WERUM
KÖRBER SOLUTIONS

PAS-X FOR CELL THERAPY MANUFACTURING

Controlling Chain of Identity: Managing the risk of tracking patient's material from collection through infusion

The past years have seen rapid growth in the number of cell therapy products in late stages of clinical trials. However, moving closer to market approval brings significant operational challenges for companies as their patient populations grow. Electronic systems are emerging as the only option for managing large product volumes. Werum's PAS-X is ideally suited to target the key challenges for Cell Therapy manufacturers.

Electronic Chain of Identity

The Chain of Identity has emerged as one of the key challenges. Tracking and control of a patient's material from collection through infusion poses the greatest risk for the process. A properly deployed electronic system can control this risk. Werum's PAS-X has the ability to barcode patient material, and track it as it moves through each process in the plant. Enforced verification at each processing step minimizes the risk of mix-ups and increases patient safety.

Accelerated release and Review by Exception

An additional challenge for an industry with ramping demand is the review and release process. As we move to having one production batch per patient, quality review and verification processes become time critical and a significant effort for reviewers. PAS-X EBR functionality provides a full Electronic Batch Record capability to the plant, eliminating the need for paper on the shop floor. A key capability of electronically controlled processing is the ability to review batches by exception, minimizing the per batch effort of reviewers and assuring patients can receive their unique dose in time.

Ability to scale up & scale out

When it comes to autologous or patient specific therapies, a key challenge is scalability. Reaching an economies of scale becomes a much different path than traditional pharma or biotech processes. As we explore new ways to scale up

or scale out therapies, PAS-X becomes a part of the solution. PAS-X MBR, through its user-friendly design and ability to create process libraries, offers a way to expedite recipe creation by creating building blocks to be used in any other design. Once a specific unit operation is defined, there may be updates necessary as new processes are developed and efficiencies are introduced. The ability to easily copy & paste one design or import a previously approved element greatly reduces the time needed to introduce new process steps into the shop floor. With the click of a button one can understand the delta between recipes to accommodate faster release of newly minted or updated designs.

Raw material traceability and e-logbooks

The significant use of single use processing systems in Cell Therapy brings with it increasing needs to verify and trace product-contacting materials and components. Werum's PAS-X provides a platform for Point of Use Verification of critical production components and real-time building of the product genealogy. Additionally, by scanning each equipment item during process, a real-time electronic logbook is created that manages the history of all batches processed on specific equipment.

Increased data integrity

Regulatory agencies have been increasing their focus on data integrity among pharmaceutical manufacturers. Werum's PAS-X provides a platform for increasing compliance by controlling user input and focusing on completeness, assuring timely entry of production information, preventing loss of batch record data, automating entry steps and calculations, and providing detailed audit trails. This reduces risk for your organization while increasing efficiency of your quality organization.

WHY PAS-X

- Chain of Identity management
- Electronic Batch Recording and Review by Exception
- Material Tracking & Tracing / Genealogy
- Electronic equipment logbooks
- 21 CFR part 11 compliant electronic system
- Full GMP warehouse management capability
- Pre-defined integrations to equipment and other software systems, including ERP

CAR-T BUSINESS CASE

For CAR-T manufacturing the main business case is around head count avoidance for batch record review. This is especially critical for scaling out production.

One of our current CAR-T customers calculation shows 30 hours are required to review one batch record using the manual paper processes. With a PAS-X MES implementation the time for review is reduced to 4 hours per patient. For this particular customer this translates to $9.4M in savings between 2018 – 2021.

MES Benefits:

- Avoidance of hiring future headcount to support the handling of manual paper systems
- Increased quality through standardization and elimination of paper based batch record system
- A reduction in paper and paper management in cleanroom

Not executing the project would lead to:

- Manufacturing site would need to increase batch record review personnel by >80%
- Increased risk around the manual process, human entry, review / approval and document control

Other key benefits:

- Additional headcount avoidance around issue, review and release of batch records
- Intelligence: patient data is available electronically in real time for analysis. This will help with continued process optimization and KPIs
- Increased quality, enforcing correct material usage, preserving the chain of identity throughout the entire process.
- Reduction of human error
- Ability to ensure that these lifesaving drugs arrive to the patient on time
- Elimination of paper from the shop floor
- Ability to look at batch record and review deviations in real time. QA has ability to access and begin deviation review while process is still being executed

PAS-X can run stand-alone (in growing organizations), or be fully integrated into ERP and other IT systems.

PAS|X

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