancillary equipment
- Device should fit snugly to afford a good seal to the forehead area and to prevent slippage of the device
- Device should withstand impact from sharp or fast projectiles
- If available, device should display anti-fog behavior on inside and outside of shield
- User contacting materials should provide adequate material biocompatibility

During this emergency hour, all the PPE manufacturers in Canada are obliged to adhere to the above-mentioned key factors for successful compliance. For a streamlined market-entry devoid of last-minute challenges, partner with the right Regulatory adept. Stay safe. Stay informed. Stay compliant.

EAEU Mandates Electronic Submissions

For New Market Authorizations and Follow-up Submissions



Mock Audit and Training for Stage II MDSAP Assessment



Aim for Compliant Transition Before the Deadline

 New Market Authorizations
Dec 31, 2020

 Follow-up Submissions
Dec 31, 2025

Leverage
Freyr SUBMIT PRO



Request A Demo



Client
Innovator in Medical Aesthetic Technologies



Therapeutic Area / Indication
Medical Devices- Aesthetic Equipments



Solution
1. Mock Audit For Stage II MDSAP Certification
2. Online MDSAP Training Program

BENEFIT HIGHLIGHTS

- Readiness for Stage II MDSAP Certification
- Well-trained Internal Resources on MDSAP Requirements
- Training Certificates Justifying Resource Capabilities
- Training Material Facilitating Periodic Internal Training Session for Resources



Manufacturing site
3 Manufacturing Sites Located in Spain and Bulgaria



Geography
Spain

Business Imperatives

- The Quality Management System of the client ISO 13485:2016 was certified with multi location centralized QMS system. The devices were CE marked as per the EU MDD and were actively distributed in the EU, US, Brazil, Canada and 20+ other countries
- Client was in the process of obtaining MDSAP certification in order to comply with Canada MDSAP requirements and as well as to comply to MDSAP program for other regulated markets
- Documentation review under Stage I audit was concluded and on-site audit under stage II assessment was due in a month's time
- The client approached Freyr for assistance with the mock audit of their QMS systems for compliance with MDSAP requirements and for on-site training of their internal resources on QMS requirements under the MDSAP program

Challenges

- Apart from existing multi-site and centralized QMS system, client had a proposal to transfer certain manufacturing operations to a new site
- The yearly surveillance audit for ISO 13485:2016 was due in couple of months
- Restrictions imposed on international travel owing to COVID-19 pandemic proved to be a bottleneck for the on-site training session
- The participants for the training included a pool of Spanish-speaking and English-speaking audience
- The manufacturing operations were carried out at multiple manufacturing sites located in Spain and Bulgaria

Freyr Solutions and Services

- Freyr supported the client with a multiphase approach comprising of Pre-Audit, On-site Audit and Post – Audit phases to facilitate smooth and timely execution
- Audit report submitted was bilingual to enable both Spanish-speaking and English-speaking audience
- Proposed remediation plan for addressal of audit observations was submitted along with the audit report
- The mode of training was smoothly transitioned from on-site module to online module within a very short notice
- The 2-days on-site training sessions were split into multi day online sessions
- Training content was developed in Spanish language for better comprehension of the specific audience

Client Benefits

- Readiness for Stage II MDSAP Assessment and the certification with minor observations
- The internal resources are well trained on MDSAP requirements enabling better compliance
- Training certificates issued for justifying the resource capability during the actual audit
- Training material is useful for periodic training of internal resources or newly added functional team members

Case Study 2

Successful Execution of Validation Procedure



Client
Top India-based Company



Services
cGMP



Function
Compliance and Audit Function

BENEFIT HIGHLIGHTS

- Quick turnaround with planning, report was completed in 2 weeks by expert team with high quality briefing and recommendations



Products
Formulation



Geography
India



Therapeutic Area / Indication
Multiple

Business Imperatives

- ▶ A top India based pharma company wanted Freyr to audit their cleaning validation procedures and documentation such as :
 - Validation master plan
 - Project validation plan for cleaning validation
 - Cleaning validation protocols

Challenges

- Acquiring information and related documents and records from the client
- Travelling to the client's site and explaining and making them understand the identified gaps

Freyr Solutions and Services

- Freyr performed Gap Analysis and made the report with **48 gaps**
- Explained Gap Analysis report to clients for better understanding

Client Benefits

- Quick turnaround with planning, execution, and Gap Analysis report completed in **2 weeks**
- Expert team produced high quality briefing and recommendations as per the latest Agency standards

Leadership Connect

LEAD THE WAY

With **Adnan Subhani**

Leading a business towards success and growth requires innovative thinking, hard work and unparalleled leadership skills - a rare combination of skill set found these days in new-age leaders. With this Freyr CONNECT, we are glad to bring you one such inspiring persona, who has inspired many with his innovative thinking and led the business towards success.

We wonder! How could he do all this with just a pleasant smile!

Let's CONNECT with Adnan Subhani, AVP – Regulatory Operations at Freyr.



Hey Adnan! Hope you are doing great. Firstly, congrats on winning the Circle of Excellence. With an everlasting smile, you inspire all of us at Freyr.

My heartfelt gratitude to everyone who has been a part of this journey. Yes, this has been a big achievement, but honestly, it was not just me who deserve it, but also a whole lot of people that I work with. I believe that the highest appreciation is not to utter words, but to actually live by them. Thanks to each and every member of the Freyr family for making me perform better.

We all know that you've extensive experience across multiple industries. What is it about the life sciences industry and Freyr that has fuelled your enthusiasm for the past 5 years?

When I started my career with Freyr, it was altogether a fresh start; I joined the company not for the sake of taking up another "job" but for a "CAREER". Over my career span of 20 plus years, there were several learning's that I encountered – both in the realm of self and team building towards leading a high performing business.

The first thing I did after joining Freyr was to align myself with Freyr's ways of working standards and its overall value system and culture. I believe, it is imperative to find out all you can about the organisation which you are looking to pursue your career with. This includes their values, attitude towards different situations or factors, business strategies, etc. The list is never-ending. But, apart from all this, the most important aspect for one to know about any organization is its long term vision.

The next step was to ensure that I knew clearly what was expected from me by discussing the goals and changes that would affect me and the way I work. Understanding this was the key, as it helped me build the base for planning the short term and long term goals for myself and for my team, and in doing so, for the organization.

There were some fundamental changes I had to make within myself and these were different from managing a group and a department. A lot of these changes can't be explained in words, these are real experiences!

Being Proactive was one of it as I was aware that Freyr is growing and there are many opportunities to grab and there is no stopping. Right from managing one account, to two and so on, the opportunities started pouring in. Our customer base is huge, and I believe this is a USP for Freyr. If you prove yourself there are many great leaders to hold you back, if they know that you are doing it in all good spirits looking at organisation's long term goal. I started slowly and now honoured to manage few of the biggest

engagements and I still believe this is just the beginning and there is a long way to go, as there is so much to do and achieve in the trillion dollars life science industry and in the Regulatory space.

To sum up, over the past 5 years, Freyr taught me that leadership is in every way a journey. A journey because you are always going where you may not have gone before. It's a journey of learning how to deal with different clients and associates, a journey of growth where you constantly push the envelope for yourself. And above all, it is a journey of personal transformation.

"As a leader, you learn just how much of a follower you are..."

The world today is deeply impacted by COVID-19. Despite that fact, Freyr as a proven Regulatory partner is going on a mission to help many life sciences manufacturers to reach markets across the globe right on time. En route, what according to you could be a major operational challenge? How can Freyr overcome that?

For operations teams' efficiency has long been a byword. Having a passion for and taking advantage of new technologies—especially during a pandemic—is a huge part of running operations responsibly and with resilience in extreme circumstances. Workforce augmentation and paying attention to data and security protocols, technology infrastructure and support means organizations can perform their best. I think, Freyr is on the right path and ready to take on any challenge, as we have the most amazing assets **"OUR ASSOCIATES"**.

The new normal is supposedly testing the integrity of many businesses across the globe. As someone who has always been customers' most preferred choice, what is that one thing that you would want others to practice while addressing clients' needs? "Customer Success" is the key. A relationship-focused client management that aligns with client and vendor goals is necessary for mutually beneficial outcomes. It is a long-term and professionally directed strategy for maximizing customer's and company's sustainable proven value. My aim is to become a True Business Transformation Partner for which you need to let your customers know that you are there for them.

"Responsiveness Matters!!"

Either inside the organization or outside of it, we heard many people saying that Adnan is most receptive, jovial and sympathetic in any given situation. How is it even possible for a person who carries multiple tasks under his belt?

"Where there is a will there is a way", and you can do anything that you set your mind to. If you treat your job as a task, then it becomes difficult for you to manage multiple projects/priorities. But, when your job is your passion, no one can stop you. My Mantra is "Follow Your Passion and You Will Never Work a Day in Your Life". It does make sense that if we love what we do, we will do it better, longer, with greater passion and SMILE.

Given your experience in handling some of the biggest accounts of Freyr, may we ask you to share some real-time experiences of Freyr bringing the change in clients' business processes or outcomes? We really admire the way you have explained it in one of the cross-functional team meetings.

There is a lot that goes on in Freyr and giving one or two examples will miss the bigger picture as we have achieved some huge wins in terms of managing customers, end-to-end processes and in fact creating strategies, that has helped our customers to transform their entire business practise and outlook. Yes, the journey is never ending and it continues ...

At Freyr, our primary business is providing **world class services**. Product is an integral part of our services for few clients, whereas, it acts as standalone for few others. But our overall value is based on the services. Our ability to provide **world class services** and to consistently exceed the expectations of clients will help us to be one-step ahead in this competitive market.

However, before that, we need to understand the following:

- Each client and prospect counts
- Each person counts
- Each deed counts
- Each interaction between a client/prospect and an associate counts.

Apart from this, we also need to focus on:

- Moving from SLA-driven operational efficiencies to consistent improvements in cost efficiencies
- Delivering greater business values to the client by improving productivity and quality through **innovation**
- Improving processes at all business stages

- Using tools and technology to reduce drudgery and monotony and increase the efficiencies
- Taking up work not as a task but to deliver performance and value with passion

In achieving this we will realize that we all will become ICONs, (Innovation Comes On Naturally)

If not Regulatory aspect of life sciences, what would Adnan choose as his career pathway?

I take things as they come. But yes, once I commit myself to something there is no looking back, as commitment leads to action. Action brings your dream closer...

Rapid Fire:

Your Motto – "Chase your passion and never quit"

Super Strength – "My family" - Freyr is family, too

Ideal Day – "Monday" back in action

WANDERLUST

WHY DO I LOVE TRAVELLING?

What do you do to rejuvenate your mind and soul? Read? Take a walk? Listen to some old school music? Workout? If you talk about me, I travel. Traveling for me is like meditation, because, it clears my head and provides me a clearer perspective of life and its situations. My family has always been a bunch of travel lovers, and we would have one or two holidays every year just to wash our souls and get back to own respective lives. I guess that's where I get my travel bug from. I have been traveling a lot since my teenage. And, after traveling to various locations across India and outside as well, I was convinced that I wanted to share my travel experiences with others as well. That's how I began my journey as writer, by writing travel blogs.

I may not be a well-established travel blogger, but writing about my travel experiences has given me a new perspective of traveling altogether. I have started enjoying it way too much. I started noticing and absorbing even the smallest experiences of my journey in order to convert them into words. And in doing so, I also started expanding my horizon of thoughts. These small and tiny experiences made me realize, we get caught so much in our day-to-day mundane life that we miss on things that are around us. So now, every year, I allocate a few days, almost twice a year, to go and explore some places where I have never been before. (I know that's not much, but you gotta work to earn as well, right?!) And rest of the time, I'm dreaming about a trip or planning one.



Basically, I don't like the idea of missing out on amazing things and places that are out there. In the past 5 years, I have explored a total of three countries outside India and more than 4-5 states in India – along with some weekend getaways. But, why am I telling you this? Because, each trip has taught me some valuable and beautiful lessons. And I'd like to share them with you.

1. Exploring Stories – Every place has a story of its own which demands to be heard. This is one of my favourite reasons to travel, to explore these stories. Why? Because they aren't just mere stories, they are a plethora of learning lessons. Each place has its own culture and life style and you cannot truly appreciate any culture and lifestyle unless you experience them yourself. These experiences open your mind to fresher perspective, which is just WOW!

2. Learning About Oneself – In our busy lifestyle, one of the things that we try to focus on is self-care. I truly believe that traveling does allow one to understand himself/herself in a clearer manner. You are out there,

wandering in a new place, exploring everything which is new to you all by yourself. It is the best way to learn about yourself; what you like, what you dislike, etc. Believe me, once you take a trip of your liking, you'll come back knowing yourself more than ever.

3. Escaping – Traveling is my escape route. A tough quarter at office, a bad break up or a dull month, all you need to overcome these or any other issue is – traveling. Maybe escaping is a bad word, but you need a way to help your soul relax and rejuvenate. And what's better than losing yourself in a totally new and fresh culture.

I could go on and on about traveling, but at the end all I want to say is that if you really want to know your worth in life – travel. It'll help you understand that there are so many stories that needs to be heard. So, before signing off, I would like to leave you with a quote by Oscar Wilde which I try to live by, "Live with no excuses and travel with no regrets."



Client Testimonials

Thank you so much Freyr for being a great partner in our Regulatory compliance journey. As safety assessment is a key requirement in ASEAN countries, Freyr's support has helped us significantly in meeting those requirements well ahead in Vietnam.

- R&D Manager

A Leading Beauty and Wellness Products Company

Thank you very much Freyr team for the kind help and support. The service Freyr provided us with and their assistance were brilliant!

- Sales Manager

Manufacturer of High-Quality Oral Brands

The news of our product approvals is wonderful! Thank you so much for all that the Freyr team has done and continue to do for us; we really appreciate it.

- Regulatory Affairs Specialist

US Based Leading Skincare Products Manufacturer

Thank you Freyr for your hard work and support of the submission with a quick turnaround. We really appreciate Freyr's expertise and are very pleased to be working with Freyr team.

- Vice President, Regulatory Affairs CMC

US Based Leading Clinical-Stage Biotechnology Company

Thank you Freyr team. We were able to sign-off internally on all the artwork files Freyr helped us with. I appreciate Freyr's professionalism, and quick turnaround. Project met its stated objectives. Thanks!

- CEO

A US Based Pharmaceutical Company

The entire Freyr team was exceptionally responsive and collaborative in providing a quick turn-around and a quality product, which allowed us to meet a critical FDA deadline. We are extremely thankful for the extra effort put forth by the Freyr team in the preparation of this submission. We look forward to working with Freyr again soon.

- Associate Director, Regulatory Affairs

Australia Based Leading Regenerative Medicine Company

Thank you Freyr team for your support on the BLA submission. I appreciate Freyr's support on the compilation, publishing and QC of the documents as well as the ongoing tracking of the issue log data. Appreciate Freyr team for relentless support on the weekends for this submission which helped us to meet our company goal.

- Senior Manager, Regulatory Operations

A Leading Global Specialty Pharmaceuticals Company

Excellent. As always, thank you Freyr team for your timely efforts!
Have a great holiday weekend

- Director, Regulatory Affairs

A Speciality Pharmaceutical Company

Thank you Freyr team for supporting and making the ANDA submission happen without any deficiencies. We would also like to extend our thank you to the Freyr publishing team. Let's continue this!

- Senior Associate – Regulatory Affairs

A US based Generic Pharma Company

Thank you to the entire Freyr team for pulling out all the stops to push the PPM Master through in just one-day for the launch. We appreciate everyone's time and efforts to meet this extremely short timeline.

- Global Regulatory Affairs

Canada Based Leading Pharmaceuticals Company



- ★ **The Customer:** Japan-based, Beauty and Wellness Brand Development Company

Project Details: Food Supplements Product Classification & Formulation Review

- ★ **The Customer:** Switzerland-based, Leading API & Biochemicals Manufacturing Company

Project Details: PDE Report Preparation

- ★ **The Customer:** Germany-based, Innovative Medical Technology Company

Project Details: RI Report Preparation

- ★ **The Customer:** UK-based, Top Multinational Consumer Goods Company

Project Details: UK-based, Top Multinational Consumer Goods Company

- ★ **The Customer:** Poland-based, Pharmaceutical and Biotechnology Company

Project Details: Product Classification

- ★ **The Customer:** Germany-based, Technology Driven Medical Device Company

Project Details: App Registration & LR Support in Brazil

- ★ **The Customer:** India-based, Leading Pharmaceuticals and Biotechnology Company

Project Details: EU Registration of Four Generic Molecules

- ★ **The Customer:** South Korea-based, Leading Pharmaceutical Manufacturing Company

Project Details: Regulatory Assessment for Food Ingredient in USA

- ★ **The Customer:** US-based, Leading Food and Beverages Company

Project Details: Product Registration & Responsible Person Support for the EU & the UK

- ★ **The Customer:** Swiss-based, Top Global Multinational Healthcare Company

Project Details: Publishing Activities for Medical Device and IVDs

- ★ **The Customer:** Canada-based, Leading Consumer Centric Brand Incubator Company

Project Details: Regulatory Support for the European Union, UK, USA, and Canada

- ★ **The Customer:** US-based, Leading Dental Products Manufacturing Company

Project Details: 510k Regulatory Support & NIOSH Certification

- ★ **The Customer:** US-based, AI-driven Ultrasound Based Tools Manufacturing Company

Project Details: Product Registration & Mexican Registration Holder Support

- ★ **The Customer:** US-based, Global \$10+ Bn, Mass Media and Information Services Company

Project Details: Staffing - RI Support

- ★ **The Customer:** US-based, Leading Food Supplements Manufacturing Company

Project Details: Label Compliance Support

- ★ **The Customer:** South Korea-based, Chemicals Manufacturing Company

Project Details: Regulatory Consulting

- ★ **The Customer:** India-based, Global Top Generic Pharma Company

Project Details: Technology Support - Freyr IMPACT & Freyr PRISM

- ★ **The Customer:** Russia-based, Personal Care and OTC Manufacturing Company

Project Details: Cosmetic Label Assessment

- ★ **The Customer:** US-based, Leading Biopharmaceutical Company

Project Details: Technology Support - Freyr SUBMIT PRO

- ★ **The Customer:** Australia-based, Leading Nutraceutical company

Project Details: Product Classification and Formulation Review

- ★ **The Customer:** UK-based, Leading Multinational Consumer Healthcare Products Company

Project Details: Registration Support in CEE Countries

- ★ **The Customer:** Australia-based, Leading Pharmaceutical Company

Project Details: PDE Reports

- ★ **The Customer:** US-based, Leading Global Biotechnology Company

Project Details: RI Support

- ★ **The Customer:** UK-based, Multinational Consumer Goods Company

Project Details: Formulation Assessment



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Complying with the General Data Protection Regulations (GDPR), we have made changes in the way we collect, store, process and transfer data. We hope you understand Freyr's efforts in complying with mandatory GDPR requirements. Let us be compliant, together.

Kindly note that the Regulatory scenarios and mandatory deadlines discussed in this Issue may be altered in near future. This might be due to the current Pandemic outbreak or the periodic Health Authority updates. Hence, it is probable to find different perspectives/opinions in comparison. Kindly be aware.

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About Freyr

Freyr is a leading, niche, end-to-end global Regulatory solutions and services company supporting large, mid, and small global organizations across different life sciences verticals - Pharmaceuticals | Generics | Medical Devices | Biotechnology | Biosimilars | Consumer Healthcare | Cosmetics | Food and Food Supplements | Chemicals. Freyr supports life sciences organizations in their entire Regulatory value chain - Intelligence Driven Submissions/Product Registrations | Labeling | Artwork | Post - Approval Change Management | Regulatory Software and other related services.



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