Part I: Aligning Regulatory Compliance with Optimized Business Processes

Process Driven Compliance for a Competitive Advantage Webinar Series

9 September 2010
Process Driven Compliance Webinar Series

Aligning business process with regulatory requirements to accelerate product performance in the new era of regulatory enforcement.

- **Webinar #1**
  - Sept 9
  - Aligning Regulatory Compliance with Optimized Business Processes

- **Webinar #2**
  - Sept 29
  - Development: Ensuring Compliance During Clinical Trials

- **Webinar #3**
  - Oct 20
  - Thriving in the FDA's New Reign of Enforcement

- **R&D**
- **Later Stage**
- **Post Marketing**
About Quintiles and Consulting

Quintiles is the only fully-integrated life sciences services company offering clinical, commercial, consulting, and capital solutions worldwide.

Our Difference

Unparalleled ability to transform drug development and commercialization through a unique melding of business thinking and industry expertise grounded in practical operational know-how.

Benefit

More effective & executable solutions.
Brad Dawson
Director, Regulatory & Quality Practice – Quintiles Consulting

– Extensive expertise leading strategic growth initiatives, process improvement, and quality systems optimization solutions for leading pharmaceutical, biotechnology, and medical device companies

– Leads the design and implementation of strategic R&D transformation and process improvements initiatives

– Prior to Quintiles:
  • Director, Life Sciences Consulting Services, Conformia Software
  • Associate Director, Health & Life Sciences Industry, Navigant Consulting
  • Manager, Strategy and Operations, Life Sciences Industry Practice, Deloitte Consulting
  • Consultant, Life Sciences Industry Practice, Ernst & Young Management Consulting

– B.A. in Psychology, Public Health Epidemiology Focus, from the University of California, Los Angeles (UCLA).
New Reign of FDA Enforcement

– Hundreds of new inspectors
– 3X as many warning letters issued so far this year
– Increased misdemeanor citations
– Great personal liability

You can’t afford to take a traditional compliance approach
Traditional Approach

– Reactive response results in poor quality
– Costly, laborious business and scientific processes
– Not sustainable in the new health environment
– Compliance and business processes operate in separate silos

 Dependencies between process and compliance are critical to understand
The Challenge
How to Align Compliance and Business Performance

<table>
<thead>
<tr>
<th>Regulatory Compliance</th>
<th>Process Optimization</th>
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<tbody>
<tr>
<td>❖ Adherence to rules and requirements, as mandated by governing regulatory bodies</td>
<td>❖ The discipline of adjusting core business and scientific processes to improve outcomes, reduce variance, and ensure consistent execution</td>
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<tr>
<td>❖ Assurance that processes, practices and products are developed and maintained in compliance with established guidance and regulations</td>
<td>❖ The most common goals are to minimize cost, maximize throughput, and or efficiency, and increase predictability</td>
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The Opportunity
Compliance through Consistent Execution

Achieve higher compliance through optimized business processes tied to global regulations

- Globally harmonized processes that leverage industry-leading practices to optimize performance, reduce inefficiencies and minimize risk
- Regulatory requirements incorporated into process steps to ensure quality, safety, and compliance
- The Quality System aligned to operational performance, tightening the symbiotic relationship between SOPs and business activities
- A web-based tool to help ensure there is a sustainable framework for consistent execution and continuous improvement
- Pre-defined performance criteria defined and actively managed
Integrated Effort
Maximum Value Through Harmonization

Combined Quality Systems and Process optimization efforts yields a more valuable outcome to the organization than either focus alone.
Proven Methodology
Results Delivered
Standard Project Approach
A Snapshot: Design and Delivery

- Delivery and Process Transformation
- Change Management
- Technology Transition

1. Evaluate the Situation
   - Assess Compliance Vulnerabilities
   - Identify Performance Improvement Opportunities

2. Solution Design
   - Develop Future State Operating Model and Optimized Quality System

3. Implementation
   - Assessment
Regulatory Compliance & Process Optimization
Integrated Approach
Mapping of Stage-Gate to Business Processes and SOPs

GATE 3  ▲
Management Approve Entry into the Product Portfolio

▼ EVIDENCE REQUIRED AT GATE 3*
  • Proof of Concept established
  • Updated Protocol/Development Plan & Timeline
    • Refined estimate of project costs
    • Work plan and budget for Confirmatory
    • Updated Target Product Profile
    • Project Risk Management Plan
    • Detailed valuation analysis

- Develop Protocol/Protocol Amendment
- Conduct (Pre)Clinical PoC Studies
- Develop Plan and Materials for Advanced Testing/Regulatory

- Clinical Preparation
- Study Startup
- Study Execution
- Clinical Safety
- CDM & Biostatistics
- Clinical Supplies
- Audits

*Sampling of Gate 3 Deliverables
Business Processes are Supported by Detailed Work Instructions

**Study Startup**

- **CD1.2.1** Create Trial Master File
- **CD1.2.2** Develop Protocol
- **CD1.2.3** Develop Protocol Amendment
- **CD1.2.4** Establish Study Budget & Timeline
- **CD1.2.5** Develop Informed Consent Form
- **CD1.2.6** Develop Document Translations
- **CD1.2.7** Obtain Approval from IRBs/IECs
- **CD1.2.8** Develop Patient Enrollment and Recruitment Strategy
- **CD1.2.9** Develop and Implement Monitoring Plan
- **CD1.2.10** Identify, Qualify and Select Sites
- **CD1.2.11** Develop and Manage Clinical Study Agreement (CSA)
- **CD1.2.12** Manage Selection and Contracting of Vendors
- **CD1.2.13** Plan and Conduct Internal and Site Training
- **CD1.2.14** Plan and Conduct Internal and Site Training
- **CD1.2.15** Obtain Approval for Initial Test Articles Shipment
- **CD1.2.16** Obtain Approval for Ancillary Clinical Supplies Shipment
Business Activities are Described by Specific Processes

CD1.2.3 | Develop Protocol Amendment Level 2 Process

- **CD1.2.3** Develop Protocol Amendment
- **CD1.2.9** Develop and Implement Monitoring Plan
- **CD1.2.14** Plan and Conduct Internal and Site Training

1. Change to Protocol Requested
   - **CD1.2.3.1** Evaluate Scope and Implications of Change
     - Study Design Change?
       - **Y**: Draft, Review and Approve Protocol Amendment
       - **N**: Change to Protocol Requested

2. Protocol Approved
   - **Y**: Draft, Review and Approve Administrative Change
   - **N**: Change to Protocol Requested

3. Draft, Review and Approve Protocol Amendment
   - Distribute Protocol Amendment
   - Trial Master File

4. Updated Protocol Available
Specific Processes Link to Roles and Tasks

CD1.2.3.1 | Evaluate Scope and Implications of Change

- Change to Protocol Requested
  - Change Request
  - Evaluate Scope and Nature of Change
    - Recommendation
    - Escalated Evaluation Rqd?
    - Y
      - Draft, Review and Approve Administrative Change
        - Change Required?
          - Y
            - Notify Requester of No Change
          - N
            - Amendment Needed?
              - Y
                - CD1.2.3.2 Draft, Review and Approve Protocol Amendment
              - N
                - End

- Clinical Trial Manager
  - Evaluate Request

- Clinical Sub Team
  - Evaluate Request

- Regulatory Sub Team
  - Evaluate Request

- CMC Sub Team
  - Evaluate Request
The Quality Connection
Case Study
## R&D Transformation Initiative

**Midsized Specialty Pharmaceutical Company**

### Situation

<table>
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<tr>
<th>Lack of alignment with regulatory requirements</th>
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<td>Burdensome SOPs based on units rather than activities</td>
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<td>Locally specific vs. global focus</td>
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<td>Compliance risks</td>
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<td>Non-existent/anemic processes in key disciplines</td>
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<td>Inefficient, non-value added activities</td>
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### Action

- Standardization of clarity, purpose, scope
- Definition of industry-leading hierarchy, lean templates and a controlled document hierarchy
- Global, top down regulatory review
- Alignment to stage-gate governance model
- Adoption of industry-leading practices
- Creation of efficient, need-based activity maps

### Result

- Activity-based SOPs focused on regulatory compliance
- Reduced administrative and training burden
- Globally streamlined procedures to enable focus on science
- Regulatory compliance
- Increased focus on science/unmet needs
- Enhanced speed to market
Impact: SOP Rationalization

SOP rationalization yielded 98% reduction in total SOP volume while infusing leading practices and harmonizing SOPs globally.

Initial assessment yielded opportunity for improvement…

Over 4,500 SOPs in R&D globally
Regulatory adherence unclear
No global harmonization
Leading practices not applied
Instructional detail lost in overall document volume
Lack of governance controls

driving a series of activities across multiple areas...

Regulatory compliance review and assessment**
SOP consolidation focusing on regulated activities
Redefined R&D documentation hierarchy adopting a streamlined, cascade approach
New SOP/WI templates
Global SOP harmonization

leading to significant reductions and compliance clarity.

**Note:** The table shows the reduction in SOP volume from Initial to Proposed.

- Initial SOP Volume: 4,500
- Proposed SOP Volume: 500

98% Reduction
Impact: Process Optimization

Process Optimization focused on delivering optimized and globally harmonized process maps with integrated SOPs and other documents

- Incorporated industry-leading practices through review by leaders in the Industry
- Produced evidence-based deliverables that support the stage-gate model
- Applied “Fail Fast” for projects through focus on scientific-driven development

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<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
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<td>Models to meet client-specific needs and nomenclature</td>
<td>Deconstructed processes into detailed activities, drivers, and owners</td>
<td>Completed remaining maps</td>
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<td>Incorporated expert point of view aligned to client needs</td>
<td>New processes to support Medical Affairs</td>
<td>Alignment/integration SOPs to processes</td>
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<td>Robust Medical Safety/Clinical processes</td>
<td>Developed and refined definition of responsible parties</td>
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<td>High level identification of capability requirements</td>
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Realized solution delivering measurable performance improvement and enhance global regulatory compliance

- Staff access central portal...
- Obtain role based processes...
- Adhere to governing tools and materials...
- And execute their work.

- Standardized and central repository
- Lean processes to fulfill individual roles
- Direct access to regulatory aligned procedures, instructions & tools
- Focused activity aligned with staff role

SOPs & Work Instructions

Process Optimization
Process Driven Compliance

– A proven methodology combining deep regulatory domain expertise and process optimization to enhance operational effectiveness

– An application of industry-leading business and scientific processes across the organization

– A sustainable framework linking business strategy, regulatory compliance, and roles and responsibilities
For Additional Information

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