GMP Compliance: Better to Start Now

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CURRENT ENVIRONMENT CHALLENGING AND EVOLVING

- Repeated inspection failures
- Increasing number of 483s
- Multiple warning letters
- Consent decrees
- Disgorgement of profit
- Systems-based approach

COMPLIANCE INVOLVES MULTIPLE PROCESSES

- Training and culture create the environment and mentality
- Quality Assurance monitors the day-to-day and trend actions
- FDA regulation mandates several distinct activities
- Internal enforcement assures prescribed actions are completed

GMP ACTIONS OFTEN REACTIONARY

- Historical focus always after-the-fact
- Expense focus creates little incentive for fore thinking
- Compliance generally seen as production cost
- Viewed as lower priority within an organization

GMP COMPLIANCE OFTEN MISUNDERSTOOD

- Perceived as a burden
- Corporate view continues to be as an expense
- Traditional view is a leash with little up side potential
- Rarely seen as a revenue-generating opportunity

CONSEQUENCES PAINFUL AND COSTLY

- Loss of money
  - Warner-Lambert estimates $1B*
  - Abbott close to $1B and growing*
  - Consent decrees are long standing
- Loss of time
  - Application approvals
  - Getting new product to market
- Loss of image
  - Damage to credibility

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CORPORATE CHANGE REQUIRED

- GMPs must be integrated into the process, not an additional component
- Process must evolve from one of police action to one of forethought
- Corporate culture must change

CULTURE CHANGE DRAMATIC AND DIFFICULT

- Quality function must be valued by management
- Increase visibility of quality unit
- Visibly exhibit an intolerance for lack of compliance
- Quality must be seen as a priority

PROACTIVE APPROACH NECESSARY

- Approach regulations proactively
- "It is often said at FDA that firms that are in compliance tend to stay in compliance, but once a firm gets out of compliance getting back into compliance is a very steep road to climb. Try to avoid that road." – Daniel Troy, FDA Chief Counsel

FOCUS ON BUILDING THE RIGHT QUALITY SYSTEM

- Create a self-determining culture
- Make regulatory mandates obvious and routine, not the focus
- Use Quality Assurance as a cost-improvement methodology

PROACTIVE APPROACH TO INCREASING PROFITABILITY

- Approach facilities' inspections proactively
  - Use third parties
  - Assess all business operations
  - Act on things immediately
- Change focus from compliance to improvement

DEMONSTRATE THAT COMPLIANCE IS SUBSET OF QUALITY

- Make compliance a way of life
- Focus on improvement
- Enjoy savings from this change

DIFFICULTY IN CHANGING MINDSET

- Change from compliance mentality challenging
- Vigilance must be maintained
- Adaptation in outlying plants will take time

CHANGE BEGINS WITH STUDY AND THOUGHT

- First step is to plan for change
- Plan should include all elements of change process
- Focus on instituting means of process improvement