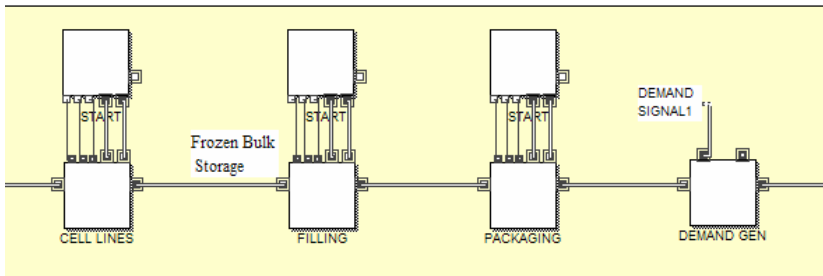


# Lean Manufacturing Model

## A New Use of Simulation Technology in the BioPharma Industry

Achieving sustainable manufacturing improvement for pharmaceutical and biological products has been difficult in the past due to the complexity of processing and the lack of tools. OpStat's lean model can be used to make improvements in existing operations, analyze capacity in new and existing installations, and plan for the future based on demand scenarios. The model is like a dynamic value stream map so analysts and engineers can see material moving through all work centers/equipment in the process.

### Material, Information & Financial Flows are Visible

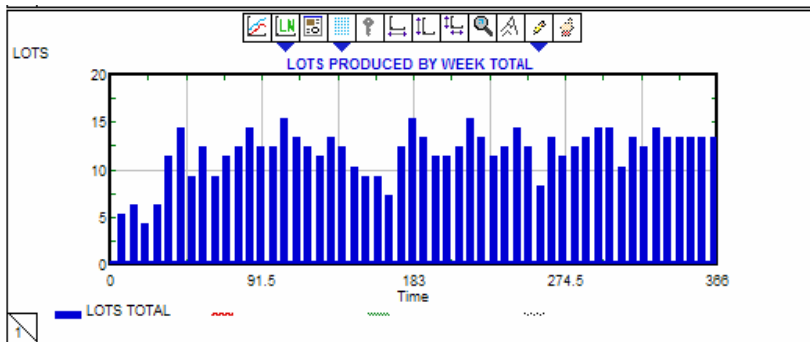


Statistics on throughput, cycle time, yield & service levels

#### END TO END PROCESSING OF LOTS

|  |      |
|--|------|
| MEAN CYCLE TIME (days): MTL AVAILABLE TO FULFILLMENT | 32.3 |
| STND DEV OF CYCLE TIME (days)                        | 11.3 |
| MAX CYCLE TIME (days)                                | 62   |
| MIN CYCLE TIME (days)                                | 8    |

Flexible graphical summaries on performance



#### THROUGHPUT

|                                 |        |
|---------------------------------|--------|
| LOTS PRODUCED                   | 599    |
| LOTS RELEASED                   | 599    |
| <b>DEMAND &amp; FULFILLMENT</b> |        |
| TOTAL LOTS ORDERED              | 579    |
| FULFILLED                       | 512    |
| BACKORDERED                     | 67     |
| <b>CUMULATIVE YIELD</b>         |        |
|                                 | 0.8983 |

Chemistry and protein based product forms – e.g., API, tablets, capsules, liquids, lyophilized vials & syringes, inhalers, transdermal patches - may be configured by your own employees after training and benchmarking to actual metrics.

### Validated Equipment & Rules

Current and proposed validations as well as all cleanout and sterilization rules by product are maintained in Excel spreadsheets for ease of use.

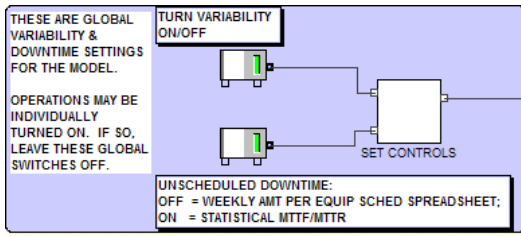
| Product Equip - Multiple Equipment Paths Allowed |              |              |               |                | Path 1       |                | All times in hours |              |                   |                 |  |
|--|--------------|--------------|---------------|----------------|--------------|----------------|--------------------|--------------|-------------------|-----------------|--|
| Product ID                                       | Product Name | Product Code | Operation Nbr | Operation Name | Nbr of Paths | 1 Equip Select | 2 Process Time     | 3 Recon Time | 4 Full Clean Time | 5 BB Clean Time |  |
| 50   | LIGHT 80     | 1021         | 7             | Pouching       | 3            | 1              | 15.25              | 0            | 6                 | 3               |  |
| 53   | LEIJU 80     | 1121         | 7             | Pouching       | 2            | 1              | 15.25              | 0            | 6                 | 3               |  |

ProcessingTimes / Process Times Variability / QualityReleaseTimes / Multiple Validated Paths / Mult Times Variability

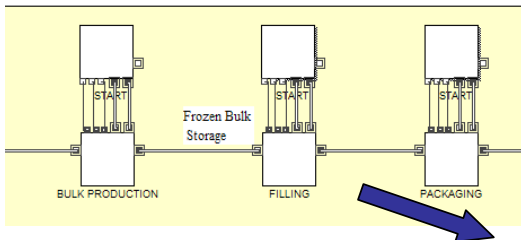


## Detailed Processing Through Equipment

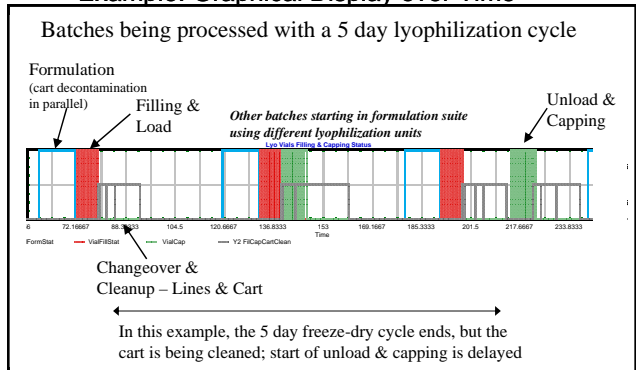
Models are configured hierarchically for supply chains and manufacturing streams down to work centers and individual sets of equipment as required.



Variability and planned/unplanned downtimes in all processes, as well as in demand, is incorporated in the *monte carlo simulation* employed.



### Example: Graphical Display over Time



## Resource Utilization: People & Equipment in both Manufacturing & Labs

The utilization of critical skilled personnel and of individual sets of equipment in each is tracked, as well as confidence intervals of results. Overall Equipment Effectiveness (OEE) is also calculated for each set of equipment.

### Manufacturing Equipment & Product

| LOTS Completed | LOTS WAITING |       |   | EQUIP UTILIZATION |          |         |
|----------------|--------------|-------|---|-------------------|----------|---------|
|                | NBR          | DAYS  |   | IN USE            | CLEANOUT | DOWN    |
| 121            | 4.576        | 3.471 | 1 | 0.43925           | 0.31153  | 0.17267 |
| 76             | 3.886        | 4.661 | 2 | 0.41077           | 0.14419  | 0.09346 |
| 66             | 4.236        | 6.009 | 3 | 0.58745           | 0.12283  | 0.02136 |

### Lab Equipment & People

| Block           | Utilization    |
|-----------------|----------------|
| E1 ASSAY        | 0.815±0.08933  |
| E2 SPECTROSCOPE | 0.9041±0.02643 |
| E3 CENTRIFUGE   | 0.9207±0.02429 |
| E4 VORTEX MIXER | 0.7308±0.1396  |
| LAB SKILL1      | 0.4645±0.1382  |
| LAB SKILL2      | 0.5541±0.04996 |
| LAB SKILL3      | 0.2598±0.01081 |
| LAB SKILL4      | 0.1864±0.0747  |

OpStat Group Inc. has a proven track record with pharmaceutical and biological companies. Founded in 1986, our staff is expert in operational improvement, and uses simulation tools for analysis of operations. We have adapted our simulation models to be licensed to companies focused on lean operations.



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