

# THE SOURCE

MAGAZINE OF THE PLASMA PROTEIN THERAPEUTICS INDUSTRY

FALL 2022

PPTA Member  
Spotlight: Learning  
More About Takeda

.....  
Building a Stronger  
Health Union – Toward  
a Stronger Role for EMA

.....  
Advocating for Plasma-  
Derived Medicines  
in Washington, D.C.



# PLANOVA™

## Assurance Beyond Expectation

### World's First Virus Removal Filter

Unrivalled History of Trusted Use in Production of Biotherapeutics



**AsahiKASEI**  
BIOPROCESS

Visit us on the website!



#### GLOBAL EXECUTIVE BOARD OF DIRECTORS

Bio Products Laboratory

CSL Behring

Grifols USA | David Bell

Kedrion SpA | Paolo Marcucci

Takeda | Giles Platford, *Chair*

General Counsel | Paul Rosenthal, Esq.

#### PPTA STAFF

Sr. Vice President,  
Head of U.S. | Julie Birkofer

Sr. Vice President,  
Head of Global Plasma | Joshua Penrod

Executive Director,  
Head of Europe | Maarten Van Baelen

#### THE SOURCE STAFF

Editor | Mat Gulick

Managing Editor | Rachel Liebe

Requests for permission to reprint should be directed to the editor at [thesource@pptaglobal.org](mailto:thesource@pptaglobal.org).

THE SOURCE is available as a PDF file at [www.pptaglobal.org](http://www.pptaglobal.org).

In the interest of encouraging broad and open discussion of issues relating to plasma protein therapies, collection, and fractionation, **THE SOURCE** magazine may contain statements of opinion on such issues. These statements are those of the author and do not necessarily reflect the opinion of PPTA or its members. ©Plasma Protein Therapeutics Association 2022

#### DESIGN AND PRODUCTION

B. Creative Group | [www.agencybcg.com](http://www.agencybcg.com)

THE SOURCE is published three times a year by PPTA.  
147 Old Solomons Island Road, Suite 100  
Annapolis, MD 21401

PHONE: +1.202.789.3100

EMAIL: [thesource@pptaglobal.org](mailto:thesource@pptaglobal.org)

# FALL 2022 Contents

## 3 OUTLOOK

4 PPTA Member Spotlight: Learning More About Takeda

6 All in for Patients

8 How the Plasma Industry Can Become More Environmentally Sustainable

10 Building a Stronger Health Union – Toward a Stronger Role for EMA

14 European Policymakers Visit a Fractionation Plant

16 Parliamentary Initiative Plasma and Plasma Products in Germany

18 Attendees Gather in Berlin, Germany at the 2022 IPPC

22 Promoting Reciprocal Acceptance of EU-U.S. GMP Inspections

24 What Makes Plasma-Derived Medicines So Different? and Why Should Congress Care?

26 Advocating for Plasma-Derived Medicines in Washington, D.C.

28 Save the Date: PPTA's 2022 Plasma Protein Forum Is Around the Corner!

30 PPTA Welcomes First Member in Egypt

33 Plasma Donor Spotlight: Christian Koch

34 IPAW: A Decade of Plasma Donor Recognition

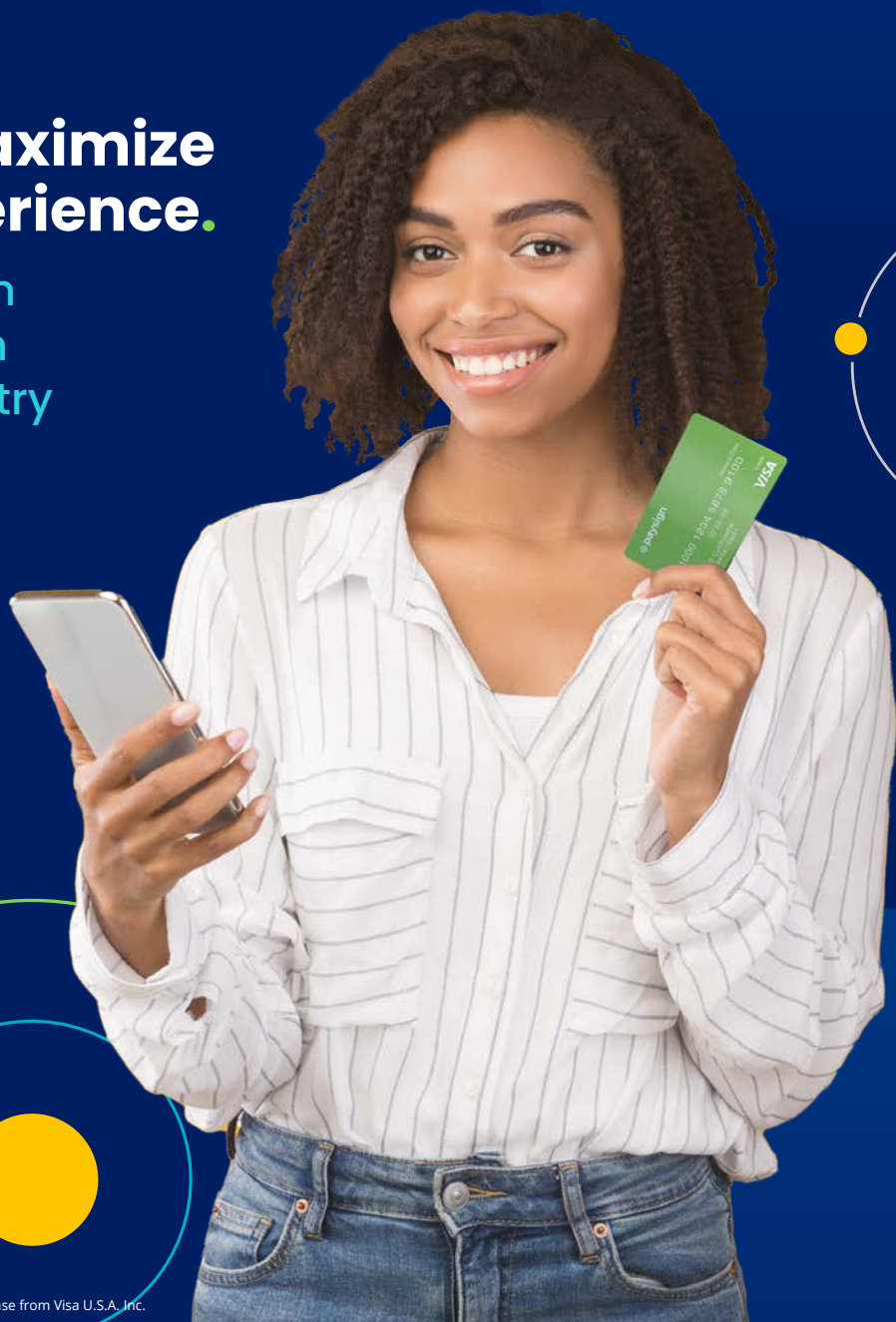
## 37 UPCOMING EVENTS

## 38 GLOSSARY OF TERMS



# Helping You Maximize The Donor Experience.

The Most Benefit-Rich  
Donor Compensation  
Program in the Industry



This card is issued by Patriot Bank N.A., Member FDIC, pursuant to a license from Visa U.S.A. Inc.

Paysign has been a trusted partner to the plasma industry for more than a decade. Our dedication to enhancing the value of solutions we bring to clients allows them to innovate and grow. We pride ourselves on offering the most benefit-rich donor compensation program in the industry, with in-house, bilingual, customer care 24/7/365. Our solution offers donor benefits such as:

- Paysign Premier Digital Bank Account
- Paysign Pays Cashback Rewards
- Paysign Pharmacy Discount Card
- Two-Way SMS Text Alerts

Contact us today to learn how we can help enhance your donor compensation program.

[plasma@paysign.com](mailto:plasma@paysign.com) • 888.522.4845 • [paysign.com](https://paysign.com)







# Outlook

**BY MAARTEN VAN BAELEN**, PPTA EXECUTIVE DIRECTOR, HEAD OF EUROPE

**JULIE BIRKOFER**, PPTA SENIOR VICE PRESIDENT, HEAD OF U.S.

**JOSHUA PENROD**, PPTA SENIOR VICE PRESIDENT, HEAD OF GLOBAL PLASMA

**T**his year marks PPTA's 30<sup>th</sup> anniversary. As a trade association representing the leading collectors of source plasma and manufacturers of plasma-derived therapies, PPTA has maintained several programs and initiatives through the years that focus on maintaining the health of plasma donors who are essential to meet the clinical needs of patients. The International Quality Plasma Program (IQPP) is an example of a voluntary standards program administered by PPTA that has changed over time and will continue to evolve.

There is a relationship deep with shared meaning between plasma donors and patients. Through the years, we have seen more patient groups developing programs to visit plasma donation centers and thank donors for their lifesaving plasma donations. We have witnessed the tremendous positive impact these visits have on donors who have the opportunity to interact with the patients whose lives are improved by their donations. In addition, as discussed in previous issues of this magazine, several patient organizations have developed their own plasma awareness campaigns designed to motivate people to donate plasma and recognize plasma donors as heroes. This type of collaboration makes a tremendous difference and has a positive impact.

The Association convenes industry and allied groups via in-person and virtual events every year, offering participants an opportunity to discuss issues that impact the ability

of people around the world to donate plasma and patients to access plasma-derived medicines. One event sponsored by PPTA is the International Plasma Protein Congress (IPPC). In June, the Association held its first in-person meeting in more than two and a half years in Berlin, Germany. Positive energy and goodwill coursed through the meeting. The benefit of convening thought leaders from the plasma protein therapeutics sector was evident throughout the Congress. The IPPC was well attended by a diverse group of experts from a variety of sectors, including patient organization representatives, regulators, policymakers, physicians, academics, scientists, industry leaders, the press, and other interested parties. Attendees participated in vibrant exchanges with expert panels and shared perspectives on challenges facing the sector. We are grateful to return to in-person meetings and are hopeful they will continue as we look forward to October 11–12 this year when we will host the Plasma Protein Forum (PPF) in Washington, D.C.

After 30 years, meetings such as the IPPC and the PPF are examples of the value that PPTA provides to not only its membership, but to the community of plasma protein therapeutics users. PPTA has changed over the years, and we will continue to adapt to the needs of our membership. We all understand that change is inevitable, and change can be a catalyst for improvements and progress. One thing that will remain constant is PPTA's mission to focus on the well-being of patients and plasma donors. •



# PPTA Member Spotlight: Learning More About Takeda

BY MAT GULICK, PPTA SENIOR DIRECTOR, LEAD FOR U.S. COMMUNICATIONS

**A**s PPTA celebrates its 30<sup>th</sup> anniversary, we are glad to highlight Takeda for its longtime involvement in, and support of, the Association's activities. We recently chatted with Deborah Hibbett, Head of Global Communications, Policy & Advocacy at Takeda to learn a bit more about the company, its priorities, and what inspires its employees to remain so invested in PPTA's success.

**Q Please tell us a little bit about Takeda and BioLife. How long have you been a PPTA member?**

Takeda is a patient-focused, values-based, R&D-driven global biopharmaceutical company committed to bringing Better Health and a Brighter Future to people worldwide. Our passion and pursuit of potentially lifesaving and life-sustaining treatments for patients are deeply rooted in our distinguished history in Japan over the past 240+ years.

Takeda's Plasma-Derived Therapies Business Unit is a trusted global leader and industry partner whose ambition

is to transform the lives of patients worldwide from donation through to delivery of medicines. With an 80-year legacy of developing treatments for rare and complex chronic diseases, we thrive on innovation, offering a broad, differentiated portfolio of more than 20 plasma medicines with integrated care solutions to patients in more than 80 countries.

Dedicated to the collection of plasma that enables the production of these essential therapies, Takeda's BioLife Plasma Services offers one of the most innovative and high-performing plasma donation networks in the world. With more than 200 state-of-the-art BioLife donation centers throughout the U.S. and Europe, we build strong relationships, essential connections, and long-term partnerships to offer the best possible donation experience — providing more people than ever with the opportunity to change and save lives.

As an industry leader, Takeda and its legacy companies have played an important role in PPTA since the beginning of the organization.

“Takeda’s Plasma-Derived Therapies Business Unit is a trusted global leader and industry partner whose ambition is to transform the lives of patients worldwide from donation through to delivery of medicines.”

---

**Q What does it mean to Takeda’s business to participate in PPTA’s activities as a Global Member?**

Takeda sees significant value in being part of an industry association focused on the right activities and with full member commitment. A strong industry association provides us the opportunity to speak with one voice and partner both within industry and together with other stakeholders to strengthen health systems and improve standards of care for patients around the world. The opportunity to be engaged as a Global Member offers the possibility to explore and strengthen work in areas where our industry peers and partners have common interest, and which enable us to act in the best interest of donors and patients.

PPTA has an important role to play in helping Takeda and other companies inform public policies and debates on issues surrounding plasma and plasma-derived therapies. This is particularly relevant when policymakers and regulators look to update their policies, such as the revision of the EU’s Blood, Tissues, and Cells (BTC) regulation. Where members align on key topics, we can be stronger in making our case and encouraging positive change.

At a time when clinical need for plasma-derived medicines continues to increase, it is even more important that the industry brings better understanding of this valuable resource and the importance of adapting plasma donation policies to ensure reliable access to plasma for patients who depend on PDMPs globally.

**Q How do you engage with the Association?**

Our engagement with PPTA is multifaceted. Our President, Giles Platford, currently serves as chair of the Global Executive Board of Directors. Takeda is an active member in various working groups and committees at the regional level and in specialist areas, e.g., regulatory and quality, plasma sourcing, policy, etc. This broad and diverse representation enables our executives and subject matter experts to contribute directly to defining priorities, mobilizing resources, and responsibly advocating industry positions with policymakers. Being part of PPTA also affords the opportunity to take part in the congresses and events organized by PPTA staff with the broader stakeholder community of patient organizations, regulators, policymakers, research agencies, etc.

**Q What are the key advantages to being an active PPTA member?**

Takeda believes in the value of an effective trade association can bring its members, as well as to donors, patients, and health care systems. To that end, we participate in many different associations across the world spanning multiple diseases areas. Driving impactful policy change today requires diverse engagement among a broad bench of stakeholders. Building bridges and collaborations not only among industry players but across the health care system between other stakeholders in the private and public sectors will go a long way to addressing today’s health care challenges. For our work with PPTA, we see that our joined efforts on key priorities, like informing the revised EU BTC legislation and EU general pharmaceutical legislation, as pivotal to building trust with our industry and increasing donation of plasma to manufacture plasma-derived therapies. Working together, there is an opportunity for greater impact and the ability to get more done.

**Q What would you tell other companies considering joining PPTA as a member?**

These are critical times for our industry. COVID has further exposed the vulnerability of the plasma ecosystem while also drawing the attention of regulators and policymakers of the need to have reliable access to plasma. While awareness has increased, understanding remains low. We have an important opportunity — and responsibility — to educate on the importance of plasma as a unique natural resource as well as to address patient access challenges to plasma-derived therapies. On issues where we have common ground, we can be more effective when we work together. We would further benefit from having more diverse voices, fresh perspectives, and the new thinking that new members can bring. We welcome new and interested parties to examine the different membership levels available within PPTA and join our industry effort to improve understanding of plasma and plasma therapies. The Association is only as strong as its members. With passionate, dedicated industry members, PPTA will thrive and ultimately have the ability to do even more for the industry. Working together means we are working in the best interest of the many patients with rare and complex chronic diseases who rely on us every day. ●



# ALL IN — FOR — PATIENTS



BY AINHOA MENDIZABAL ZUBIAGA, VP DACH-H AFFAIRS OFFICE, GRIFOLS

## NEW CHAIR OF THE PPTA EU BOARD OF DIRECTORS URGES THE INDUSTRY TO RESET THE CONVERSATION AROUND EFFORTS TO HELP PATIENTS ACCESS THE PDMPs THEY NEED



It's a great honor and a point of professional pride to have recently been named the Plasma Protein Therapeutic Association's (PPTA) chair for its EU Board of Directors. I gladly and humbly assume this role, eagerly diving into it as

I continue my work at Grifols as head of the region, covering Germany, Austria, Switzerland, and Hungary.

I'm excited to contribute to the advancement of the industry's goals, driving plasma awareness and expanding access to plasma therapies for patients.

Patient access is an area I'm particularly passionate about.

Throughout my career I've had the good fortune to meet many patients who depend on plasma-derived medicinal products (PDMPs), some of whom I know personally. Their stories are moving. They're grateful for the treatments

we produce and the lengths we go to as an industry to ensure there's sufficient plasma, particularly during the pandemic. But they all have the same question on their minds.

How is it, they ask, that with everything known today about their conditions and the value of PDMPs to treat them, there are still roadblocks to accessing optimal therapies? By "optimal" I mean what they really need for their individual medical profiles and not just any treatment "the system" is willing to give.

In the industry, we like to talk about the "patient journey," which ideally includes a linear progression of reasonable duration during which a patient is diagnosed and then begins treatment. For many patients, though, this journey can seem endless and frustrating.

Consider that many patients need five to eight years from the moment they first experience symptoms to the time they have a confirmatory diagnosis and learn of PDMPs as their only (or most suitable) therapeutic option. Fearful and distraught, they become resigned to what could very well be a lifetime dependency on a very specialized medication.

Three difficulties that often follow deepen their anguish and are what we as an industry must fight even harder to avoid:

- 1. Reimbursement Policies.** One challenge patients face is payer reimbursement. In Europe, there's no consistency in reimbursement coverage. It can depend on which country we're talking about, or even which disease. Countries known for comprehensive reimbursement policies, such as Denmark and Finland, reimburse fewer PDMPs than some that aren't as wealthy, like Greece or Czech Republic. And when there's a reimbursement policy, patients often find they don't meet complex eligibility criteria and end up having to pay high costs out of their own pockets, or they aren't treated. Such disjointed policies only add to patient stress.
- 2. Cost Containment.** Complicating the economic conversation even more is the thoroughly exasperating issue of the financial squeeze being put on PDMPs, specifically in the context of what is considered a "cost-effective" medicine. Established and proven PDMP therapies are losing out to new and high-cost treatments being launched (for instance in oncology).  
What happens is that payers, when contemplating new treatments, are considering the overall impact on a country's health care system and look to offset new expenditures with cuts elsewhere. This greatly impacts targeted PDMPs. So does the additional economic strain brought on by external reference pricing and so-called cost-containment measures such as clawbacks, payback taxes, and mandatory discounts that threaten the industry structure's already fragile balance and, more directly, patient access. There has to be a way to manage the economics that take into account the unique nature of plasma medicines and their value to patients and society.
- 3. Purchasing Practices.** A third challenge affecting patient access to PDMPs is procurement. It's clearly the case that plasma-derived therapies are too often commoditized. This one-size-fits-all thinking can be seen in how European health care systems go about acquiring medicines. Invariably their tenders look for the cheapest alternatives so they can ensure the greatest number of units purchased and, consequently, benefit the broadest patient population.

This may work for treatments that are interchangeable or those that have bioequivalents, such as generics or biosimilars, but not for PDMPs. Switching from one to another can lead to tolerability and compliance issues, as well as adverse effects. Purchasing decisions based on purely economic factors shouldn't decide patient access.

**WE NEED TO RESET THE CONVERSATION, TAKING INTO ACCOUNT THE PROVEN VALUE OF PDMPs, THEIR NATURE, AND THE RISK TO THEIR AVAILABILITY. WE MUST KEEP PUSHING EUROPEAN POLICYMAKERS AND MEMBER STATES TO OPTIMIZE REIMBURSEMENT POLICIES, REVISE ILLOGICAL COST-CONTAINMENT MEASURES, AND ALIGN PROCUREMENT POLICIES WITH CLINICAL NEEDS.**

We need to reset the conversation, taking into account the proven value of PDMPs, their nature, and the risk to their availability. We must keep pushing European policymakers and member states to optimize reimbursement policies, revise illogical cost-containment measures, and align procurement policies with clinical needs.

In the absence of a more informed and intelligent approach to enhancing patient access, the discourse, regrettably, turns to how to ration or restrict access to PDMPs.

The pandemic-induced disruption in plasma collection has stretched plasma supplies across the continent and led to limitations on treatments. For example, several countries have applied or thought about instituting a form of "patient tiers," or levels, to decide which specific patient sub-populations should be first in line to receive limited quantities of immunoglobulins.

This categorization of patients provokes controversy about selection criteria and distresses patients and their families, who more likely than not have already had enough turbulence in their "journeys" and don't need another point of tension because they might be excluded from hastily conceived treatment regimens.

Therapeutic rationing is bad policy and should only be a last resort when everything else has failed. We shouldn't have to have this ethical debate. While plasma levels are recovering and perhaps further hard choices about who gets treated can be avoided, there has already been an impact. Let's use this as an opportunity to avoid this problem in the future.

We should be working together across all interested stakeholders — policymakers, industry, payers, etc. — to ensure patients have access to the optimal care they need. This is the dialogue we must insist on.

I'm looking forward to collaborating closely with the industry to reach our objectives. I want my own personal journey to make sure the patient journey is the experience it should be. ●



# How the Plasma Industry Can Become More Environmentally Sustainable

BY ALEXA WETZEL, PPTA DIRECTOR, LEAD FOR EUROPEAN PLASMA

Sustainability has become an increasingly important topic for companies across all industries, including the plasma industry. Finding the balance between strategy and sustainability is no longer optional. While society evolves toward becoming more environmentally conscious, many industries will need to adapt and keep pace.

According to a report from [The New Climate Economy](#), 95% of plastic packaging — the equivalent of \$120 billion annually — is wasted after the first use, and microplastics have been found in 114 aquatic species. Around 170 chemicals used to produce plastic have known human health impacts.

The plasma collection industry contributes to the plastic waste footprint, to the tune of about 18,000 metric tons annually. During the past decades, the industry has become reliant on single-use disposable medical devices, such as tubing, bags, and bottles, for obvious safety reasons. The shift toward single-use material also has an environmental impact. As the clinical need for plasma-derived medicinal products is constantly growing, the potential to generate plastic waste will also increase. (See chart on next page.)

Making the industry more sustainable starts with awareness of how crucial it is to start thinking differently and to make changes — both for the industry and the planet.

The old context of the linear economy, where goods are made, used, and disposed, is giving way toward a more circular economy, where materials are kept in use as long as possible. There is little question that efforts to move toward a circular model will require preparation to solve complex issues related to the plasma industry. It is true that becoming more sustainable is related to an initial investment, but, over time, the industry will be able to reduce costs by prioritizing sustainability.



To take a step forward, industry members can work together to create efficient sustainability practices and shape broad solutions to reduce adverse environmental impact and the industry's collective carbon footprint.

---

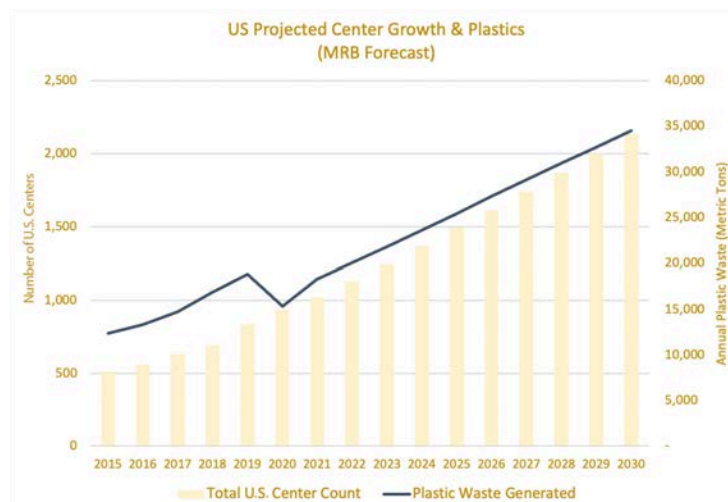
Not only for consumers but also for donors and patients, it is growing increasingly important for organizations to show strong environmental values. Of course, going green results in more than economic outcomes; a balanced scorecard across many communities presents a more complete picture. The recent Coronavirus pandemic has created momentum and provides us with an opportunity to create a new, sustainable reality. A shift in people's mindset has already been observed mainly because of the noted vulnerabilities in the supply chain.<sup>1</sup>

To take a step forward, industry members can work together to create efficient sustainability practices and shape broad solutions to reduce adverse environmental impact and the industry's collective carbon footprint. It will be challenging to actually implement these changes, as there are complexities involved in legal and regulatory requirements, manufacturing operations, and many other areas. Nonetheless, social expectations remain and are growing.

Proactivity is indeed needed; the European Commission has introduced disposal fees for all plastic not recycled and set a recycling target of 50% of all plastics to be recycled by 2025.<sup>2</sup> In the U.S., the Break Free from Plastic Pollution Act was reintroduced in March 2021, aiming to phase out all unnecessary single-use plastics at the U.S. federal level.<sup>3</sup>

Developing collaborative circular solutions for medical waste can help advance the entire plasma industry through enhanced innovation and representation of all interests.

PPTA is well-positioned to foster such collaboration and has created a Sustainability Task Force, a diverse industry group that brings together key members of the value chain in the plasma industry. This group is currently assessing several options to undertake as an Association, including best practices, usage assessments, material science, and other potential steps that can be taken to become more sustainable.



Source: Marketing Research Bureau

The next steps include in-depth discussions on the principles and scope of possible initiatives and expert assessments regarding each initiatives' feasibility, opportunities, and challenges, eventually making solid recommendations for the industry.

There is a long path ahead, but together we can shape a more sustainable plasma industry — and future. ●

#### References

1. MacNeill AJ, Hopf H, Khanuja, A, et al. Transforming the medical device industry: Road map to a circular economy. Health Affairs. December 2020.
2. European Commission
3. Consumer Reports



# BUILDING A STRONGER HEALTH UNION

## Toward a Stronger Role for EMA

BY DOMINIKA MISZTELA, PPTA SENIOR DIRECTOR, LEAD FOR EUROPEAN REGULATORY & QUALITY

**O**n March 1, 2022, [Regulation \(EC\) 2022/123](#)<sup>1</sup> came into effect, reinforcing the role of Europe's central regulator, the European Medicines Agency (EMA), in crisis preparedness and management of shortages<sup>2</sup> of medicinal products and medical devices in the European Union (EU). The need to strengthen EMA's role and enable it to respond better to cross-border health threats and crises has been highlighted during the COVID-19 pandemic.

As part of the regulation, EMA received additional capabilities and resources to monitor, report, and coordinate EU-level responses during public health emergencies<sup>3</sup> and major events.<sup>4</sup> This includes assessing and mitigating shortages of medicines and medical devices considered to be "critical" and also providing scientific advice on development of these medicines and coordinating studies, including clinical trials to monitor effectiveness and safety of medicinal products.

The regulation builds upon the frameworks and processes established during the COVID-19 pandemic. EMA's [COVID-19 EMAPandemic Task Force \(COVID-ETF\)](#) provided expedited scientific advice, accelerated clinical trial approval, and regulatory assessment of COVID-19 vaccines and therapeutics. An overarching [Emergency Task Force \(ETF\)](#) has taken over this role and will function as an advisory body during public health emergencies.

### PRACTICAL IMPLEMENTATION

A key deliverable of the new regulation is the establishment of the "[Medicine Shortage Steering Group](#)" (MSSG). The group's [main activities](#) are coordination of actions with the European Union on medicines' supply,<sup>5</sup> as well as evaluation of information on safety, quality, and efficacy of medicines affected by or used to address public health threats and major



events. This involves establishing lists of so-called “critical medicines” that need to be specifically monitored for supply issues. The MSSG will monitor the availability of, and need for, these medicines and will issue EU-wide recommendations to prevent and address any potential or actual shortages.

The first deliverable of the MSSG has been the adoption of the list of critical medicines and vaccines for COVID-19 in June 2022. The next deliverable is the finalization of the “main therapeutic groups” for hospital and emergency care. These will form the basis of EMA’s critical medicines lists in the future.

## EUROPEAN SHORTAGE MONITORING PLATFORM

A single European online portal called the [European Shortage Monitoring Platform \(ESMP\)](#) is being set up to monitor and report on EU-wide supply and demand. All EU Marketing Authorisation Holders (MAHs), manufacturers and distributors, as well as EU member states’ competent authorities will have to report data on supply and demand of critical medicines. The ESMP will go live in 2023, with full functionality expected by early 2025. The ESMP will feature a public website where anyone can search for information on critical medicines shortages.

## SCOPE OF DATA REQUESTS AND REPORTING OBLIGATIONS FOR MAHS

Reporting of data will be limited to final medicinal product,<sup>6</sup> including PDMPs. Plasma for manufacturing is excluded from reporting obligations. The regulation imposes additional reporting obligations for MAHs and manufacturers, in addition to existing provisions.<sup>7,8</sup> Once the MSSG has identified a medicinal product as critical, the relevant MAH will be required to submit data. This includes details of actual or potential shortage(s), including start/end date and suspected/known causes, sales and market share, available stocks, forecast of supply (including vulnerabilities in supply chain), future demand, as well as information on planned minimum stocks, available stocks, and estimates.

## INDUSTRY INVOLVEMENT

PPTA participates in the implementation of the regulation through membership in a permanent EMA industry committee, the Industry Standing Group (ISG). The first meeting was held on [June 21, 2022](#). PPTA’s position is that while a streamlined EU reporting system for shortages will assist in better highlighting access issues for patients who



Source: <https://www.eu-patient.eu/news/latest-epf-news/2021/extending-mandates-of-ema-ecdc/>

rely on PDMPs, it will not provide the necessary solutions as plasma collection volumes and national collection policies directly impact the amount of PDMPs produced. Currently, there are insufficient EU plasma collections as only four countries contribute to plasma availability, with approximately 40% of plasma for PDMP manufacturing in Europe coming from the U.S.<sup>9</sup> Therefore, insufficient EU plasma collections need to be addressed to strengthen the entire PDMP supply chain.<sup>10</sup> PPTA calls upon EMA to acknowledge existing shortage monitoring instruments for PDMP manufacturers, including national data reporting, monitoring of plasma collections, and reporting through the EU Plasma Master File, before considering any new mechanisms.

PPTA further emphasized that the unique nature of PDMPs needs to be considered when issuing any assessments, recommendations, or guidance related to PDMP shortage preparedness and management.

## WHAT’S NEXT?

The EC is currently [revising the EU general pharmaceutical legislation](#), with provisions expected to enhance the security of supply and address shortages. A revised legislation could, for instance, cover a further extended role for EMA.

PPTA will meet with the EMA ISG on September 21, and discussions will focus on the issuance of lists of critical medicines after the adoption of the main therapeutics groups, harmonization of reporting requirements through the ESMP, and reduction in reporting burden for manufacturers.

Reports on activities of the ETF, the MSSG, the ESMP, and progress on implementation of the regulation will also be presented to the European Parliament every four years;



## EMA adopts first list of critical medicines for COVID-19



Source: [https://twitter.com/EMA\\_News/status/1534499446700007424?ref\\_src=twsrc%5Etfw](https://twitter.com/EMA_News/status/1534499446700007424?ref_src=twsrc%5Etfw)

the first report is expected in 2026. Based on the findings in the report, the regulation might be considered for review, such as scope, definitions, compliance with data requests, and remit of the ESMP and the MSSG; the regulation foresees the possible extension of the ESMP after 2025. ●

### References

1. Regulation (EU) 2022/123 of the European Parliament and of the Council of January 25, 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. OJEU, Volume 65. January 31, 2022.
2. Regulation (EU) 2022/123 of the European Parliament and of the Council of January 25, 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. OJEU, Volume 65. January 31, 2022. Art. 2 (Definitions): (h) 'shortage' means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State or of a CE-marked medical device does not meet demand for that medicinal product or medical device at a national level, whatever the cause.
3. Regulation (EU) 2022/123 of the European Parliament and of the Council of January 25, 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. OJEU, Volume 65. January 31, Art. 2 (Definitions): (a) 'public health emergency' means a situation of public health emergency recognised by the Commission in accordance with Article 12(1) of Decision No 1082/2013/EU.
4. Regulation (EU) 2022/123 of the European Parliament and of the Council of January 25, 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. OJEU, Volume 65. January 31, 2022. Art. 2 (Definitions) (b) 'major event' means an event which is likely to pose a serious risk to public health in relation to medicinal products in more than one member state, which concerns a deadly threat or otherwise serious threat to health of biological, chemical, environmental or other origin, or a serious incident that can affect the supply of or demand for medicinal products, or quality, safety or efficacy of medicinal products, which may lead to shortages of medicinal products in more than one Member State and necessitates urgent coordination at Union level in order to ensure a high level of human health protection.
5. Regulation (EU) 2022/123 of the European Parliament and of the Council of January 25, 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. OJEU, Volume 65. January 31, 2022. Art. 2 (Definitions) (f) 'supply' means the total volume of stock of a given medicinal product or medical device that is placed on the market by a marketing authorisation holder or a manufacturer.
6. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Art. 1(10): Medicinal products derived from human blood or human plasma: Medicinal products based on blood constituents which are prepared industrially by public or private establishments, such medicinal products including, in particular, albumin, coagulating factors and immunoglobulins of human origin. Article 2: The provisions of this Directive shall apply to industrially produced medicinal products for human use intended to be placed on the market in Member States.
7. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Article 81: With regard to the supply of medicinal products to pharmacists and persons authorized or entitled to supply medicinal products to the public, Member States shall not impose upon the holder of a distribution authorization which has been granted by another Member State, any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorized to engage in equivalent activities. The said obligations should, moreover, be justified, in keeping with the Treaty, on grounds of public health protection and be proportionate in relation to the objective of such protection.
8. EMA/ HMA. Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA). July 1, 2019.
9. Vintura. White paper: Key Economic and Value Considerations for Plasma-Derived Medicinal Products (PDMPs) in Europe. 2020.
10. PPTA. BTC position paper: <https://www.eunedsmoreplasma.com/images/files/ppta%20position%20paper%20on%20the%20eu%20btc-20may22.pdf>.

Confident teams.

Comfortable devices.

Speedy visits.

# Every thing it takes to make a donor smile.

Smooth procedures.



**Fresenius Kabi Plasma**

Experience is  
every thing.

Devices. Software. Support.

From the moment they arrive to the moment they leave, every detail makes a difference in the donor experience. How quickly they get set up. How comfortably and smoothly the process goes. How skillfully your phlebotomists work. It all adds up. That's why we put donor experience at the center of every thing we do.

Learn more at:  
[fresenius-kabi.com/us](https://fresenius-kabi.com/us)



**FRESENIUS  
KABI**

caring for life



# European Policymakers Visit a Fractionation Plant

**BY ATHINA GIANNOUTSOU, PPTA MANAGER, LEAD FOR EU PUBLIC AFFAIRS & COMMUNICATIONS**

On June 2, PPTA, [EU40](#) — a platform of members of the European Parliament (MEPs) under the age of 40 — organized the visit of representatives of the European Commission and the Czech permanent representation to the EU at the Brussels-based fractionation plant of [Prothya Biosolutions](#).

In attendance at the site visit were policymakers from the European Commission — DG SANTE B4, the penholder unit on the EU Blood, Tissues, and Cells (BTC) legislation, as well as the health attaché of the Czech Permanent Representation at the EU and liaison of the current Czech EU Presidency. These policymakers will be sitting at the trilogue negotiations on the EU BTC legislation.

This event allowed the policymakers to become better informed on the complex plasma ecosystem and better understand that: plasma used to manufacture PDMPs is different from blood used for transfusion purposes, that plasma donations are important for more than 300,000 patients in the EU who rely on plasma-derived medicines to treat a range of critical medical conditions, and that without these lifesaving therapies, many patients would not survive or would have a severely reduced quality of life.

Attendees also had the opportunity to learn about the complex steps in manufacturing PDMPs from donated plasma, while finding out more on the transformation history of Prothya Biosolutions, formerly the Dutch public sector entity Sanquin and Belgian DCA-CAF, which has plants in the Netherlands and in Belgium.

Importantly, the event was instructive for the policymakers to understand the EU's growing need for plasma as a crucial element and also for having adequate amounts of plasma to fractionate to serve the growing clinical need of patients in the EU for PDMPs. In this context, however, the EU currently has a shortfall of 5.15 million liters (38%) of the plasma needed to manufacture PDMPs for patients in the EU (Marketing Research Bureau 2022 data).

PPTA intends to organize another site visit with key MEPs in charge of the newly published EU Draft Regulation on Substances for Human Origin, who will be involved in running the legislative process as to the adoption of this key EU Regulation, covering blood and plasma, tissues, and cells.



Importantly, the event was instructive for the policymakers to understand the EU's growing need for plasma as a crucial element and also for having adequate amounts of plasma to fractionate to serve the growing clinical need of patients in the EU for PDMPs.

---

#### **ABOUT PROTHYA PLASMA FRACTIONATION PLANT**

Prothya Biosolutions Belgium (formerly Plasma Industries) was established in 1957 as part of the Belgian Red Cross. Prothya developed into a fully commercial entity in 2016, providing solutions for the separation of blood plasma into proteins that improve the quality of life. Stable plasma derivatives such as clotting factors, immunoglobulins, and albumin solutions are produced with the fractions isolated by Plasma Industries. Prothya Biosolutions processes around 3 million liters of plasma each year for several international partners. ●





# Parliamentarian Initiative Plasma and Plasma Products in Germany

BY SÁNDOR TÓTH, PPTA DIRECTOR, LEAD FOR PUBLIC AFFAIRS, EUROPE



On World Immunology Day (April 29, 2022), the Parliamentarian Initiative Plasma and Plasma Products (PIPP) was launched in Germany. The [kickoff event](#), a hybrid press

conference attracting some 20 journalists, brought together politicians, health care professionals, patient organization representatives, and PPTA to launch a [resolution](#), signed by the participants of the event. The resolution included suggestions as to what needs to be done in Germany to ensure sustainable access to plasma-derived medicinal products (PDMPs).

Germany is one of the four countries in Europe where public and private plasma collection systems coexist and where donor compensation is possible and not under scrutiny at all. The country collects the highest amount of plasma in Europe,

around 3 million liters annually, and, in principle, all PDMPs are reimbursed for all indications.

But even in such a “role-model country” like Germany there is space and need for improvement.

On one hand, the framework conditions for plasma collection need to be readjusted to collect more plasma. The regulations, in place for more than 20 years, must be urgently updated. A country like Germany, with a well-functioning plasma collection system, could set an example for other countries in Europe, and thus substantially contribute to collect enough plasma in Europe to cover the European clinical need.

On the other hand, the legislative and regulatory environment must be optimized to promote reliable patient access to PDMPs as standard cost containment measures currently applied on PDMPs, like on any other drugs, are posing risks to patient access to therapies.

The PIPP is a cross-factional coalition of members of the German Bundestag united by the goal of securing long-term access to plasma and PDMPs in Germany. It aims to raise awareness about the specificities of the plasma ecosystem,

A country like Germany, with a well-functioning plasma collection system, could set an example for other countries in Europe, and thus substantially contribute to collect enough plasma in Europe to cover the European clinical need.

European dependency on plasma from the U.S., and the need for action to ensure patient access to PDMPs.

At the PIPP launch press conference, patient representatives gave a detailed report of the challenges patients in Germany are currently facing due to the COVID-19-related decrease of plasma collection, mainly in the U.S. Although, in principle, all patients undergoing regular treatment have access to therapy, there are some difficulties on closer inspection. Patients are experiencing forced product switches, and they must deal with extended dosing intervals or reduced dosages to save product. In addition, newly diagnosed patients are postponed to a later date for the start of their therapy.

According to one of the supporters of the resolution, Mrs. Martina Stamm-Fibich from the Social Democratic Party, the current challenges in access to immunoglobulins reflect the need to address specific challenges for certain groups of medicines individually.

"We must not take access to plasma products lightly, it is not a given that there will always be enough plasma to manufacture these products. We have to look closer at both plasma collection and the sufficient provision of the finished products," she said.

All stakeholders involved continue to address the proposals listed in the resolution for sustainable access to PDMPs toward governmental bodies and other authorities. The "Arbeitskreis Blut," a panel of experts convened by the government that advises the German authorities on questions of safety in the collection and use of blood and blood products, is currently evaluating potential measures to increase plasma collection. These include an adaptation of the permanent obligation for doctors to be present during plasma donation and an update of donor selection criteria to the current state of science. The outcome of these consultations remains to be seen but will hopefully bring relevant progress for the benefit of patients in need. ●

## The plasma facility design team you know:



**Fractionation Specialist**  
Bill Jarvis



**Purification Specialist**  
Bill Donahue



**Aseptic Filling Specialist**  
Christa Myers



**IPD Strategy & Account Manager**  
Clay Seese



**Plasma-Derived Therapies Market Lead**  
Eddie Munoz

## And the team we're ready to introduce you to:

ENGINEERING | ARCHITECTURE | CONSTRUCTION | CONSULTING  
[crbgroup.com](http://crbgroup.com)



**Energy & Sustainability Specialist**  
Jeff Wegner



**Digitalization & 4.0 Specialist**  
Yvonne Duckworth



# Attendees Gather in Berlin, Germany at the 2022 IPPC

**BY FARAZ KERMANI**, PPTA SENIOR DIRECTOR, HEAD OF GLOBAL COMMUNICATIONS

PPTA was delighted to hold its first in-person meeting in more than two years at the 19<sup>th</sup> International Plasma Protein Congress (IPPC), in Berlin, Germany, from June 14-15. Hosting nearly 300 delegates from across five continents and 30 countries, this year's congress focused on the unique opportunity for EU Member States to increase plasma collection volumes in the face of the forthcoming revisions to the Blood, Tissues, and Cells (BTC) legislation.

Opening the congress, PPTA Executive Director Europe, Maarten van Baelen, first welcomed the appointment of the new PPTA Global Executive Board of Directors chair, Giles Platford, from Takeda. Following this, he noted the historic juncture at which the plasma protein therapy sector found itself in Europe, as the EU institutions look to revise the BTC legislation. "There are a number of legislative and nonlegislative opportunities that we should seize if we are to improve plasma collection and patient access to PDMPs [plasma-derived medicinal products] across the European Union," Mr. Van Baelen said.

Dr. Karl Lauterbach, German federal minister for health, delivered the keynote address on the first day. He outlined the value of plasma in the manufacture of lifesaving therapies in the rare disease sector and stressed the importance of securing the long-term availability of this vital raw material across the member states, pointing out that this could be encouraged by compensating donors and by running awareness campaigns.

"Our joint objective in revising the EU legislation on blood and medicinal products must be to ensure an even more reliable supply of plasma preparations in Germany and Europe," Dr. Lauterbach concluded.

The first panel discussion at IPPC2022 focused on Germany's well-functioning plasma collection system, which is based on the coexistence and cooperation of all plasma collection stakeholders. Moderated by Stephan Walsemann of Scinomed GmbH, the session looked at a successful coexistence model in Germany, access issues, awareness campaigns, and the possibility of placing a nurse rather than, specifically, a medical doctor in collection centers to allow for greater flexibility in the collection process.

In session two, moderated by PPTA's Director and Lead for European Plasma, Alexa Wetzel, the panel showcased a variety of plasma collection models worldwide, noting that a wide range of solutions exist that are designed to ensure stable and safe access to PDMPs. Representatives from Biotest, GRIFOLS Egypt Plasma Derivatives, Biopharma Plasma, and the UK's NHS Blood and Transplant discussed various new and innovative models in Hungary, Egypt, Ukraine, and the UK focused on increasing the collection of plasma for producing PDMPs.

Session three examined the EU's call for strategic autonomy on starting materials for medicines aimed at reducing its dependency on third countries, particularly the U.S., from





which it sources almost 40% (around 5.15 million liters) of its plasma needs. Moderated by Leo Cendrowicz, editor of the Brussels Times, the session looked at the rapid growth in the need for immunoglobulin and the subsequent increase in plasma collection prior to the negative impact of the COVID-19 pandemic. Delegates received an update on progress in the EU BTC legislation, which focuses on safety and quality but also looks at solutions to potential supply disruption. There was a plea from the patient representatives for a clear definition of plasma for fractionation in the legislation and for an understanding that the EU's vision of strategic autonomy can only be realized if the public and private sectors work together.

The final session of the first day saw the discussion turn toward establishing a successful plasma fractionation plant, based on experiences from the past and present. There was an initial overview of the fractionation landscape across Europe and the world, with statistics provided by the Marketing Research Bureau on specific countries on the establishment and closures of various plants. Delegates were told that many closures were due to a lack of investment in order for plants to comply with good manufacturing practices (GMP). Radosław Sierpiński, the Polish Prime Minister's High Representative for the Development of Biotechnology, explained that the pandemic

and the war on Ukraine had acted as a catalyst to put Poland on the road to being self-sufficient in plasma fractionation. He asked for expertise to be supplied to help change the ecosystem for donation, research and development, and production – the latter is planned to start in 2026. Sinisa Varga, former Croatian Minister of Health, told delegates that Croatia has a plan to process 60,000-100,000 liters of plasma collected domestically, with this figure rising as patient need increases. Adrian Goretzki, President of the Polish Healthcare Education Institute, pointed to the fact that the Czech Republic, despite its much smaller population, collects a lot more plasma than Poland, but took it as a sign of the potential for his country to increase collection. Ruud Zoethout from Prothya Biosolutions noted that the problem with countries that establish domestic plasma fractionation plants was that they received “domestic amounts of plasma,” noting also that building a plant was straightforward but running it required further skills.

The first day ended with the presentation of the Hilfenhaus Award by Oliver Schmitt, former chair of the PPTA EU Board of Directors, to the well-deserving Professor Volker Wahn from the Charité University Hospital Berlin.

Day two opened with a welcome address by PPTA's new chair of the EU Board of Directors, Ainhua Mendizabal Zubiaga.

---

Moderated by Leo Cendrowicz, editor of the Brussels Times, the session looked at the rapid growth in the need for immunoglobulin and the subsequent increase in plasma collection prior to the negative impact of the COVID-19 pandemic.



Andreas Glück, a German member of the European Parliament from the Renew Europe Party, gave the second day's keynote address. A surgeon by profession, he noted that the current level of plasma supply in Europe is a cause for concern and is one that has been worsened by the pandemic.

She focused initially on access challenges for patients who require lifesaving PDMPs, noting that while product availability is a serious issue, so is reimbursement, which is approached differently across the EU member states. Moreover, cost containment measures, such as reference pricing and clawbacks, continue to complicate the landscape, she observed. Ainhoa also discussed problems with interchangeability of PDMPs and concluded that economic considerations should not impact the decision-making process and the quality of life for patients.

Andreas Glück, a German member of the European Parliament from the Renew Europe party, gave the second day's keynote address. A surgeon by profession, he noted that the current level of plasma supply in Europe is a cause for concern and is one that has been worsened by the pandemic. He called for the EU and the member states to raise awareness about the importance of plasma donation, adding that we could learn from the U.S. about how to increase donation levels.

The first full session of the day focused on the EU Pharmaceutical Strategy's key objective of ensuring patient access to critical medicines, including PDMPs. This means guaranteeing that there are no disruptions along the entire chain from donor to patient. The focus should be on the value to the patient, budget impact, medical need, and sustainability

of plasma availability. The lifesaving value of PDMPs for rare disease patients was also highlighted, with a particular emphasis on patient autonomy. Delegates also heard about the lack of equality in access to PDMPs across the member states, with some countries receiving such a low quantity that patients are essentially being left untreated. Nevertheless, positive changes to the European law on plasma collection would certainly encourage member states to increase collection, thereby reducing the EU's reliance on U.S. plasma.

Introducing clear definitions into the EU legislation and allowing for the differentiation between blood for transfusion and plasma for manufacturing could enhance access to PDMPs for patients. This was the subject of the second session on the second day of the Congress. Panelists noted the current legal landscape does not meet the needs of stakeholders. This was followed by a presentation on the status of inspections on both sides of the Atlantic, with news that the decision of whether to permit mutual recognition of inspection of plasma collection sites by the FDA and EMA should be available "within the next few months." The revision of the EU BTC legislation offered the possibility of a clear definition of plasma for manufacturing and for an expert body or bodies to define specific standards for source plasma, taking into account current manufacturing

practices, scientific knowledge, and testing methods. While there is a push for more harmonization at the EU level in the areas of quality and safety, a Commission representative pointed out that member state differences would remain because some countries were more technologically advanced and the prevalence of communicable diseases varies among countries.

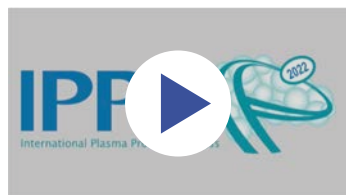
The final panel of the day focused on the highlights and developments in the area of pathogen safety. Questions were raised: as to whether a physician at a German plasma collection site needed to always be present; about donor recruitment, retention, and remuneration; and whether the commercial aspect of plasma collection and fractionation was putting off young donors.

Regarding transmissible viruses in immunoglobulin, delegates heard that there were two questions that needed to be addressed: Does the virus transmit; and could immunoglobulin manufactured from the plasma that contains the virus protect against it? Further emphasis was made that blood for transfusion and plasma for fractionation are different and therefore require different regulatory frameworks. Concerning the current pandemic, there was discussion as to whether a specific variant in a donor would be capable of providing antibodies capable of protecting against other variants in the patients. From the UK, we heard that while there had been transmission of variant Creutzfeldt-Jakob disease via red blood cells, this had never been the case with a PDMP. The overall message was that PDMPs are safe.

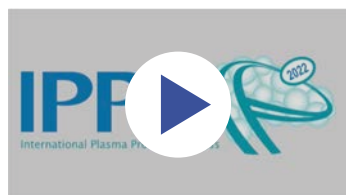
Closing out the conference, Giles Platford, PPTA's new chair of the Global Executive Board of Directors stressed that he would work with all stakeholders to deliver on the promise of a sustainable supply of PDMPs to patients around the world who need them.

In case you missed it, a recording of IPPC 2022 is now available: [Day One](#) / [Day Two](#)

You can also view photos from the event by clicking [here](#). •



**DAY ONE**



**DAY TWO**

## PPTA CONGRATULATES THE 2022 HILFENHAUS AWARD RECIPIENT: Prof. Volker Wahn, Charité University Hospital Berlin



On June 14, 2022, during the International Plasma Protein Congress (IPPC) in Berlin, Germany, Prof. Volker Wahn was presented with the Joachim Hilfenhaus Award by former chair of PPTA's European Board, Oliver Schmitt, CSL Behring GmbH. Prof. Wahn studied biochemistry and medicine and

was trained as a pediatrician at the University of Düsseldorf, Germany. There his major interest was in the field of Pediatric immunology, rheumatology, allergy, and pulmonology. In 1980, he joined the group of Prof. R. A. Good at the Memorial Sloan-Kettering Cancer Center in New York, working in the field of complement research and clinical care of patients with primary immunodeficiencies (PIDs).

After his return to Düsseldorf University, he became professor of pediatrics. From 2003-2014 he was responsible for the "Immunology and Infections" section at the Charité University Hospital Berlin where, after retirement, he is still active as a senior consultant with specific interest in PIDs.

Prof. Wahn has published several books and original papers. Since 2008 he has been a promoter of FIND-ID — a German physicians' network created to promote early diagnosis and treatment of patients with PIDs. During his presentation at the IPPC, Prof. Wahn highlighted the importance of early diagnosis and newborn screening, as well as the continued need to increase awareness among physicians about the signs of PIDs and the value of beginning treatment as early as possible.

The Hilfenhaus Award is named after Dr. Joachim Hilfenhaus, the first chair of the European Association of the Plasma Products Industry Viral Safety Working Group. Dr. Hilfenhaus was an internationally respected virologist who worked for Behringwerke. The recognition is awarded to an individual who made an outstanding contribution to the provision of safe and efficacious plasma protein therapies.

### LEARN MORE:

[www.immunodefekt.de](http://www.immunodefekt.de) | <https://find-id.net/>





# Promoting Reciprocal Acceptance of EU-U.S. GMP Inspections

BY **EVELINA KOZUBOVSKA**, PPTA MANAGER, LEAD FOR EUROPEAN REGULATORY POLICY

**BILL SPEIR**, PPTA SENIOR DIRECTOR, LEAD FOR U.S. REGULATORY POLICY

In 1998, the European Union and the United States signed a Mutual Recognition Agreement (MRA)<sup>1</sup> including the annex on the recognition of good manufacturing practices (GMP) inspections of human medicines manufacturing sites. The aim of such an agreement is to ensure greater regulatory efficiency between the U.S. and the EU by avoiding unnecessary, duplicative inspections. The revised sectoral annex entered into operation in 2017, representing a big step toward bilateral collaboration in the field of human pharmaceuticals and achieving unified standards for inspections on both sides of the Atlantic. Nonetheless, the complexity of the agreement resulted in its full implementation only in 2019,<sup>2</sup> with a planned gradual expansion to other areas, such as veterinary medicines, and pending decision on the inclusion of vaccines and plasma-derived medicinal products (PDMPs). The inclusion of PDMPs within the MRA would result in greater efficiencies in manufacturing and would benefit patients in the U.S. and the EU.

To ensure compliance with good manufacturing practices, both the EU and the U.S. authorities once inspected numerous pharmaceutical manufacturing sites in each other's territories. Joint inspections and audits conducted by teams of experts from the U.S. Food and Drug Administration (FDA), European Medicines Agency, and national competent authorities in the EU concluded that both jurisdictions have comparable procedures to recognize GMP inspections for human medicines. Before the implementation of the MRA, regulators would usually conduct double inspections of the same facilities even if the facilities had a strong compliance record. To this end, the MRA resulted in greater efficiencies for both regulatory systems, minimizing duplicative efforts, increasing efficiencies, and diverting funds for third country inspections with potentially higher risk. Such prioritization is key for patient safety and reducing any possible adverse health outcomes, while both regulatory authorities still reserve the right to conduct surveillance inspections if the need arises, rather than as a common practice.

According to the transitory provisions of the sectoral annex on GMP inspections, outlined in Article 20,<sup>3</sup> the decision to include PDMPs within the EU-U.S. MRA should have been made no later than July 15, 2022. However, the European Commission has recently confirmed that due to the COVID-19 pandemic, it was not possible to conduct joint inspections, and therefore



## Plasma intended for manufacturing is used exclusively for the production of PDMPs and thus is a global resource, which should be considered in the context of a biologically active substance (BAS) for the production of PDMPs.

---

the decision has been delayed.<sup>4</sup> As the pandemic phase of COVID-19 seems to be ending, both the FDA and EU regulators are looking forward to restarting the negotiations on the inclusion of PDMPs within the MRA. While the new timeline has not yet been communicated, the authorities emphasized that it would depend on logistical arrangements and resources on both sides.

PPTA has recently engaged with regulators in the U.S. and the EU with an aim to discuss the inclusion of PDMPs within the agreement. In this context, PPTA has issued a statement on the importance of the EU-U.S. MRA for patient access to plasma therapeutics. The statement underscored the importance of the agreement for uninterrupted access to plasma-derived products for all patients and urged both authorities to resume the negotiations on the implementation of transitory provisions.

Although the MRA covers pharmaceutical finished products and its active pharmaceutical ingredients (APIs), this is not the case for the starting substance to produce PDMPs – human donated plasma. Under the current agreement, human plasma is explicitly excluded from the scope of the agreement (Article 4.2 “*Human blood, human plasma, human tissues and organs, and veterinary immunologicals are excluded from the scope of this Annex*”). However, there is no specification on whether the exclusion applies only to plasma for transfusion or also covers plasma for manufacturing. PPTA emphasizes the importance of including “source plasma”/“plasma for manufacturing” within the MRA with an aim to remove redundant inspections of plasma collection centers. Plasma intended for manufacturing is used exclusively for the production of PDMPs and thus is a global resource, which should be considered in the context of a biologically active substance (BAS) for the production of PDMPs.

The stated purpose of the MRA is to facilitate trade by reducing unnecessary duplications of inspections at manufacturing sites. The inclusion of PDMPs, including the collection of source plasma, would achieve that purpose. Currently, there are more than 1,200 source plasma donation centers in the U.S. (1,093) and the EU (170), and additional

source plasma donation centers open every month. The source plasma donated at these centers is eventually sent to manufacturing sites in the U.S. and the EU. For this reason, EU inspectors must regularly double inspect U.S. centers, while the oversight of these centers is already maintained through the annual Plasma Master File annual update. This results in a higher burden for the EU GMP inspectors, adding additional pressure on under-resourced inspection capacities, which were significantly affected by Brexit and the UK's departure from the EU. The recent pandemic put an additional strain on the EU GMP inspectorate, as new centers could not be inspected remotely. If not inspected timely, plasma collected in those centers cannot be released for production, therefore, restricting access to these lifesaving therapies for patients.

To conclude, there has been an enormous effort to advance EU-U.S. cooperation in the field of pharmaceuticals. While the COVID-19 pandemic has disrupted the regulators' plans to gradually expand the areas for cooperation, it has also highlighted interdependencies and the need for more flexible and less burdensome processes to ensure patient access to safe medical products. The removal of duplicative and redundant inspections between the EU and U.S. would help to increase efficiencies, better prioritize resources, and avoid disruption in supply chains by releasing more plasma for manufacturing of PDMPs without compromising the final product quality or safety. ●

### References

1. EUR-Lex. [EU–United States of America mutual recognition agreement \(MRA\)](#). July 24, 2018.
2. European Commission. 2022. Press corner. [EU-U.S. trade talks: Milestone reached in mutual recognition on pharmaceuticals](#). July 11, 2019.
3. European Commission. [Agreement on mutual recognition between the European community and the United States of America in order to amend the sectoral annex on pharmaceutical Good Manufacturing Practices \(GMPs\)](#). March 1, 2017.
4. European Medicines Agency. [Mutual recognition agreements \(MRA\)](#). European Medicines Agency. 2022.



# What Makes Plasma-Derived Medicines So Different? and Why Should Congress Care?

BY TOM LILBURN, PPTA SENIOR DIRECTOR, LEAD FOR PUBLIC AFFAIRS, STRATEGY

**T**he great majority of pharmaceuticals today are made like cakes. Take so many milligrams of active ingredient “A,” add so many milligrams of binder “B” plus an excipient to enhance stability, press it in a mill, perhaps add a delayed dose coating, and you have the pill. All closely regulated and controlled and absolutely needed. Ingredient costs are generally stable at around 14%,<sup>1</sup> and supply lines have long been established. And since 90% of U.S. drugs are generic,<sup>2</sup> there are likely to be acceptable interchangeable versions and supplies.

But what if the drug was inherently different? What if it treated so small a patient population that it was deemed an “Orphan Drug” by the U.S. Food and Drug Administration (FDA) for rare diseases with less than 200,000 patients. Or that it was made only from human tissue donated by healthy donors from all over the U.S., in highly regulated capital-intensive centers. And that in some cases it took more than 1,300 human donations to treat one patient for a year and more than a year to make the medicine.

That inherently different drug describes plasma-derived medicines or plasma protein therapies (PPTs). They are not

at all like the small molecule drugs described above, and PPTA has been working with our member companies to let Congress know how they are affected by what Congress does.

Congress and several administrations, including the Trump and Biden White Houses, have been concerned over the cost of drugs in the U.S. Although brand name pharmaceuticals overall declined in cost by 1% in 2021, that concern has caused the Centers for Medicare and Medicaid Services to bring forward several proposals to lower U.S. drug costs. Most of these have been rules centered on using price structures in other foreign markets and forcing U.S. prices to match these reference countries. None of these proposals have passed legal and regulatory hurdles. These proposals were developed with the larger pharmaceutical markets in mind, such as insulin.

Plasma-derived medicines don’t fit these models in any way. They are non-interchangeable biologics made from donated human tissue. While the starting material cost of small molecule drugs is 14% of cost, PPTs overall plasma costs are well over 57% and may reach significantly higher before any of the highly complex and expensive manufacturing process begins. Dual regulatory burdens at both collection and manufacturing

The most important reason for Congress to differentiate between PPTs and other drugs are the patients who need them. Many take PPT's their entire life. They are immune-deficient patients, hemophilia patients and those with other clotting disorders, patients with Alpha-1 antitrypsin deficiency or genetic emphysema.

---

contribute to the 7-12 months manufacturing time. Then there's the burden of collecting enough plasma to ensure every patient's needs are met.

COVID-19 lowered U.S. donations in 2020-2022 by 20% even though more than 200 new donation centers were built.<sup>3</sup> Then in June of 2021, the U.S. Customs and Border Protection agency changed a 30-year policy of allowing Mexican and Canadian donors to cross the borders to donate plasma, further reducing collections by approximately 10%. Only plasma-derived medicines face these daunting hurdles, and it further demonstrates why they are so different and need to be treated differently by Congress and the administration.

The most important reason for Congress to differentiate between PPT's and other drugs are the patients who need them. Many take PPTs their entire life. They are immune-deficient patients, hemophilia patients and those with other clotting disorders, patients with Alpha-1 antitrypsin deficiency

or genetic emphysema. And the list goes on to include those suffering from Guillain-Barré syndrome (GBS), chronic inflammatory demyelinating polyneuropathy (CIDP), and related conditions. Burn patients, oncology patients, and newborn babies with Rh incompatibility, as well as those patients needing tetanus or rabies treatment are often treated with PPTs.

PPTA seeks to educate and inform Congress about the differences in these drugs and the needs of the men, women, and children who live productive lives because of them. Access to PPTs is vital and critical to the health of so many. ●

#### References

1. Marketing Research Bureau
2. FDA Office of Generic Drugs 2021 Annual Report
3. PPTA. [https://www.pptglobal.org/images/Data/Plasma\\_Collection/2021\\_NA\\_Collections-Centers.PNG](https://www.pptglobal.org/images/Data/Plasma_Collection/2021_NA_Collections-Centers.PNG). July 1, 2022.

## Helping you provide the plasma they depend on.



With blood plasma, nothing can be left to chance. That's why Norlake Scientific goes the extra mile in designing our freezing and storage rooms.

Our blood plasma freezers deliver a **consistent -40°F environment** to safely store your plasma and extend its lifespan. Advanced electronic controller systems further ensure product safety and make it easy to monitor freezer performance.


We understand the importance of providing life-giving plasma and are ready to help with solutions you can count on.



[nlsscientific@refsg.com](mailto:nlsscientific@refsg.com) • 800-477-5253, option 1







# Advocating for Plasma-Derived Medicines in Washington, D.C.

**BY TIM SWOPE**, PPTA ASSISTANT DIRECTOR, LEAD FOR PUBLIC AFFAIRS,  
FEDERAL & STATE

**O**n June 21, 2022, PPTA held its annual Capitol Hill Fly-in virtually with the mission to educate the U.S. Congress about the unique nature of plasma-derived medicines. The messages shared included differentiation of plasma medicines, the ongoing challenges from the U.S. border issue, joining the plasma caucus, the support of H.R. 3808, and regulatory actions that could help increase plasma collections. The event drew strong representation from patient groups, U.S. members, as well as PPTA's Plasma members.

PPTA teams highlighted the ongoing concern with the U.S. Customs and Border Protection policy, meeting with 11 House of Representative offices that had signed onto letters opposing the policy. We also had the opportunity to meet with the co-chair of the newly established Plasma Caucus, Rep. Larry Bucshon (R-IN) and the office of co-chair Rep. Scott Peters (D-CA).

Fly-In by the numbers:

- 38 Congressional office meetings, including four member-level meetings
- 21 states represented
- 21 Democratic offices, 17 Republican offices
- 46 participants: 24 PPTA member company representatives, 11 stakeholders, 11 PPTA staff

Each meeting had a central focus on differentiating plasma-derived medicines from other pharmaceuticals, noting the starting material relies on human donors and the seven-to-12-month time from plasma donation to the delivery of treatment to a patient. PPTA will continue to work with members and stakeholders to advocate for these unique treatments as Congress undertakes renewed efforts to enact drug pricing legislation. In addition, PPTA will coordinate with the patient-led Congressional Plasma Caucus to identify new opportunities to raise awareness and maintain access to plasma-derived medicines. ●





Life is golden.

Plasma is a golden-colored blood component that only comes from one source: people. Many patients with rare, chronic, and life-threatening conditions need regular treatments of plasma-derived therapies. So donate plasma today. It's a golden opportunity to help make life brighter and healthier for so many.

**To learn more about plasma donation and locate a plasma center near you, visit [lifeisgolden.us](https://lifeisgolden.us)**



**FRESENIUS  
KABI**

caring for life

# SAVE THE DATE

## PPTA'S 2022 PLASMA PROTEIN FORUM IS AROUND THE CORNER!

2022

## PLASMA PROTEIN FORUM

October 11-12 | Washington, D.C.



### MARK YOUR CALENDARS!

After two years of virtual meetings, PPTA is very happy to announce that we will be back in person for the 2022 Plasma Protein Forum (PPF)! This year's forum will be held October 11-12 at the Georgetown Marriott in Washington, D.C., and will feature a keynote address from Peter Marks, M.D., Ph.D., Director of the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration.

Registration, hotel, and sponsorship information is available at [www.pptaglobal.org](http://www.pptaglobal.org). We look forward to seeing our members, partners, and supporters in person this year!

GRIFOLS ENGINEERING

## QUALITY

**ENGINEERING:** PROJECT MANAGEMENT, BIOTECH PROCESSES, GENERAL PROCESSES, IV SOLUTIONS PLANT  
**MACHINERY:** TAILOR-MADE SOLUTIONS, PHARMACEUTICAL ROBOTICS, STANDARDIZED PROCESSES  
**CONSULTING:** ANALYSIS OF REGULATORY REQUIREMENTS, TECHNICAL STUDIES, TECHNICAL TRAINING

**GRIFOLS  
ENGINEERING**  
WE  
KNOW  
HOW

### FOR BAGS AND BOTTLES



**PBO**  
PLASMA BAG  
OPENER



**ABO**  
AUTOMATED  
PLASMA  
BOTTLE  
OPENER

### TWO CASES

The automated plasma, thawing, cutting and emptying processes offer maximum safety and quality as plasma is not handled by the operator while the bags or the bottles are opened, thereby minimizing external contamination and also reducing costs with increased and consistent performance. Applicable to other biological products.

GRIFOLS

Grifols Engineering, S.A.  
C/Palou 6, 08150 Parets del Vallès - Barcelona - SPAIN - Tel. [34] 93 571 00 42

Grifols Engineering USA  
2410 Lillyvale Avenue, Los Angeles - California 90032 - USA  
8368-US Hwy 70 West, Clayton - North Carolina 27520 - USA - Tel. +1(919)359-7842  
[info.ge@grifols.com](mailto:info.ge@grifols.com) - [www.grifolsengineering.com](http://www.grifolsengineering.com)



# Donors come in every size.

Now, so do collection volumes.



Plasma Collection Solution

Individually tailor plasma donation targets to each donor based on their total available plasma with Persona™. A proprietary plasma collection solution built upon the NexSys PCS® platform, Persona™ has been clinically shown to yield +9% to 12%\* more plasma per donation on average†. Persona™—the more personal way to collect more plasma.

**More personal. More plasma.**

\*Based on baseline device, software configuration and donor population. † Demonstrated by the IMPACT study, a multicenter, prospective, double-blinded, randomized controlled clinical trial involving 23,137 plasma donations

U.S. Patent Number 10,792,416

© 2020 Haemonetics Corporation. Haemonetics, NexSys PCS, and Persona are trademarks or registered trademarks of Haemonetics Corporation in the USA, other countries, or both. 10.2020 USA. COL-AD-000287-US(AA)



For the NexSys PCS®

**HAEMONETICS®**





# PPTA Welcomes First Member in Egypt

BY SONIA BALBONI, PPTA SENIOR DIRECTOR, HEAD OF WIDER WORLD



PPTA proudly welcomes its first Plasma member outside of North America and Europe — Grifols Egypt. Grifols Egypt for Plasma Derivatives is a joint-venture between Egypt's National Service Projects Organization and Grifols. The company opened its first plasma collection center, in Cairo, in October 2021, with plans to roll out 20 centers overall across Egypt. Quality and safety parameters, as well as local regulations, are similar to those in the United States and Europe. Over time, the plasma collected in Egypt will be

converted into hemoderivatives in manufacturing installations in the country, including a plasma fractionation plant, a purification plant, and testing and warehousing operations, all expected to be up and running by 2025. Until then, all collected plasma will be processed in Spain before returning to Egypt.

The vast majority of plasma used for plasma protein therapies worldwide is collected in the United States and a few countries in Western Europe. Consequently, most countries rely on the import of plasma protein therapies from a select few countries, making the opening of this center and the plans in Egypt historically significant for the industry globally. It is hoped that there will be more opportunities for building safe, viable local and regional plasma infrastructures organically to diversify the world's source of plasma-derived medicinal products.

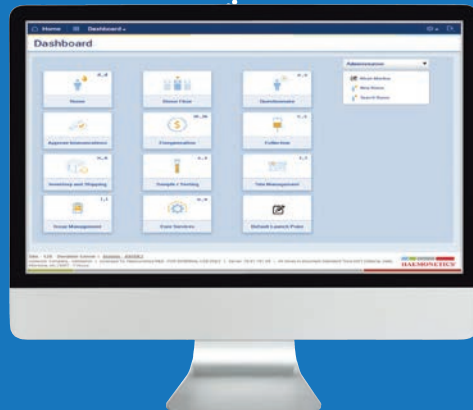
According to the [World Bank](#), there are more than 104 million people in Egypt. In 2021, the government of Egypt approved new legislation that fosters safety and quality in the collection of blood and plasma, as well as for the preparation of plasma protein therapies. "Once more, Egyptian health care is demonstrating regional leadership as we continue investing resources to enhance the well-being and quality of life of all Egyptians," said Dr. Magdy Amin, CEO Grifols Egypt. •



# This is plasma collection optimized



**Donor360®**  
Donor Engagement  
Software



**NexLink DMS®**  
Donor Management  
System



**NexSys PCS®**  
Plasma Collection System  
available with  
**YES®** | **Persona** Technologies

## Maximize your output efficiency with the industry's only integrated end-to-end plasma collection solution

Powered by the NexSys PCS device, the Haemonetics end-to-end integrated plasma collection solution has proven to deliver a more streamlined collection process maximizing the safe, efficient output for plasma collection centers and an enhanced experience for donors.

**More plasma. More productivity. More value.**

Learn more at [www.haemonetics.com/businesses/plasma](http://www.haemonetics.com/businesses/plasma)





Her *precious* gift

His *priceless* outcome

## **Delivering confidence in transfusion safety from donor to patient.**

At Roche, we understand the vital connection between the donor and patient. Our unwavering pursuit of ensuring a safe blood supply is achieved through our collaboration with customers, focused on advancing science, technology and digital solutions in transfusion safety.

As the only single provider for NAT, serology, lab automation and software solutions to blood centres and plasma fractionators worldwide, we are dedicated to helping preserve the donor population and ultimately deliver better outcomes for patients.

---

*Our commitment to helping you make this connection possible.  
To learn more, visit [diagnostics.roche.com](https://diagnostics.roche.com)*

---



# PLASMA DONOR SPOTLIGHT

## CHRISTIAN KOCH

HAEMA DONOR



**NAME:** Christian Koch

**AGE:** 63

**JOB:** School companion

### **How did you find out about plasma donation?**

I became aware of plasma donation in 2015 through a mobile Haema blood donation appointment in Fürstenwalde, Germany, where I live, then I learned about the center in Frankfurt/Oder. There I then wanted to know more precisely what plasma is and now I have now been donating plasma, as well as whole blood, since 2016. The informational materials in the waiting area at the center convinced me to become a donor. After learning how important plasma is for life-threatening diseases, I didn't hesitate and have been donating weekly ever since.

### **How many times have you donated?**

275 times

### **Why do you donate?**

My motto is: Donating plasma is part of saving lives.

### **Do you know what happens to your plasma and why it is so important to patients?**

To treat life-threatening diseases, to prolong and improve the lives of these patients. This motivates me to donate.

### **Have you already met people who rely on plasma therapies?**

Not yet, but I learned more through the info materials at Haema centers.

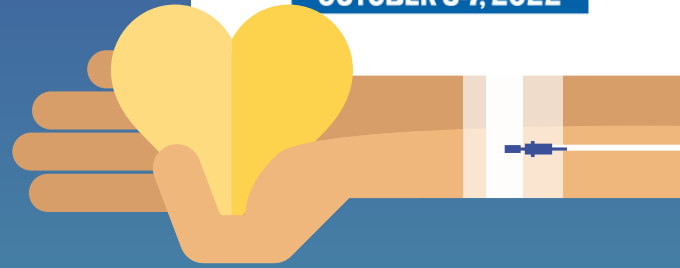
### **What do you think could be done to bring plasma donation more into the public focus?**

Most people don't know about plasma donation. I feel more awareness campaigns are needed to make this form of donation more known. The incentives on site are great: there are drinks, free Wi-Fi, and I also feel that the compensation is quite fair.

Without us donors, the patients would be much worse off. On top of that, I get regular medical check-ups (protein, hemoglobin), which in turn confirms my healthy lifestyle.



# IPAW: A DECADE OF PLASMA DONOR RECOGNITION



2022 marks the 10<sup>th</sup> anniversary of PPTA's recognition of International Plasma Awareness Week (IPAW). Although the Association and all our members are grateful every day for each person who rolls up their sleeve to donate plasma and help save someone's life, IPAWE offers all of us a dedicated week to show our appreciation and to share the stories of dedicated donors. IPAWE2022 will be recognized October 3-7.

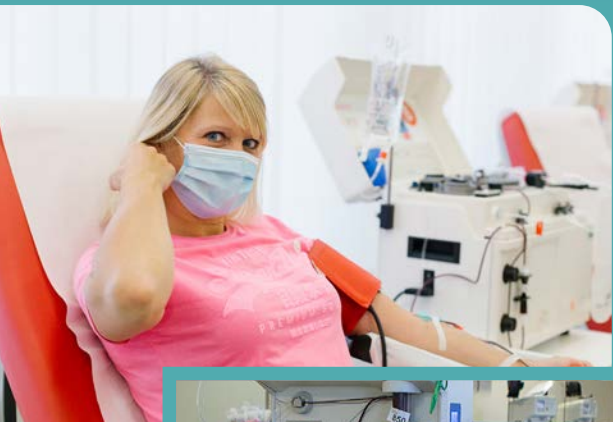
This year, we are capitalizing on a decade of IPAWE to further show our appreciation to donors across the U.S. and in the four countries in the European Union where the public and private sectors coexist to support plasma donation. IPAWE2022 will feature testimonials from plasma donors and messages of appreciation from patients who receive

treatments only available because of donor commitment, new graphics for our members and patient advocates to use in their respective celebration of IPAWE, and promoted social content intended to amplify the week's activities.

We invite readers of THE SOURCE to visit [PPTA's website](#) to download IPAWE2022-branded materials, available in English, German, Hungarian, and Czech, and to keep an eye out for our press releases when published on October 3. In the U.S., we will continue to focus on increasing awareness of the ongoing need for plasma and helping potential donors find donation centers near them.

In the European Union, we will leverage IPAWE2022 to further promote the need for Europe to collect more plasma, particularly considering the upcoming revision of the Blood, Tissues, and Cells (BTC) legislation. The BTC is our most promising opportunity to impact legislation across the EU to support increased plasma donation and to reduce the European patient reliance on plasma-derived therapies made from plasma coming from the U.S. PPTA will be hosting an event during the week of IPAWE in the Strasbourg Parliament to highlight the importance of plasma and plasma donors and will be inviting several members of the European Parliament to amplify the reach of our messages. During the event, a virtual reality film will be shown to give a first-hand experience of a plasma donation center. The event will also include an exhibition of pictures by plasma donors and a whole series of infographics.

PPTA is grateful for the past decade of support we have received from our membership, from the patient advocate community, and from national and regional legislators across the U.S. and Europe. IPAWE2022 promises to be the biggest celebration yet of plasma donors — after all, plasma donors save lives, and each one of them deserves our appreciation, admiration, and gratitude! •



# DigiPla 80



Nonconventional  
Integrated  
Generating  
Automated  
Logistical  
Efficient



Gathering **30** years of exploration and experience in blood transfusion, we understand the interconnection between donors and operators relies on the device.



At the core of our responsibility, Nigale endeavors to support a **smooth experience** of blood component donation and an **efficient plasmapheresis** through our invention.

Bringing a comprehensive portfolio of blood transfusion devices, disposables and solution, **productivity** comes from high-quality plasma collected.

Yield results from the our responsive **service**, continuous **synergy**, and progressive **development**. With the compatibility of customized disposable sets, DigiPla 80 conducts **diversity** in solutions for blood centers and plasma centers.



# Drive donor engagement with onbe<sup>TM</sup>

Grow donor loyalty and engagement with innovative payment experiences powered by Onbe. Ask us about perks to enhance your donor compensation program:

- VIRTUAL BONUS PROGRAMS
- SWEEPSTAKES
- LOYALTY INITIATIVES





# Upcoming Events

## CONFERENCES & SYMPOSIA

### September

**1 – 30** Immune Thrombocytopenia Purpura (ITP) Awareness Month

**21 – 22** 28<sup>th</sup> IPFA/ Paul-Ehrlich-Institute (PEI) International Workshop  
*Porto, Portugal*

### October

**3 – 7** International Plasma Awareness Week (IPAW)

**6 – 8** PI Conference: Primary Immunodeficiency in Focus [hybrid event]

**11 – 12** PPTA Plasma Protein Forum (PPF)  
*Washington, D.C., U.S.*

**12 – 16** European Society for Immunodeficiencies (ESID) 20<sup>th</sup> Biennial Meeting  
*Gothenburg, Sweden*

**13** PPTA Business Forum  
*Washington, D.C., U.S.*

**20 – 22** GBS-CIDP International Patient Symposium  
*Ponte Vedra Beach, Florida, U.S.*

### November

**1 – 30** Alpha-1 Awareness Month

**10 – 14** ACAAI (American College of Allergy, Asthma & Immunology) Meeting  
*Louisville, Kentucky, U.S.*

### December

**27 – 28** International Conference on Rare Diseases and Orphan Drugs  
*Vienna, Austria*

## GLOSSARY OF TERMS

**BAS – BIOLOGICALLY ACTIVE SUBSTANCE**

**BTC – EU BLOOD, TISSUES, AND CELLS LEGISLATION**

**CIDP – CHRONIC INFLAMMATORY DEMYELINATING  
POLYNEUROPATHY**

**EMA – EUROPEAN MEDICINES AGENCY**

**ESMP – EUROPEAN SHORTAGE MONITORING PLATFORM**

**ETF – EMERGENCY TASK FORCE**

**EU – EUROPEAN UNION**

**FDA – U.S. FOOD AND DRUG ADMINISTRATION**

**GBS – GUILLAIN-BARRÉ SYNDROME**

**GMP – GOOD MANUFACTURING PRACTICES**

**IPAW – INTERNATIONAL PLASMA AWARENESS WEEK**

**IPPC – INTERNATIONAL PLASMA PROTEIN CONGRESS**

**IQPP – INTERNATIONAL QUALITY PLASMA PROGRAM**

**ISG – INDUSTRY STANDING GROUP**

**MAH – MARKETING AUTHORISATION HOLDER**

**MEP – MEMBER OF THE EUROPEAN PARLIAMENT**

**MRA – MUTUAL RECOGNITION AGREEMENT**

**MRB – MARKETING RESEARCH BUREAU**

**MSSG – MEDICINE SHORTAGE STEERING GROUP**

**PDMP – PLASMA-DERIVED MEDICINAL PRODUCT**

**PID – PRIMARY IMMUNODEFICIENCY**

**PIPP – PARLIAMENTARIAN INITIATIVE PLASMA AND PLASMA  
PRODUCTS**

**PPF – PLASMA PROTEIN FORUM**

**PPT – PLASMA PROTEIN THERAPY**

**HOW IS  
YOUR DAY?**  
Plasma Donors Save Lives

Lifesaving therapies are available for those living with rare, chronic disorders because of the generous contributions of plasma donors around the world. Learn more at:

**<https://howisyourday.org>**

Become a part of the initiative — Follow, like, and share!

  @HIYDglobal



**QUALTEX**  
LABORATORIES

A SUBSIDIARY OF

**BioBridge**  
GLOBAL



## Providing state-of-the-art testing services

### Services

- ▶ Donor Screening
- ▶ Immunohematology Reference Laboratory
- ▶ Method Suitability and Sterility Testing
- ▶ Cellular Therapy Testing Services
- ▶ Biological Raw Material Infectious Disease Testing
- ▶ Production Pool Release Testing
- ▶ Research and Development

### About QualTex

- ▶ Continuity of service
- ▶ 24/7/365 laboratory and customer service operations
- ▶ FDA registered
- ▶ CLIA, EU, TGA, ISO 9001:2015 certified



### Locations

SAN ANTONIO  
ATLANTA



# HEMOBILIZE<sup>®</sup>

Softgoods at Bedside

By

TrippNT

**SG ACCESS  
CART<sup>®</sup>**  
Softgoods  
Storage  
is integrated  
with  
Donor Bed

15  
Softgoods  
Kits

**SG SUPPLY  
CART<sup>®</sup>**

Softgoods and  
Ancillary Supply  
Storage and  
Stand for  
Today's  
Plasmapheresis  
Machines

21  
Softgoods  
Kits

**CUSTOM  
OPTIONS**

The HEMOBILIZE  
System Provides  
Customization  
Options to Fit Your  
Design Needs

**SG Transport  
Cart<sup>®</sup>**

Replenish your  
bedside  
Softgoods with  
the mobile  
transport  
system

60  
Softgoods  
Kits

## Increasing Efficiency in the Plasma Industry

Lean out the flow and delivery of Softgoods from the Critical Supply Room to the Donor Bed with the HEMOBILIZE<sup>®</sup> System for more donor turns, increased ROI, reduced touch points and streamlined facility structures.

Come see us at

October 11-12, 2022

PLASMA PROTEIN  
FORUM

Washington, DC

Want information now?

Contact Bob Wright, 941.875.1964

[bobwright@trippnt.com](mailto:bobwright@trippnt.com)



[TrippNT.com/Hemobilize](http://TrippNT.com/Hemobilize)