



CONVERGE-**OE**
Operational Excellence Services

Redesigning Core Business Processes for
Commercial Success

The Convergence of Strategy and Execution in Life Sciences

PROPRIETARY AND CONFIDENTIAL



Who We Are...

Converge Consulting

Strategy, Execution & Solutions for Commercial Market Success

- Highly experienced team of professionals exclusively supporting Life Sciences companies.
- Beyond Science: We assist companies with the *business transformation* required to transition from scientific and technical excellence to business and commercial excellence.
- Key disciplines necessary to design & implement effective & scalable capabilities:
 - Operational Excellence & Business Process Design
 - Supply Chain Strategies & Management
 - Product Launch Planning
 - Strategic Decision Support and Risk Management
 - Core Business Systems
- Sound understanding of the unique industry structure, requirements & challenges of life science companies



Converge partners with our clients to provide the supplemental expertise needed to scale their business.

Our Operational Excellence Proposition

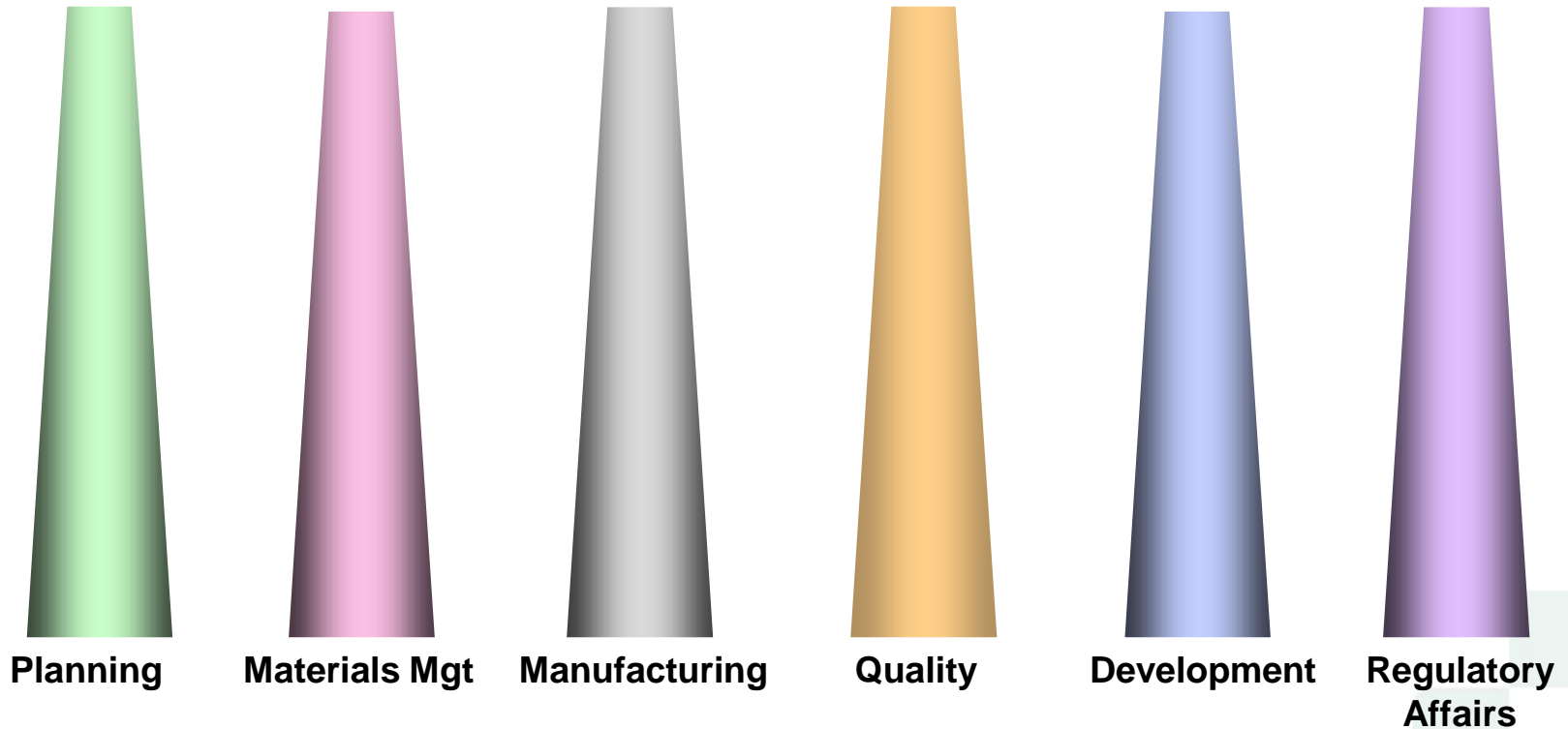
We package and modify “best of breed” tools specifically for our Life Sciences clients to deliver rapid and sustainable performance improvement.

- Best Practice Business Processes
- Best-In-Class Tools & Information Technology Solutions
- Deep Life Sciences Expertise
- Experienced Practitioners



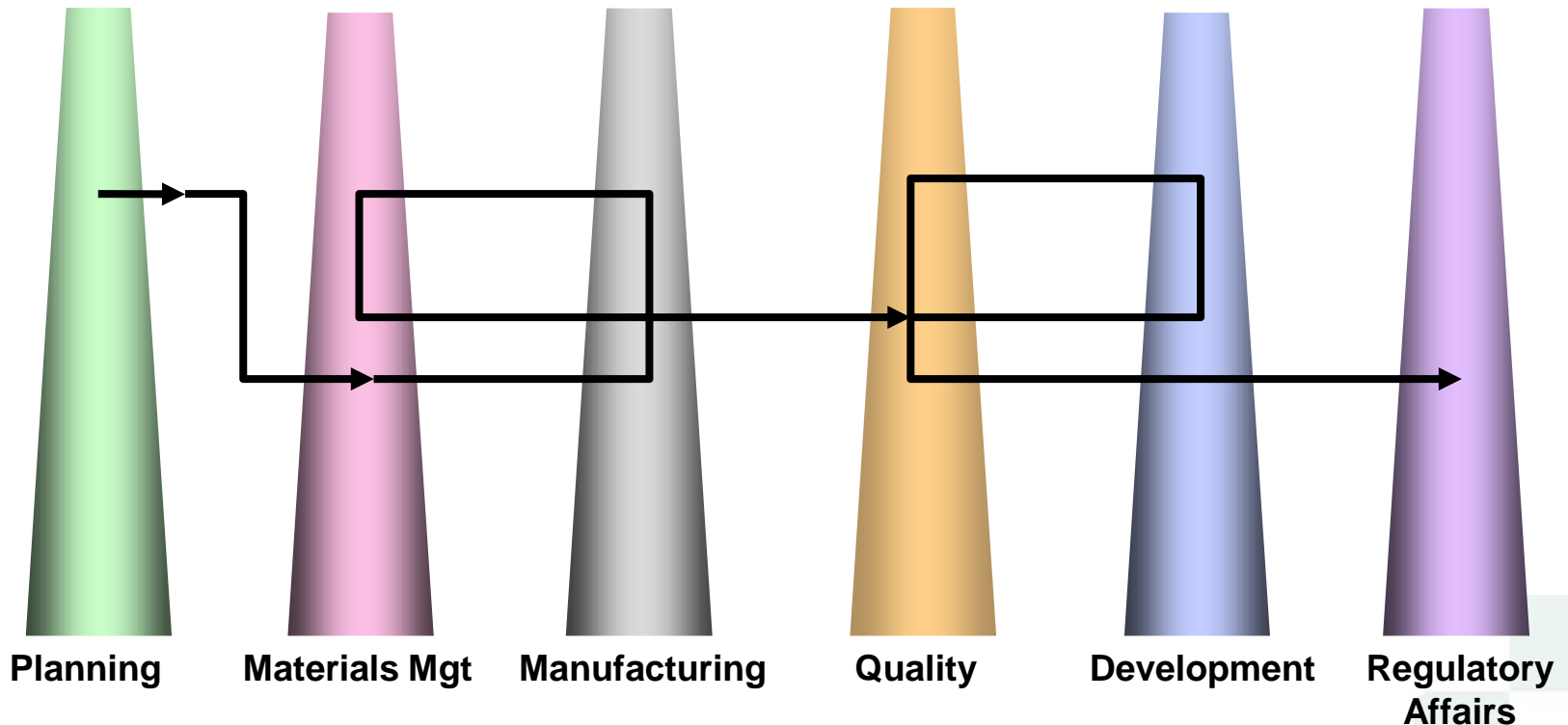
The Way We Work...

Improving performance requires rethinking the way we work.



The Way We Work (cont.)

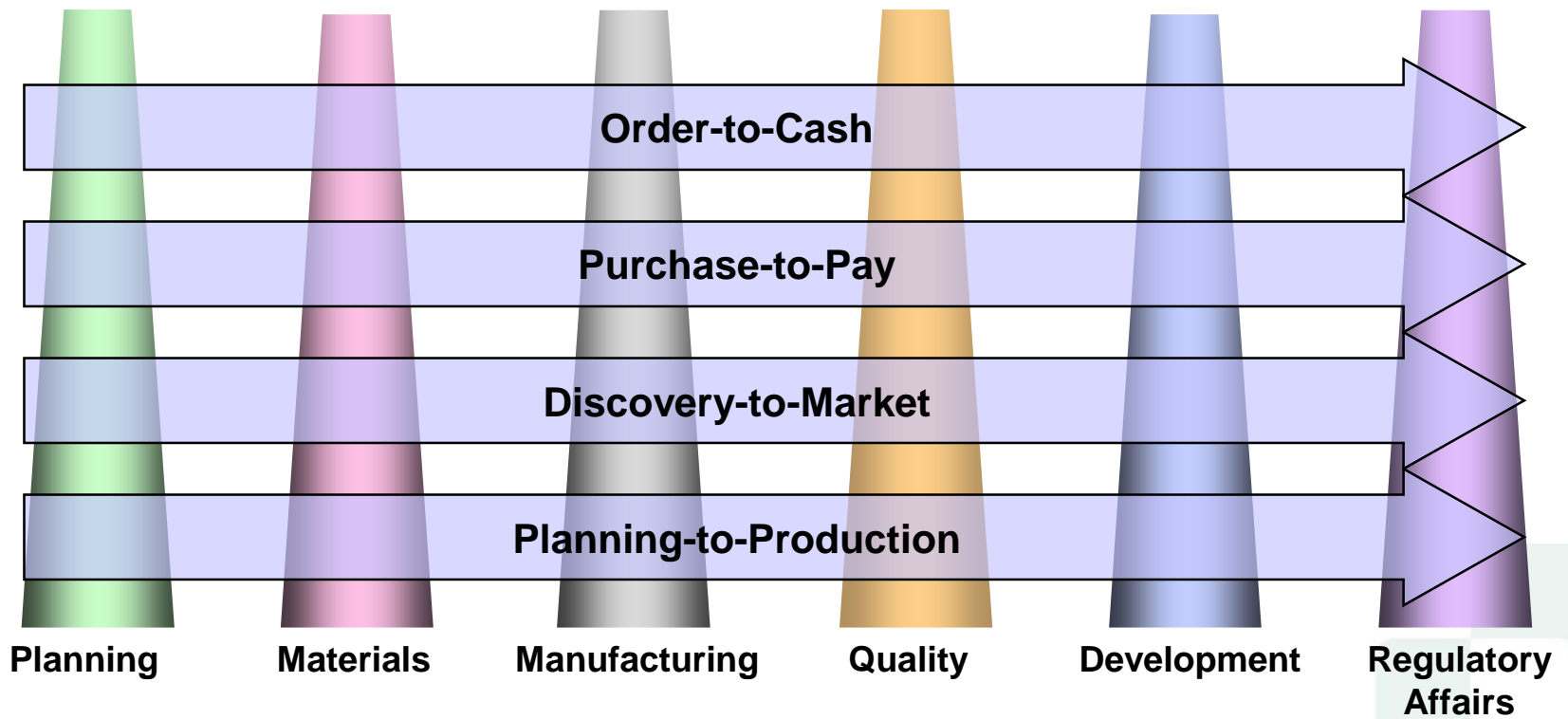
...Commercial business processes cut across functional silos on a day-to-day basis.



Opportunities for improvement often arise at the handoffs, or white space, between functions.

A New View

...By thinking about, and managing the organization as a set of integrated processes, we see it the way work is actually performed.



4 Principles of Redesign

How do we reduce time, effort, and cost?

- Eliminate waste
 - Non-value-adding activities
 - Errors, defects, & rework
 - Duplication of activities
 - Wait & queue time
 - Move/transport time
- Simplify
 - Flow
 - Reduce variability
 - Contact points & communications
 - Methods
- Question the status quo
 - Organizational boundaries
 - Job roles
 - Rules vs. judgment
 - Policies & practices
 - Metrics & incentives
- Remove from critical path
 - Wait time
 - Prep time
 - Constraints

Experience has shown the advantages of drawing on a variety of techniques and perspectives.

What Can We Redesign?

- Business Processes
 - Workflow
 - Activities
 - Boundaries
 - Metrics
- Information Flows
 - Information storage
 - Business Systems Functionality
 - Knowledge Base
 - Subject matter experts
- Organizational Support
 - Job design
 - Organization structure
 - Governance & decision making
 - Skills & training
 - Physical location
- Performance Management
 - Metrics
 - Objectives & Targets
 - Incentives & Rewards



CONVERGE-OE Program Design

Guiding Principles

In order to facilitate the business transformation, our experience has shown a program should be designed to...

- Align with the Business Objectives
- Be flexible to change over time with the business
- Use the “right tool” for the job
- Tap the expertise, creativity, and motivation of people doing the work
- Provide “just-in-time” learning
- Transition as appropriate to internal resources
- Speed to Results, in 60-to-90 day sprints



The CONVERGE-OE Solution

- Life Sciences Business Process Model
 - Process hierarchy
 - Definitions
 - Best Practices
- Established, Packaged Business Improvement Tools
 - Packaged “Workout” breakthrough sessions
 - Business process analysis tools
 - Lean concepts
 - SPC and Six Sigma
 - Daily operational discipline (5S, Poka-Yoke, Dashboards)
- Experienced Guidance & Facilitation
- Accelerated Team Process
 - 60-day sprint
- Proven Templates & Methods
 - Leadership Alignment Workshop
 - Workout project templates
 - Team templates
 - Standard working sessions
- Program Governance
 - Program design
 - Planning & budgeting
 - Project prioritization
 - Benefits tracking
- Communications & Change Management



What's Unique About CONVERGE-OE?



Operational Excellence Case Examples

Cycle Time Reduction

Led cross-functional “Hunting Parties” in analyzing and reducing cycle times of biologics, from date of manufacture to release at DC. Resulted in 32% reduction in DS cycle times and 19% for DP.

Streamlining Suite Startup (after maintenance shutdown)

Led action team to reduce re-qualification requirements resulting in 13-day annual reduction in suite downtime after maintenance shutdown calculated to save \$1.5M per suite

Streamlining the Investigations Process

Led Breakthrough team in revising SOPs to allow concurrent evaluations and re-testing, resulting 20 day reduction in disposition cycle times

Reducing Environmental Monitoring Effort

Led Kaizen effort leading to a 41% Reduction in water sampling frequency and 11% reduction in related investigations

Business Process Redesign

Led cross-functional business process teams to redesign processes to support product launch and global operations scale-up

5S Techniques

Led a client team to enhance housekeeping and visual management to eliminate mistakes and improve location accuracy in Sample Mgt.

Reducing Batch Record Verifications

Led Kaizen effort resulting in 40% reduction in verified steps

Improving Throughput in Facility Ramp-Up

Organized effort to identify and remove organizational and business process constraints to production ramp-up of a new biologics manufacturing facility

Risk-Proofing Batch Records

Led teams across production departments in Failure Mode & Effects Analysis (FMEA) to identify and mitigate process risks, and mistake-proof batch records

Streamlining QC Laboratory Processes

Organized and led 7 teams in redesigning and streamlining QC business processes in conjunction with the implementation of LIMS