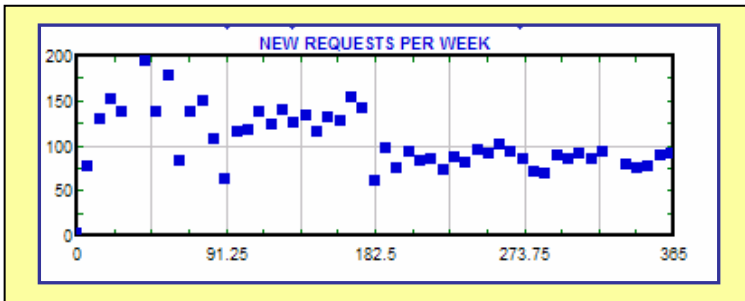


Lean Laboratory Model

Using Simulation Technology to Improve Quality Processes

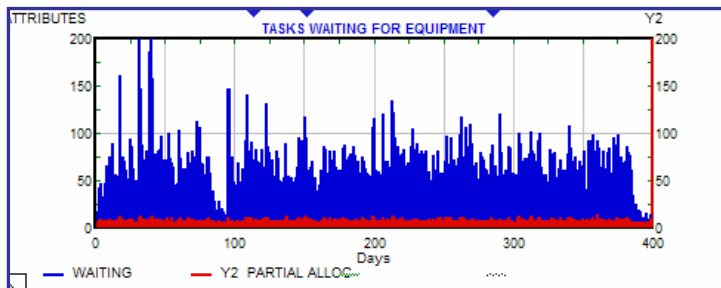
The advances in simulation technology have made it possible to incorporate the complexity of laboratory operations into a configurable model for managers and supervisors. It is now possible to analyze capacity constraints, both people skills and equipment, for all work centers/equipment in the process. The thousands of asynchronous events occurring at a given time may be captured, analyzed and scheduled.

Requests May Be Entered from LIMS History or as Forecasts



The model handles an unlimited volume of requests, with varied types of attribute tests, seasonal & daily patterns for raw materials, in-process tests, lot clearances, stabilities and ad hoc projects.

Statistics on service levels, throughput, test time & variability may be compared to daily or hourly service commitments, in flexible summary formats.



% of Requests Meeting Target	TEST TIMES (days)	
	Mean 7.134	Max 28.1
0.704	StDev 6.979	Min 0.04
TEST REQUESTS SUBMITTED	VALID REQUESTS	REQUESTS COMPLETED
6109	5653	5396
TOTAL INDIVIDUAL TESTS SUBMITTED	IND TESTS COMPLETED	TOTAL TASKS COMPLETED
50624	48114	178946

Detailed Root Cause Information

Parameters related to each request, attribute test, task and resources are available for analysis.

EACH REQUEST COMPLETED							
	Arrival(days)	Priority	Identifier	ID Item Type	ModelTestType	Mod Cycle Tim	
66	9.604168887	1	50013	18	11	5.74548021297	
67	9.6875	14	59	18	11	5.44781038195	
68	10	10	163	19	14	0.59420671297	
69	10	21	135	9	13	2.42343827548	
70	10	21	136	9	13	2.42088159722	
71	10.041688887	1	50068	14	17	0.44168888867	

The scope of the model is flexible enough to incorporate controlled substance labs, GMP release treated work-centers, and links to manufacturing streams using raw material bills of material and in-process flow tests.



Detailed Test Profiles

Each product/request may be set up hierarchically for attribute tests, with tasks, equipment and skills necessary. Within the test profiles, parallel and sequential tasks are specified, as well as probabilities of occurrence, rules for batching, and regularly recurring test setups.

Nbr of tasks	Test Sequence	Test ID	Name	Prer eq	% of Time	Task Code	Task Name	Batch Max Lots	Batch Freq	Min	Max	Most Likely	Skill Code	Nbr of People	Equip Codes	
9	1000	21	Assay/Impurities		0.16	1	Setup			0.5	1	0.75	12	1		
						2	Sample Prep			1	3	2	12	1		
						3	Stirring	4		4	4	4			92	
						4	Setup Analysis	4		6	6	6	12	1	32	35
						5	Analysis			2	2	2			32	35
						6	Initial Rept	4	1	1	2	1.5	12	1		
						7	Reporting			0.5	1	0.75	12	1		
						8	Initial Rev	4	1	1	2	1.5	12	1		
						9	2nd Review			0.5	1	0.75	12	1		
5	1000	26	Water Content		0.2	1	Setup	12	3	0.16	0.16	0.16	12	1	6 100	
						2	Sample Prep			0.16	0.16	0.16	12	1	6 100	
						3	Analysis			0.16	0.16	0.16	12	1	6 100	
						4	Reporting			0.16	0.16	0.16	12	1		
						5	2nd Review			0.16	0.16	0.16	12	1		

As each of the tests arrive, the model accesses individual sets of equipment, critical skilled personnel and shift schedules to track utilization, backlogs & service targets.

Equipment Inventory

Equip Code	Equipment Name	Number Available
103	RM Low Use	15
104	RM Balance	2
105	Microbalance	1
106	Deadbox balance	1
107	Vacuum oven	2
108	105 Oven	20
109	Muffle furnace	2
110	Desiccator	40
111	Hot plates	15
112	thermometer	20

People/Skill Levels/Shifts

People Schedules		Probability of people Shortage (If Top Level Variability Switch is Turned On)													
Days per Week	7	Hours per Shift	10												
Shifts per Day	2	<table border="1"> <thead> <tr> <th>Value</th> <th>Probability</th> </tr> </thead> <tbody> <tr><td>0</td><td>0</td></tr> <tr><td>1</td><td>1</td></tr> <tr><td>2</td><td></td></tr> <tr><td>3</td><td></td></tr> <tr><td>4</td><td></td></tr> </tbody> </table>		Value	Probability	0	0	1	1	2		3		4	
Value	Probability														
0	0														
1	1														
2															
3															
4															
		Scientists	Shift 1												
		Shift 2													
Chromotography Instrumentation		4	2												
Skills Master / EquipmentMaster		4	3												

Test time variability as well and planned/unplanned equipment downtimes, repair and requalification times are used in *Monte Carlo simulation* runs to develop confidence intervals for results.

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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