

A Modelling approach to Increasing Capacity through Plant Optimisation and Cycle Time Reduction in Industrial Scale Bio-Pharmaceutical Manufacturing

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Introduction

- **Capacity expansion**
 - Cycle time vs batch size
- **Investigation**
 - Data gathering and interpretation
- **Design**
 - Process modelling
 - Scheduling and plant optimisation
- **Implementation and effectiveness review**
- **Overview**

Capacity Expansion in Existing Facilities

- Batch size increase

- Large capital investment
 - Equipment
 - Validation
- Regulatory submissions
- Reduces operational costs

- Cycle time reductions

- Low capital investment
 - Setup-times
 - Labour organisation
 - Batch type scheduling
- Medium capital investment
 - Decoupling critical path process units
 - Testing improvements
 - New technology

CSL Behring: Broadmeadows

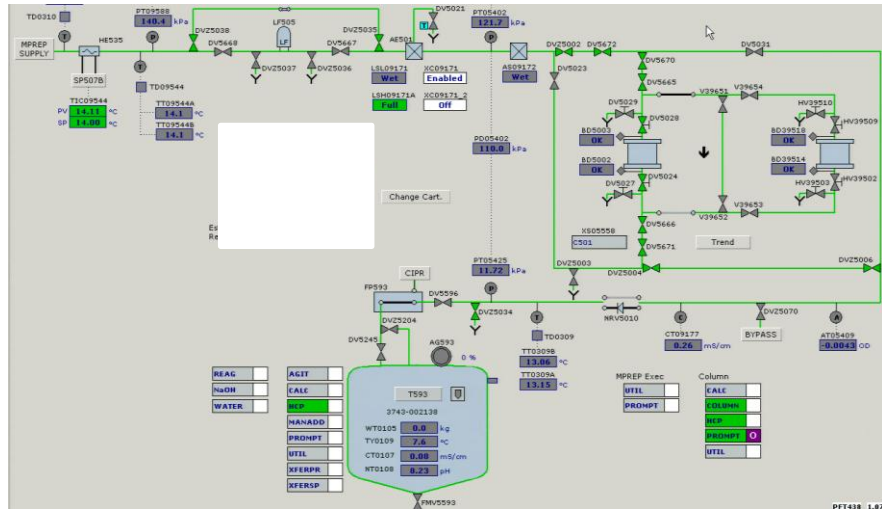
- Toll manufacturing facility commissioned in 1994
- Main production streams
 - Chromatographic IVIG
 - Albumin 2VI



Initial Investigation: Big Data

- **Data Collection**

- Export data from SCADA System (Siemens PMCS 7) into raw csv files
 - Start and stop times of operations
 - 28,000 data/batch x 100 batches
 - 2.8 million data points



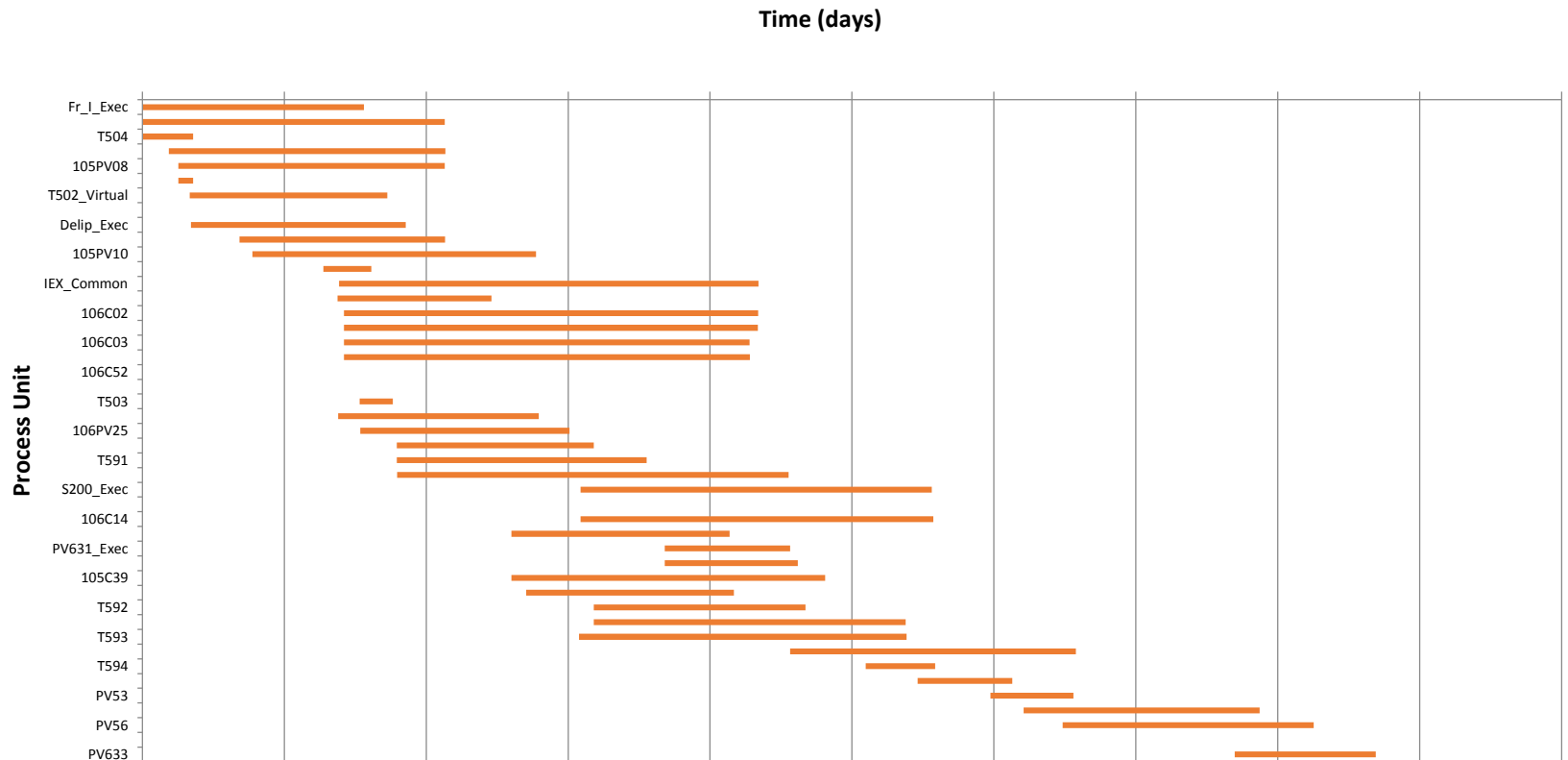
- **Data Manipulation**

- Formatting into usable data
 - Equipment, batch and type categories
- Align meaningful data points to calculate idle or hold times

Data Interpretation: Primary level

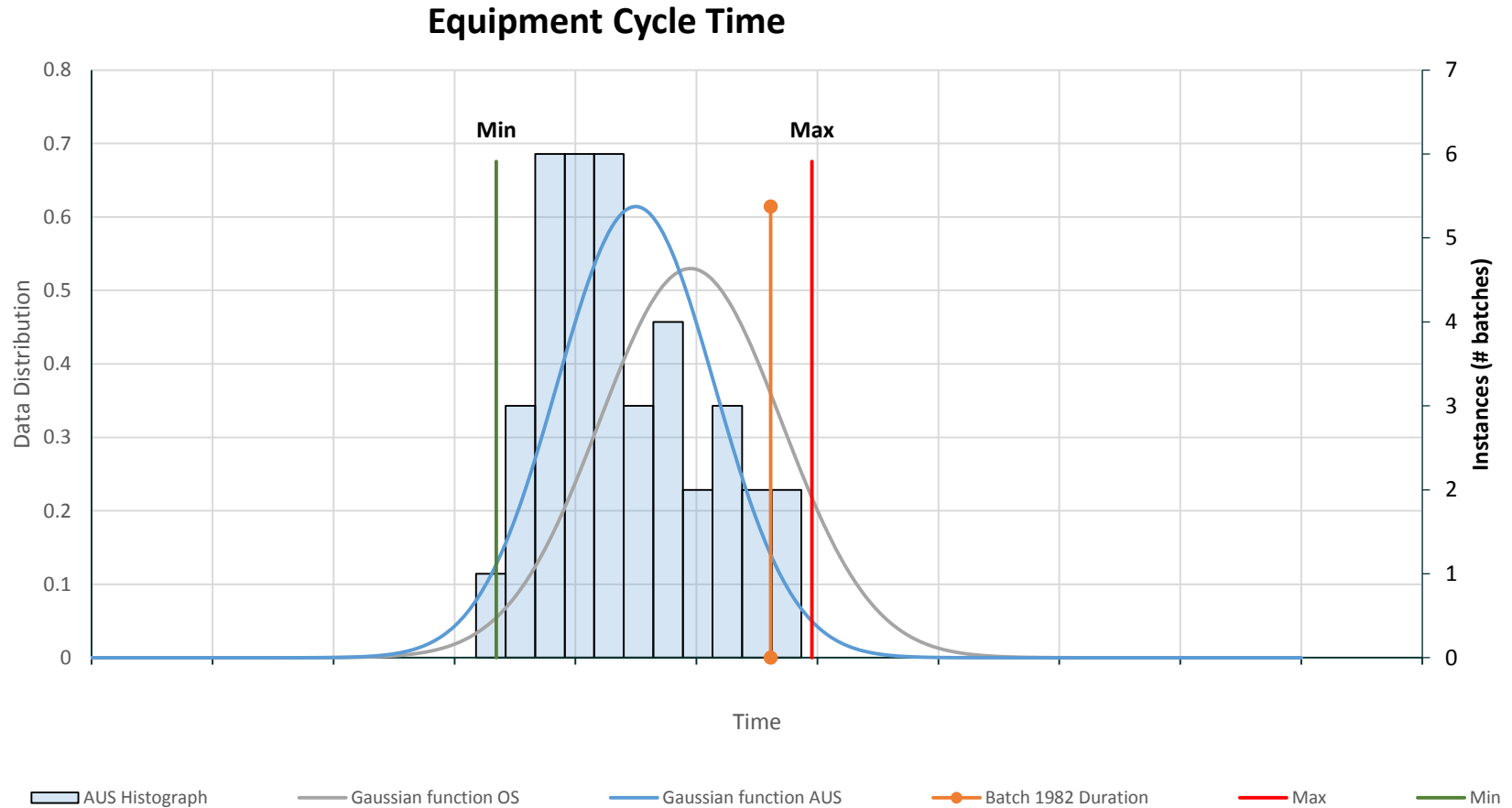
Single Batch

- Individual equipment cycle time for a single batch



Data Interpretation: Primary level

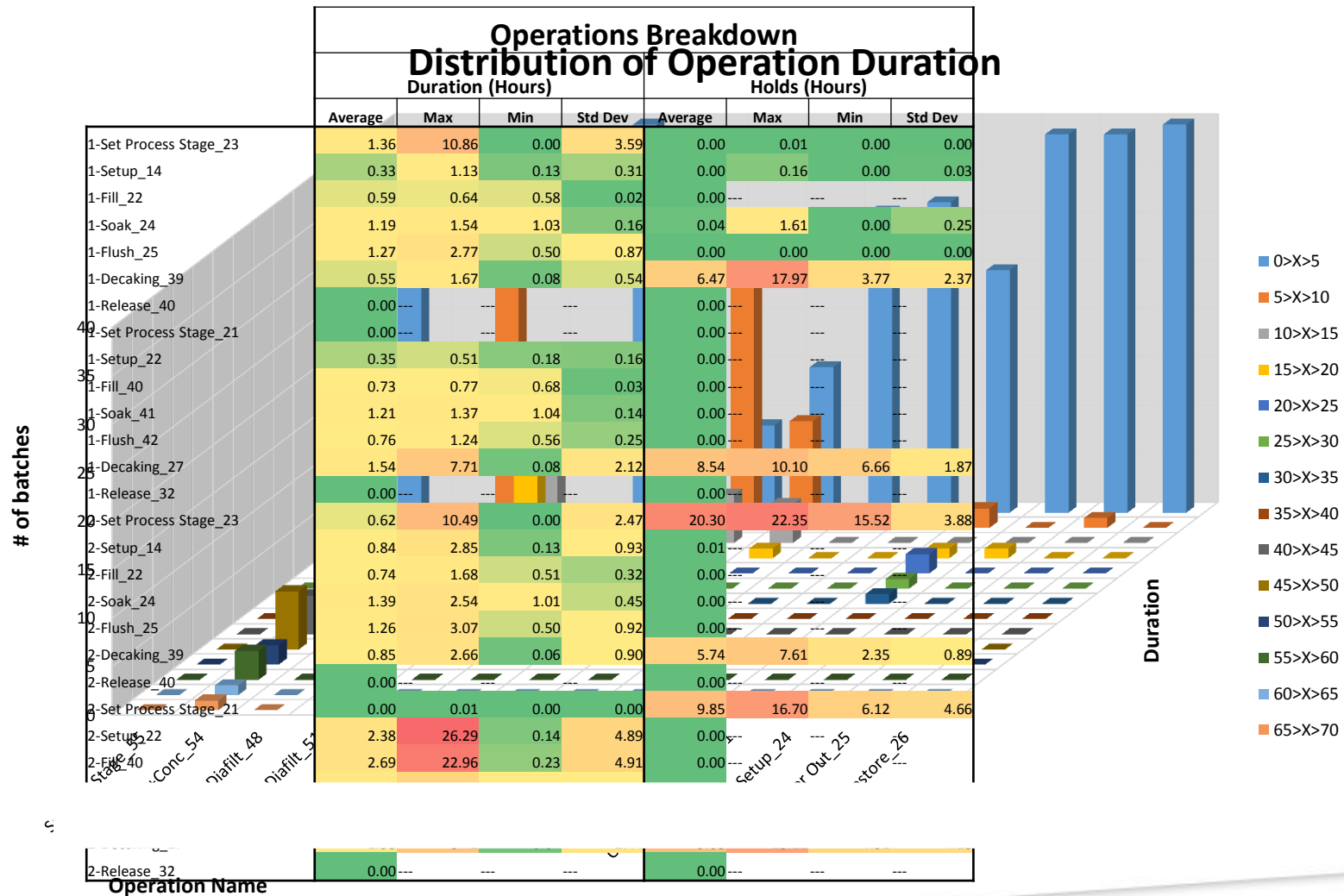
Multiple Batches



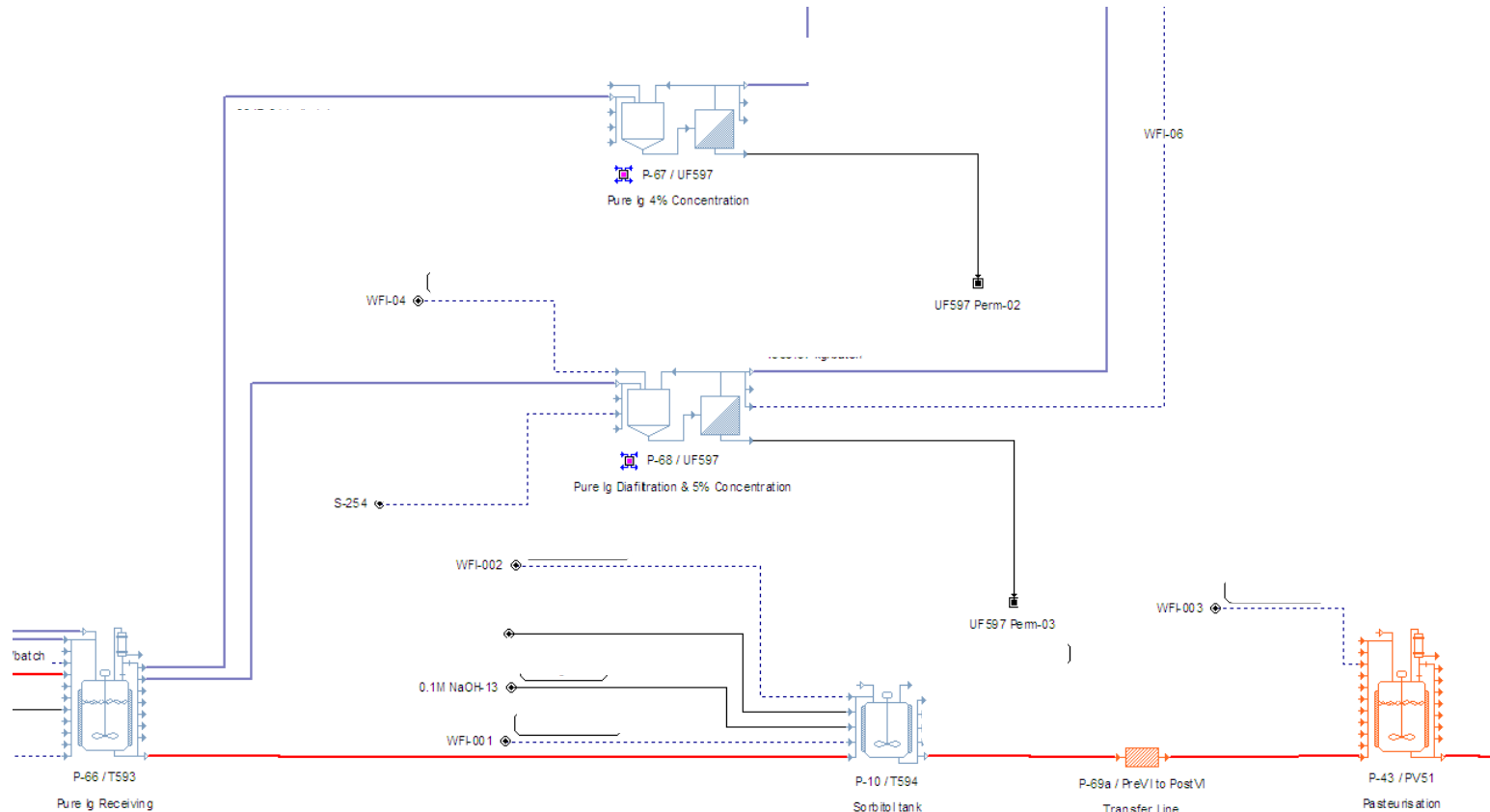
Data Interpretation: Secondary level Operations within a Single Batch

Batch 0000				
Operation	Start	Finish	Duration	Hold time
3452-001982/Collection Tank._6/Set Proc Stage_55	22/07/2012 7:36	22/07/2012 7:36	0.000	0
3452-001982/Collection Tank._6/Receive+Conc_54	22/07/2012 7:36	24/07/2012 1:42	1.754	0
3452-001982/Collection Tank._6/ Diafilt_48	24/07/2012 1:42	24/07/2012 8:15	0.272	0
3452-001982/Collection Tank._6/ Diafilt_51	24/07/2012 8:15	25/07/2012 5:54	0.902	0
3452-001982/Collection Tank._6/Further Conc_52	25/07/2012 5:54	25/07/2012 7:04	0.0487	0
3452-001982/Collection Tank._6/Recover UF_53	25/07/2012 7:04	25/07/2012 11:30	0.184	0
3452-001982/Collection Tank._6/Addition_57	25/07/2012 11:30	25/07/2012 16:59	0.228	0
3452-001982/Collection Tank._6/Adjust_66	25/07/2012 16:59	25/07/2012 18:46	0.074	0
3452-001982/Collection Tank._6/Release_10	25/07/2012 18:46	25/07/2012 18:48	0.001	0
3451-001982/Transfer PV631 to PV635_31/Set Process Stage_38	25/07/2012 21:35	25/07/2012 21:35	0.000	0.116
3451-001982/Transfer PV631 to PV635_31/OP187 Calculations_21	25/07/2012 21:35	25/07/2012 22:34	0.040	0
3451-001982/Transfer PV631 to PV635_31/Transfer Setup_24	25/07/2012 22:36	25/07/2012 22:53	0.011	0.001
3451-001982/Transfer PV631 to PV635_31/Transfer Out_25	25/07/2012 22:53	26/07/2012 1:39	0.115	0
3451-001982/Transfer PV631 to PV635_31/Restore_26	26/07/2012 1:39	26/07/2012 1:54	0.010	0

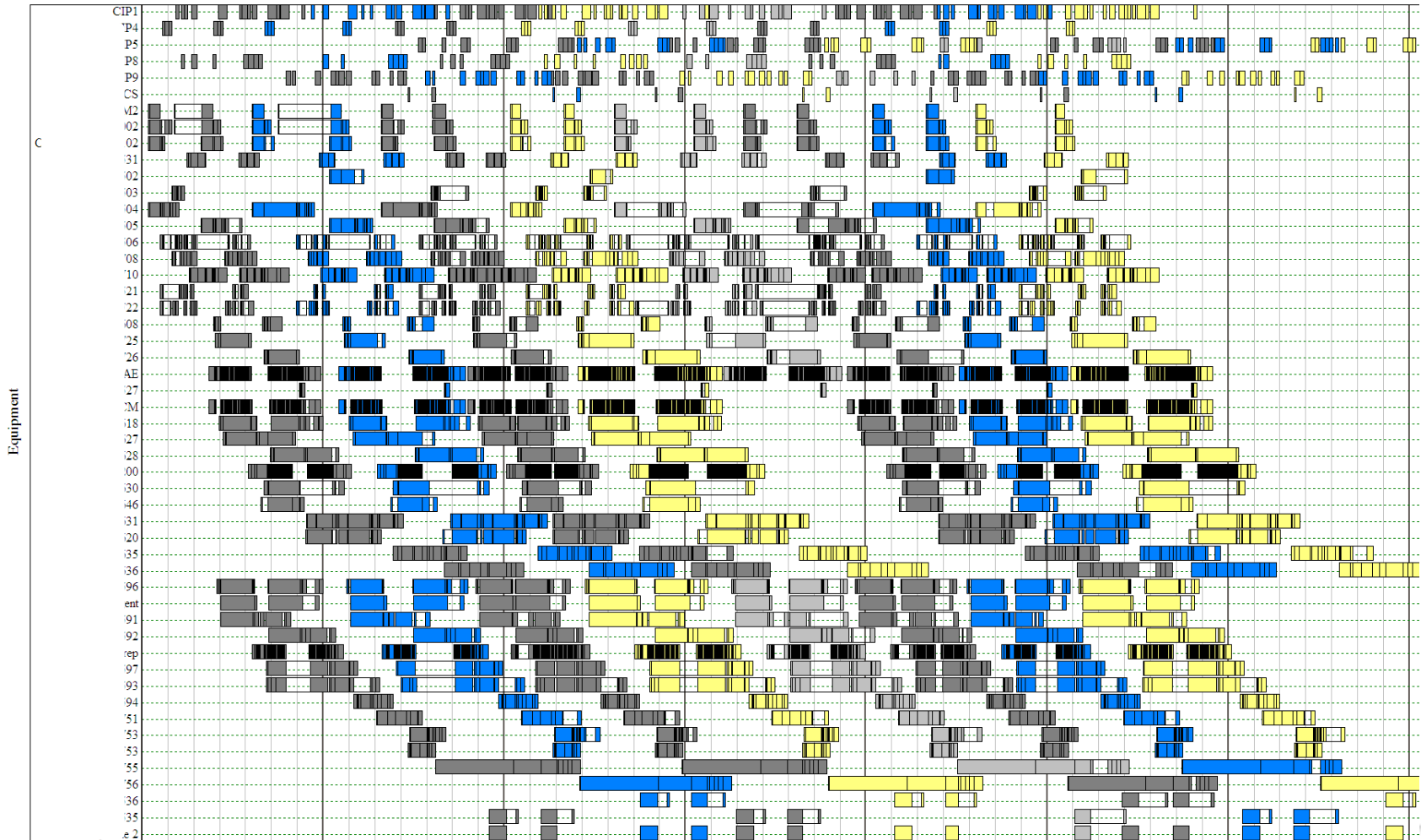
Data Interpretation: Secondary level Operations within a Multiple Batches



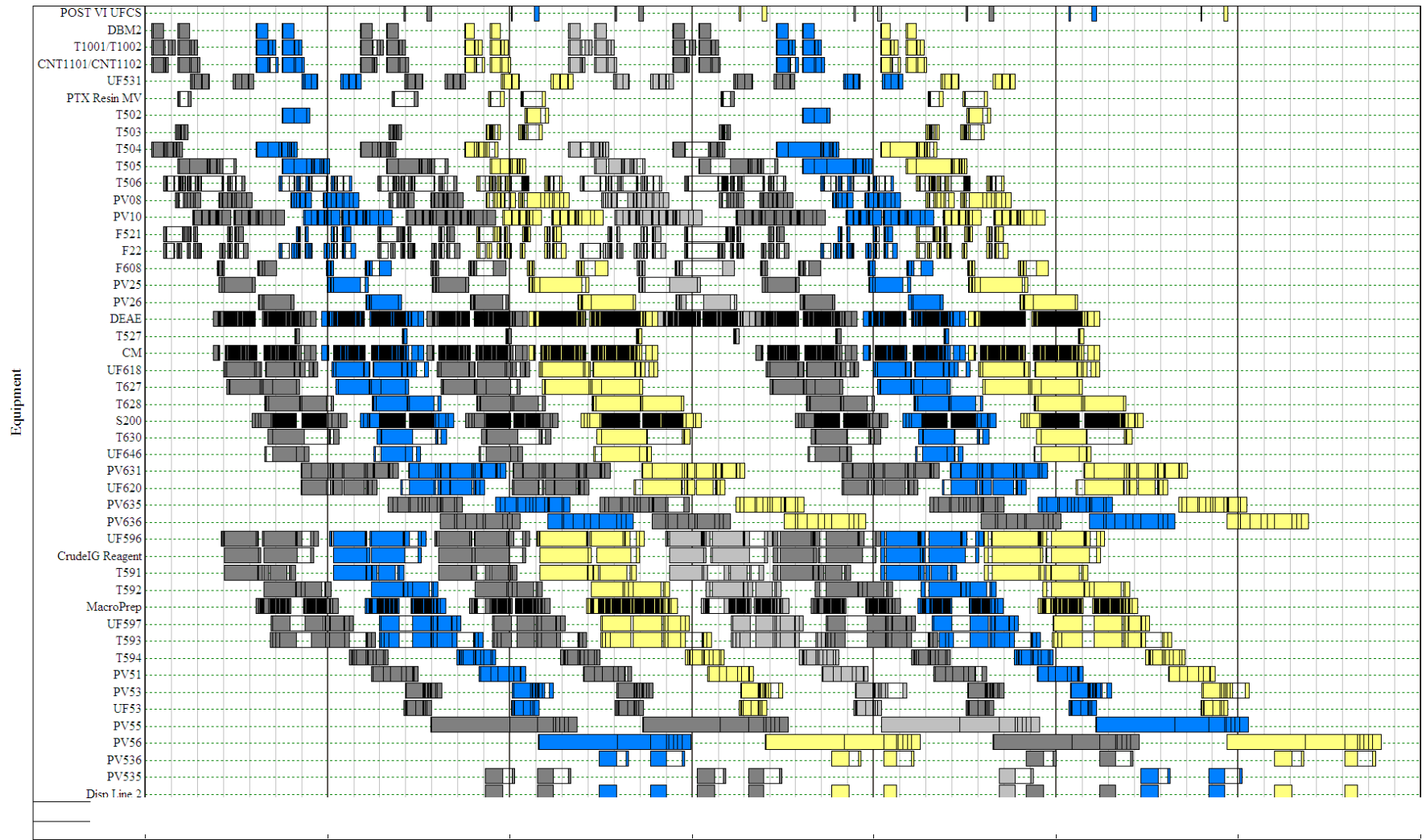
Computational Modelling



Plant Scheduling: Current



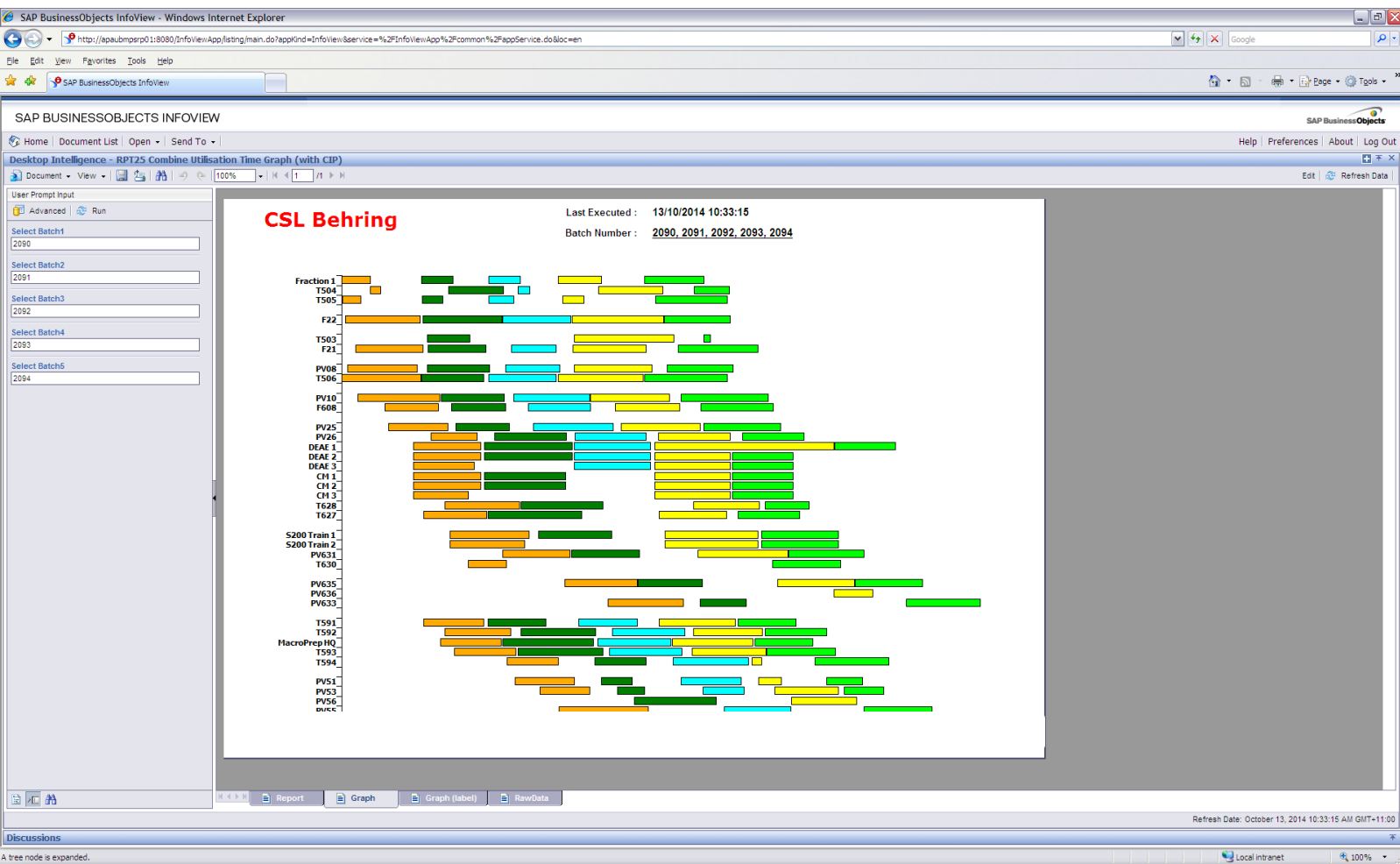
Plant Scheduling: Design Solution



Implementation

- Communicate a clear vision of changes required and accountabilities
 - Educate and empower staff to achieve
 - **Data is king**
 - Presenting new scheduling patterns and work plans quantitatively to managers, shift supervisors and operators
- Constant review
 - Daily meeting to track batch progress with management stakeholders
 - Review hits and misses
 - Follow and communicate operation by operation with shift supervisors in real time
 - Critical path decisions (eg CIP prioritisation)
 - Informed by the model (adjusted for actual conditions)
- Allow failures: **First Atttempt In Learning**
- Review and record operation level data (shift report)
- Staff learn new work day over time
- Use lessons learnt to prioritise continuous improvement projects to ensure a robust and lasting change

Effectiveness Review: Cycle time reporter



Shift reporter

http://172.17.163.92:8080/businessobjects/enterprise115/desktoplaunch/viewers/cdz_adv/viewCDZDo - Windows Internet Explorer

http://172.17.163.92:8080/businessobjects/enterprise115/desktoplaunch/viewers/cdz_adv/viewCDZDocument.jsp?id=101274&kind=FullClient&ventrystore=widtoken&ViewType=H&entSession=CE_ENTERPRISESESSION&lang=en&doctype=rep&useCustomPro

File Edit View Favorites Tools Help

InfoView

Document View Find Undo Redo Zoom 100% 3

Refresh Data

User Prompt Input

Advanced Run

1. Start Time
2014-02-16 06:00

2. End Time
2014-02-18 18:00

3. Report Type
Pre VI Albumin

CSL Behring

12 Hours Shift Report

Report Type : Pre VI Albumin

Start Date : 2014-02-16 06:00
End Date : 2014-02-18 18:00

Operation	Equipment	StartDate	EndDate	Duration	Exp. Time	Delta	Type	Comment	Initial
3453-B-002087/CM1_5/CM Wait Ready_82	106C03	16/02/2014 09:49:00	16/02/2014 09:49:00	0.00	0.00	0.00			
3453-B-002087/CM1_5/CM Wait Ready_82	106C03	16/02/2014 09:49:00	16/02/2014 09:49:00	0.00	0.00	0.00			
3453-B-002087/Crude IG Tk_7/Wait Ready_119	T592	16/02/2014 09:51:00	16/02/2014 15:07:00	5.27		-5.27			
3453-B-002087/DEAE2_55/DEAE Wait PS80_58	106C12	16/02/2014 09:58:00	16/02/2014 11:06:00	1.13	3.07	1.94			
3453-B-002087/CM2_19/CM Clean+Regen_104	106C13	16/02/2014 10:03:00	16/02/2014 16:30:00	6.44	6.99	0.55			
3453-B-002087/CM2_19/CM Store Values_99	106C13	16/02/2014 10:03:00	16/02/2014 10:03:00	0.00	0.00	0.00			
3453-B-002087/CM2_19/CM Store Values_99	106C13	16/02/2014 10:03:00	16/02/2014 10:03:00	0.00	0.00	0.00			
3453-B-002087/CM2_19/CM Wait Ready_96	106C13	16/02/2014 10:03:00	16/02/2014 10:03:00	0.00	0.00	0.00			
3453-B-002087/CM2_19/CM Wait Ready_96	106C13	16/02/2014 10:03:00	16/02/2014 10:03:00	0.00	0.00	0.00			
3452-002087/S200 Train 2_4/S200 Wait Ready_25	106C15	16/02/2014 10:49:00	16/02/2014 20:00:00	9.17	6.81	-2.36			
3453-B-002087/DEAE3_28/DEAE Wait PS80_76	106C52	16/02/2014 10:49:00	16/02/2014 16:22:00	5.55	3.69	-1.86			
3453-B-002087/CM3_123/CM Clean+Regen_116	106C53	16/02/2014 10:59:00	16/02/2014 16:30:00	5.52	6.51	0.99			
3453-B-002087/CM3_123/CM Store Values_111	106C53	16/02/2014 10:59:00	16/02/2014 10:59:00	0.00	0.00	0.00			
3453-B-002087/CM3_123/CM Store Values_111	106C53	16/02/2014 10:59:00	16/02/2014 10:59:00	0.00	0.00	0.00			
3453-B-002087/CM3_123/CM Wait Ready_108	106C53	16/02/2014 10:59:00	16/02/2014 10:59:00	0.00	0.00	0.00			
3453-B-002087/CM3_123/CM Wait Ready_108	106C53	16/02/2014 10:59:00	16/02/2014 10:59:00	0.00	0.00	0.00			
3453-B-002087/DEAE1_3/DEAE PS80 Wash_43	106C02	16/02/2014 11:06:00	16/02/2014 17:26:00	6.33	6.14	-0.19			

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Report

Done

Local intranet 100%

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Overview

- Data is king!
 - Shift away from anecdotal, from $n=10$ to big data
- Computer modelling allows visualisation of complex problems
- Informs the right amount and type of resources applied to the areas of highest return
- Implementation requires
 - Teamwork
 - Education
 - Tools that empower staff to make informed real time decisions

Thank you

- Questions?