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PlasmaJan

The Blood Plasma Sector: Transforming Healthcare & Creating Opportunities

Chintan Acharya, VP Finance, PlasmaGen

The blood plasma-based healthcare has made enormous strides in recent years, revolutionizing the space, and offering a ray of hope for patients where classical cures were ineffective. No wonder, the demand for blood plasma has surged significantly. Let's explore the impact of the blood plasma industry on overall healthcare, the opportunities it presents, the challenges, the future evolution, and the role governments can play in realising the sector's potential.

The power of Secor is consistently emerging as it unfolds essential therapeutic options for patients suffering from immune deficiencies, haemophilia, and other rare diseases. Plasma-derived therapies, such as immunoglobulins and clotting factors, have positively impacted the prognosis and has improved quality of life.

The sector presents a range of opportunities for various players, including plasma collection centres, pharmaceutical companies, and healthcare providers. Plasma collection centres serve as the foundation of this industry, collecting and processing donated plasma to meet the growing demand. Entities processing plasma into life-saving drugs have noticed a surge in the product demand.

The sector has its own notable challenges and risks. One challenge is ensuring a sufficient and safe supply of plasma. Collection centres need to up their screening procedures to protect against potential infectious agents and other contaminants. Moreover, plasma donations are dependent on voluntary donors, which can fluctuate, leading to potential supply shortages. Additionally, the industry faces risks related to regulatory compliance, pricing pressures, and intense competition, which can impact players' profitability and sustainability.

The sector is poised for remarkable growth and evolution in the next 3-5 years. Advances in technology and manufacturing processes are expected to lead to increased efficiency and cost-effectiveness in plasma collection and processing. Furthermore, ongoing research and development hold the promise of developing new and innovative plasma-derived treatments, expanding the industry's reach and impact even further.

Finally, government's role in supporting the sector is pivotal to its success. Firstly, regulatory frameworks and strict guidelines pertaining to the collection, processing, and distribution of plasma are essential to Safeguard patients' health. Secondly, governments can provide financial incentives and support R&D efforts to promote innovation in the industry. Finally, establishing partnerships and collaborations between governments, healthcare providers, and industry stakeholders can facilitate the advancement and growth of the blood plasma sector, ultimately benefiting patients worldwide.

Overall, this sunrise sector would need all the support, caution, and enthusiasm to deliver on the significant healthcare disruption it has begun to uncover.

Thought for the month

"Pay it forward"

We are a product of the kindness and generosity of the universe around us. This month's thought is about consciously extending the idea of creating a chain of generosity to enable a continuous "flow" of good around us. "I Contribute First" is a close approximation of this powerful thought that could make every person a stakeholder in the blood donation space

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Sector Highlights: Prime Movers

Global Plasma Fractionation: Sector Overview – Part 1

Dr. Chandra Vishwanathan

A mechanised set up used to isolate useful plasma proteins clinically from human plasma is known as Plasma fractionation. Over the years, plasma fractionation has evolved from a medical service activity restricted to local communities into a global manufacturing powerhouse conforming to high regulatory standards. Over 55 million Liters of human plasma are fractionated each year in the world, in about 70 odd such fractionating facilities. Modern plasma fractionation combines manufacturing steps to isolate, in a sequential and integrated manner, the crude fractions that are further purified into individual therapeutic products. Validated dedicated steps inactivate and/or remove infectious agents potentially present in the starting plasma pool. This sophisticated industrial process is performed under highest grade hygienic conditions in closely monitored and regulated facilities, that are operated in compliance with good manufacturing practices and scrupulously follow quality assurance principles that are in force in that geography. These factors, compounded by the huge set up costs and limitations on the supply of human blood makes new entrants strive harder to make a space for themselves.

There are over thirty companies that have the capability to fractionate plasma and/or offer contract services to those countries in need. Currently, CSL Behring, Grifols, Kedrion, LFB, Octapharma, Biotest, Takeda [Shire] are some of largest global players. Medical fraternity have been using their products for patient care for several years now.

CSL Behring Biotherapies for Life™ octapharma GRIFOLS KEDRION BIOPHARMA bpl Bio Products Laboratory

Plasma Applications: New Developments

- The FDA has granted breakthrough device designation to a phospho-tau 217 blood-based biomarker to assist in the diagnosis of Alzheimer's disease, according to the manufacturer.
- In a company press release, Quanterix Corp. said the Simoa assay is a semi-quantitative in vitro diagnostic immunoassay intended to measure p-tau 217 concentration in plasma using the Quanterix HD-X immunoassay system. Recent Gene-editing breakthrough for a rare hereditary disorder – angioedema, a genetic disorder that manifests as painful and unpredictable (and sometimes fatal) swelling attacks. Plasma kallikrein - a trypsin-like serine protease whose activation results in the initiation and amplification of the plasma kallikrein/kinin system, research showed promising therapeutic results.
- A new way of assessing proteins in a person's blood may be able to predict the likelihood of developing dementia more than a decade later, according to a study published this week in the journal Nature Aging. The results could lead to what researchers call "ultra early detection" of brain changes that can lead to severe cognitive problems.

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Star Blood campaign of the month

A 21,000-Kilometer Journey of Hope

In a display of unwavering commitment and selflessness, Kiran Verma embarked on a journey that transcends the boundaries of ordinary humanitarian efforts with a mission to raise awareness about blood donation among people so that "nobody should die waiting for blood in India after 31st December 2025". Starting his monumental trek from Thiruvananthapuram on December 28, 2021, Verma set out to cover an astonishing distance of 21,000 kilometres, spanning over two years.

The motivation behind Verma's campaign stems from a deeply personal experience that shook him to his core. It was a fateful encounter in 2016 when Verma's blood was sold to a desperate family grappling with medical expenses in Delhi. Learning that the family resorted to such drastic measures, including the wife's entry into prostitution to afford her husband's treatment, ignited a fire within Verma. Determined to prevent such tragedies from recurring, Verma left his job and started working a mission that "nobody should die waiting for blood by 2025 in India".

Verma firmly believes that mobilizing just 5 million new blood donors can eradicate fatalities stemming from blood shortages entirely. However, achieving this ambitious target necessitates a drastic shift in societal attitudes towards blood donation, particularly in a country where the culture of voluntary blood donation remains nascent.

Kiran Verma has founded "Change with One Foundation" under which he runs two programs Simply Blood and Change With One Meal.

Simply Blood, the world's first virtual blood donation platform, operates like Uber, seamlessly connecting donors with recipients in real-time, free of charge. Since its inception in January 2017, Simply Blood has facilitated over 70,000 life-saving blood donations, exemplifying the power of technology in addressing societal challenges.

Change With One Meal, an initiative providing affordable meals priced at Rs.10 in Delhi. Over the past three years, the program has served over 1.5 million meals, underscoring Verma's holistic approach to addressing systemic issues of poverty and hunger.

As Verma travels across India, his journey reminds us of the transformative impact of individual action. With each step, he inspires others to join him in saving lifes through blood donation. His dedication reminds us that a single individual armed with determination can catalyse profound societal change.

Policies and Regulation – The global perspectives for success

Dr. Chandra Vishwanathan

It's a herculean task to set up and run a safe, progressive, economical, and relevant blood plasma unit. The regulatory framework and GMP compliance form the basis for ensuring this, however, there are several other factors that drive success here. These include:

A. Growing role of the United States as the global supplier of source plasma, they are challenging the norms of plasma contribution and strengthening the supply chain. Rest of world needs to catch up soon.

B. The rise of China's plasma sector, both domestically and globally, is on expected lines and they would yield significant pressure on margins, volumes, and specializations.

C. Changing laws/ suitable modifications of the existing compensation to pedigreed plasma donors in UK, this compensation is for their time and efforts. One can expect similar changes in the plasma donation policies.

D. Permitting source plasma easier in countries such as ours, with suitable legislation, will help improve quality of plasma and make uninterrupted plasma availability, is a critical need of the sector.

E. A better quality of domestic R&D leading to newer products for rarer country specific diseases with speedier clinical translation is desirable, although scrutiny and ongoing follow up is imperative

F. Immunoglobulin usage for newer domains is on the rise globally. Neurology and immunological segments show robust growth; an increasing number of infections, and rare and inherited coagulation disorders treated by plasma derived products is promising.

G. Emergence and growth of several specialty products, including C1 esterase inhibitor (C1-INH), prothrombin complex concentrate (PCC) and alpha-1 antitrypsin (AAT); building capability in these is recommended for staying relevant in the future.

H. Availability and disruption caused by recombinant products is showing steady uptrend globally, looking at these solutions is critical to future growth.

I. Availability and the cost of raw materials is a critical factor, as the industry develops, opportunities for the ancillaries to up the raw material supply would be tremendous; special impetus on developing most critical raw materials domestically.

J. Easier and simpler methods to confer safety, cost effective and single use technologies will help cost control, public debate to build a larger thought pool is critical to address this aspect and stay at the forefront of global leaders.

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Readers contribution

Vipul Kumar Shrivas, QA Executive

An extraordinary life is all about daily, continuous improvements in the areas that matter most -Robin Sharma

Recently I came across a news that Nicaragua becomes first Spanish-speaking nation to recognise Indian pharma standards. In a significant diplomatic development, Nicaragua has become the first Spanish-speaking nation to officially recognise the Indian Pharmacopoeia (IP) or Indian Pharma standards. This development follows the signing of a Memorandum of Understanding (MoU) on Pharmacopoeia Cooperation between the governments of India and Nicaragua.

This is a milestone for Indian Pharmaceutical companies, as now the horizon is widening for business implications. Previously where we were dependent to abide by the foreign Pharmacopoeia to expand our market services now it can be achieved through our own standards.

Moreover, as the pharmaceutical industry becomes increasingly globalized, with products being manufactured, marketed, and distributed across borders, adherence to standardized regulations becomes imperative for ensuring patient safety and facilitating trade. The Indian Pharmacopoeia's formal recognition not only enhances the credibility of Indian pharmaceutical products but also contributes to strengthening regulatory frameworks and fostering trust among stakeholders worldwide.

Expert Speak - Medical

We often talk about Fresh frozen plasma. What is it?

Dr. Chandra Vishwanathan

It is the fluid portion of a unit of whole blood frozen usually within 8 hours of collection. Fresh frozen plasma [FFP] contains all coagulation factors except platelets. Fresh frozen plasma also contains fibrinogen (400 to 900 mg/unit), albumin, immunoglobulins, protein C, protein S, antithrombin, tissue factor pathway inhibitor, some being important components of the blood clotting mechanism.

Such units are better to be rapidly frozen, so that we do not lose out on certain temperature sensitive proteins like the haemophilia factor or factor VIII and contain no red cells and white cells.

One unit of FFP volume varies from 180ml- 220 ml, depending on how much blood was drawn from a voluntary donor. Usually, it is 350 ml, and in better donors, we draw 450 ml of blood.

Fresh frozen plasma corrects bleeding episodes by replacing or supplying plasma proteins in patients who are deficient in or have defective plasma proteins. A standard dose of 10 to 20 mL/kg (4 to 6 units in adults) will raise factor levels by approximately 20%. An increase of roughly 10% of several factors is enough to bring about arrest of bleeding. Also, fresh frozen plasma provides some volume replacement. Fresh frozen plasma is stored at -30 Celsius. Before administration, fresh frozen plasma is thawed in a water bath at 30 to 37 Celsius over 20 to 30 minutes or in a suitable device in as quickly as 2 to 3 minutes. The FFP given to patients must be group matched.

All our blood banks are expected to make this component from all the units of blood collected.

We will continue to talk about other components in our forthcoming issues of PlasmaJan.

Knowledge Centre

Fascinating world of careers in blood plasma industry

Alok Chandrashekar, HR, PlasmaGen

Health science as a career option has gained prominence post covid and India has realised the urgent need for robust healthcare infra and skilled professionals in pharma and life sciences. As companies invest in technology advancements and embrace digital transformation, exciting opportunities emerge for aspiring individuals.

Diverse Roles in the Blood Plasma Industry

A. Plasma Sourcing

Plasma sourcing involves collecting high-quality plasma from donors or blood centers. Companies establish plasma collection centres to ensure a steady supply. If you're passionate about logistics and ensuring a reliable raw material stream, this role might be for you.

B. Plasma Testing and Quality Control

Quality control is paramount in plasma manufacturing. Specialists test plasma samples rigorously to ensure safety and efficacy. If you have an eye for detail and a commitment to quality, consider a career in plasma testing or quality control.

C. Research and Development (R&D)

R&D scientists drive innovation in plasma fractionation. They explore novel technologies, optimize processes, and enhance yield. If you're curious, analytical, and love pushing boundaries, R&D awaits you.

D. Fractionation and Fill Finish

Fractionation involves separating plasma into its valuable components. Skilled technicians operate fractionation equipment, ensuring the purity and potency of plasma-derived products. Fill finish professionals handle the final stages of product preparation.

E. Sales and Marketing

Sales and marketing teams promote plasma-derived products. If you're a people person with excellent communication skills, consider joining this dynamic field.

F. Human Resources and Finance

Behind the scenes, HR professionals manage talent acquisition, employee well-being, and organizational development. Finance experts handle budgets, financial planning, and resource allocation.

G. Industrial Safety

Safety specialists ensure compliance with safety protocols in plasma facilities. Their role is critical to maintaining a secure and hazard-free environment.

Candidates with backgrounds in Microbiology, Chemistry, Biotechnology, Pharmacology, HR, Finance, and Industrial Safety can find their niche in the blood plasma industry. Whether you're a scientist, engineer, manager, or administrator, your contribution matters. Remember, every step-in plasma production impact lives—making it a fulfilling and purpose-driven career choice.

So, if you're ready to be part of a sector that saves lives, consider a career in the blood plasma industry.

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Expert Speak: Quality by design for PlasmaGen's Products

Umesh Baikunje, Quality Advisor, PlasmaGen

It is said, "Quality is never an accident. It is always the result of intelligent effort". PlasmaGen, being a plasma product making company, wants to make an imperative 'one stop' destination for the medical fraternity by building quality into the products with an intelligent effort and not by testing or on paper. With the inbuilt quality products, the company wants to fill the gap that exists between the requirements and availability of blood Plasma products for the patients.

Quality has been built considering all international regulations and standards like European medical agency (EMA), US -Food drugs and administration (FDA), Central Drugs Standard Control Organization (CDSCO (India)), South African Health Products Regulatory Authority (SAHPRA), and the World health organization (WHO). These standards are applied in developing plasma products, starting from designing of the facility, Equipment/System/Instrument selection, hiring of experienced technical personnel, appropriate training, providing manufacturing capabilities, testing of the products as per regulations.

We ensure that quality is built into every unit of product, and what we deliver to the needy patient is consistent, safe, and effective, and affordable, Quality Risk assessment/ Management (QRM) tools are used to complete life cycle of the product. Also, at PlasmaGen, Quality tools are used in a very effective manner while executing the Commissioning, qualification, validation for e.g., in computer system validation (CQV and CSV), Selection of Blood plasma, Process Validation, Cleaning Validation, Analytical method validation, assigning the shelf life to the product and cold chain validation for distribution etc.

Current good manufacturing practice (cGMP) and GxP (x-CQV/CSV, Qualification/Validation, Testing and Distribution) is always practiced, for maintaining the Quality in every aspect of the products made by PlasmaGen.

Just as individual mindset determines his /her behaviour, at PlasmaGen, an excellent "Quality culture" is practiced considering all international, national regulations and standards in all facets of work done to deliver safe and effective quality Plasma products to the patients. PlasmaGen is built for providing quality product by the people with a 'quality mindset' in quality time to help give some improvement in the quality of life to the patient.

Monthly Quiz

Q1- WHICH OF THE FOLLOWING IS NOT FOUND IN BLOOD PLASMA?

A. Proteins B. Red blood cells C. Antibodies D. Clotting factors

Q2- WHAT IS THE PRIMARY FUNCTION OF RED BLOOD CELLS?

A. Oxygen transport B. Immune response C. Blood clotting D. Phagocytosis

Q3- WHICH PROTEIN IN PLASMA IS ESSENTIAL FOR BLOOD CLOTTING?

A. Albumin B. Fibrinogen C. Haemoglobin D. Globulin

Q4- WHICH TYPE OF WHITE BLOOD CELL IS RESPONSIBLE FOR ENGULFING AND DESTROYING PATHOGENS?

A. Neutrophils B. Lymphocytes C. Monocytes D. Eosinophils

Q5- WHAT IS THE AVERAGE LIFESPAN OF PLATELETS IN THE BLOODSTREAM?

A. A few hours B. A few days C. Several months D. Few weeks

please share your quiz responses to reach@plasmajan.in

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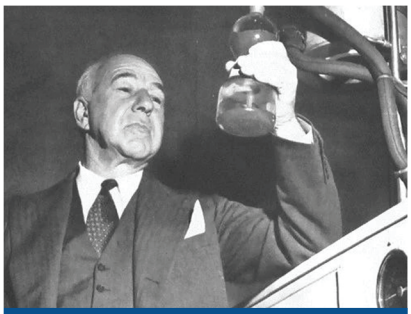

Edwin Joseph Cohn

With the detection of transfusion transmitted HIV in the year 1986, the blood banks in our country, got the much-needed attention from the health officials. The Indian regulations made HIV testing mandatory for all the units of blood collected at the blood Centres and added other testing measures like hepatitis B testing too before they are transfused to patients.

Safety of blood units was perceived to be very important and optimum use was even considered more relevant. Thus, component separation, plasma derived products with more layers of inbuilt safety was sought after. By this time, other countries had already put this mechanism in place for providing safe blood units and preventing transfusion transmitted diseases by adding testing protocols to their operations.

Thus, was born the first Plasma Fractionation project in the country, called the National Plasma Fractionation Centre. This was in the year 1988, that was supported by the SIDA, The Swedish International Development agency, and the Bombay Municipal Corporation that also gave some financial assistance. This Centre was housed in the KEM hospital campus. This pilot plant was designed to fractionalize 10000 Liters of plasma annually. The method adopted was pure chromatography given the small volumes to be handled.

As can be expected, the raw material aspect was to be fixed. So, after the first component laboratory was established in the KEM blood bank, many more component laboratories came into being, across the country. The medical fraternity embraced components, started learning the 'dos n Don'ts' and thus the first steps of mobilization of plasma for extraction of albumin and immunoglobulin became a reality. Virus inactivation was possible as chromatography helped remove the virus inactivation agents, purify the proteins, and gave better recovery of immunoglobulins and other proteins. Special types of PF Chromatography like Ion exchange and size exclusion Chromatography were applied. Albumin and IgG were supplied to the hospitals for clinical use, and it was soon realized that the produce was too little to address the huge clinical demands.

Regulators, clinicians, technicians, and other resources were trained on various aspects of fractionation and biopharmaceutical manufacturing aspects. By the year 1994, there was complete capacity utilization with no scope for additional production due to certain infrastructural limitations.

Thus, the first pilot plant was a good experiment. This paved the way for making plans to establish larger fractionation plants in the country, in line with the best in the other countries.

You are invited to make your contributions for the next issue of PlasmaJan. Please feel free to share your feedback and suggestions to make PlasmaJan more interesting.

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