

## BIOTECH CUSTOMER STORY

# Real-Time Scheduling and Debottlenecking Capabilities Accelerate Biotech Ramp Up



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## Customer Situation

The driving expectation for manufacturing is to continuously improve year over year. As this customer's facility continued to ramp up production, each minute and every resource became increasingly valuable to optimize in a methodical manner. See how they improved manually-based schedules and created a plan for better utilization of their existing resources.



# Moving From Spreadsheets to a Real-Time Scheduling System

## What Is RTMS?

- RTMS is a scheduling and capacity analysis tool

## How Does RTMS Work?

- RTMS uses a digital model of the facility including the operational tasks, time, constraints and dependencies
- RTMS is connected to source shop floor manufacturing systems (MES & Pi)

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## What Are Its Main Capabilities?

1. Always feasible & optimized schedule
2. Real-time schedule with automated shop floor execution updates
3. Capacity analysis tool understands impact of changes and potential improvements



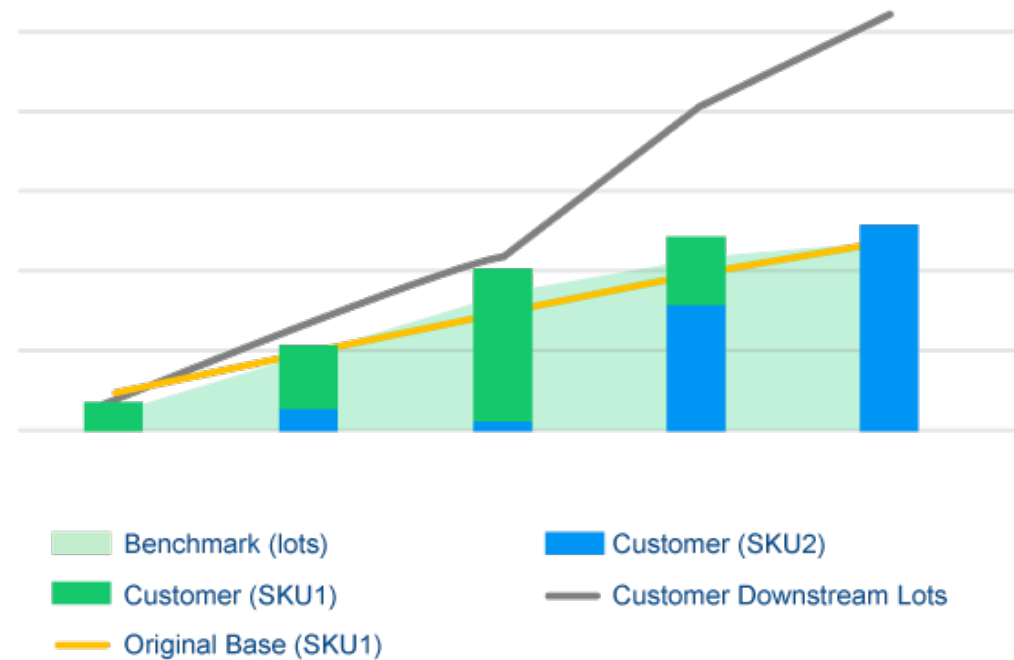


# Customer Facility Ramp Up

The Customer is targeting one of the fastest BDS (Bulk Drug Substance) facility ramp ups in history + introduction of new process to support growth BDS products

	Time to Max Cadence	Years post PPQ
SKU 1	Q1 2024	2.5 years
SKU 2	Q1 2025	2 years

### Comparison of Customer Ramp up vs. Benchmark



## EXAMPLE 1

# Simplifying Complexity in a Dispensary

### Problem:

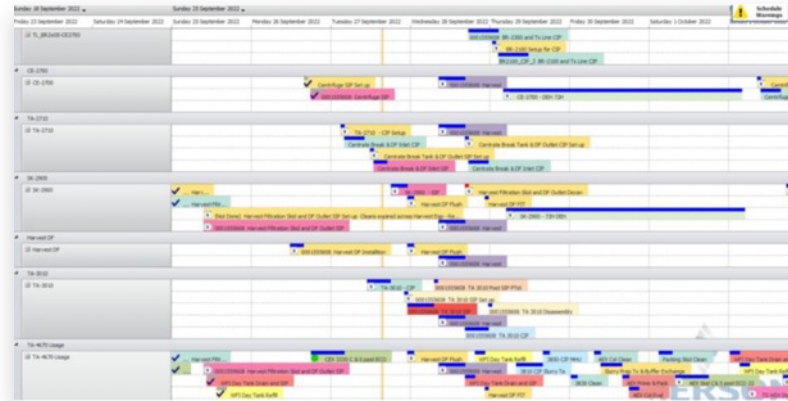
No platform driving a live finite schedule to the dispensary to support materials being dispensed on time, when required in manufacturing.

### Simplify Complexity

- 31 BoM's
- 23 materials
- 69 dispenses per batch
- Availability of booths
- Varying material hold times

The schedule needs to detail **when material within each PO needs to be dispensed**

### Manufacturing Schedule

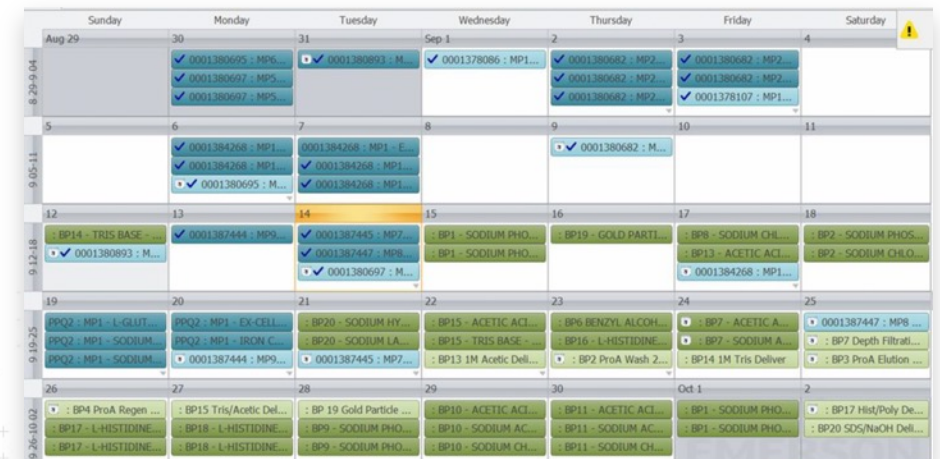


No delays in manufacturing associated with waiting on materials from Dispensary

### Dispensing Schedule

Web App Calendar View simplifies planning complex Dispense operations and enables:

- Rapid response to changes in real time
- Level loading & balancing work

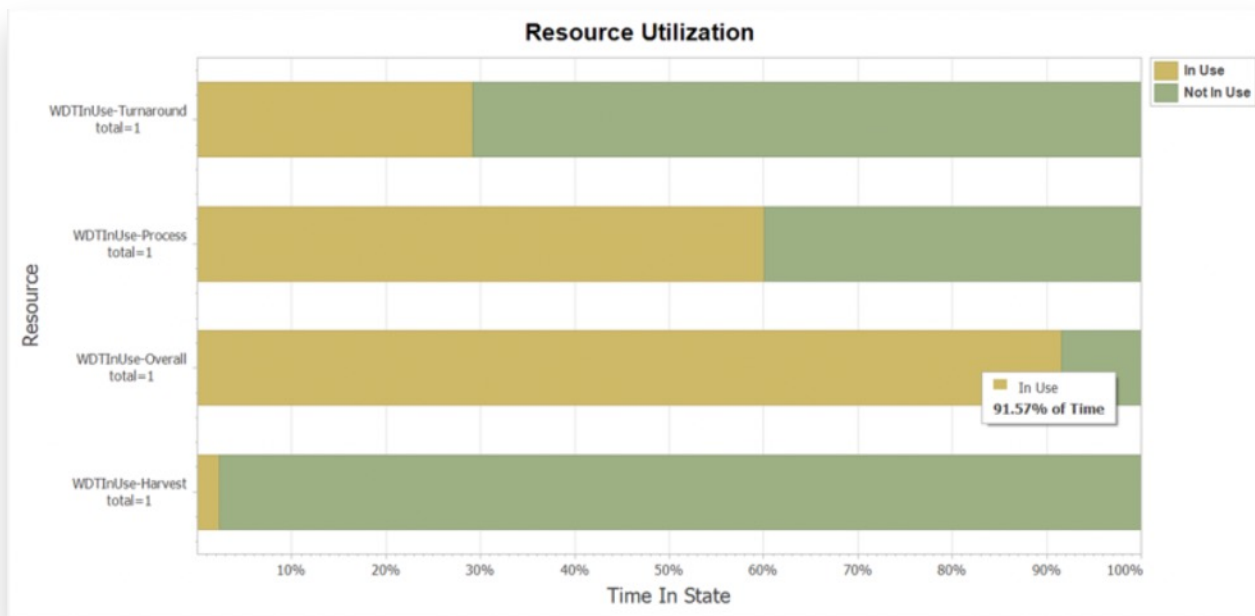




## EXAMPLE 2

# Finite Schedulers Identified WFI Supply Tank as a Critical Constraint

## Before (91% Utilization)



37 conflicts identified while WFI Supply Tank is running

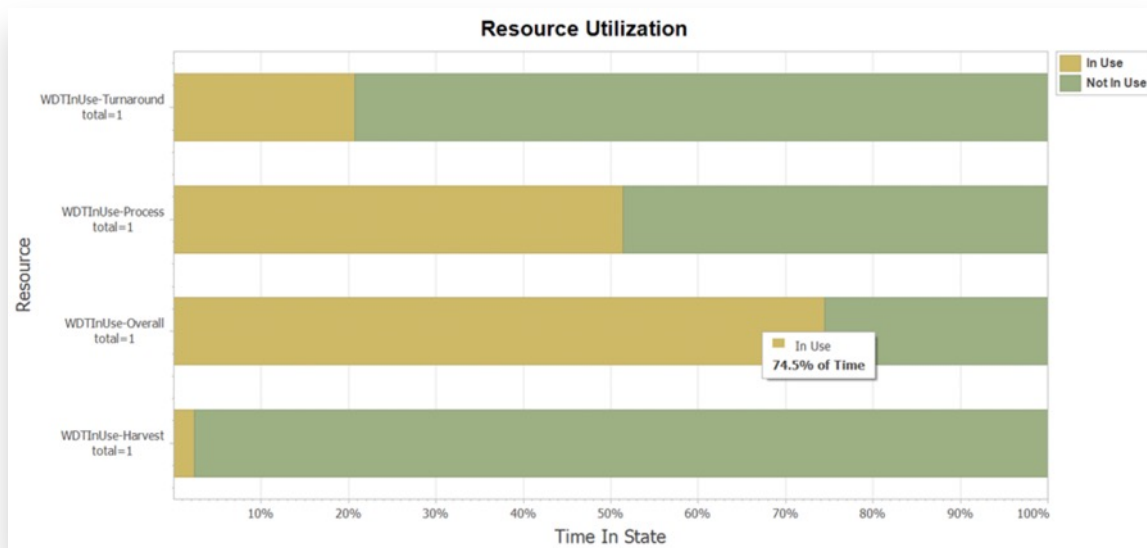
## Problem Statement:

91% WFI Supply Tank Utilization, as Harvest, Chromatography, VIDF, UFDF, Column Packing production recipes cannot run while WFI Supply Tank SIP ongoing, resulting in significant conflicts for production

USP Harvest		
Depth Filtration flush		
Harvest Flush (Product)		
HF & HDF Outlet CIP	VI & DF	
Harvest FIT	DF SKID CIP (3140)	
Day tank Vent	DF SKID SIP (3140)	
Harvest Depth and HF CIP (CBT & H	3210 CIP	CEX
SIP	VI & DF Cycle 1	CEX skid setup
ProA	VI & DF Cycle 2	CEX Cycle 1 + CEX Cycle 2
3110 CIP	Aqueous flush	CEX Column Clean & Store
TX line 3110-3140	AEX	CEX skid clean and store
3120 CIP	3310 CIP	UFDF
TX line 3120-3140	WFI flush & Skid set up	CIP 3610 (with Caustic)
ProA skid setup & CIP	AEX Processing	SIP 3610
ProA Equil	AEX Column Clean & Store	Setup & Flush
Cycle 1	AEX post use clean and store	CIP UFDF
Cycle 2		SIP UFDF
ProA strip filters & sanitisation		
ProA Skid clean store		

# Finite Schedulers Identified WFI Supply Tank as a Critical Constraint

## After (74% Utilization)



Decoupling VIDF & Chromatography alleviates capacity constraints for Gen1 process, reducing utilization from 91% to 74%

## Solving Using MPS + Digital

1. Worked with GES to identify WFI Supply Tank automation upgrades to alleviate resource constraint for Gen 1 process at no capital cost; decoupling the IDF & Chromatography production recipes removed 7 conflicts and 4 CIP conflicts
2. Initiated MPS project to reduce SIP Turnaround from 13 hours to 6 hours

ProA
Cycle 1
Cycle 2
ProA strip filters & sanitisation
VI & DF
VI & DF Cycle 1
VI & DF Cycle 2
AEX
AEX Processing
CEX
CEX Cycle 1 + CEX Cycle 2

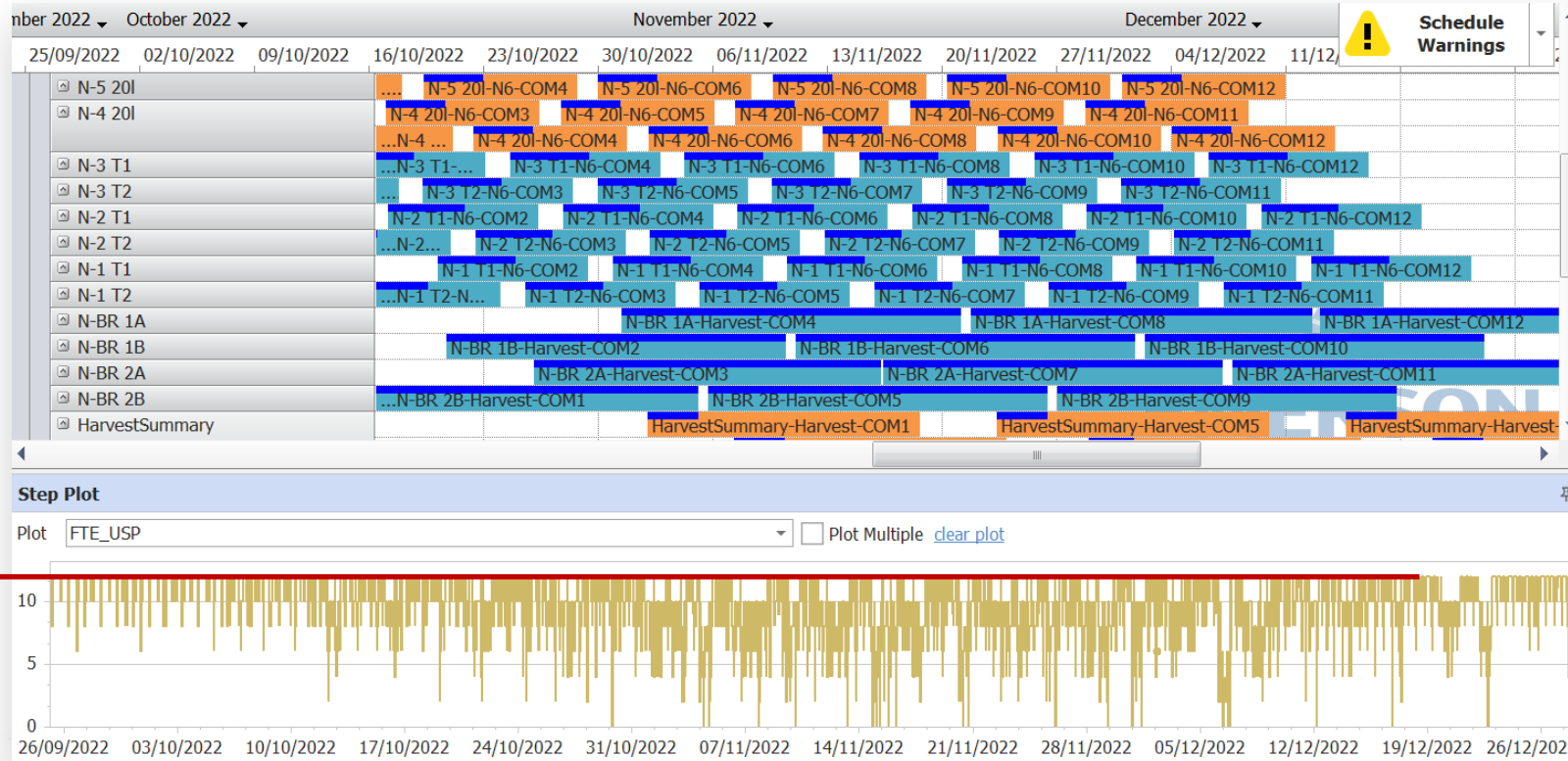
3110 CIP
3120 CIP
3210 CIP
3310 CIP



### EXAMPLE 3

# Labor Analysis Gives Us Confidence in Capability to Deliver the Supply Plan With Our Current Staffing

## Upstream



12 BPA's

- Helped establish standard times for all activities and update standards based on actual performance
- Allowed to avoid headcount peaks above available labor

# Summary: Real-Time Scheduling and Debottlenecking Capabilities Accelerate Biotech Ramp Up

## Project Takeaways

Resources, such as labor and WFI, can be a bottleneck when scaling manufacturing. By optimizing and balancing these resources, our scheduling tool can automatically generate an optimized schedule that avoids unplanned downtime and loss of production.

Through proper scheduling and modeling, peaks can be avoided, and production targets can be met!

