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it.lifesciences for plasma: Accelerator for the human blood plasma manufacturing industry



Bielefeld (ots) -

The roughly 80 life sciences companies that operate in the global human blood plasma manufacturing industry all face the same

challenge: Very few are able to assure traceability from single plasma donations to the first plasma batch. Using the SAP S/4HANA® built-in intelligence with machine learning, the quality and compliance processes so critical to the blood plasma manufacturing industry were able to be accelerated.

Without a functionality available to support the "Single Donation Management" processes, most of these companies currently depend heavily on separate systems, nearly always custom-built applications. This situation often results in unnecessary manual - or even duplicate - work since there is no single source system. The process is therefore error-prone and results in a longer time to insight. The use of these custom-built applications for this crucial process is often not a future-proof scenario. Upgrades can be time consuming and are not without risk.

"intelligence now provides one of the first industry solutions to support the Single Donation Management processes," commented Frans Nieuweboer Director Life Sciences & Chemicals at itelligence Benelux. "[it.lifesciences for plasma](#) enables one-click batch traceability reporting from single plasma donation to the finished product. Our flexible accelerator also supports the Contract Manufacturing Organization (CMO) model and offers a high level of flexibility due to the partner-specific configuration setup."

End-to-end processes for the plasma manufacturing industry it.lifesciences for plasma covers all relevant end-to-end processes for the plasma manufacturing industry. The use cases that are supported by the itelligence industry solution involve partner interaction processes, for example the import of the Electronic Bleeding List, test results and post-donation information. Also included are single donation conformity verification, warehouse processes, pool preparation, plasma batch composition processes and quality processes such as lookback management and unit isolation. Standard reporting is available for unit traceability, shipment reconciliation as well as quality, conformity and compliance reports.

Implementing in a regulated industry

Due to the [highly regulated nature of the life sciences industry](#), it will come as no surprise that the it.lifesciences for plasma comes with a standardized set of deliverables supporting the different aspects of Good Manufacturing Practice and Computer System Validation. The documentation is based on a business process model and includes best practice user requirements, process flows and descriptions, configuration specifications, functional designs, test scripts and training documentation. Previous implementations were successfully submitted against CFR 21 Part 11 and EudraLex Volume 4.

The all-SAP approach simplifies the IT landscape [it.lifesciences for plasma](#) is installed on top of SAP ERP Central Component (SAP ERP) or SAP S/4HANA, which creates a single source system for the plasma manufacturing processes and master data maintenance - even when the plasma operations are distributed across multiple sites in different countries. The system helps to future-proof and, due to the SAP Fiori® frontend using SAPUI5, also enable the scanning application to process high-speed data transaction volumes. The user interface was specifically designed for the Single Donation Control process and is therefore not only intuitive and user-friendly but also easy to integrate with hardware like scales, signal towers, label printers and peripherals like handheld radio frequency scanners.

The industry solution makes use of standard SAP functionality like SAP Extended Warehouse Management and/or SAP S/4HANA stock room management, Quality Management (QM), Handling Unit Management (HUM) and Production Planning - Process Industries (PP-PI) and can even be extended with SAP Global Batch Traceability.

it.lifesciences for plasma is targeted at plasma manufacturing organizations that use SAP ERP or SAP S/4HANA or plan to do so in the future.

SAP-based solution with full range traceability In March 2020, one of itelligence' Belgian life sciences customers successfully completed the implementation of itelligence' industry solution it.lifesciences for plasma. Subsequently, this company became a leading life sciences expert with an integrated all-SAP-based plasma management solution that enables one-click full batch traceability reporting from single donation to the finished product. For itelligence, the first customer for this solution represents a major step towards global success.

Grafik: Life Sciences Grafik.jpg

it.lifesciences for plasma covers all relevant end-to-end processes for the [plasma manufacturing industry and complies with international regulations for the Life Sciences industry](#).

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Medieninhalte



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