

News Release

Managing Cell and Gene Therapies: Werum IT Solutions partners with Blood Centers of America

Strategic partnership to develop a "vein-to-vein" digital supply chain solution suite integrating manufacturing / Cell and Gene Therapy players benefit from standardization, scalability and compliance / Werum's PAS-X MES plays decisive role

Lüneburg, Germany, 11 July 2019 – Werum IT Solutions, the world's leading supplier of manufacturing execution systems (MES) and manufacturing IT solutions for pharma and biotech, announces a strategic partnership with Blood Centers of America (BCA) to provide a standardized, scalable and compliant platform for the cell and gene therapy market. BCA is a member-owned organization comprised of over 50 independent blood centers throughout North America, representing nearly 40% of the U.S. blood supply.

The two partners will jointly develop a seamless digital supply chain solution suite for cell and gene therapy. It will integrate manufacturing and supply chain logistics as well as the collection of autologous/allogenic cell-based raw material in the manufacture of cell and gene therapies. The cell and gene market will benefit from standardized processes, scalability of their products, full control of the chain of compliance (CoI, CoC) and electronic batch recording.

"We are excited to partner with Werum IT Solutions, the leading MES supplier in FDA approved cell and gene therapies," says Charles Mooney, VP Bio-Development & Quality Management at the Oklahoma Blood Institute and BCA Cell Therapy Committee Chair. "To efficiently manage cell and gene therapies the market needs a comprehensive 'vein-to-vein' IT solution that we will create together with Werum – a novelty and important milestone in the cell and gene business."





"We are proud to work together with Blood Centers of America and its members on this live-saving initiative," says Dr. Andreas Fischer, Senior Head of Business Unit SafeCell at Werum IT Solutions. "We will share knowledge and resources in order to develop an end-to-end supply chain management solution of cell and gene therapies integrating manufacturing and logistics for the complex process of delivering such therapies to the patient."

In this context, Werum's PAS-X MES will play a decisive role through its capabilities to track and control patient's material. There are thousands of data points between patient, donor, raw material and material management. PAS-X provides one GMP compliant electronic batch record allowing real-time data access and analysis, increasing data quality and reducing per batch execution effort and risk of human error.

Picture



From left: Dr. Andreas Fischer, Werum IT Solutions, and Charles Mooney, Blood Centers of America, closing the agreement.





About Werum IT Solutions

Werum IT Solutions is the world's leading supplier of manufacturing execution systems (MES) and manufacturing IT solutions for the pharmaceutical and biopharmaceutical industries. Its PAS-X software product is run by the majority of the world's top 30 pharmaceutical and biotech companies and also by many mid-sized manufacturers. Werum's manufacturing IT solutions help pharma manufacturers to increase efficiency, improve productivity, and meet regulatory requirements. Founded in 1969, Werum is headquartered in Lüneburg, Germany, and has many locations in Europe, America, and Asia.

www.werum.com

Werum is part of Medipak Systems, the Pharma Systems business area of the international technology group Körber. The Business Area's companies, Dividella, Fargo Automation, Mediseal, Rondo, Seidenader Maschinenbau, Systec & Services, Traxeed and Werum IT Solutions, are global leading providers of high-quality solutions for the manufacturing and packaging process of pharmaceutical products. As a Medipak Systems company, Werum provides integrated IT solutions for all phases of pharmaceutical and biopharmaceutical production – including process development, commercial production, and packaging as well as track & trace serialization. Körber unites around 10,000 professionals in industry-leading companies worldwide, achieving annual earnings of 2.6 billion Euros.

www.medipak-systems.com, www.koerber.com

About Blood Centers of America

Blood Centers of America (BCA) is a member-owned organization comprised of over 50 independent blood centers throughout North America, representing nearly 40% of the U.S. blood supply. Along with their core business of providing a substantial portion of U.S. blood supply, other BCA member services include patient blood management, transfusion services, immunohematology testing, therapeutic apheresis and tissue and cord blood banking. In addition, BCA members provide a variety of human blood products, cells and tissues to the therapeutic, diagnostic and cell therapy industries. www.bca.coop

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