



TRANSFORMING LIFE SCIENCES

*Maxiom Group OE
Collaborative*

OE in Laboratory Operations

September 22, 2011

Maxiom Consulting Group, Inc.

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Agenda

5:00 Networking

5:30 Introductions & Topic Overview

6:00 OE in Laboratory Operations – *Dave Gardner, Global OE Head - Novartis Vaccines & Diagnostics*

6:30 Breakout Groups

7:15 Wrap-Up & Survey

7:30 Networking

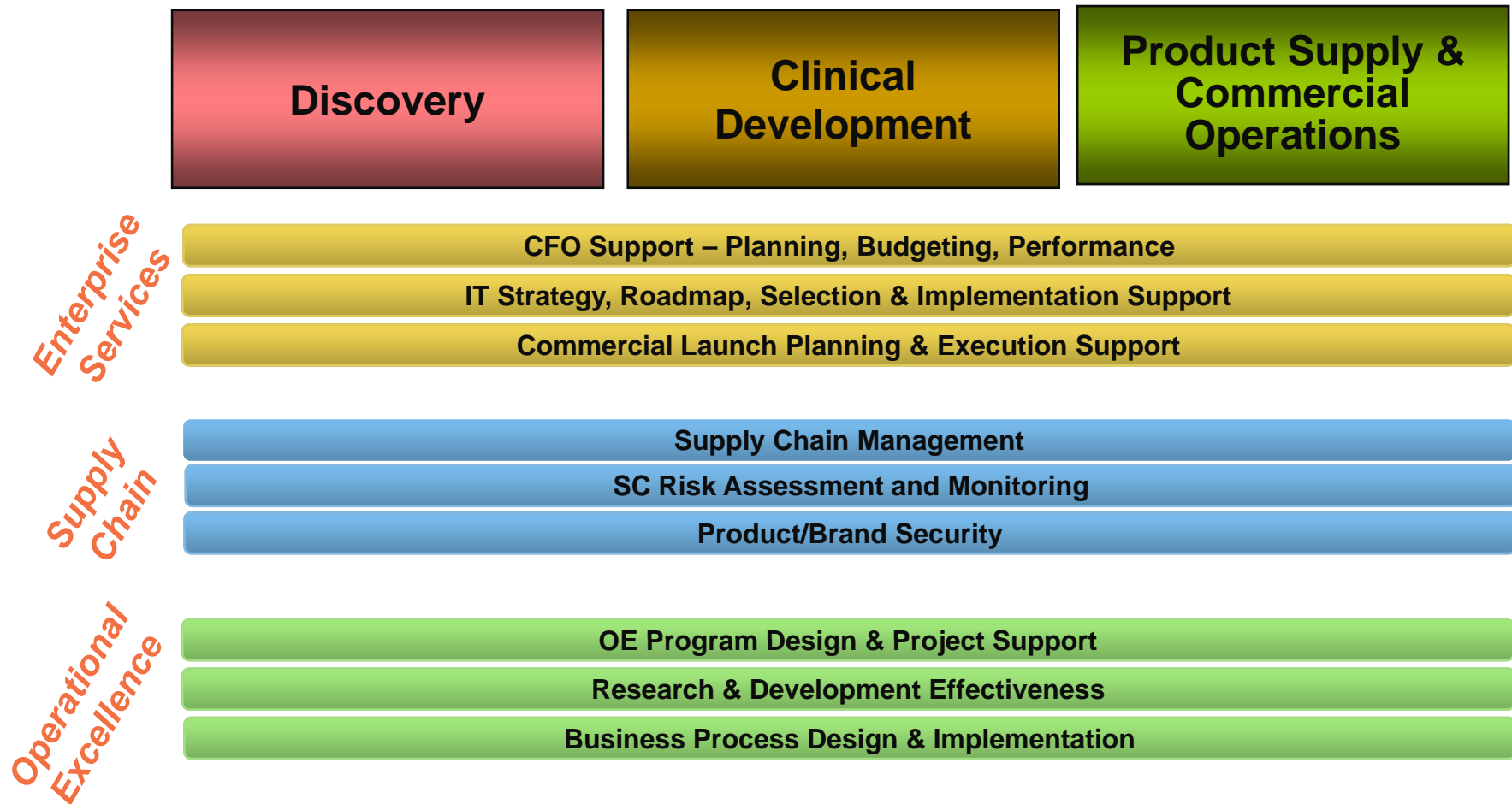
8:00 Adjourn

Maxiom Group Overview

- Business and information technology consulting firm exclusively serving the life sciences industry
- Clients include emerging, established, and mature Biotechnology, Pharmaceutical, Diagnostic and Medical Device companies
- We help companies transform their operational strategies, business processes, and systems to achieve excellence at each life cycle stage
 - From drug discovery to clinical development
 - From clinical development to commercial launch
 - From commercial launch to market leadership
- We blend Focus, Insight and Approach to guide clients through transforming their businesses and meeting their business challenges



Solutions Across the Value Chain



Maxiom Group addresses key business and information needs of Life Sciences companies as they progress through the commercialization life cycle.



Why implement lean in lab environments?

Labs are one of the next frontiers for application of lean, but labs have not typically focused on efficiency and productivity...

- Lean labs make sense – both in QC and R&D
 - Provide focus on testing that delivers quick, cost-effective results
 - Typically produce better quality results
 - Save people resources, time and expenses
 - Safer and less frustrating workplaces
 - Allow scientists to focus on the science
- Adopting Lean principles is the best way to improve efficiency and reduce cost
 - As demonstrated in manufacturing and other business areas

Are there other business benefits?

How are labs different?

Implementing lean in labs is somewhat different than manufacturing, since the environment has unique characteristics...

- Typically more workload volatility and variability
- Less “process reliability and predictability” (versus manufacturing) and often longer task cycle times
- More frequent need to deal with the abnormal, e.g.
 - Out of spec results
- Mix of routine and non routine testing, ‘non test’ tasks and projects
- Generally less OE/productivity focus
 - More on testing accuracy and cycle time

What does the current state look like?

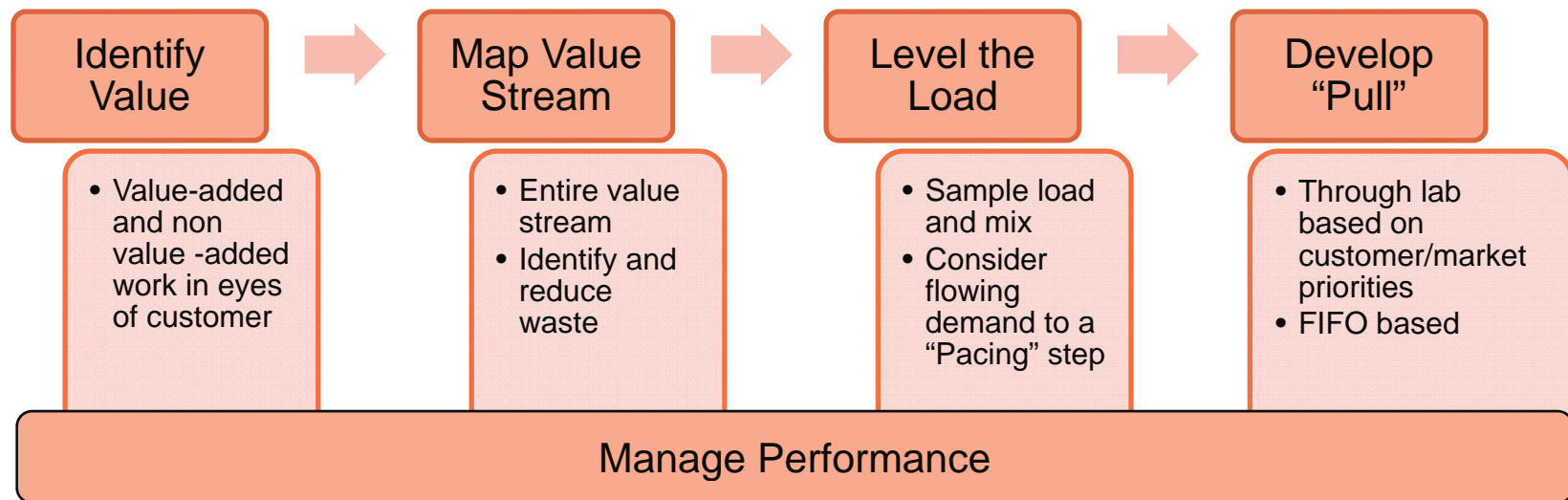
The “As Is” situation in many labs usually has some subset of the following characteristics...

- Variation in incoming workload (amount and mix)
- Resources dedicated by test/task, “weekly bucket” scheduling, and/or “available work through available people”
- Queues and high volumes of WIP
- Significant effort in controlling, tracking and prioritizing samples
- Ineffective ‘fast track’ systems
- Analyst roles not optimized or balanced; lack of defined sequences, batch sizes or standard work
- Focus solely on individual test accuracy and efficiency
- Lack of performance management – some focus on cycle time, little on productivity
- Lots of non value-added activities (e.g. wasted motion and waiting)
- Long lead times and/or low productivity
- Software (LIMS) implemented on top of flawed processes

Do you see your lab environments described here?

So what's the path to improvement?

Implementing lean in labs follows the same basic “steps” as in other areas, though some of the specifics will vary...



Lean in labs includes both a focus on flow and the elimination of waste.

Breakout Questions

For those who have not started a lab OE rollout...

- What have been the impediments to getting going?

For those who have begun a lab OE rollout...

- What have been your key accomplishments so far?
- What are the approaches/tools that have worked best?

Breakout Responses – Question 1

For those who have not started a lab OE rollout, what have been the impediments to getting going?

- Lack of a clear need or business case
- Too many conflicting priorities
- Not enough time and/or resources
- Proving OE fits in the lab environment is a tough sell
- Obtaining senior leadership support has been a challenge
- Demonstrating a value proposition and/or Return on Investment (ROI)
- Obtaining support that “lean” and “GMP” can be applied together
- Scientist mindset is not accepting of how OE would impact them
- Evolution of the lab and constantly changing environment has made OE difficult to implement
- Getting senior leaders to take the “Leap forward” and trust OE can work in labs
- Fighting a history of previous false starts/failed lean initiatives in our organization (why try again?)
- Lack of trained OE resources who understand the lab environment
- Not all levels of the organization are on the same page and/or support the OE initiative
- No incentives to motive people to push OE forward

Breakout Responses – Question 2

For those who have begun a lab OE rollout, what have been your key accomplishments so far?

- We now have defined and understand the need for lean beyond manufacturing
- Grass roots champions are supporting the effort
- Improved comprehension of the processes that drive OE
- We're focused on common processes in the storage and handling of materials
- Work flow has improved
- Personnel has embraced “new lean thinking”
- Our senior management team has been willing to be trained in OE
- Implementation of 6S
- Increased sales by higher throughput
- Improved discipline and buy in regarding our processes
- Morale has improved and internal fighting has declined
- Learned to focus on “needs” before solutions, which has allowed our people to offer feedback and buy-in to the new process
- Improved utilization of our capital
- Have been able to “right size” our physical sites (labs)
- Improved communication and knowledge sharing
- Been able to ID and track our risks and deficiencies
- Developed a common language and metrics
- Improved communication with customers
- Increased our percentage of doing things right the first time (fewer deviations)
- Greater sense of team unity

Breakout Responses – Question 3

For those who have begun a lab OE rollout, what are the approaches/tools that worked best?

- We've created visual management boards that has resulted in improved communication and accountability
- We have identified internal champions to lead by example and mentor others
- Initiated daily and/or shift huddles to plan out goals and objectives
- Required attendance/representatives from all areas to join the huddles
- We have cascading huddles to communicate activities throughout all levels (staff, supervisors, managers...) of the organization
- Communicating and sharing the benefits of OE
- Minimized the amount of jargon within the organization
- Implemented 5S
- Walked through the current state mapping process with the team
- Developed spaghetti maps
- Improved visibility and access to current state data
- Implemented work cells for improved communication and improved QC
- Offering OE awareness and leadership training
- Implemented steps to obtain and understand the Voice of the Customer (VOC)
- Stepped up benchmarking in order to better understand what improved or good looks like in our organization