



UL COMPLIANCE TO PERFORMANCE  
LEADERSHIP FORUM 2016

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# Compliance to Performance Evolution Model

A Framework to Help Your Organization Move to High Performance

Priya Tabaddor

*Director, Advisory Solutions*



# Outline

- What We've Heard from You
- Compliance to Performance Framework
- What the Framework Means to You





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# Common Global Challenges Life Science Companies Face

## Effective Market Entry

- Identifying and understanding complex regulations
- Market entry roadmaps showing clear path to entry
- Regulatory readiness and preparedness

## Moving to High Performance

- From check-the-box compliance to business performance
- Creating a culture of quality and performance
- Process and procedure simplification; From local to global
- Paperless environments, IT automation and digitization
- Effective merger integrations

## Supplier Compliance and Quality

- Raising the level of consistency.
- Assessing and monitoring. Visibility into changes in the system.
- Analyzing and determining key risk areas.
- Complexity of larger, global supply chains.

## Competency and Knowledge Management

- Raising competency levels to impact enterprise compliance/performance
- Setting clear learning management objectives and strategies
- Creating effective competency development plans
- Effective execution, tracking and measuring of results. Governance.
- Linkages to control access to job activities and tasks

## Growth Outpacing Ability to Scale

- Creating “virtual” companies and networks to move and scale fast
- Leverage partners and outsourced services/capabilities to gain access to resources that can’t be built fast enough (or cost effectively)
- Selecting what core competencies to keep/build internally

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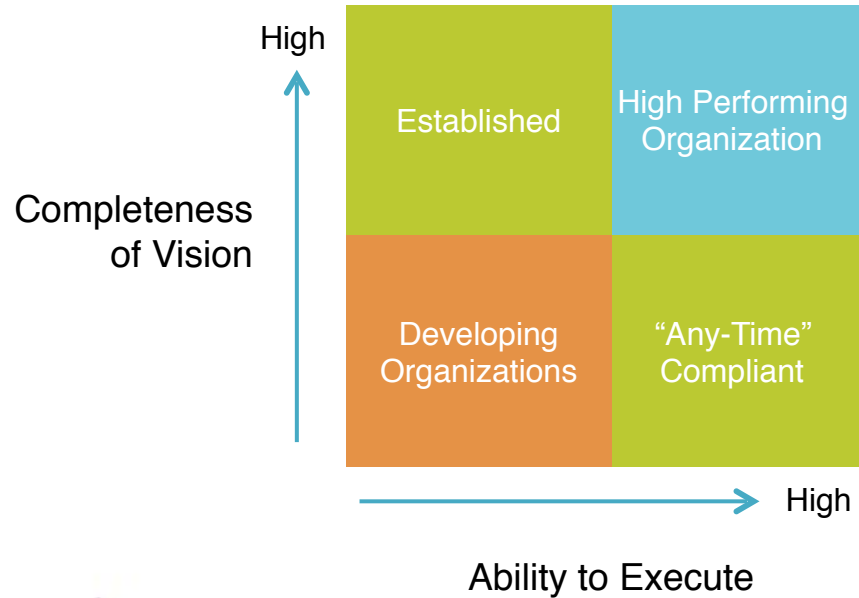
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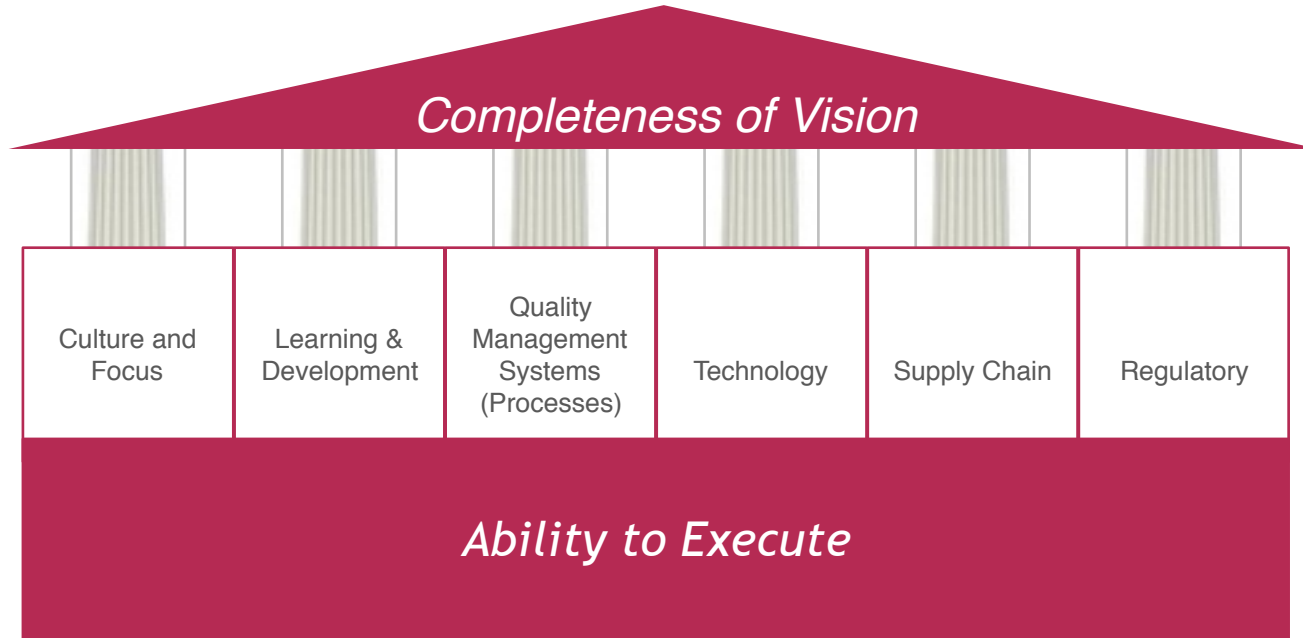
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# High Performing Organizations Have Fully Developed and Articulated Strategy with Flawless Execution



# Performance Drivers



# The “Compliance to Performance” Framework

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Regulatory	<ul style="list-style-type: none"> <li>• Rudimentary knowledge of regulations. “We don’t know what we don’t know”</li> </ul>	<ul style="list-style-type: none"> <li>• Experience based regulatory knowledge</li> <li>• Focus on regulatory readiness across all locations</li> </ul>	<ul style="list-style-type: none"> <li>• Deep knowledge of or access to regulatory information</li> <li>• Active and proactive engagements with key regulators</li> </ul>



# The “Compliance to Performance” Framework

	Developing	Established & Performing	World-Class/High Performing
Culture & Focus	<ul style="list-style-type: none"> <li>• <b>Emphasis on Compliance</b></li> <li>• Check the box culture doing the necessary minimum</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Emphasis on “Anytime Compliance” &amp; Quality</b></li> <li>• “Compliance and Quality are everyone’s job”</li> </ul>	<ul style="list-style-type: none"> <li>• Emphasis on Performance</li> <li>• Driven by results, KPIs, continuous improvement and risk management practices</li> </ul>
Learning & Development	<ul style="list-style-type: none"> <li>• Disconnected training activities for L&amp;D driven by compliance</li> </ul>	<ul style="list-style-type: none"> <li>• Scattered L&amp;D activities within a few departments with added focus on cross training/development</li> </ul>	<ul style="list-style-type: none"> <li>• Clear, harmonized L&amp;D strategies widely communicated</li> <li>• Fully developed talent and competency management program</li> <li>• Analytical, problem solving culture</li> </ul>
Quality Management Systems	<ul style="list-style-type: none"> <li>• Limited documentation discipline</li> <li>• Siloed by region or function</li> <li>• Complex or over simplified procedures with duplication &amp; redundancies</li> </ul>	<ul style="list-style-type: none"> <li>• GxP practices implemented</li> <li>• Disparate approaches to documentation around the globe</li> <li>• Some harmonization of processes in high risk areas</li> </ul>	<ul style="list-style-type: none"> <li>• Strong focus on implementation of GxP practices</li> <li>• Disciplined in documentation practices, paperless</li> <li>• Well integrated processes with optimal use of digital technology</li> <li>• Lean, continuous improvement in DNA</li> <li>• Well defined governance</li> </ul>
Technology	<ul style="list-style-type: none"> <li>• Paper based, home grown or localized IT solutions</li> </ul>	<ul style="list-style-type: none"> <li>• SW supporting critical functions</li> <li>• Limited integration</li> <li>• Limited data analytics capabilities</li> </ul>	<ul style="list-style-type: none"> <li>• Bold/clear IT strategy</li> <li>• Paperless</li> <li>• Fully integrated systems – HRIS, QMS, etc.</li> <li>• Sophisticated data analytics &amp; capabilities</li> </ul>
	<ul style="list-style-type: none"> <li>• Rudimentary transparency into</li> </ul>	<ul style="list-style-type: none"> <li>• Some visibility, control, transparency</li> </ul>	<ul style="list-style-type: none"> <li>• Sophisticated visibility, control, audit processes</li> </ul>

Developing

Established & Performing

World-Class/High Performing

Regulatory

- Rudimentary knowledge of regulations. “We don’t know what we don’t know”

- Experience based regulatory knowledge
- Focus on regulatory readiness across all locations

- Deep knowledge of or access to regulatory information
- Active and proactive engagements with key regulators



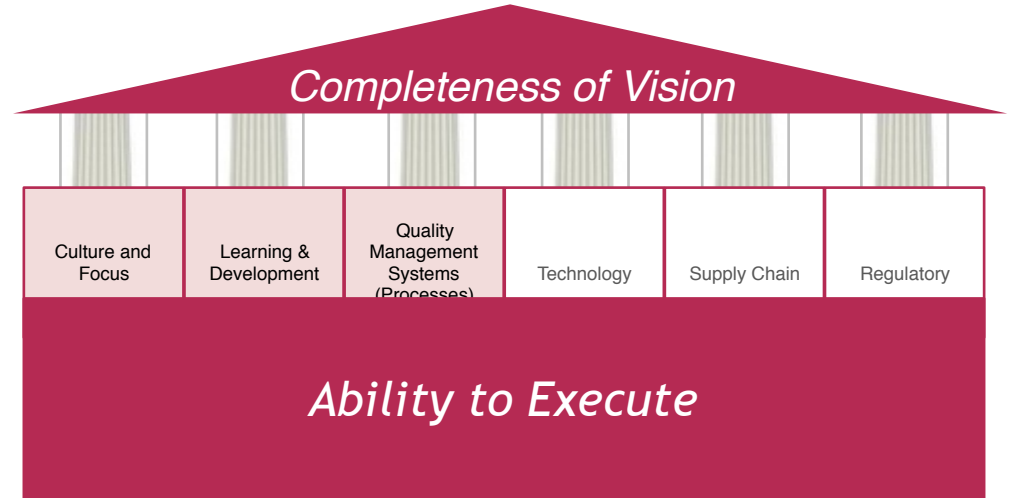
# Case Study 1: Driving Anytime Compliance & Quality

Fast growing Pharma Company in India adding new plants in rural locations, hiring locals

*Challenge:* Driving “Any time” Compliance

*Achieving the strategic objectives through*

- Cultural transformation – quality processes, data integrity
- Knowledge management and sharing at newly opened factory locations in rural India
- Consistency of processes – training & onboarding



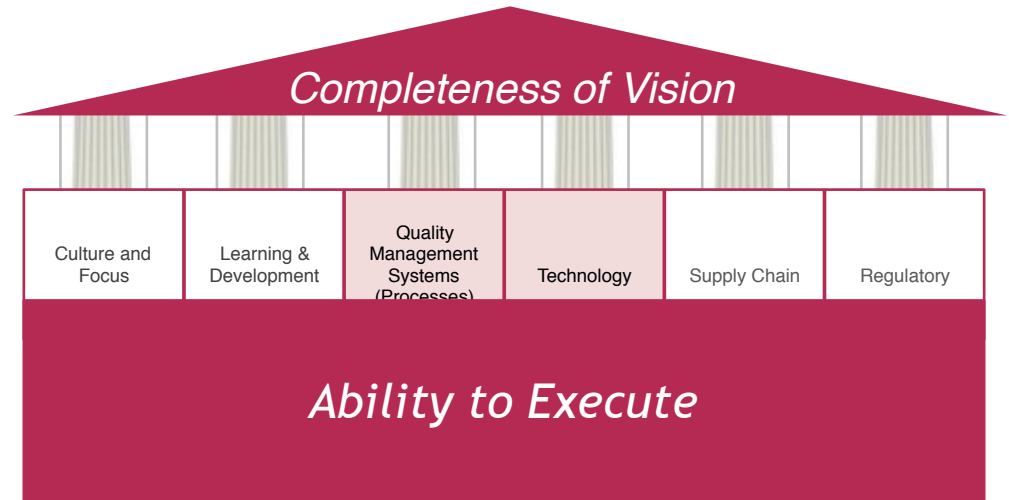
## Case Study 2: Streamlining & Automating Processes

Head of IT of a Global Med Device Company looking to drive a higher level of organizational performance and ROI on technology investments

*Challenge:* Paper based systems, disparate approaches to documentation globally, complex processes with redundancies

*Achieving the strategic objectives through*

- Streamlined and harmonized processes
- Leveraged well integrated IT systems to enable processes



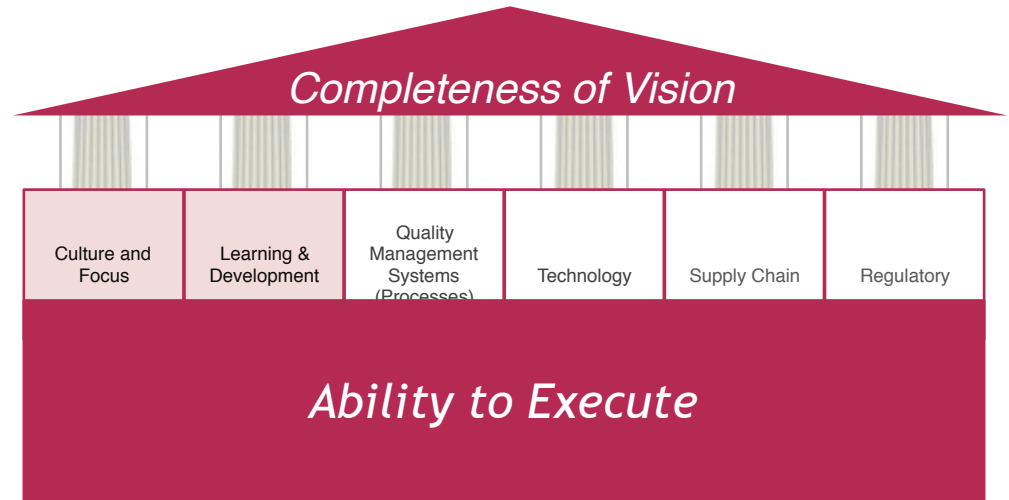
## Case Study 3: Driving a Culture of Learning & Development

A Global Pharma looking to drive effectiveness of people development and talent retention

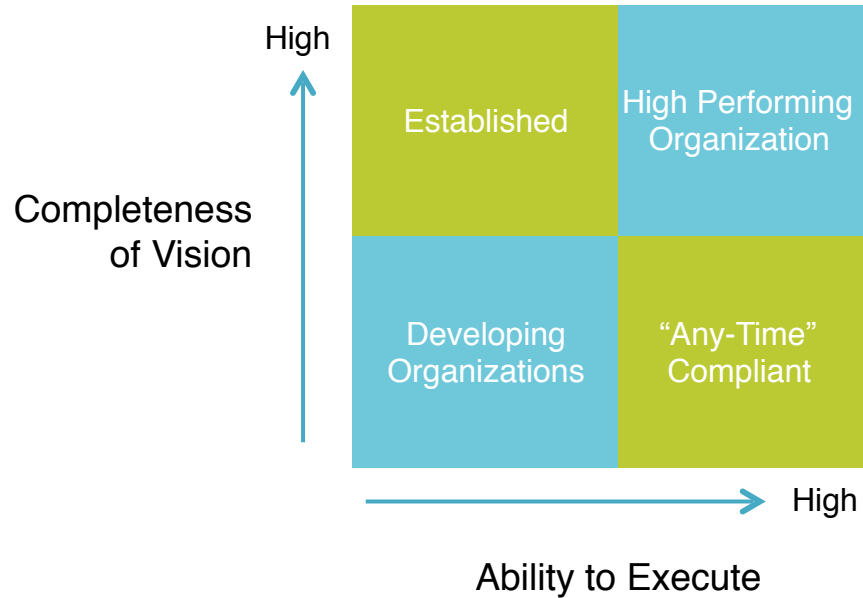
**Challenge:** Disconnected training activities at a functional & department level. Regional siloes

**Achieving the strategic objectives through**

- Developed a strategy for the enterprise that helped them transform their culture from “check the box” training to a learning organization



# Benefits of Driving to High Performance



- Faster market entry and revenue generation
- Operational excellence (Quality, Compliance, Productivity)
- Higher employee retention rates – lower risk on non-compliance & poor quality



# Compliance to Performance

*Helping You Develop & Execute a Vision  
for High Performance*

