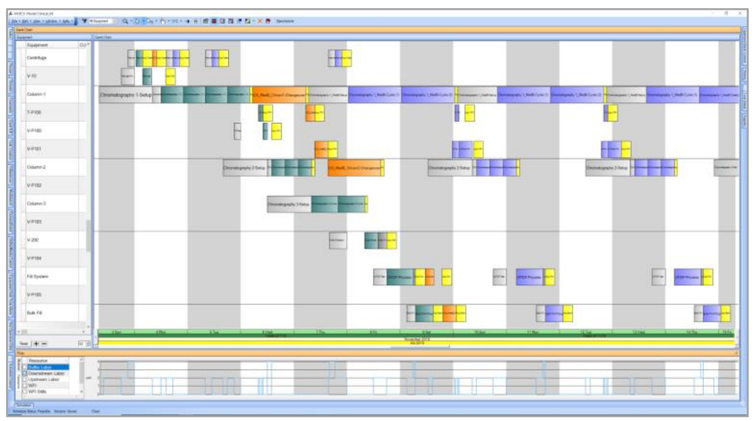
VirtECS® Biologics CLINICAL MANUFACTURING

VirtECS software provides proven scheduling and analysis solutions adapted to the unique challenges posed by the clinical manufacture of Biologics.

Drug Substance Tool for Clinical Facility

VirtECS approaches clinical manufacturing within the broader Drug Substance tool, using the same underlying computational methods, which are well suited to the challenges of manufacturing at the clinical scale. The clinical manufacture of Biologics drugs has much in common with larger scale manufacture in terms of sharing similar manufacturing steps and the same style of equipment. Both scales also share similar objectives and priorities for modeling and scheduling; however clinical manufacturing presents its own particular nature of challenges. For example, clinical plants must adapt to the needs of manufacturing a host of different products within the plant. This often presents radically different manufacturing process recipes and frequently operates on mutable campaign schedules that must be responsive to rapidly changing circumstances. This environment particularly well suits the VirtECS approach to user modelling of product recipes, and its host of available tools for managing the relative timing of sequential batches of any number of products.

Challenges of Clinical Manufacturing



In addition to divergent product recipes and a larger number of products, there are other key challenges for scheduling a clinical facility, including interacting cross-area constraints and shared resources. Even within a single product, clinical manufacturing presents unique challenges: the combination of limited equipment availability and the needs of meeting a wide range of manufacturing processes often results in the occurrence of shared resources across process areas. For example: a storage vessel may be used as part of a purification stage, before being cleaned and re-purposed for buffer storage. While not unheard of in larger scale manufacturing, such shared constraints are much more frequently encountered at the clinical scale and add complexity to process modeling and scheduling that can frustrate attempts to study the plant's capabilities and schedule.

- **Easily Modified Recipes**
- **Schedule Edits for Rapidly Evolving Situations**
- **Capacity Analysis and Planning**

Solution for Clinical Manufacturing

VirtECS helps overcome these challenges through the combination of its core mathematical programming approach to scheduling, and the Biologics Drug Substance tool's ability to define widely divergent process recipes within a single user-editable model. VirtECS fully enforces all cross-area constraints, combined with the necessary tools to fully customize the handling of product-to-product timing and changeovers, producing only feasible and executable schedules within all defined constraints.

VirtECS schedules are driven by a batch schedule that is easily modified and updated. Batches can be deleted, added, or edited allowing for rapid adaptation of the schedule to changing circumstances without loss of fidelity or existing user modification to existing or past schedules. The same functionality allows for the exploration of planning scenarios, for example to determine the feasibility of a newly proposed modification to a campaign.

Clinical manufacturing capability is available with the Biologics Drug Substance tool, and includes use of all of its standard functionality such as capacity analysis, engineering analysis, long term planning, access to scheduling tools and to the Symphony web client.

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