
Introduction to OpStat

LEAN SIMULATION MODELS

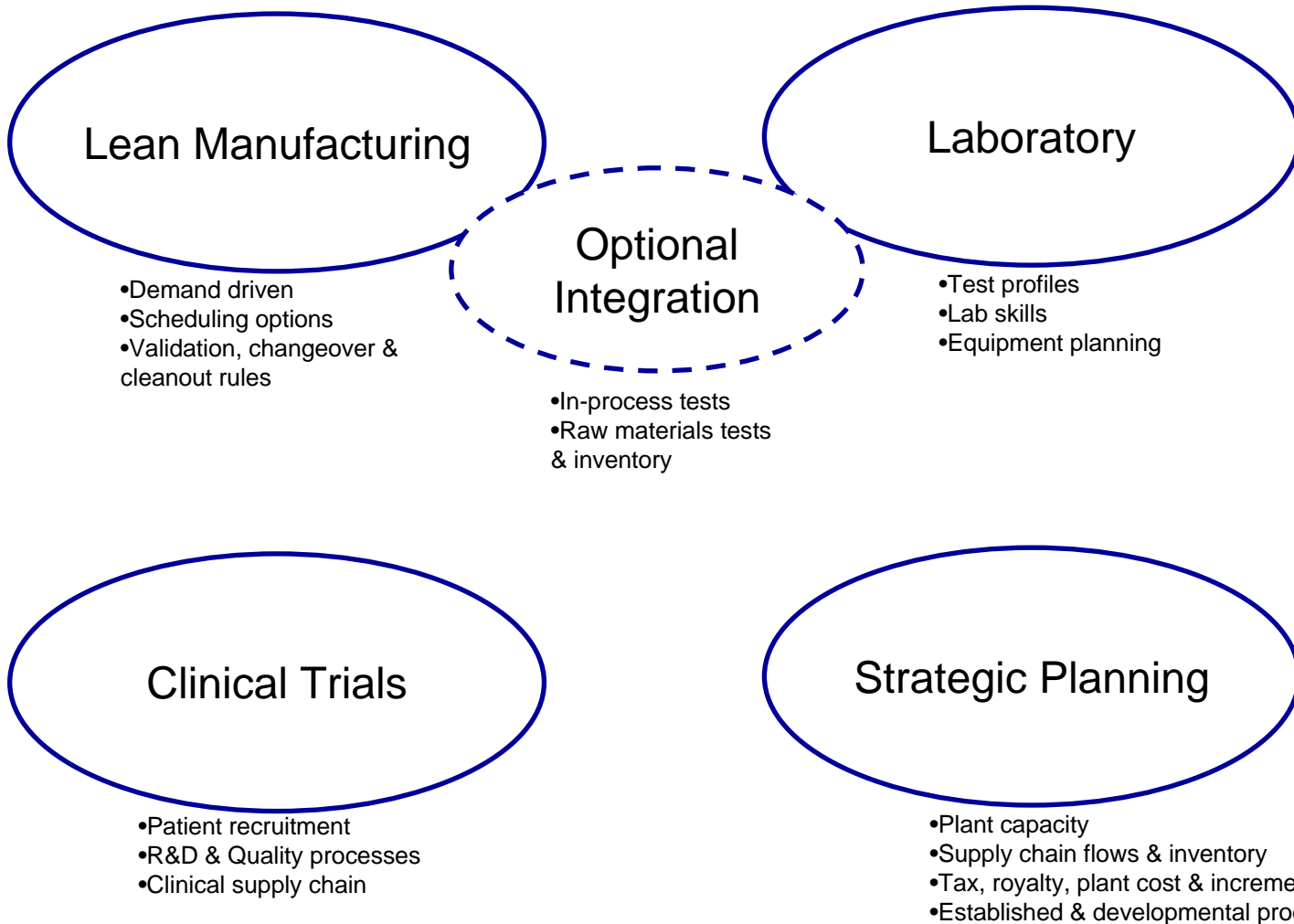
Contents

1. Overview of OpStat Models
2. Highlights of the Lean Manufacturing Model
3. Background on OpStat

Enclosures

- Documentation & Setup Guides for each Model

1. OpStat Models



1. OpStat's Models Are Essential Tools for Lean Programs To Test Alternative Solutions Before Implementing Them

- To analyze *plant capacity* – to trade-off volume & mix (variety) of products
- To analyze *service levels* – to balance demand and supply
 - Make-to-Stock inventory, typical in commercial environments
 - Make-to-Order lead times, typical during clinical trials and pilot plant operations

There can be a multiple sites across a supply chain to be analyzed - from chemical to finishing and packaging operations.

Simulation models take variability (in processing, cleanouts and downtime) into account which is not possible to do with an equation.

2. Highlights of Lean Model

Spreadsheets



Arrays



Run parameters



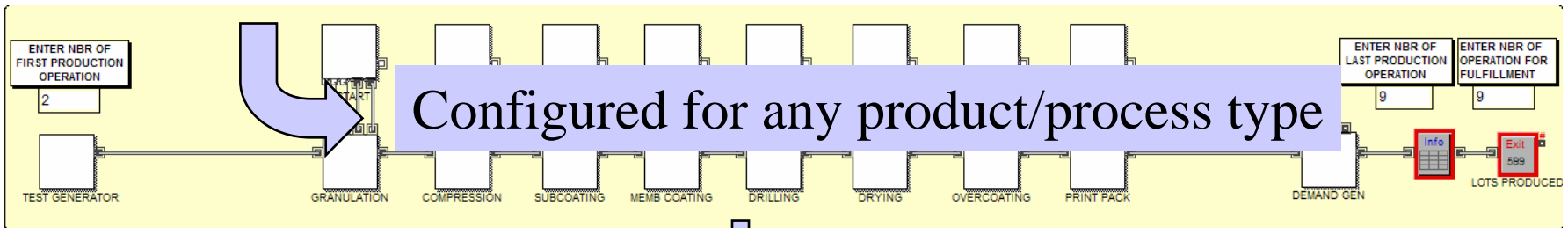
Start rules



Provide timing, sequence, campaign lengths, etc.

Provide process times, valid equipment, etc.

Switches to activate functions



Summary Reports
in Spreadsheets

Graphs

Lot detail in
Reporting
Spreadsheet

2. Lean Model Folder – spreadsheet capable

Name ▲	Type	Packed Size	Size
Lean Model 70.MOX	Extend Model	6,067 KB	64,216 KB
Master Equipment Availability.xls	Microsoft Excel ...	9 KB	56 KB
Master Test Batch Input.xls	Microsoft Excel ...	11 KB	52 KB
MasterDemandForecast.xls	Microsoft Excel ...	13 KB	79 KB
MasterMatrix.xls	Microsoft Excel ...	1,409 KB	8,723 KB
Operations-Equip for Notebook.xls	Microsoft Excel ...	4 KB	19 KB
Report OEE.xls	Microsoft Excel ...	18 KB	250 KB
Report Products by Op Month.xls	Microsoft Excel ...	321 KB	1,789 KB
Report Products by Operation.xls	Microsoft Excel ...	28 KB	192 KB
Report Rhythm Starts.xls	Microsoft Excel ...	1,237 KB	6,986 KB
Reporting Inventory.xls	Microsoft Excel ...	25 KB	187 KB
Reporting Matrix.xls	Microsoft Excel ...	1,272 KB	6,993 KB
Setup Checklist.xls	Microsoft Excel ...	6 KB	25 KB

Master workbooks are inputs automatically read in at the start of a run

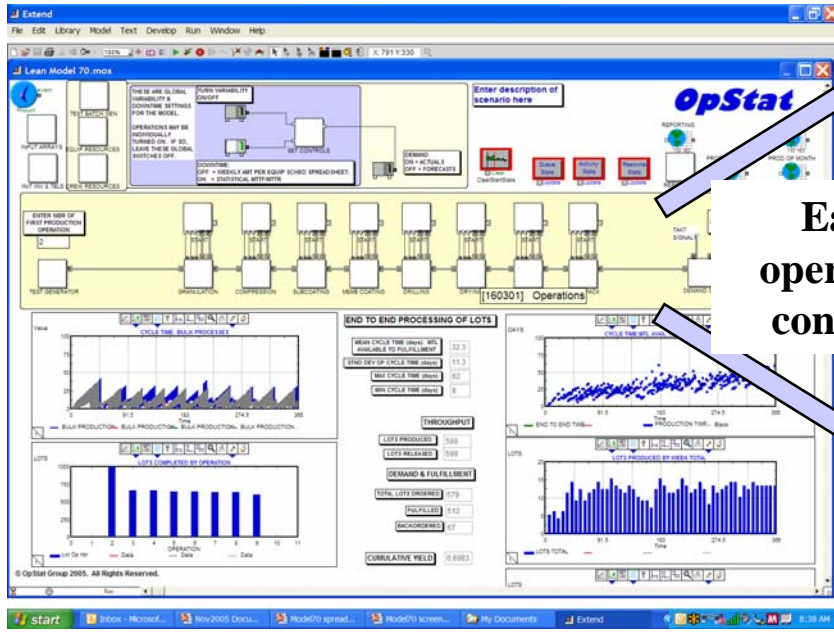
Operations-Equip for Notebook is a reference information-only spreadsheet

Report workbooks are outputs updated automatically at the end of a run

Setup Checklist is a reference spreadsheet

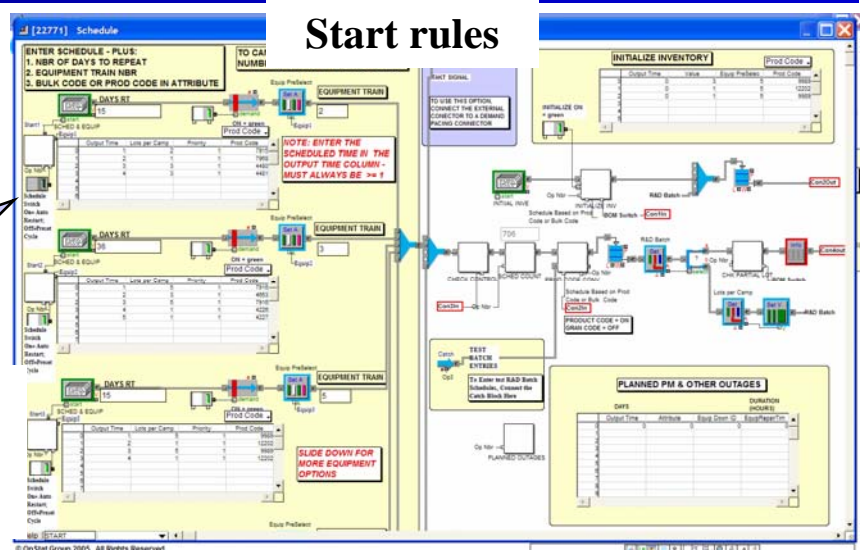
2. Lean Model Overview – Panel Hierarchy

Top level of model

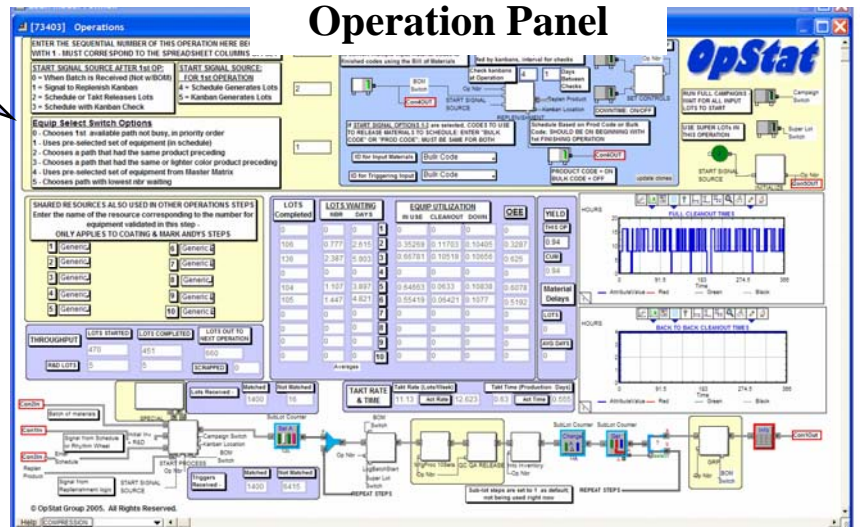


Each operation contains

Start rules



Operation Panel



These panels and the spreadsheets contain inputs & outputs

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2. Parameters & Results for each operation

The screenshot displays the OpStat software interface for operation [73403]. The interface is divided into several sections:

- Parameters Section:** Includes fields for 'START SIGNAL SOURCE AFTER 1st OP' (0-3), 'START SIGNAL SOURCE FOR 1st OPERATION' (0-5), and 'Equip Select Switch Options' (0-5). It also features a 'BOM Switch' and 'Check kanbans at Operation' section.
- LOTS WAITING Table:**

LOTS Completed	NBR	DAYS	1	2	3	4	5	6	7	8	9	10
0	0	0	1	0	0	0	0	0	0	0	0	0
106	0.777	2.615	2	0.35269	0.11703	0.10405	0.3287	0	0	0	0	0
136	2.387	5.903	3	0.66701	0.10519	0.10656	0.625	0	0	0	0	0
0	0	0	4	0	0	0	0	0	0	0	0	0
104	1.107	3.897	5	0.64663	0.0633	0.10838	0.6078	0	0	0	0	0
105	1.447	4.821	6	0.55419	0.06421	0.1077	0.5192	0	0	0	0	0
0	0	0	7	0	0	0	0	0	0	0	0	0
0	0	0	8	0	0	0	0	0	0	0	0	0
0	0	0	9	0	0	0	0	0	0	0	0	0
0	0	0	10	0	0	0	0	0	0	0	0	0
- YIELD Table:**

THIS OP	CUM
0.94	0.94
0.94	0.94
- Material Delays Table:**

LOTS	AVG DAYS
0	0
- Throughput Table:**

THROUGHPUT	LOTS STARTED	LOTS COMPLETED	LOTS OUT TO NEXT OPERATION
R&D LOTS	470	451	660
SCRAPPED	5	5	0
- TAKT RATE & TIME Table:**

TAKT RATE (Lots/Week)	Act Rate	Takt Time (Production Days)	Act Time
11.13	12.623	0.63	11.255
- Charts:** Two bar charts showing 'FULL CLEANOUT TIMES' and 'BACK TO BACK CLEANOUT TIMES' over a period of 360 hours. The first chart shows multiple peaks, while the second shows a single large peak.
- Flowchart:** A detailed process flowchart at the bottom showing the sequence of operations, including 'Batch of materials', 'Signal from Schedule or Rhythm Wheel', 'Campaign Switch', 'SubLot Counter', 'BOM Switch', 'MfgProc 10Sets', 'QC QA RELEASE', 'Into Inventory', 'Change', 'Select', 'GRP', and 'BOM Switch'. It also includes 'Lots Received' (1400) and 'Not Matched' (16) counts.

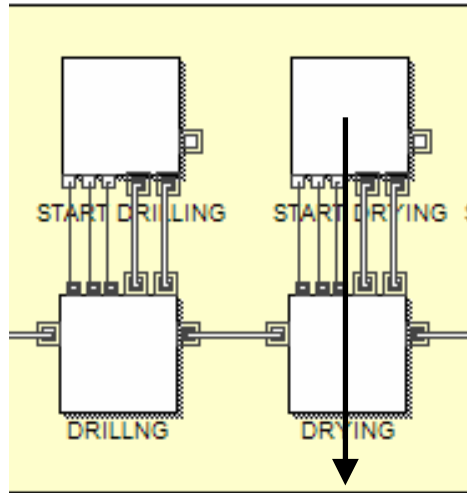
Within each operation, Takt Time & OEE is calculated for each set of equipment

Within each operation, there is also logic for processing each lot through quality lab or release processes after the manufacturing process completes

2. Scheduling & Replenishment Design

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Materials flow
from operation

Trigger starts
processing

The Start Signal determines how the trigger is created

Product/equipment validation matrix drives the choice of path used with the scheduling rules.

Rhythm Wheels, CONWIP, Kanban Options:

- Schedules (including rhythm wheels) & campaign lengths can be evaluated
- Kanban triggers & sizes integrated
- Takt rates from actual demand.

[159358] Operations	
ENTER THE SEQUENTIAL NUMBER OF THIS OPERATION HERE BEGINNING WITH 1 - MUST CORRESPOND TO THE SPREADSHEET COLUMNS OFF SET	<input type="text" value="4"/>
START SIGNAL SOURCE AFTER 1st OP: 0 = When Batch is Received (Not w/BOM) 1 = Signal to Replenish Kanban 2 = Schedule or Takt Releases Lots 3 = Schedule with Kanban Check	START SIGNAL SOURCE FOR 1st OPERATION 4 = Schedule Generates Lots 5 = Kanban Generates Lots
Equip Select Switch Options 0 - Chooses 1st available path not busy, in priority order 1 - Uses pre-selected set of equipment (in schedule) 2 - Chooses a path that had the same product preceding 3 - Chooses a path that had the same or lighter color product preceding 4 - Uses pre-selected set of equipment from Master Matrix 5 - Chooses path with lowest nbr waiting	<input type="text" value="5"/>

2. Details of Cleanouts/Changeovers for all Production & Shared Equipment

Cleaning Rules

Include types of cleans required:

- Between lots or campaigns
- Between product groups
- Between colors (lighter to darker, darker to lighter)
- Between strengths
- After a number of lots
- After a time period
- Shared tanks, bins, carts also included

Variability

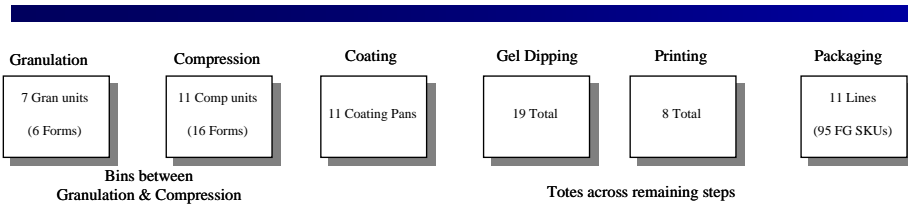
Uses probabilistic processing for:

- Processing times
- Full & Back-to-Back Cleanouts
- Quality lab & Release times
- Late materials
- Scrap rates
- Absentee rates in labor crews
- Hold & Equilibration times

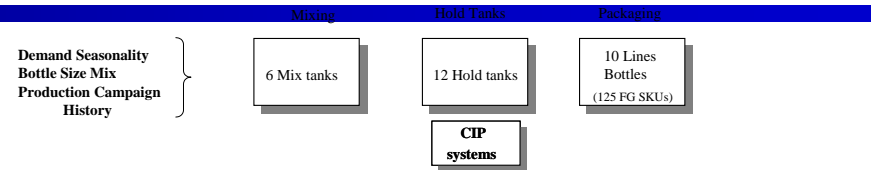
If there are sufficient data, STAT::FIT® distribution-fitting software is used to create statistical distributions. Alternatively, minimum, maximum and most likely values may be used to populate triangular distributions.

2. All Types of BioPharma Operations

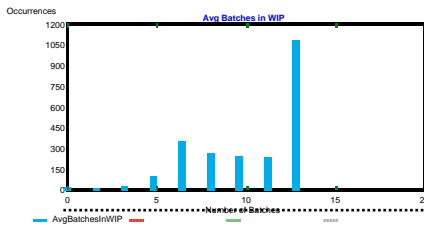
Solids Products



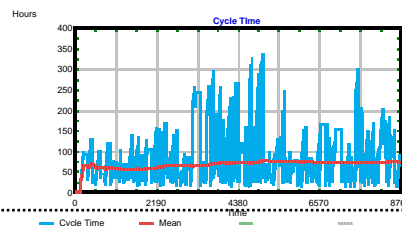
Liquids Products



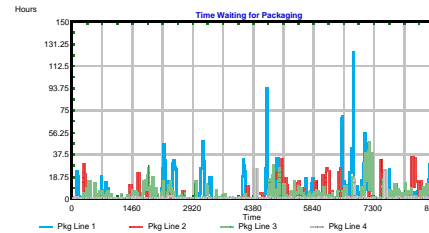
WIP measured across entire process



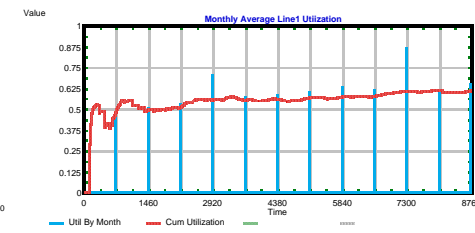
Cycle time of every batch recorded



Wait times recorded for all batches

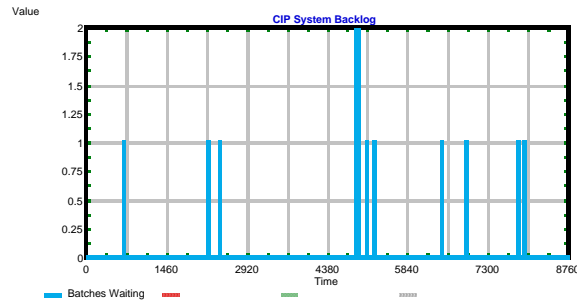


Utilizations of all resources computed vs. scheduled time

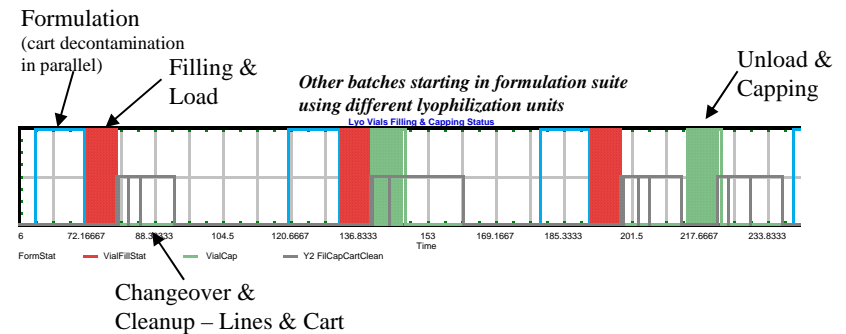


Shared Resources Utilization & Backlogs

Resource	Type	Number	Utilization (95% confidence int)
CleaningUnits	Resource Pool	2	0.2431 ± 0.04727
TotalCrewsAvail	Labor	5	0.4347 ± 0.02713



Detailed Analysis of Manufacturing Lines e.g., Sterile Products with Lyophilization Units



In this example, the 5 day freeze-dry cycle ends, but the cart is being cleaned; start of unload & capping is delayed

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2. QC / QA Release Included As a Process

Notebook - ManufacturingTablets v30.mox

QC TEST / RELEASE TIMES

Manufacturing

PSD QC RELEASE TARGET TIME (days) DRUG PRODUCT:

ADDITIONAL % TIME FOR 2nd & succeeding batches:

PSD QC RELEASE TARGET TIME (days) CHEMISTRY BATCHES:

ADDITIONAL % TIME FOR 2nd & succeeding batches:

Packaging

CIP QC RELEASE TARGET TIME (days) BLISTERS & KITS:

ADDITIONAL % TIME FOR 2nd & succeeding batches:

CIP QC RELEASE TARGET TIME (days) DRUG PRODUCT:

ADDITIONAL % TIME FOR 2nd & succeeding batches:

TESTING STAFF

TECHNICIANS:

SUPERVISORY:

VARIABILITY FOR UNIT PRODUCTS

VARIABILITY: NO = 0; YES = 1:

VARIABILITY FOR PKG PRODUCTS

VARIABILITY: NO = 0; YES = 1:

Distribution Plotter: Percent Members vs Member Value. X-axis: 6.658847, 9.202102, 11.74556, 14.28901, 16.83247. Y-axis: 0 to 8. Legend: % Members.

Distribution Plotter: Percent Members vs Member Value. X-axis: 4.281047, 5.329109, 6.377171, 7.425233, 8.473298. Y-axis: 0 to 7.5. Legend: % Members.

QC TECHNICIANS AVAILABLE: Value vs Time. X-axis: 0, 133.3333, 266.6667, 400, 533.3333, 666.6667, 800. Y-axis: 0 to 12. Legend: Requests (red), NumberAvailable (blue), Green (dotted), Black (dotted).

Resource utilization & impacts in QC across multiple manufacturing centers can be tracked

3. Some OpStat Background

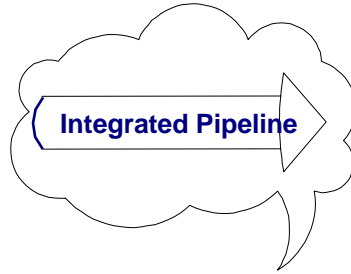
- Operations improvement consulting since 1987
 - Strategic to operational level
 - Physical and IT expertise
 - Improvement methodology
 - Simulation and optimization modeling
 - www.OpStat.com has some other examples & information
- Founded by Jim Curry
 - Led large IT and operational process development organizations, including 10 years in wine and spirits industry (Seagram)
 - Educational background in Operations Research
 - Teaches simulation as a tool in lean manufacturing and supply chain design in graduate program at Fairfield University

3. Some Client Examples

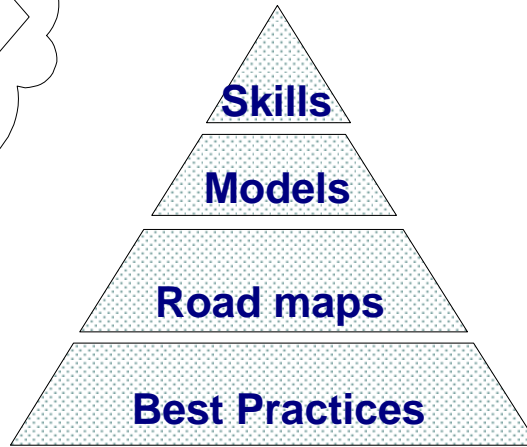
- Supply Chain Improvement & Simulation Modeling
 - Rohm and Haas
 - Arco Chemical
 - Honeywell
 - 3Com
 - Blue Circle Cement
 - J&J
 - Sanofi-Aventis
 - Aventis-Behring
 - Parke-Davis
 - Pfizer
- IT Planning / Architecture
 - Hewlett-Packard
 - UPS
 - Gillette
 - Nestle
- Logistics
 - Arkema
 - Minerals Technologies

3. OpStat's Value Added

VISION



**TOOLS &
METHODOLOGIES**



PRODUCT *Lean Simulation Models

IMPLEMENTATION

