



Carolina Parenterals
Center of Excellence Overview

Pfizer

Erick J. García
Senior Supervisor
QC Chemistry Laboratories

This slide features a photograph of the Carolina Parenterals facility, a modern building with large glass windows and a fountain in the foreground. The Pfizer logo is in the bottom left, and a text box in the bottom right identifies Erick J. García as the Senior Supervisor of QC Chemistry Laboratories.



Pfizer

Carolina

Vision

We are recognized by our shareholders as the Center of Excellence for innovative manufacture of parenteral products

Mission

Pfizer Carolina manufactures life-saving parenteral products. We will meet our patients needs by enabling

- A safe workplace
- First Time Quality
- Empowered, High Performance Teams
- Competitive Advantages

This slide features a background image of the Earth from space, with a map of North America overlaid. The state of North Carolina is highlighted in green and labeled 'Carolina' with a red star. The Pfizer logo is in the top left. The Vision and Mission statements are positioned on the left and right sides of the slide, respectively.



Chemistry Laboratory Mission and Services

Mission:

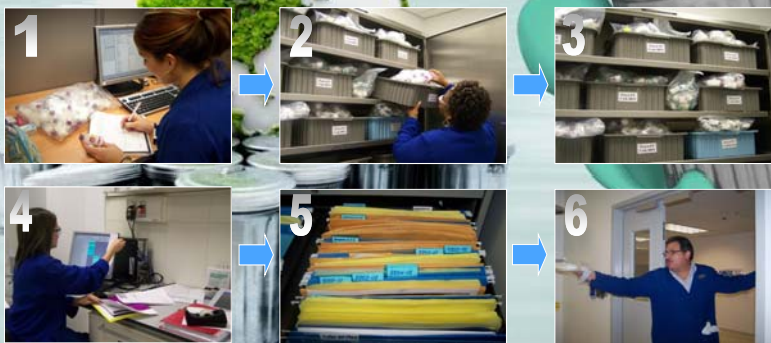
- ▣ Provide quality service, knowledge, support, and experience in an efficiently fashion to our internal and external customers assuring scientific, regulatory and professional excellence.

Services and Scope:

- ▣ QC release testing of active pharmaceutical Ingredients (API's), raw materials, excipients, in process samples, components and finished products.
- ▣ Chemical testing of complaint samples, technology projects and validations.
- ▣ Compendial chemical testing of water monitoring system.
- ▣ Provide technical and testing support to the network as a lead site.
- ▣ Management of the stability program; testing and reports.
- ▣ Management of laboratories equipment support (Calibrations and PM,s)

Baseline and Current State Analysis

- ❑ Only Cycle time as a key lab metric
- ❑ Testing samples as soon as they come to the lab
- ❑ Analyst levels determined by individual skills
- ❑ Unbalance tasks assigned based on skills or methods
- ❑ Individual performance



Lean & Green Laboratories

Smart, agile, innovative & environment friendly

Chemistry Laboratories
Pfizer - Carolina



Project Objectives

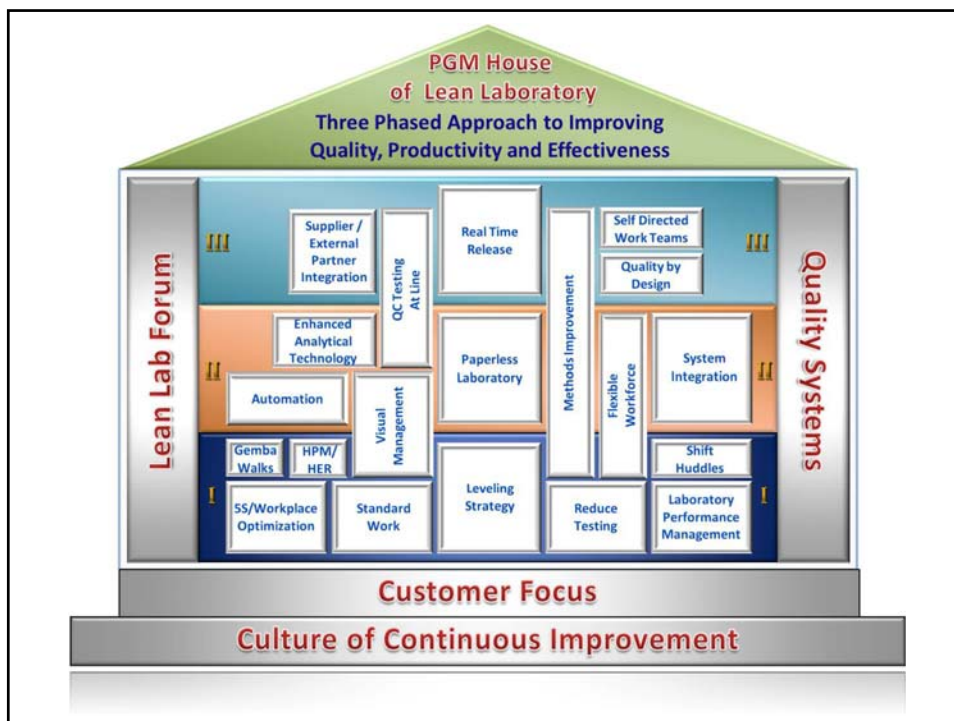
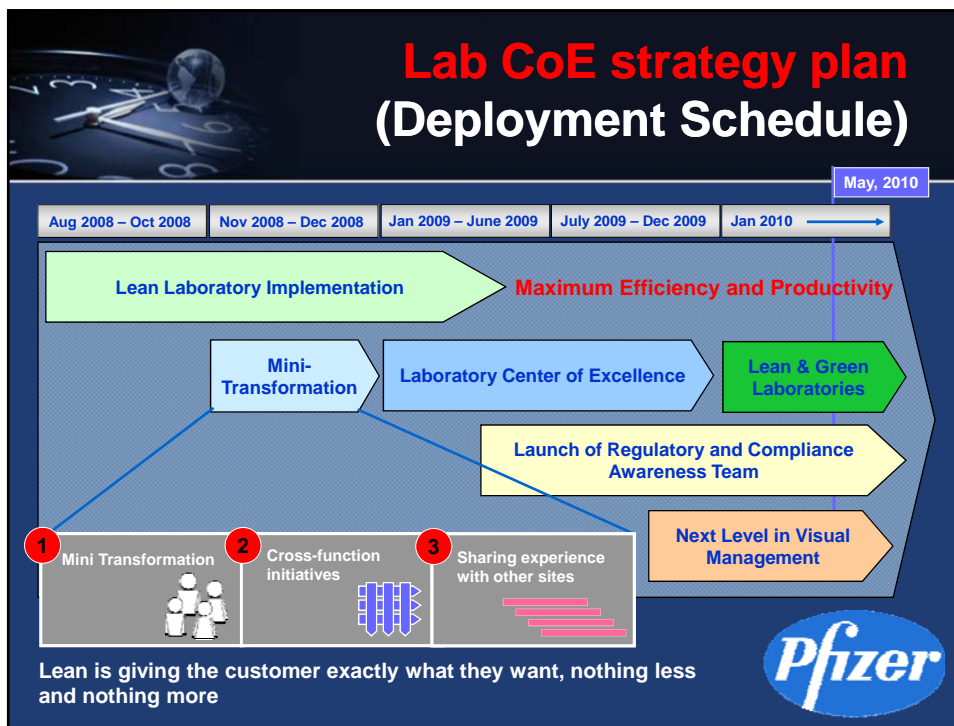
Transform the Zosyn Chemistry Laboratories operating system, management infrastructure, and mindsets and behaviors to make a significant improvement in efficiency while maintaining or improving cycle times, schedule adherence and quality.

The need for change

- Improve Laboratory flexibility to support Site and Network activities (as lead site)
- Maximize utilization of Laboratory resources (People, Equipments and Space)
- Improve and sustain testing Cycle time
- Reduce Laboratory related Investigations
- Promote a cultural change
- Control and reduce waste generation
- Control and reduce testing cost

Deployment Schedule






Laboratory Center of Excellence






Electronic Visual Management Board

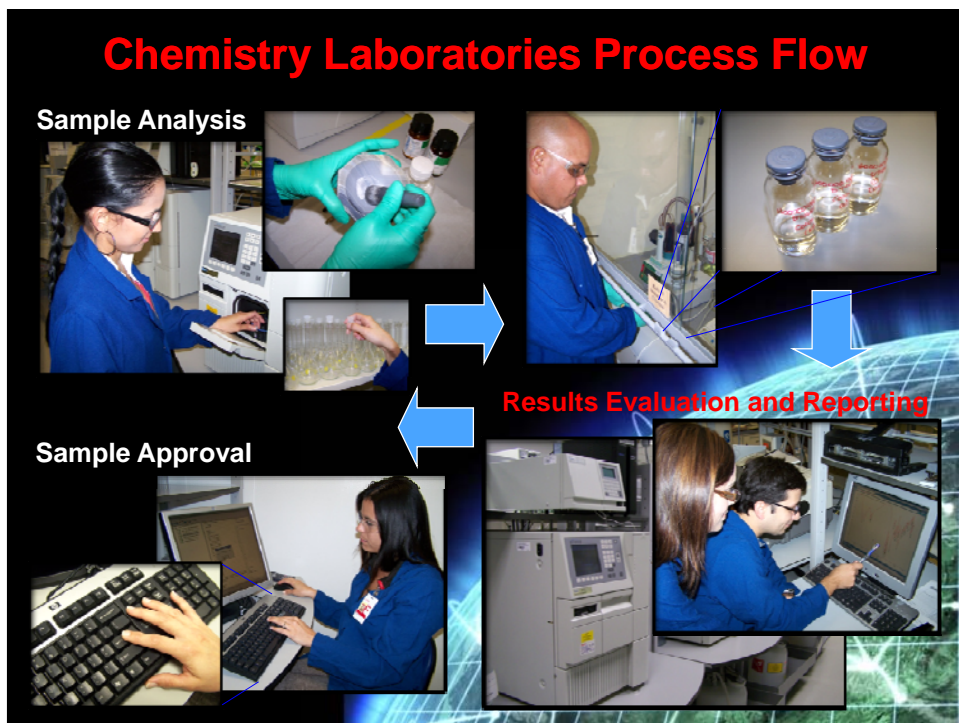
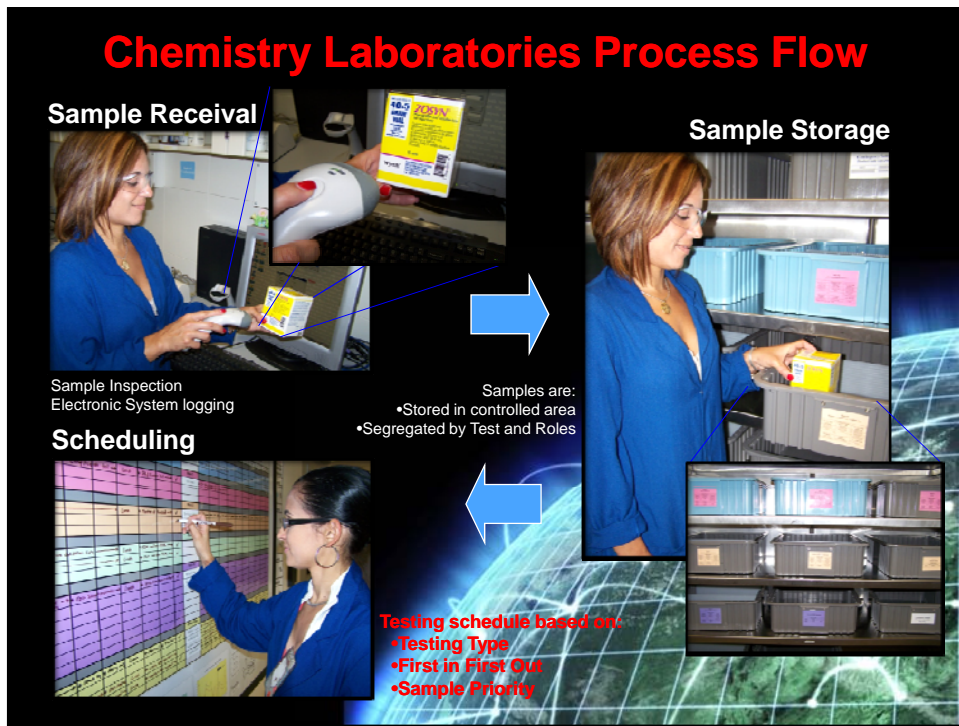
Chemistry Laboratories
Pfizer - Carolina

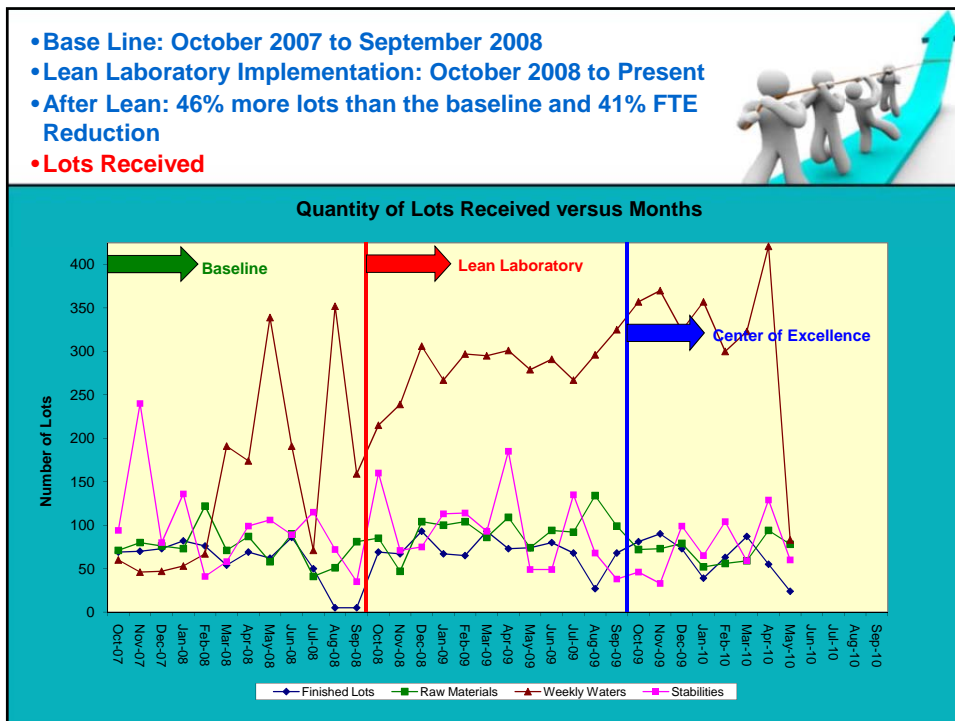


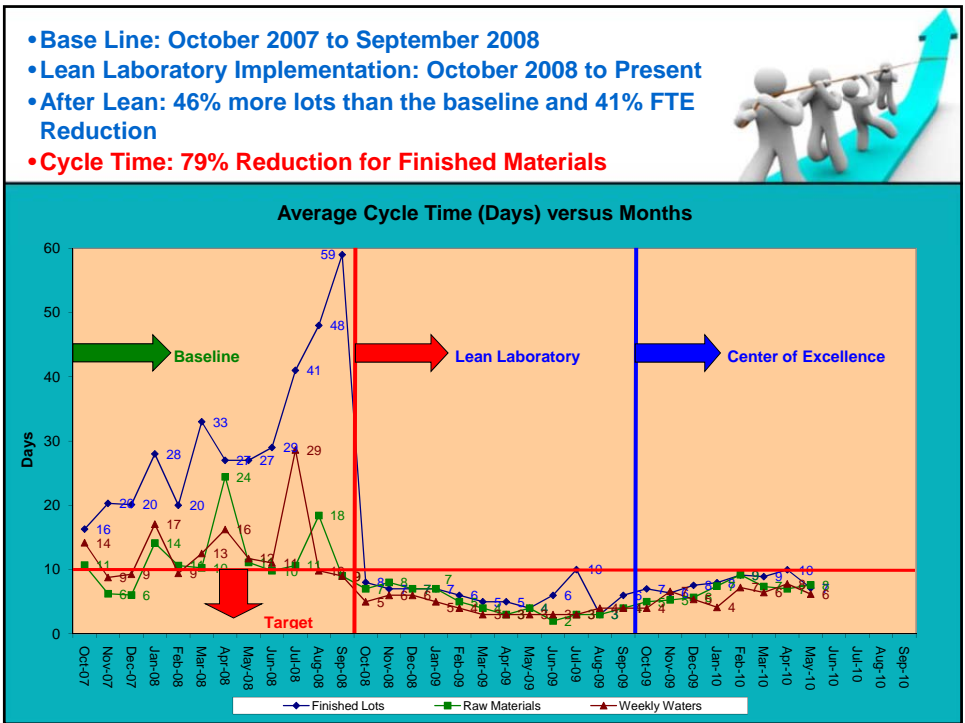
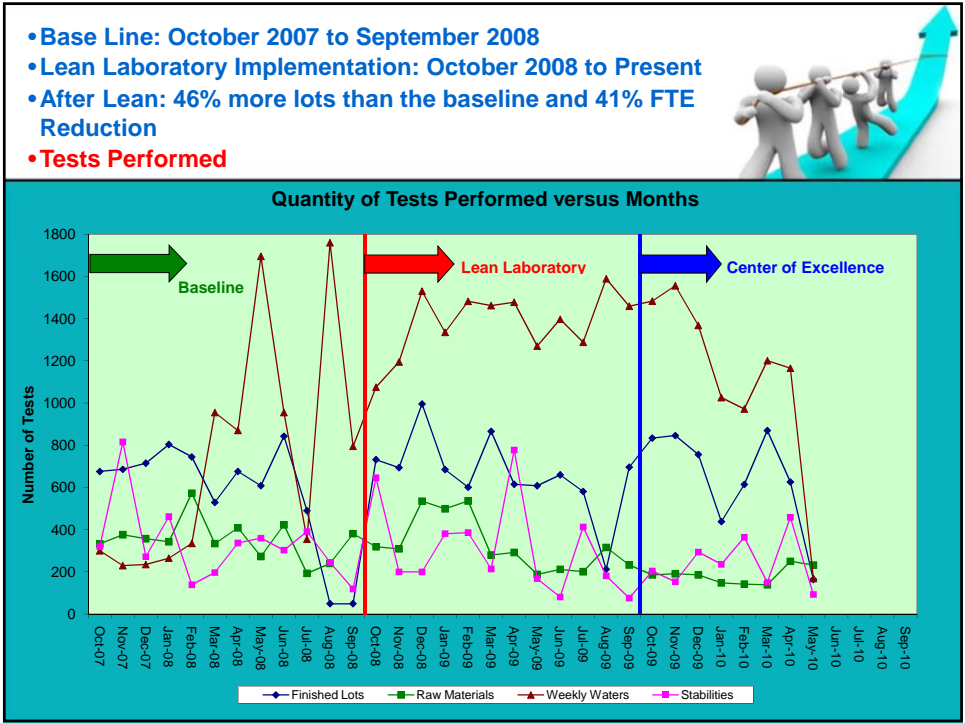
Next Level in Visual Management

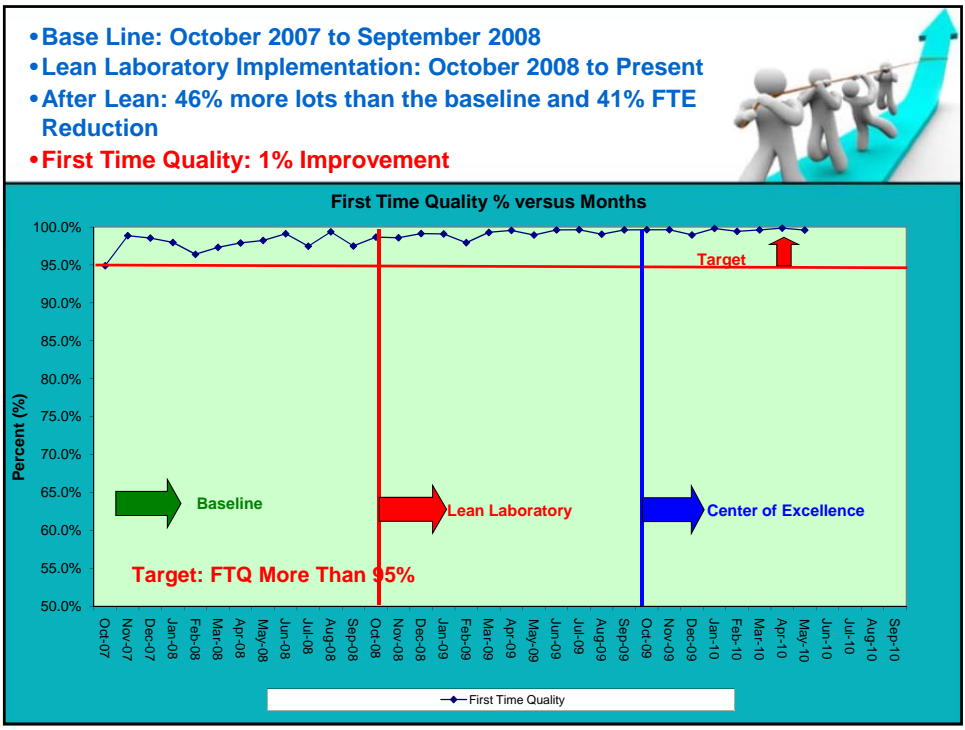
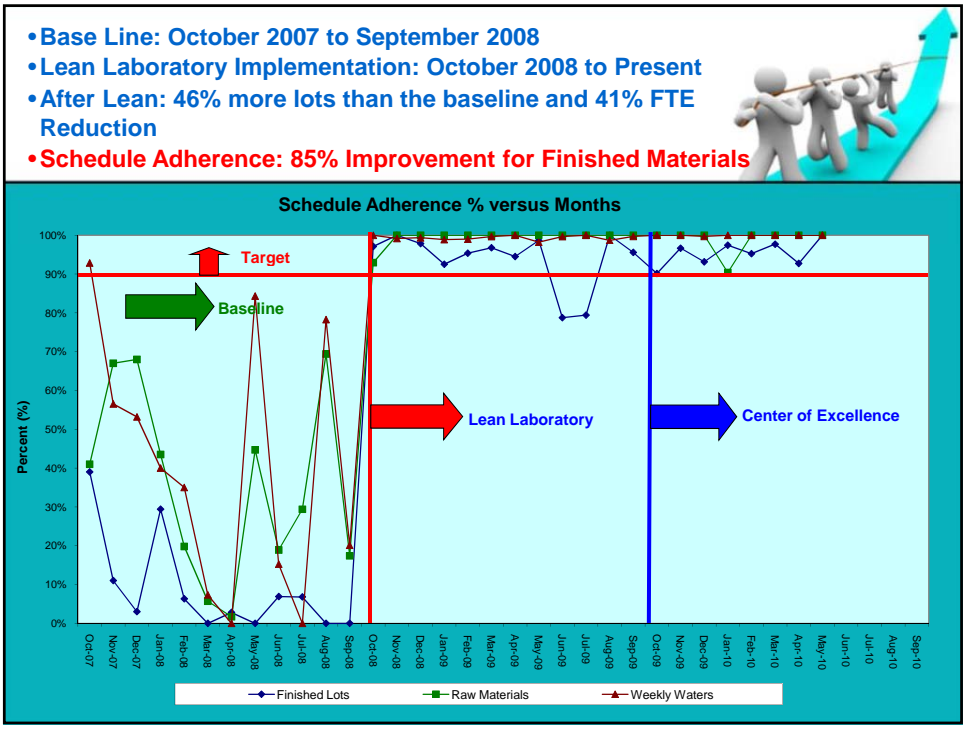
- Electronic visual management display
- Remote access from any computer in the network
- Trainings without leaving laboratory facilities
- Real time performance data evaluation
- Data archive for laboratory operation
- Color coding aligned with laboratory Roles

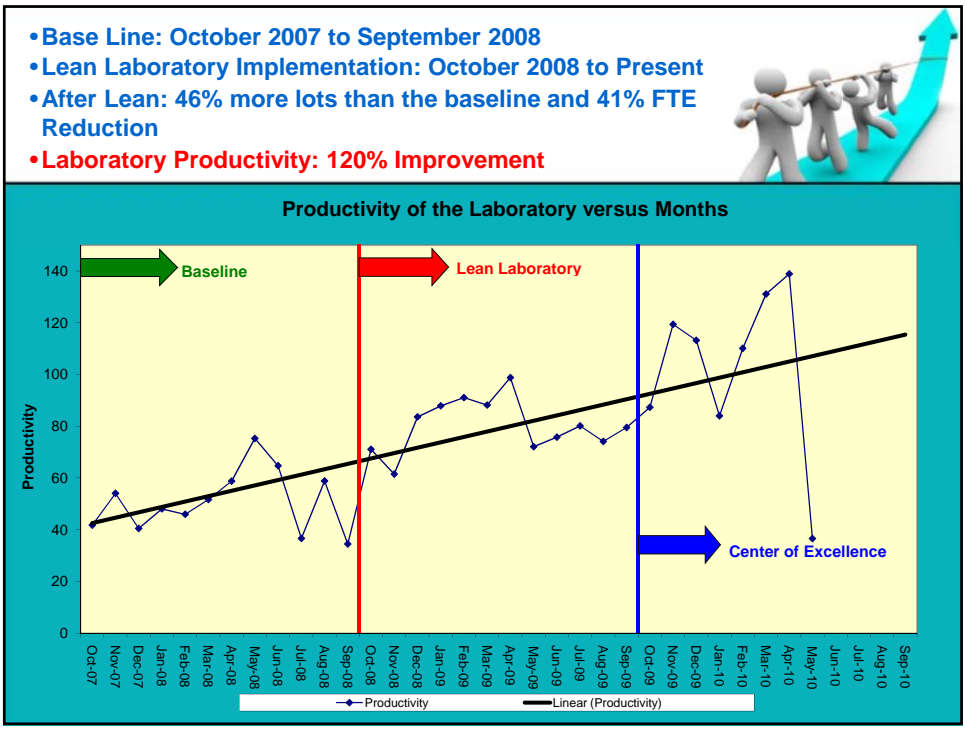
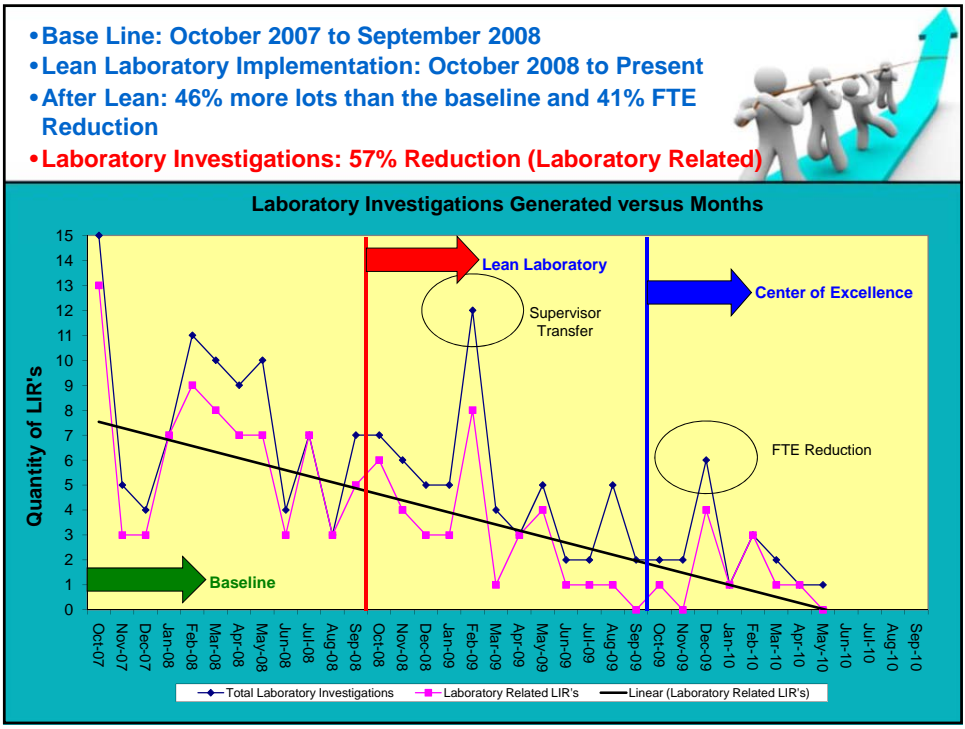














Area	Savings
Workload reduction	
• Use PMH Std COA moisture value for system suitability	TBD
– Reduce 20 standard moisture determination per month	
• Piperacillin Monohydrated reduce testing (from 9 to 2 tests)	\$140,169
• Content uniformity incorporation in moisture testing	\$71,120
– Saving of 6 vials per lot	
• EDTA test mobile phase expiration date extension	\$5,400
– From freshly prepare to 10 days	
Sampling reduction	
• Update sample quantity requirements	\$181,500
• Moisture test workload (from 9 to 3 samples per dryer)	\$142,240
– Savings of 24 vials per lot	
Total	\$540,429

Improvements & Efficiencies

Area	Improvements
Documentation, workload and reduction:	
• HPLC Integration workload	• 70%
• HPLC template / LIMS – LACES continuing work	• 90%
• Constituted uniformity incorporation in moisture testing	• 90%
• Reduce conductivity test documentation	• 50%
• Standardize mobile phase and adjust timing of mixture	• 75%
• EDTA test mobile phase expiration date extension	• 75%
Improve scheduling process and utilization:	
• Introduce visual scheduling board	• 54%
• Optimise scheduling process	• 54%
Total 72%	

Environment Friendly Labs Waste Reduction

Zosyn Chemistry Lean Lab Waste Elimination Reduction

Initiative	Waste Reduction
• Piperacillin Monohydrated reduce testing	• 40%
• EDTA test mobile phase expiration date extension	• 50%
• Content uniformity incorporation in moisture testing	• 36%
• Moisture test sample reduction (from 9 to 3 Vials)	• 67%
• Update sample quantity requirements	• 10%



Lean & Green Operations Net (LGO-Net)



**Initiative Under
Construction !!!**

- People
- Workload
- Equipments
- Reagents
- Metrics
- Environment





Laboratory Roles

Role Number	Zosyn Chemistry Laboratories Roles						
1	Optical Rotation	ID-FTIR (PMH/Tazo)	ROI	Heavy Metals	TOC	Conductivity	Nitrates
2	pH	Constituted	Color	Ethyl Acetate	TLC	Description	
3	Moisture A	Moisture B	Moisture C	Moisture D	Uniformity		
4	Visual Particles	HIAC	New HIAC				
5	Assay (Zosyn)	EDTA	Assay (PMH)	Related (CL115425/PMH)	Assay (Tazo)		
6	Approvers	Metrics	Trends	APR's			
7	Supervisor						

Sample Receipt

Finished								
#	Product Name	Lot Number	LIMS Sample Id	Received	Due Date	Expected Completion	Date Approved	Cycle Time
1	Zosyn EF	F8854-08-02-D63444 M/J	239532	9/2/2009	9/12/2009	9/10/2009	9/10/2009	8
2	Zosyn EF	F8854-08-02-D63447O/N	240017	9/3/2009	9/13/2009	9/10/2009	9/10/2009	7
2								8

Sample Receipt

Finished								
#	Product Name	Lot Number	LIMS Sample Id	Received	Due Date	Expected Completion	Date Approved	Cycle Time
1	Zosyn EF	F8854-08-02-D63444 M/J	239532	9/2/2009	9/12/2009	9/10/2009	9/10/2009	8
2	Zosyn EF	F8854-08-02-D63447O/N	240017	9/3/2009	9/13/2009	9/10/2009	9/10/2009	7
3	Zosyn EF	F8855-08-03-D50412K/I	239982	9/3/2009	9/13/2009	9/10/2009	9/10/2009	7
3								7

Sample Receiptal

Finished								
#	Product Name	Lot Number	LIMS Sample Id	Received	Due Date	Expected Completion	Date Approved	Cycle Time
1	Zosyn EF	F8854-08-02-D63444 M/J	239532	9/2/2009	9/12/2009	9/10/2009	9/10/2009	8
2	Zosyn EF	F8854-08-02-D63447O/N	240017	9/3/2009	9/13/2009	9/10/2009	9/10/2009	7
3	Zosyn EF	F8855-08-03-D50412K/I	239982	9/3/2009	9/13/2009	9/10/2009	9/10/2009	7
4	Zosyn EF	F8855-08-03-D50493R/P	240395	9/4/2009	9/14/2009	9/10/2009	9/10/2009	6
4								7

Sample Receiptal

Finished								
#	Product Name	Lot Number	LIMS Sample Id	Received	Due Date	Expected Completion	Date Approved	Cycle Time
1	Zosyn EF	F8854-08-02-D63444 M/J	239532	9/2/2009	9/12/2009	9/10/2009	9/10/2009	8
2	Zosyn EF	F8854-08-02-D63447O/N	240017	9/3/2009	9/13/2009	9/10/2009	9/10/2009	7
3	Zosyn EF	F8855-08-03-D50412K/I	239982	9/3/2009	9/13/2009	9/10/2009	9/10/2009	7
4	Zosyn EF	F8855-08-03-D50493R/P	240395	9/4/2009	9/14/2009	9/10/2009	9/10/2009	6
5	Zosyn EF	F8852-08-02-D50352 G/P	241904	9/8/2009	9/14/2009	9/11/2009	9/11/2009	3
5								6

Sample Receival

Finished								
#	Product Name	Lot Number	LIMS Sample Id	Received	Due Date	Expected Completion	Date Approved	Cycle Time
1	Zosyn EF	F8854-08-02-D63444 M/J	239532	9/2/2009	9/12/2009	9/10/2009	9/10/2009	8
2	Zosyn EF	F8854-08-02-D63447O/N	240017	9/3/2009	9/13/2009	9/10/2009	9/10/2009	7
3	Zosyn EF	F8855-08-03-D50412K/I	239982	9/3/2009	9/13/2009	9/10/2009	9/10/2009	7
4	Zosyn EF	F8855-08-03-D50493R/P	240395	9/4/2009	9/14/2009	9/10/2009	9/10/2009	6
5	Zosyn EF	F8852-08-02-D50352 G/P	241904	9/8/2009	9/14/2009	9/11/2009	9/11/2009	3
6	Zosyn EF	F8852-08-02-D50014 N/K	241834	9/8/2009	9/14/2009	9/11/2009	9/11/2009	3
								6

Sample Receival

Finished								
#	Product Name	Lot Number	LIMS Sample Id	Received	Due Date	Expected Completion	Date Approved	Cycle Time
1	Zosyn EF	F8854-08-02-D63444 M/J	239532	9/2/2009	9/12/2009	9/10/2009	9/10/2009	8
2	Zosyn EF	F8854-08-02-D63447O/N	240017	9/3/2009	9/13/2009	9/10/2009	9/10/2009	7
3	Zosyn EF	F8855-08-03-D50412K/I	239982	9/3/2009	9/13/2009	9/10/2009	9/10/2009	7
4	Zosyn EF	F8855-08-03-D50493R/P	240395	9/4/2009	9/14/2009	9/10/2009	9/10/2009	6
5	Zosyn EF	F8852-08-02-D50352 G/P	241904	9/8/2009	9/14/2009	9/11/2009	9/11/2009	3
6	Zosyn EF	F8852-08-02-D50014 N/K	241834	9/8/2009	9/14/2009	9/11/2009	9/11/2009	3
7	Zosyn EF	F8855-08-03-D50727 O/B	241881	9/8/2009	9/14/2009	9/11/2009	In Process	3
								5

Sample Analysis

		Finished								
#	Product Name	Lot Number	Assay	GC	TLC	pH, Const.	Uniformity	Color	Water	Approved By
1	Zosyn EF	F8854-08-02-D63444 M/J								
2	Zosyn EF	F8854-08-02-D63447O/N								
3	Zosyn EF	F8855-08-03-D50412K/I								
4	Zosyn EF	F8855-08-03-D50493R/P								
5	Zosyn EF	F8852-08-02-D50352 G/P								
6	Zosyn EF	F8852-08-02-D50014 N/K								
7	Zosyn EF	F8855-08-03-D50727 O/B								
7										

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Sample Analysis

		Finished								
#	Product Name	Lot Number	Assay	GC	TLC	pH, Const.	Uniformity	Color	Water	Approved By
1	Zosyn EF	F8854-08-02-D63444 M/J	Scientist A			Scientist A		Scientist A		
2	Zosyn EF	F8854-08-02-D63447O/N	Scientist A			Scientist A		Scientist A		
3	Zosyn EF	F8855-08-03-D50412K/I	Scientist A			Scientist A		Scientist A		
4	Zosyn EF	F8855-08-03-D50493R/P	Scientist A			Scientist A		Scientist A		
5	Zosyn EF	F8852-08-02-D50352 G/P	Scientist A			Scientist A		Scientist A		
6	Zosyn EF	F8852-08-02-D50014 N/K	Scientist A			Scientist A		Scientist A		
7	Zosyn EF	F8855-08-03-D50727 O/B	Scientist A			Scientist A		Scientist A		
7										

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Sample Analysis

		Finished								
#	Product Name	Lot Number	Assay	GC	TLC	pH, Const.	Uniformity	Color	Water	Approved By
1	Zosyn EF	F8854-08-02-D63444 M/J	Scientist A	Scientist B	Scientist B	Scientist A		Scientist A		
2	Zosyn EF	F8854-08-02-D63447O/N	Scientist A	Scientist B	Scientist B	Scientist A		Scientist A		
3	Zosyn EF	F8855-08-03-D50412K/I	Scientist A	Scientist B	Scientist B	Scientist A		Scientist A		
4	Zosyn EF	F8855-08-03-D50493R/P	Scientist A	Scientist B	Scientist B	Scientist A		Scientist A		
5	Zosyn EF	F8852-08-02-D50352 G/P	Scientist A	Scientist B	Scientist B	Scientist A		Scientist A		
6	Zosyn EF	F8852-08-02-D50014 N/K	Scientist A	Scientist B	Scientist B	Scientist A		Scientist A		
7	Zosyn EF	F8855-08-03-D50727 O/B	Scientist A	Scientist B	Scientist B	Scientist A		Scientist A		
7										

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Sample Analysis

		Finished								
#	Product Name	Lot Number	Assay	GC	TLC	pH, Const.	Uniformity	Color	Water	Approved By
1	Zosyn EF	F8854-08-02-D63444 M/J	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
2	Zosyn EF	F8854-08-02-D63447O/N	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
3	Zosyn EF	F8855-08-03-D50412K/I	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
4	Zosyn EF	F8855-08-03-D50493R/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
5	Zosyn EF	F8852-08-02-D50352 G/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
6	Zosyn EF	F8852-08-02-D50014 N/K	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
7	Zosyn EF	F8855-08-03-D50727 O/B	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
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Sample Analysis

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#	Product Name	Lot Number	Assay	GC	TLC	pH, Const.	Uniformity	Color	Water	Approved By
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2	Zosyn EF	F8854-08-02-D63447O/N	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
3	Zosyn EF	F8855-08-03-D50412K/I	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
4	Zosyn EF	F8855-08-03-D50493R/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
5	Zosyn EF	F8852-08-02-D50352 G/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
6	Zosyn EF	F8852-08-02-D50014 N/K	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
7	Zosyn EF	F8855-08-03-D50727 O/B	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
7										

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Sample Analysis

		Finished								
#	Product Name	Lot Number	Assay	GC	TLC	pH, Const.	Uniformity	Color	Water	Approved By
1	Zosyn EF	F8854-08-02-D63444 M/J	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
2	Zosyn EF	F8854-08-02-D63447O/N	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
3	Zosyn EF	F8855-08-03-D50412K/I	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
4	Zosyn EF	F8855-08-03-D50493R/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
5	Zosyn EF	F8852-08-02-D50352 G/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
6	Zosyn EF	F8852-08-02-D50014 N/K	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
7	Zosyn EF	F8855-08-03-D50727 O/B	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	
7										

Airplane Legend	
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Sample Analysis

#	Product Name	Lot Number	Assay	GC	TLC	pH, Const.	Uniformity	Color	Water	Approved By
1	Zosyn EF	F8854-08-02-D63444 M/J	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
2	Zosyn EF	F8854-08-02-D63447O/N	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
3	Zosyn EF	F8855-08-03-D50412K/I	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
4	Zosyn EF	F8855-08-03-D50493R/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
5	Zosyn EF	F8852-08-02-D50352 G/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
6	Zosyn EF	F8852-08-02-D50014 N/K	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
7	Zosyn EF	F8855-08-03-D50727 O/B	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
7										

Airplane Legend
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Approved

Sample Approval

#	Product Name	Lot Number	Assay	GC	TLC	pH, Const.	Uniformity	Color	Water	Approved By
1	Zosyn EF	F8854-08-02-D63444 M/J	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
2	Zosyn EF	F8854-08-02-D63447O/N	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
3	Zosyn EF	F8855-08-03-D50412K/I	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
4	Zosyn EF	F8855-08-03-D50493R/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
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7	Zosyn EF	F8855-08-03-D50727 O/B	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
7										

Airplane Legend
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Sample Approval

		Finished								
#	Product Name	Lot Number	Assay	GC	TLC	pH, Const.	Uniformity	Color	Water	Approved By
1	Zosyn EF	F8854-08-02-D63444 M/J	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
2	Zosyn EF	F8854-08-02-D63447O/N	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
3	Zosyn EF	F8855-08-03-D50412K/I	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
4	Zosyn EF	F8855-08-03-D50493R/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
5	Zosyn EF	F8852-08-02-D50352 G/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
6	Zosyn EF	F8852-08-02-D50014 N/K	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
7	Zosyn EF	F8855-08-03-D50727 O/B	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
7										

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		Finished								
#	Product Name	Lot Number	Assay	GC	TLC	pH, Const.	Uniformity	Color	Water	Approved By
1	Zosyn EF	F8854-08-02-D63444 M/J	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
2	Zosyn EF	F8854-08-02-D63447O/N	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
3	Zosyn EF	F8855-08-03-D50412K/I	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
4	Zosyn EF	F8855-08-03-D50493R/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
5	Zosyn EF	F8852-08-02-D50352 G/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
6	Zosyn EF	F8852-08-02-D50014 N/K	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
7	Zosyn EF	F8855-08-03-D50727 O/B	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
7										

Airplane Legend
In Process
Ready to Check by
Ready to Approve
Approved

Sample Approval

#	Product Name	Lot Number	Assay	GC	TLC	pH, Const.	Uniformity	Color	Water	Approved By
1	Zosyn EF	F8854-08-02-D63444 M/J	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
2	Zosyn EF	F8854-08-02-D63447O/N	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
3	Zosyn EF	F8855-08-03-D50412K/I	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
4	Zosyn EF	F8855-08-03-D50493R/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
5	Zosyn EF	F8852-08-02-D50352 G/P	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
6	Zosyn EF	F8852-08-02-D50014 N/K	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
7	Zosyn EF	F8855-08-03-D50727 O/B	Scientist A	Scientist B	Scientist B	Scientist A	Scientist C	Scientist A	Scientist C	Supervisor
7										

Airplane Legend

- In Process
- Ready to Check by
- Ready to Approve
- Approved