

"Market Authorization of Biosimilar Drugs in the U.S and Europe "

By

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CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled "**Market Authorization of Biosimilar Drugs in the U.S and the Europe** " and submitted by **Gaurav Enrollment No.0068** under the supervision of Mr. Gaurav for award of MBA in Pharmaceutical Management of the University carried out during the period from 5th February to 4th May embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Signature



PlasmaGen BioSciences is an Indian Bio-pharmaceutical organization specializing exclusively in Plasma Protein Therapy.

Headquartered in Bangalore- India, PlasmaGen has been making every effort in the domain of Plasma product Industry and has become an Imperative one stop destination for the medical fraternity for most of the plasma products need. We have a basket of plasma products and the widest range of immunoglobulins in India catering to the requisites of various realms viz. Haematology, Oncology, Immunology, Paediatrics, Rheumatology, Dermatology and Neurology.

South Asian Association for Regional Co-operation (SAARC) includes 8 countries; India, Afghanistan, Bangladesh, Bhutan, Maldives, Nepal, Pakistan and Sri Lanka, these countries not only share geographical proximity and political agenda but also share many common social concerns- Healthcare, Education, Economic Infrastructure and many more. SAARC region share similar challenges when it comes to awareness, accessibility, availability and affordability of safe plasma products because of the limited consistent supply of safe plasma and low plasma fractionation capacity.

We therefore pursue a vision of ushering in the Plasma Protein industry in SAARC region & endeavour to provide an extensive assortment of safe plasma products to enrich the quality of life of patients. This is a step working towards addressing the very contemporary concept of regional self-sufficiency.

PlasmaGen BioSciences, having a niche and expertise in the cosmos of plasma product therapies; also works closely with the government on various plasma policies and hemovigilance, which can be extended and leveraged for growth of this industry in entire SAARC region.

Vision:

To achieve global recognition and trust, as an Indian plasma product company, dedicated towards improving the health and quality of life of patients in India and SAARC (South Asian Association for Regional Cooperation) region.

Purpose, Culture and Value at DelCure LifeSciences:

At PlasmaGen BioSciences, we strongly believe in promoting the purpose of **Happiness** and creating the culture of **Helpfulness** for DLL family members and the society, with the learning from Mother Nature, promoting sustainability and augmenting life with growth. We firmly believe in value of **Truthfulness**.

The Visionary:

To achieve global recognition and trust, as an Indian plasma product company, dedicated towards improving the health and quality of life of patients in India and SAARC (South Asian Association for Regional Cooperation) region.

Our Mission

Provide a wide range of safe plasma products to patients, in India and SAARC (South Asian Association for Regional Cooperation) region, on consistent basis.

Create strategic partnership to enable the global market accessible to India and SAARC region.

Develop a consortium of stakeholders involved in Plasma Protein Therapy to optimize the use of surplus unutilized plasma for India and SAARC region.

Pave the road for achieving self-sufficiency in Plasma Protein Therapy in India and SAARC region.

Work in close association with regulatory agencies and collaborate with research institutions to change the landscape of Plasma Protein Industry in India.

Culture

PlasmaGen Biosciences (P) Ltd. in its infantile stage, considers each and every employee as its founders and its employees take pride and sense of responsibility in making PlasmaGen BioSciences as a workplace committed to “**Helpfulness**” & “**Happiness**”.

Diversity:

The employees coming from different culture and background create Work force diversity. The diversity also reflects in the thoughts and ideas which in turn helps in making unique strategies and working style.

Inclusiveness:

At PlasmaGen Biosciences we believe that every employee unique and different individual .Therefore everyones opinion is valued. Every single employee is encouraged to put forward the ideas and feedback is taken every 30th, 60th and 90th day of their joining.

Career Enrichment:

In PlasmaGen Biosciences more emphasis is given to Training & Coaching. With different tools , every individual is exposed to self assesment and is encouraged to take guidance to shape their career.

Community:

PlasmaGen Biosciences are well connected through various networks. You may find them on Facebook, Twitter , Linkedin & Google+. It enables them sharing of ideas, seeking guidance and helping across the globe.

Manufacturing Plant

As logical extension of our work and effort, under our new investment plan, PlasmaGen is all set to the establishment of its own manufacturing facility in Bangalore, India... This would be one small step but important one towards achieving self- sufficiency in Plasma Products arena in India...

Plasma Scenario

Global

Plasma Industry is expected to grow at a CAGR of 10.54% between the years 2015-2020.

The total global plasma collections totals to about 36.8mn liters (2014) and is expected to reach about 50 million liters by 2020.

Although Asia houses about 60% of the world's population, it has only 20% of the global plasma fractionation capacity - a huge imbalance which will be one of the key drivers of growth of the plasma products in the coming years in Asia. The improved indicators of growing Asian economy have made it the cynosure of Global Plasma Fractionation Industry.

India

India harbors a network of 2700 blood banks and accounts for 10% of the world's blood collection (10 million units); but due to only ~40% of blood being subjected to componentization and absence of source plasma collection; very limited amount of plasma is available for fractionation.

For a country that accounts for almost 18% of the world's population (1.32bn people), making up merely 1.3 % of the world's total plasma collection is not only ironic but also indicates towards a huge existing gap between the demand of plasma, needed for providing safe plasma products and its truncated supply, mainly due to underutilization of its resources and regulatory system.

It needs an integrated inclusive model of plasma protein therapy which includes: proper channel for collection of plasma, policy amendments for the collection of source plasma, contract fractionation and an increase in plasma fractionation capacity in the country.

SAARC

With a huge growing population in SAARC region, the disease burden is also on rise and puts a very heavy stress on the healthcare system and its various components. For manufacturing plasma proteins; this region is dependent only on recovered plasma, as source plasma collection for plasma fractionation is not included in the regulatory guidelines. Furthermore, within this region the rate of blood donation is fairly low and largely dependent on one-time donation; and to add to this quandary, rampant whole blood therapy, further limits the availability of safe plasma for fractionation.

But as this region is also on the path of economic prosperity, it holds a huge potential to grow in this domain. Affordability apart, the key challenge is timely and uninterrupted availability of safe plasma products. As the socioeconomic condition of SAARC is different within Asia itself, a unique sustainable model of Plasma Fractionation Industry is needed to make it socially relevant and financially viable.

Product of PlasmaGen BioSciences



