Integrated CDMO Partner for Parenteral Drug Products

IPI Speaks with Mr Anil Busimi, VP, Strategy & Marketing of Terumo Medical Care Solutions (TMCS) on the Recent Changes in the CDMO Industry and what the Market is Looking for Now.

Q: Terumo is a core player in the health-care market. Can you tell our readers a brief history of the company, how you started and your growth so far?

A: Terumo Corporation is a global leader in medical technology and has been committed to "Contributing to Society through Healthcare" for over 100 years. Based in Tokyo and operating globally, Terumo employs more than 25,000 associates worldwide to provide innovative medical solutions in more than 160 countries and regions. The company started as a Japanese thermometer manufacturer and has been supporting healthcare ever since. Now, its extensive business portfolio ranges from vascular intervention and cardio-surgical solutions, blood transfusion and cell therapy technology, to medical products essential for daily clinical practice such as transfusion systems, diabetes care, and peritoneal dialysis treatments. Terumo will further strive to be of value to patients, medical professionals, and society at large.

Terumo has three companies encompassing global businesses.

- **Cardiac and Vascular Company**
- **Medical Care Solutions Company**
- **Blood and Cell Technologies Company**

As Part of Terumo Medical Care Solutions, the Pharmaceutical Solutions Division develops patient-oriented parenteral delivery solutions for therapeutic performance and safety.

We offer pharmaceutical and medical device manufacturers around the world comprehensive product design and development services through our decades of experience collaborating with pharmaceutical companies from the earliest phases of drug development to product commercialisation to optimise critical aspects of parenteral drug delivery.

Innovation and creativity are central to our value proposition. Our expert teams lead the industry in developing and manufacturing advanced, high-performing infusion and injection technologies, including pre-fillable syringes, CDMO services for all parenteral applications.

Q: Terumo Corporation has recently renamed the "General Hospital Company" to its new name "Medical Care Solutions Company". What prompted this move, and how will this impact your standing in the industry?

A: The new Brand Medical Care Solutions Company was launched as part of our continued growth and Terumo's 5-Year Growth Strategy (GS26).

The landscape of healthcare today is facing a paradigm shift. The point of care is not limited to in-hospital treatments but has expanded to in-home care. There are increased needs for a more personalised treatment, as well as improving hospital management efficiency and safety. The brand promise of Terumo Medical Care Solutions, "Quality time for better care," embodies the values and the wide scope of solutions the Medical Care Solutions Company provides today and carries the promise to provide this quality time for better care to everyone involved in healthcare.

Q: Can you give a brief overview of Pharmaceutical Solutions Division and CDMO platform?

A: Pharmaceutical Solutions Division develops patient-oriented parenteral delivery solutions for therapeutic performance and safety. Globally trusted for quality and precision, we offer pharmaceutical and medical device manufacturers around the world comprehensive product design and development services.

We have decades of experience collaborating with pharmaceutical companies from the earliest phases of drug development to product commercialisation to optimise critical aspects of parenteral drug delivery.

Innovation and creativity are central to our value proposition. As a partner for global pharma customers to offer parenteral drug solutions with five business platforms:

1. Injection Platform includes our K-Pack™ II Hypodermic needles.
2. Infusion Platform features our Surflo™ Winged Infusion Sets.
3. Primary Packaging Platform with our Prefillable Syringes PLAJEX™ range.
4. Drug Delivery Devices with our intra-dermal injection device, Immucise™.
5. CDMO – Our parenteral Contract Development and Manufacturing Organisation (CDMO) brings customers a uniquely integrated service offering. We bring together our high-quality polymer pre-fillable syringe (PFS) manufacturing and our complete CDMO service offering that includes formulation development, fill-finish services, device assembly and packaging all in one trusted partner. For our customers, integrated innovation means end to end services that deliver injectable products of the highest quality, compliance, and with reduced time to market. Our Japanese manufacturing sites are cGMP compliant and are certified by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). Both of our aseptic fill finish sites have been successfully inspected by the U.S. FDA and the EMA has inspected one site for a commercial product inspection. This track record of success with leading international regulatory bodies demonstrates Terumo's continuing commitment to achieving the highest quality standards for its pre-filled syringe CDMO customers.

Q: Have you noticed any recent changes in the CDMO industry? What are customers looking for now? How are you addressing these changes?

A: During COVID-19 pandemic many pharma companies struggled to find manufacturing capacity in a short time, CDMOs filled the gap and will continue to play this role in future.

We see the following major changes in the global CDMO landscape..

- **Increasing capacity and modernization:** Increasing number of biologics in the pipeline demands specialised aseptic fill & finish operations and support. Globally, we see significant investments by CDMOs to increase the capacity across the value chain to meet this demand. Some CDMOs are updating their facilities with latest technologies and fill & finish equipment.
- **Quality & Compliance:** Continuous improvements to enhance the quality and compliance means latest technology, equipment, procedures.
- **Flexibility:** in operations due to drugs being very specific to a patient population or therapeutic area. CDMOs needs to adapt to provide smaller batch sizes, multiple packaging formats, just in time (JIT) production models.
- **Integrated services:** Many biosimilars or bio-betters in late stage and most of these companies rely on CDMOs for their manufacturing, supporting these pharma companies from pre-clinical to commercial stage is critical to avoid changes along the value chain.
- **Collaboration:** Industry wide collaboration to have a robust supply chain and offer best solutions to the pharma companies and ultimately to patients.

Q: How do you support companies for different stages of drug development (clinical to commercial)?

A: Terumo's CDMO services span the full range of services required to take a customer molecule from drug formulation to fully packaged commercial product, all in one company.

We can help the pharma companies simplify their supply chain as One single source for device technology, and drug product development/manufacturing services – from clinical, small batches to commercial scale production.

Whether if it is a small, medium, and large organisation, we can customise our services to meet the customer requirements. For example, a small company may not have resources and capabilities for drug compatibility, device testing or regulatory experience, whereas the big pharma may have those capabilities in-house. Depending on the customer's needs and capabilities we either offer the full package service or collaborate closely to split the responsibilities without compromising the quality and time to market for final product.

Q: Terumo Medical Care Solutions is a leading manufacturer of primary containers, you have launched a ready-to-fill polymer syringe for challenging biotech drugs with larger volume. Can you explain to our readers the latest trends in this market and how they are evolving?

A: There are more than 3000 injectable drugs in the pipeline – many of which are sensitive biologic drugs with potential stability challenges. Thus, primary packaging solutions must reduce drug-container interactions throughout the shelf life. In addition, many biologic drugs in the pipeline are targeted towards smaller patient populations, which requires the manufacture of smaller batches even in pre-filled syringes – without compromising on quality. Flex filling lines in combination with ready-to fill components like PLAJEX™ is the answer to address this trend.

Prefilled syringes kickstarted a trend that moved injectable drug delivery from hospital to home environments. Today's pharma companies want to make the self-administration of injectables as safe, convenient, and painless as possible. Combining pre-filled syringes with autoinjectors is a popular approach. And it is also possible to combine drug delivery devices with electronics to collect data at the time of administration. For example, we work with external partners to ensure compatibility of PLAJEX™ with autoinjectors and safety devices so that our customers have an integrated solution.

Q: The pharma industry faces challenges from global competition, shorter innovation cycles, legal regulations for safety and environment, and individualised product demand. How will integrated CDMO help ramp up production faster and accelerate faster products to market to combat new diseases?

A: Combining the global standard in polymer pre-fillable syringe supply with unrivalled sterile formulation development services by a uniquely coordinated approach, provides significant advantages to Terumo's CDMO customers. Working with one supplier that has an unmatched understanding of the capabilities of their own syringes, allows Terumo to select best device for each individual project. It also allows Terumo's CDMO teams to coordinate the formulation and device development steps, and to quickly arrive at an optimal formulation, that considers the challenges of potential interaction with the device. Terumo's highly efficient sterile filling operations utilise modern, flexible, and highly automated sterile filling lines suitable for both clinical and commercial manufacturing volumes. The result is that Terumo's integrated innovation approach can result in a significantly derisked project with accelerated timelines.

Q: As an industrial giant, I am sure you are governed by the vision of sustainability, emission control and circular economy. What steps are you taking to lead in this category, and what commitments have you made and gained from your customers and suppliers?

A: Based on the Group Mission of Contributing to Society through healthcare, Terumo believes that its social mission (corporate purpose) is to lead the advancement of healthcare and the enhancement of patients' QOL. To achieve this, Terumo will strive for the utmost quality in all activities, create solutions of value by utilising new technologies, and spread those solutions globally.

Amid drastic changes in social and global environments, Terumo will also take leadership toward solving a variety of social issues, and to meet the expectations of its broad range of stakeholders.

We position the reduction of environmental burden as one of the most important sustainability priorities. By committing to the 1.5°C pathway and working with various stakeholders to achieve the goal, we will further accelerate our efforts to address the global issue of climate change. Terumo Group's targets for Greenhouse Gas Emissions reduction include:

- Achieve carbon neutrality by 2040.
- Increase a ratio of renewable electricity use up to 50% by 2030.

- Reduce absolute GHG emissions 50.4% by 2030 from a 2018 base year.
- Reduce GHG emissions 60% per unit of revenue by 2030 from a 2018 base year.
- On our rooftop in Belgium, we will install 3000 solar panels by early next year, sufficient to meet the annual electricity consumption of some 385 households. This investment is a fitting example of sustainability in action, contributing to Terumo Corporation's goal to be carbon neutral by 2040.

The Terumo Group has established key sustainability activity themes to resolve issues related to healthcare, society, and the global environment, and is working to realise a sustainable society and sustainable growth for the Terumo Group while also listening to the voices of various stakeholders. Through these sustainability efforts, Terumo will contribute to the realisation of a sustainable society, create new Terumo strengths, and culture, and bring about sustainable corporate growth.

Q: What is Terumo's / PSDs vision for the future? What projects are you most looking forward to?

A: With the Terumo Mission Statement of 'Contributing to Society through Healthcare', and the Medical Care Solutions Company promise of 'Quality time for better care', the Pharmaceutical Solutions Division support this through their strategic vision of aspiring to be the preferred partner of pharma customers for innovative medical devices and injectable drug delivery solutions, providing safe and effective products that improve people's lives. We recently announced our global expansion of our more than 20 years established integrated CDMO in Japan offering end-to-end services supporting customers with pre-filled syringe (PFS) design, moulding, drug preparation, filling, assembly, and final packaging for challenging biotech drugs and small molecules.

Our CDMO capabilities with three CDMO sites in Japan, will involve engaging on projects that cover the early development stage to large scale commercial production for global pharmaceutical customers including assembly of PFS with devices like autoinjectors, needle safety devices, and supporting customers for regulatory submissions globally. Terumo has invested to expand the CDMO production facilities for pre-filled syringes at its wholly owned subsidiary Terumo Yamaguchi corporation Ltd. The total investment, including peripheral equipment, will be 15 billion yen (100m USD). As a result, Terumo Yamaguchi D&D's production capacity will increase by 3.5 times compared to when the plant started operation in 2016. This global expansion is just one example of an exciting outlook for us and aligns with our growth strategy. Moreover, the Kofu Factory site will be extended with an entire new building dedicated to the Medical Care Solutions Company. The total investment will be 52.2 billion JPY (350m USD), and the construction will be completed in fiscal year 2025. Once operation starts, the new manufacturing facility will be utilised for the contract development and manufacturing organisation (CDMO) business, as well as products related to peritoneal dialysis. Terumo is a global leader for injection devices like needles, we have capabilities to customise the needles for a specific therapeutic area. We are looking forward to expanding our portfolio. Terumo will continue to contribute to better patient care and transformation by further enhancing our solutions that leverage the strengths it has cultivated over the years, thereby providing "yasashii*" medical care for everyone involved in healthcare.

* "Yasashii" is a Japanese term that suggests a combination of kind, caring, friendly, and thoughtful.

Anil Busimi

Anil Busimi almost 20 years experience built profound understanding of the global injectable drugs industry. He is passionate about providing solutions to pharma customers and end users in the areas of primary packaging, drug delivery devices, and fill and finish aspects for injectable drugs. Anil is currently working at Pharmaceutical solutions Division of Terumo Medical Care Solutions (TMCS) as VP, Strategy & Marketing and be part of Terumo's corporate mission: "Contributing to Society though Healthcare."

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