

Agenda

- My Background
- The ICH Q10 and the FDA
- Our Journey
- Questions and Wrap-up

Questions

- Do current cGMPs require evidence of continual improvement?
- Why is CI important?

ICH Q10 Application: Pharmaceutical Quality System

Scope:

- Pharmaceutical Development
- Technology Transfer: Development – Mfg/Mfg – Mfg
- Manufacturing: includes storage and distribution
- Product discontinuation

A “Step-wise Modular Approach”

ICH Q8
Pharmaceutical
Development

ICH Q9
Risk Management

FDA
Guidance
Draft issued
07/02/07

ICH Q10 Guidance
Pharmaceutical
Quality System

FDA's Guidance On ICH Q10

Consider...

- “A model for a pharmaceutical quality system... throughout lifecycle.”
- ISO Quality Management System as foundation
- Augments GMPs by describing specific quality system elements and management responsibilities.

Q10 includes:

- ✓ Management Responsibility
- ✓ Continual Improvement of Process Performance and Product Quality
- ✓ Continual Improvement of the Pharmaceutical Quality System

The Richmond DC



Staff – 71 (v. 78 in Sept 2005):

Shifts – Two-Shifts with coverage
from 5:00am to 9:30pm

Facility – 260,000 sq ft facility

Capacity > 27,000 pallet positions

6-High Very Narrow Aisle

4-high Double Deep Racking

Picking Tunnels

Products – 600+ OTC SKU's

System – SAP

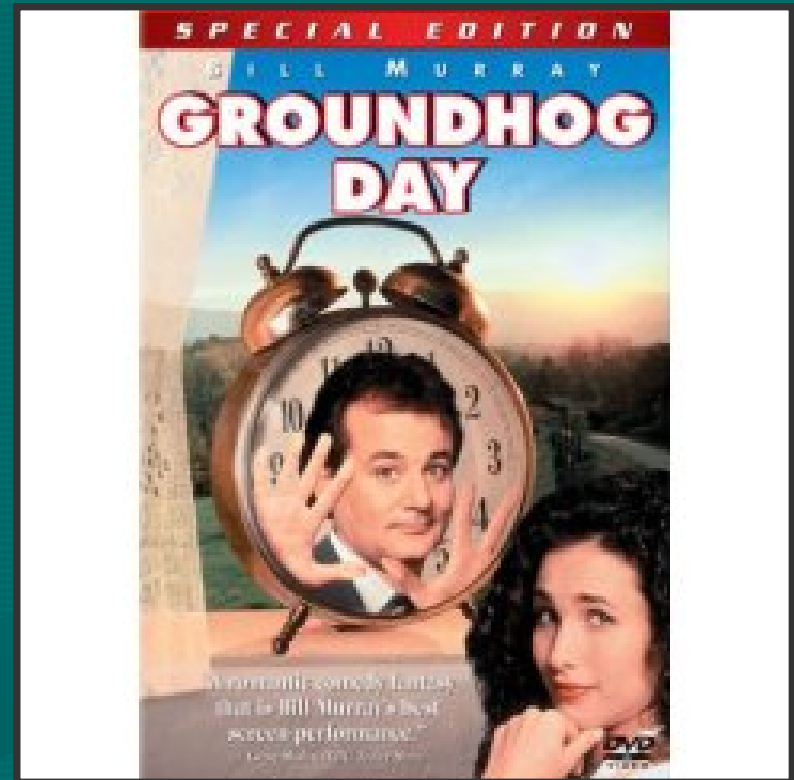
Recent Results

- ISO9001:2000 – Certified since February 2004
- Building Consolidation – ROI in 1.5 yrs
- Freight expenses reduced \$216K in 2007
- Case Pick Productivity up 43.4% in 2007
- Absolute Adjustments – Reduced by 96% vs. 2005
- Inventory Accuracy – 99.98%
- ISO re-certification audit – Zero non-conformances
- Corporate audits – Zero minor/major findings
- Oct 2007 change – Eliminated 4,000 pallet moves monthly

Our Journey

Our Needs:

- Customer Focus
- Employee Engagement
- Ownership
- Resources
- Responsibility
- Accountability



Our Journey



Management Review

- System of reviewing inputs with required outputs:
 - Quality planning
 - Operational results
 - Customer feedback
 - Resource vs. the future
 - CI and PA activity
 - Quality Council and CAs



Our Vision and Policy

Vision:

Be the model of excellence for distribution centers within the pharmaceutical industry

Quality Policy:

Our engaged workforce delivers world-class service to our customers in the most efficient and effective manner, while maintaining compliance with regulatory requirements and company conformance standards

- Quality: “We create quality through planning and execution”
- Efficiency: “We continually look for ways to improve”
- Service: “We listen to our customers and respond to their needs”
- People: “We know what to do and are empowered to do so”

Our Pledge



- Committing to the highest standards of quality.
- Providing the highest quality products and services to meet the needs and requirements of internal and external customers

Quality

- Taking ownership and being dependable.
- Meeting deadlines.

Integrity

- Respecting others' esteem when addressing problems.
- Taking responsibility for my own development.

*Respect for
People*

- Working hard, demonstrating energy, and approaching challenges with vigor.
- Demonstrating a willingness to shift priorities for changes in business needs.
- Taking initiative to make things better.

Leadership

- Being helpful to the rest of the RDC Team.
- Seeking to understand the interests of others even when there is disagreement.

Collaboration

Our Journey

Our Needs:


- Customer Focus → Quality Policy
- Employee Engagement → Quality Pledge
- Ownership → Process Ownership
- Resources → Org. Structure
- Responsibility → Management Review
- Accountability → JDs and Performance Management

Our Journey

Lessons Learned:

- Better partially right...that entirely wrong
- Quality is everyone's responsibility
- Knowing the customer changes your perspective
- Process owners are key
- Make change easier
- CI is a constant
- Management commitment is a must

Wyeth



"What we do as a DC family improves the quality of life for all families today, tomorrow and forever."

Richmond Distribution Center

Wrap-up

- Questions

