Pharmaceutical Quality Systems (ICH Q10) Conference

A Practical Approach to Effective Lifecycle Implementation of Systems and Processes for Pharmaceutical Manufacturing

October 4-6, 2011 | Crystal Gateway Marriott | Arlington, Virginia
November 14-16, 2011 | Sheraton | Brussels, Belgium

Welcome

The ICH Q10 Quality System

Steven Lynn, M.S.
Director, Office of Manufacturing & Product Quality
Center for Drug Evaluation and Research

ICH Q10 Annual Meeting
Oct. 4-6, 2011

Agenda

- The ICH Expert Working Group (EWG) Mission
- Pharmaceutical Quality for the 21st Century Initiative
- Quality Systems Models
  - ISO, Baldridge, Current GMPs
- The Pharmaceutical Quality System (PQS)
  - Robust and modernized PQS implementation needed given today's landscape
  - Benefits vs Risks
  - Senior Management Role

ICH Q10 EWG Mission

To establish a new tripartite guideline describing a model for an effective quality system needed to establish and maintain a state of control that can ensure the realization of a quality drug product and facilitate continual improvement over the product life cycle.

Pharmaceutical Quality for the 21st Century: Objectives

- **Risk-based regulatory approaches**
  - Allocate more resources toward highest risks
- **Science-based regulatory approaches**
  - Recognize and facilitate early adoption of scientific and technological advances
  - *Encourage continual improvement* through robust **Quality Systems** (including risk management), and remove regulatory hurdles
- **Coordinate review, compliance and inspection programs in a more synergistic manner**

Pharmaceutical Quality for the 21st Century

- Regulatory paradigm shift to:
  - Performance and Management-Based
  - Lifecycle focus:
    - Establish performance standards and ensure firms effectively manage risks in order to meet these standards
    - Monitor state of control throughout lifecycle
    - Allow flexibility for technological advancement and improvement

Pharmaceutical Quality for the 21st Century

- Industrial paradigm shift
  - Senior management responsibility
  - Quality Systems approach, with robust quality monitoring programs and proactive quality culture
  - Scientific risk management throughout lifecycle, with better process understanding and continual improvement

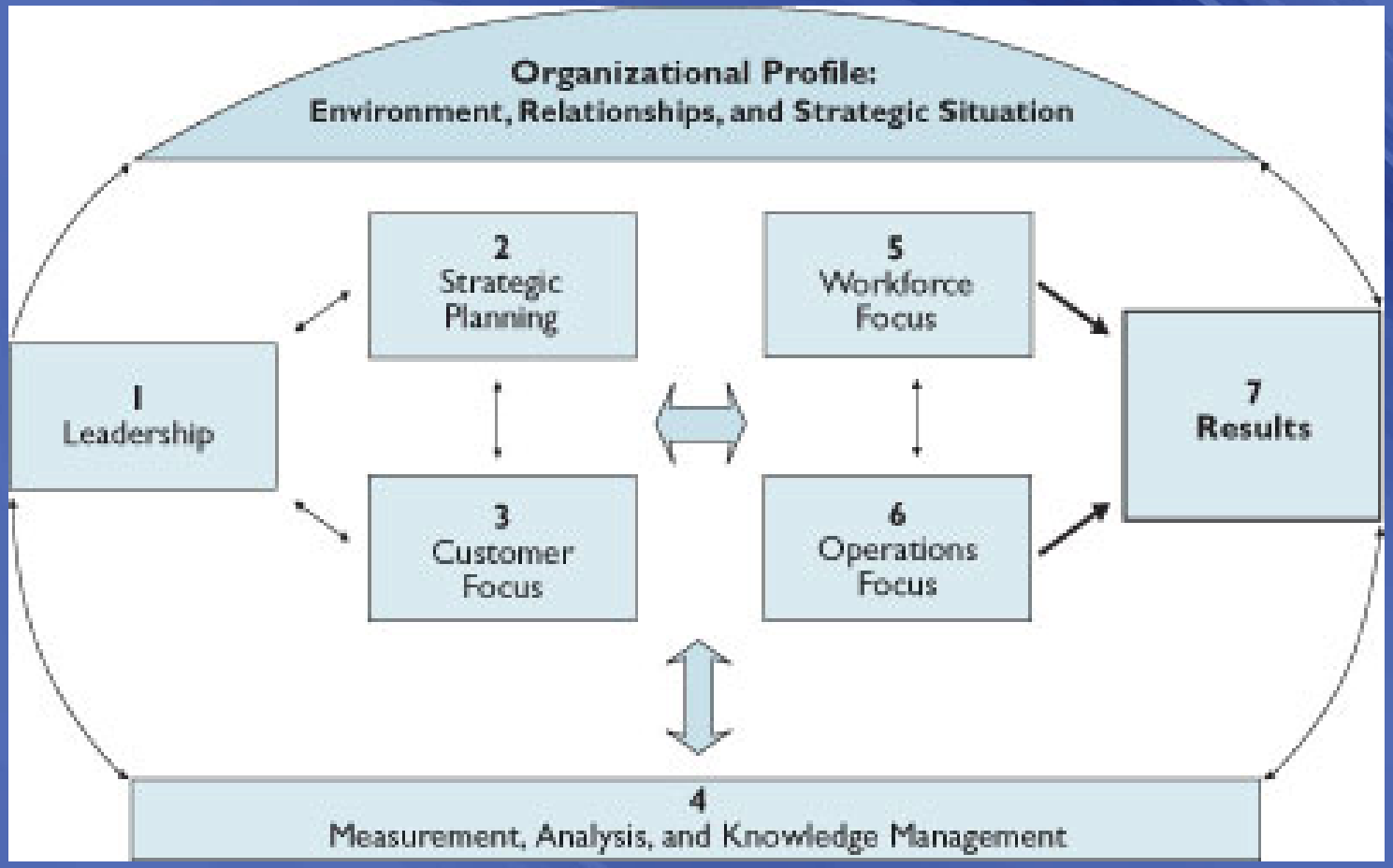
FDA and Industry Have a Common Interest in…

- Assuring consistently safe and effective drugs are available
- Building quality in throughout the lifecycle and supply chain
- Finding innovative technologies and approaches to address old problems
- Adapting to globalization

Quality Systems: CGMPs and ISO

- CGMPs
  - Systems, programs, and procedures
    - FDA's inspection program is systems-based
  - Quality unit responsibility and authority
  - Supervisory responsibilities
  - Qualified personnel
  - Flexibility to develop the most suitable operating procedures and implement novel approaches
- ISO
  - General guidelines on quality management systems for various industries
    - e.g., *ISO 9004, Performance Improvement*

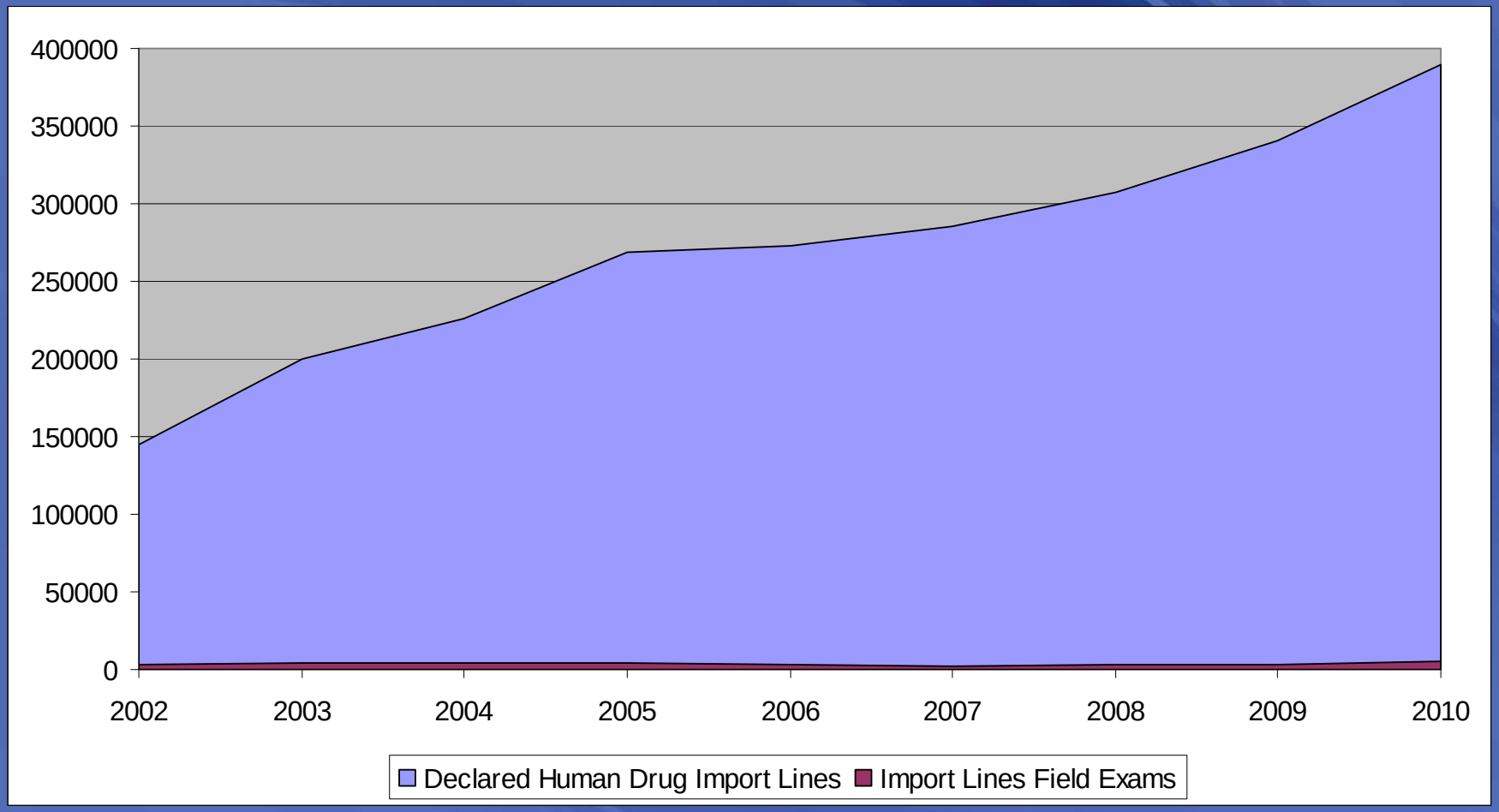
Malcolm Baldridge Framework for Organizational Excellence



The Patient is the Customer

- Voice of the Customer: Quality should be customer-focused
  - *e.g., what type of patient may receive this drug? what is the intended use of the ingredient?*
- Quality is achieved (and consumer risk minimized) by a robust Quality System. This requires Senior Management Commitment.
- In a strong quality system, senior management recognizes and leads with the philosophy that:
  - *a proactive, preventative paradigm must be ingrained in the organization's daily operations*
  - *robust supplier relationships and neural networks are essential to limit variability in materials and processes.*

Challenges of Globalization: Human Drug Imported Products



Potential Consequences of a Product or Ingredient Problem

- Corporate/business Risk
  - Interruption in manufacturing and supply.
  - Disqualification of supplier and need to qualify new supplier.
  - Customer complaints and returned goods.
  - Loss of reputation, profits, market share.
  - Decline in stock value.
- Patient/consumer Risk
  - Lessened, excessive or inconsistent therapeutic effect.
  - Side effects and transient adverse events.
  - Permanent adverse effects.
  - Loss of confidence in safety and quality of drug(s).
  - Needed drug is unavailable.

Benefits of an Effective Quality System

- Support and Ownership of Quality Goes Beyond the Quality/Compliance Units

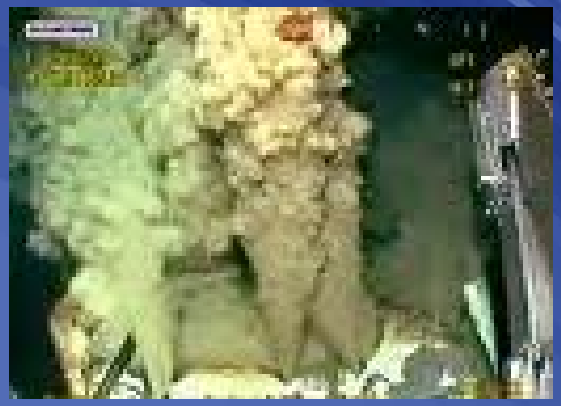
- A Culture of Quality Yields Many Benefits:
  - Enhanced Process Stability Drives Productivity and Performance.
  - Prevention Reduces Compliance Risks and Costs.
  - Best Plants have Fewer Significant Complaints and Investigations and Therefore More Efficient QA Release of Batches.
  - Protection of Brand.

A Quality System Creates Real Fixes

- A robust quality system is:
  - At the core of Good Manufacturing Practice
  - Science and risk-based
  - Vigilant and Proactive
  - Culture-focused
  - Able to identify issues while they are still small
  - Responsible for assuring any contracted site is qualified to do the function, and performed it satisfactorily
  - Supportive of business needs because it creates dependability and sustainability
- It should not be:
  - Reactive or defensive (issues should be surfaced)
  - Solely a procedural approach (only “plan-do”)

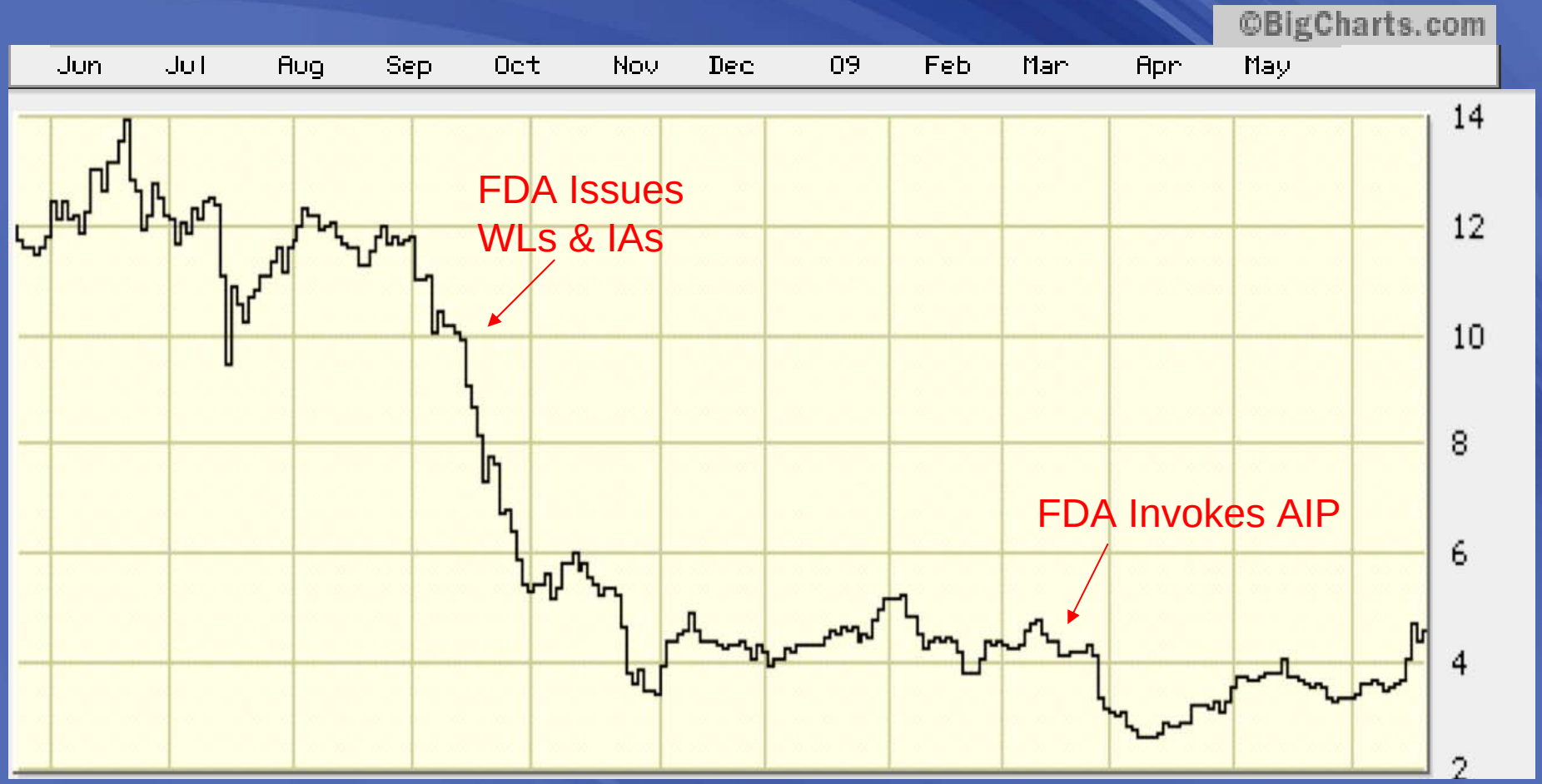
Why Comply: Impact on Reputation

- When I say BP, what do you think?



- When I say Ford Pinto, what do you think?

Why Comply: Financial Impact



FDA Expectations

- Companies are accountable for the quality of their products
- Senior Management must:
  - be supportive of product quality
  - establish mechanisms to ensure science and risk based decisionmaking throughout the lifecycle
  - remain vigilant about new variables or events that may affect product quality
  - assure clear and open communications
    - e.g., the agency should be notified when a problem arises that has potential to adversely impact public health

Conclusion

- In a global marketplace, it is crucial for industry to implement effective quality systems
- QS implementation and maintenance requires informed, committed leadership from the top
- An effective quality system allows the manufacturer to achieve consistently high quality drugs, comply with public health requirements, and meet the needs of the consumer (and shareholders)
- Robust systems (as described in ICH Q10) lead to robust processes!