CELL MANUFACTURING PLANNING

FBRI

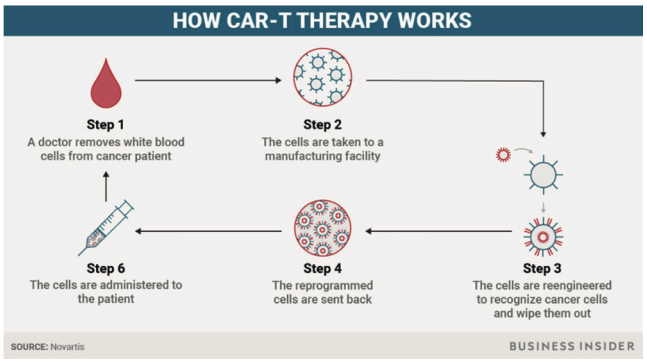
Foundation for Biomedical Research and Innovation at Kobe.

In April 2018, the Foundation changed its official name, notably in Japanese, including in it the mention of "Kobe Biomedical Innovation Cluster".

The Kobe Biomedical Innovation Cluster (KBIC) started out as a project to reconstruct Kobe's economy, which had been devastated by the Great Hanshin-Awaji Earthquake, as well as to protect and nurture local residents' lives and contribute to the international community. Since the Kobe Medical Industry Development Project Discussion Group was set up in 1998 to elaborate the project and take concrete steps, by October 2018, twenty years will have passed. During this period, the Foundation for Biomedical Research and Innovation at Kobe (FBRI), established in March 2000 as the main organization supporting the KBIC, has vigorously pursued biomedical cluster formation in Kobe through advanced clinical research and other efforts toward the construction of next-generation healthcare systems.

The KBIC has indeed developed into a remarkable healthcare cluster representative of Japan, concentrating over 340 companies, organizations, and research institutions, as well as a number of highly specialized hospitals. As for the FBRI, now reorganized under its new name, it is expected to continue making equally significant progress, promoting joint projects and other forms of collaboration among corporate, scientific, academic, and medical institutions located at the KBIC, leading to the development of innovative medical technologies and the creation of innovations beneficial to Kobe's economy.

It is also required to offer solutions to the great question as to how to build a bright future in the face of the unprecedented challenge that Japan is undergoing ahead of the rest of humanity: rapid population aging and birth rate decline.



Sector
Life Sciences

Size
340+ Companies
Organisations
Research Institutes

sedApta Modules
Capacity Planning
Slot Management & Slot Allocation
Process Order Creation
Media Product Calculation
Scheduling & Rescheduling

At the FBRI, they hope to continue to effectively fulfill the role of proposing, from Kobe to the rest of the world, solutions to problems along the way to realizing a society in which all members can enjoy a good health and longevity growing as a center of intelligence where human resources, information, knowledge and wisdom meet, and building bridges for trans-sector collaboration.

The Japanese research & development center for cell therapy is a division of the FBRI, which acts as a research partner and contract manufacturer (CMO) for Novartis. FBRI produces the Novartis product KYMRIAH, today one of only two commercial leukemia cancer cell therapies on the market.

Analysis

Especially because of the young age of cell and gene manufacturing, there is still potential for improvements. FBRI is aware of those fact, and therefore was looking for a truly innovative solution. Following an innovative approach, FBRI was looking into a software solution that allows them to serve their patients with a reliable manufacturing workflow, caused by an implemented digital industry 4.0 solution. With sedApta's Suite an integrated set of modules for the planning, management, and optimization of business processes across supply chains can be provided. In combination with Vineti's Personalized Therapy Management® (PTM) platform, to manage cell and gene therapy workflows, FBRI was able to get an enterprise solution uniquely capable of orchestrating workflow complexity of these transformative therapeutics.

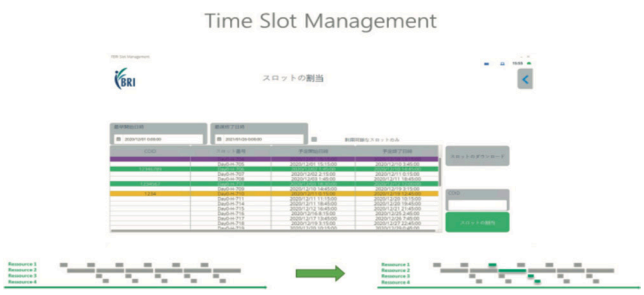
Together with FBRI the following objectives were identified:

- Fill the capacity in the production plan with theoretical load in order to produce cell therapy material.
- React on patient's requirements with adequate slot management
- COID (Chain Of IDentity)generation and connection to certain treatment date
- Produce required media in time
- Live communication with PAS-X MES
- Enable real time scheduling

Solution

The implemented solution is based on the sedApta Factory Scheduler and Slot Management specifically for cell therapy, communicating with the MES/EBR system (PAS-X) as well as with the clinical system (VINETI).
Scheduling is the first step in the construction of a production plan. It is a production planning activity that assigns a sequence of activities to each resource (mechanical, digital, human), taking advantage of production process simulation.

The sedApta modules Factory Scheduling, Workforce Scheduling and Slot Management were implemented to plan and coordinate the cell manufacturing process. The tool supports managers to create, visualize and refine the production plan. It is provided with sedApta's automatic scheduling algorithm that is able to elaborate a feasible production plan, based on heuristics and optimization rules. If needed, the automatic scheduling algorithm can be replaced by any customized plug-in algorithm.



Workforce Scheduling automatically assigns resources to the operations allowing an even distribution of work and instant responses to disruption events. The workforce and their individual's training have a significant impact on the schedule every time key resources are needed for critical orders and production phases. Individuals will be schedulable taking the organization's skill matrix into consideration.

Slot management is a platform to show, filter, modify, assign and approve time-slots for a guaranteed manufacturing date, exchanging slot information with the clinical system and track the status and the history of the slots at any time during the complete lifecycle.)

Benefits

The benefits obtained thanks to integrating Factory and Workforce Scheduling as well as Slot Management are:

- Automatically generate best feasible time slots with configurable constraints based on different simulation algorithms
- Manage the slots and allow clinical systems to choose existing guaranteed slots when a patient treatment is required.
- Make sure that a unique COID is generated and connected with the slot for its complete lifecycle, one the clinic decided for a certain treatment date.
- Check in 4-eyes principle if the allocation of the slot can be finally assigned to the patient and is ready to be scheduled and manufactured.
- Schedule the process orders for the cell manufacturing and, in the case of FBRI, calculate the corresponding media production by considering shelf life and minimum and maximum times to produce media to be used for the cell manufacturing process.
- Send process orders (lot with patient ID and correct recipe code) of a predefined period to the PAS-X MES and receive the corresponding Manufacturing Orders (MO) and shopfloor orders (SFO) from PAS-X.
- Receive progress information (Start of SFO, End of SFO, Abort,...) from PAS-X MES for real-time scheduling.
- Providing software in local, Japanese, language as well as in English to guarantee ease of use.

Why sedApta?

"sedApta was found to be the most fit software because of its superior functionality, track record of CAR-T manufacturing scheduling and having the master data interface with PAS-X system already in place."

FBRI