Beyond Compliance

2.04 Product Quality and Organizational Compliance

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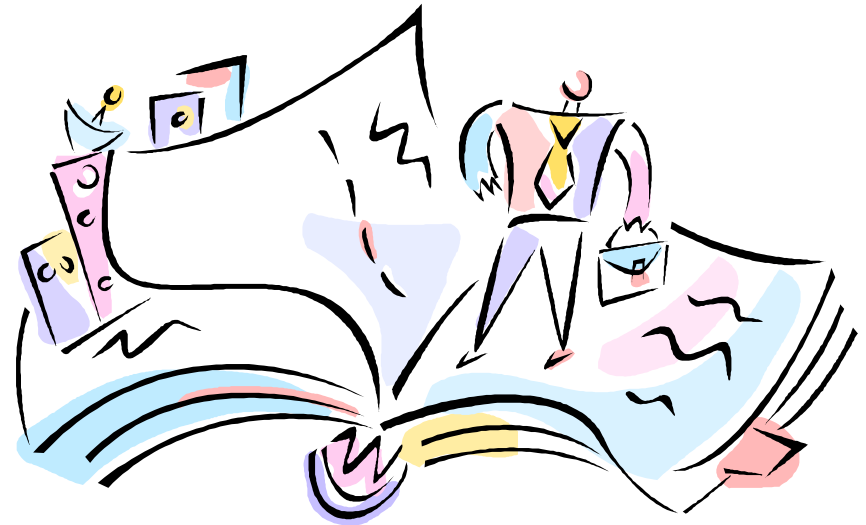Johnson & Johnson Health Care Systems, Inc.

November 16, 2004

A Recent Computer Validation Project…

Supply Chain Order Entry

- GMP system requiring CSV
  - Logistics & distribution for 14 different Rx and MD&D manufacturers
  - Electronic records

- Budget: > $7 million
- Duration: 10 months
- Project team: > 50 persons
- Validation team: 2 persons

The Language of Compliance and Quality

| Regulatory Compliance	Project/Quality Mgt
●Regulator <————————————>	●Stakeholder
●Regulation <————————————>	●Mandatory requirement
●Regulatory compliance <————>	●Conformance to requirements
●Regulate <————————————>	●Review, test, monitor, manage
●Documentation <——————————>	●Deliverables
●Risk <—————————————————>	●Gaps, unmet requirements
●Audit <—————————————————>	●Process review

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Quality … Beyond Compliance

- Compliance
  - Conformance to regulatory requirements
- Quality
  - Grade
    - Number of characteristics or features (requirements)
  - Conformance to requirements
    - All stakeholders
    - Needs, Wants and Expectations
  - "Fit for purpose"
    - No missing or incorrect requirements
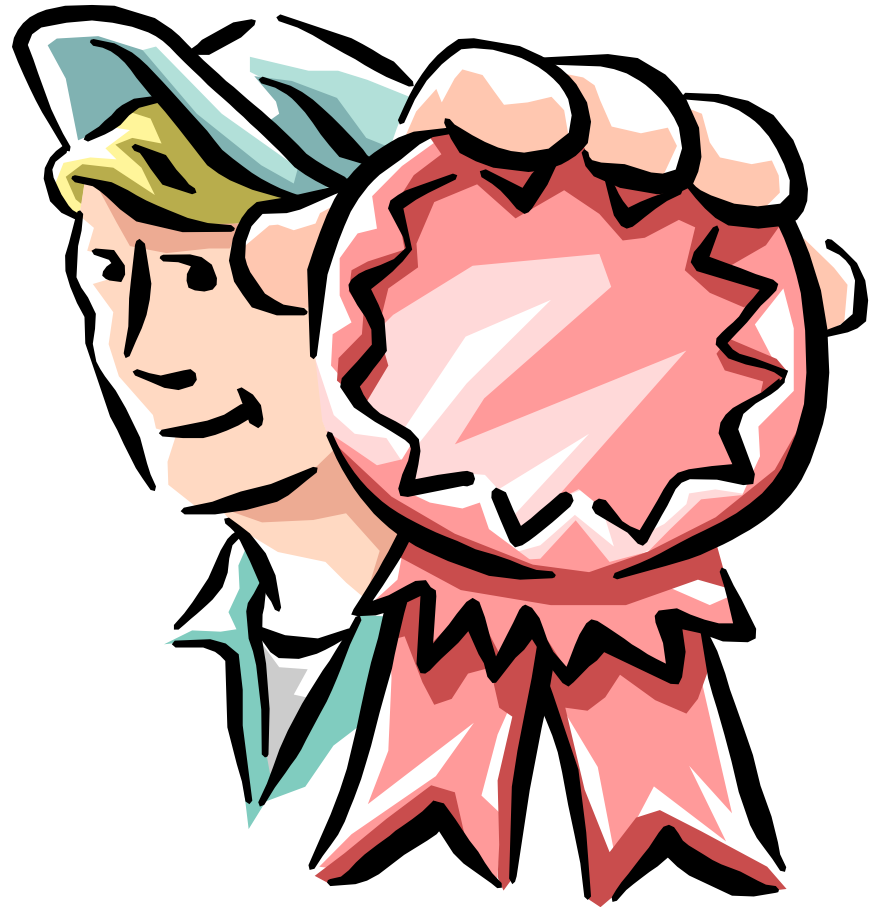
Keys to Success

- Speak the language of your audience
- Early involvement
    - Become a partner early v. a roadblock late
- Ensure all stakeholders are represented
    - Including regulatory bodies
- Incorporate regulations as product requirements
    - Quality is built in, not inspected in

Benefits

- Regulatory compliance
- High product quality
- Reduced risk
- Reduced rework, resources, cost
  - Done right the first time
- Improved time to market
  - Due to reduced rework and fewer missing or incorrect requirements
- Increased revenue, profit

Summary

Product Quality and
Regulatory Compliance…

They're not just the law…

They're good business.