Managing Compliance Productivity,
Risk and Reputation

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Overview

- Managing Risk with Process Excellence
  
  Executional Excellence

- Examples

- Key Challenges and Lessons Learned
Global Compliance Requirements
Managing Risk & Reputation

- U.S. Laws
  - OIG Guidance, Pharma Code of Practice
  - U.S. Federal Sentencing Guidelines
  - Foreign Corrupt Practices Act
  - Sarbanes-Oxley

- Country & Local Laws
- Company Policy
  - Company View vs. Country View
- Newspaper Test
Ensure Consistency in Governance Programs & Business Processes
Process Excellence

Leads change from . . . . .

- “Bolted-on” compliance rules
- Reactive solutions
- Incremental improvements
- Dependent on external consultants
- Scant knowledge sharing & interpretation

To . . .

- Integrated compliance guidelines
- Proactive: “X-ray” and take action
- Fundamental redesigns
- Trained problem solvers/project managers
- Global sharing of best practices

Source: Team analysis
What is **Executional Excellence**?

A dedicated team, trained to

- Improve business processes
- Instill compliance and efficiency
- Strengthen mindsets and skill sets
- Provide problem solving and project leadership
- Drive continuous improvement
Ex-Ex Mission

Drive sustainable change through . . .

- **Execution** of Sr. Mgt. sponsored projects with cross functional teams
- Accelerated business process transformation & continuous improvement changes
- **Change Leadership**
- Tangible deliverables & **measurable results**
- Proven **methodology**, tools and skill sets ensuring project success
Ex-Ex Focus

- Provides internal capability to plan & Execute small to large project plans
- Ensures Knowledge Transfer stays within the Company
- Assures Alignment of initiatives & Goals
- Provides Guidance to identify & appropriately scale resources to projects
How does *Executional Excellence* work?

**Business Goals & Project Intake**
- Executive Management Team, Global Compliance and Business Practices Team
- Global Ex Ex Leadership Network
- Training, Sharing Experiences, Continuous Improvement

**Project prioritization**
- Risk Reduction / Urgency (compliance risk)
- Value to business
- Resource commitment and availability

**Project methodology**
- Customized methodology of best business process improvement techniques (e.g., from Six Sigma, lean, project management)

Source: Team analysis
The methodology provides guidelines for each phase of a project:

- **Scoping & Planning**: Project objectives, rationale, scope, resources, & timing
- **Observation & Measure**: Analysis of current-state process & areas of improvement identified, & potential change impacts
- **Workout & Design**: Proposed solution to realize process or continuous improvements & change plan
- **Execution**: Solutions & process improvements implemented through change plan
- **Results & Maintenance**: Solutions & process improvements monitored and documented. Transition plan to CIP
The **POWER** of **Executional Excellence**

<table>
<thead>
<tr>
<th>Problem definition</th>
<th>Observation</th>
<th>Workout</th>
<th>Execution</th>
<th>Results</th>
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</thead>
<tbody>
<tr>
<td>&lt;1 month</td>
<td>Small team</td>
<td>Impact few</td>
<td>Not data intensive</td>
<td>Non-critical path</td>
</tr>
<tr>
<td>&gt; 6 months</td>
<td>High impact</td>
<td>Affects many</td>
<td>Change in culture</td>
<td>Critical path</td>
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- Data driven
- Cross-functional
- < 6 months
- Data Intensive
- Complex/disconnected
The Right People

Business Process Engineers
- Six Sigma Master Black Belts
- Lean engineers
- Project managers

Pharma industry managers
- Business managers
- Science or Mkt Background
- Compliance Officers / Auditors

Academic high potentials
- Top-notch MBAs
- Other Advanced professional degrees

Source: Team analysis
Ex-Ex Competences

- **Improving Business Performance**
  - Business process management
  - Continuous Improvement
  - Measurable results
  - Align Organization, Process, & changes

- **Project Management**
  - Client Contracting & goal setting
  - Definition, planning, execution
  - Outcome based deliverables
  - Cross-Functional Team Leadership, Coaching & Support

- **Change Leadership**
  - Integrated Behavior Change & Process Design
  - Align Stakeholder expectations, strategy, & organizational performance
  - Provides a mechanism for Rewards & Recognition
Developing Excellence∞ in our People

**Career Development**

- **POWER 1**
  - 1 ExEx project
  - Power 1 Training

- **POWER 2**
  - 5+ ExEx projects
  - Power 2 Training
  - Teach/mentor Power 1

- **POWER 3**
  - Lead 10+ ExEx projects
  - Power 3 training
  - Teach/mentor Power 2

**Accreditation**
## POWER TOOLS

<table>
<thead>
<tr>
<th></th>
<th>POWER 1</th>
<th>POWER 2</th>
<th>POWER 3</th>
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</thead>
<tbody>
<tr>
<td><strong>Project Management</strong></td>
<td>- Portfolio Management&lt;br&gt;- Voice of the Customer&lt;br&gt;- Project Charter&lt;br&gt;- Requirements Matrix</td>
<td>- Project Plan&lt;br&gt;- Project Tracking&lt;br&gt;- Task Development&lt;br&gt;- Phase Reviews&lt;br&gt;- Escalation Management</td>
<td>- Design Reviews&lt;br&gt;- Advanced Program</td>
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<tr>
<td><strong>Problem Solving</strong></td>
<td>- Team Building&lt;br&gt;- Brainstorm&lt;br&gt;- Cause and Effect Analysis</td>
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<tr>
<td><strong>Business Process Improvement</strong></td>
<td>- Flowcharting&lt;br&gt;- Metrics (SMART)&lt;br&gt;- Gap Analysis</td>
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Global Leadership Team

Goals

Measure Report

POWER Training

Experience Sharing
Managing Commercial Risk, Productivity & Reputation - Examples

#1 - Customer Operations Support
#2 - Corporate Integrity Agreements
#3 - Fair Market Value
#4 - Payment Processes for Global HCPs
#1 Changing Processes with the Environment

Tightening government regulations

Sales & Marketing

Customers

Business Unit

Business Unit

Business Unit
Solution: Center of Excellence
#2 Corporate Integrity Agreements

Process Requirements

- Processes to Screen New Vendors & Employees
- Processes to On-Board & Train New Employees & Vendors
- Processes to Ensure Adherence to Company Policies
#3 Fair Market Value

**Historical Approaches**

- Rate Information Schedules
- Average Rates & Upper Limits for Approval
- Based on Actual Physician Compensation Data and Consistent Assumptions
- Business Unit Review and Approval; Compliance & Legal Monitor Activity

**Process Enhancements:**
Managing Risk, Productivity & Reputation - Key Challenges and Lessons Learned

- **#1 Ensure Consistency in Process Design with Governance Program**
  - Example: Values Based vs Rules Based Program
  - Tip: Keep Responsibility for Compliance in Commercial Operations - Legal & Compliance Maintain a Business Advisory Role

- **#2 Design Processes to “Control the Forest”**
  - Example: HCP Payments Database (Transparency)
  - Tip: Define Transactional Approvals vs Monitoring Roles

- **#3 Measure Performance & Drive Continuous Improvement**
  - Example: Scorecard Compliance Processes
  - Tip: “What Gets Measured Gets Done”