BLOCK & TACKLE
Leveraging Process for Results

APQC’S 2012 Process Conference & Training
October 22-26, 2012
The Houstonian Hotel, Club & Spa - Houston, Texas
Our Mission

To improve the health of our Nation’s Veterans by providing creative **pharmaceutical solutions** to global **clinical research**.
Our Business

Pharmaceutical expertise:

• Study design/protocol
• Investigational drugs
• Packaging and distributing to study sites
• Patient safety
• Regulatory compliance—FDA
Landmark Clinical Trials

An Aspirin a Day...

Shingles vaccine

One of CSP’s earlier studies determined that aspirin was effective in preventing heart attacks.

The Shingles Prevention trial led to the FDA approval of a vaccine for those over 65 to prevent shingles, a painful, blistering skin rash.

CSP has participated in many trials related to the treatment of diabetes. One of the most recent found that lowering glucose in an effort to prevent cardiovascular events was not effective.

Diabetes

Robotics Help Stroke Victims

CSP also participates in device trials. A recent robotics trial proved that the use of robotics can help stroke victims have an improved quality of life.

Parkinson’s Research

Deep Brain Stimulators improve motor control for Parkinson’s patients, and proved more effective than the best medical therapy.
VA CSP Clinical Research Pharmacy Coordinating Center

- FDA Registered Facility
- ISO 9001:2008 and 15378
- Commitment to Quality
Baldrige Performance Excellence Criteria Framework
Baldrige Framework + Seven Tenants = Synergy

Baldrige Categories

1 – Leadership
2 – Strategic Planning
3 – Customer Focus
4 – Measurement, Analysis & Knowledge Mgmt.
5 – Workforce Focus
7 – Results
Both Baldrige PE Framework & APQC Seven Pillars Provide:

- Systems Perspective
  - Leadership focus on strategy, customers, stakeholders.
  - Central relationship between leadership and results.
  - Define processes and drive performance results.
  - Measurement, analysis, and knowledge management support performance improvement.
Key Decisions & Milestones

Baldrige Journey
- VA Carey Trophy
- National Award
- State Award
- Sharing Days

ISO Journey
- ISO 9001
- ISO 15378
- ISO Days

Regulatory Focus
- 1978
- ‘93 ‘96
- ‘03 ‘04 ‘09
- 2011-12
PCC Measures & Initiatives: A Five-Year Plan

2011-2012 focus
- Committee ownership of measures
- Further develop Vital Signs
- Further develop benchmarks
- Build consistency and competency in data analysis
- Continued HI development: leading & lagging indicators, thresholds and action levels defined.
- New: cycle time, FTE/study, sites/FTE & Green Team
- Ongoing: Dashboard V2
- Shared Data
- Use of ERP financial data in measures

2010 focus
- Committee measures
- CMC use of Vital Signs
- New measures: cycle time
- Dashboard Improved
- Shared Data for Measures

*January 2009
Strategic Planning Conference
Measures Day

*August 2009
Measures integration conference

*Revised Dashboard

To infinity and beyond!

2009
2010
*January 2010
Strategic Planning Conf.
Measures Day Plus

2011
2012

2013

2014

Sharpened focus:
Use of measures in making business decisions & driving performance excellence!
Systems Integration – Dashboard
Measures Framework

Center Measures
- Health Indicators (HIs)
  - Reviewed by CEC / Dashboard

Functional Group Measures
- Vital Signs
  - Align to HIs / Reviewed by Sections

Study Team Matrix
- Study Team Measures
  - Align to HIs / Rev. by Study Teams

Individual Members Measures
- Individual Measures
  - Align to HIs/Reviewed by Individual and Supervisor

Functional Gp Measures
- Defined as: High level Center measure, used to make Center decisions
  - Example: Mean internal customer satisfaction

- Defined as: Measure with more detail, used to run the Section or Study
  - Examples: Internal customer satisfaction by section, external customer satisfaction by study, service performance

- Defined as: Measure that each individual can impact
  - Examples: Workforce learning and growth: mean training hours
Center Balanced Scorecard Health Indicators

CUSTOMERS: Develop & maintain mutually beneficial customer relationships

Quarterly Results
About Measures
Measures List
Send Feedback

PROCESSES: Increase capability & productivity

Adequate Clinical Supplies at Sites
Internal Customer Satisfaction
Leadership Effectiveness

• I have confidence that management is leading this organization in the right direction.
• The leadership of my organization always treats me with respect.
• The leadership of my organization makes me feel enthusiastic about the future.
• I am confident in my organization's future.
Leadership: Effectiveness Index

Mean Score of C05-C08 Survey Statements
Scale of 1 to 5

2006  2007  2008  2010  2011

Our Center
Gallup 75th
All CSP
Systems Integration
Key Interlocking Committees
CAPA systems must focus on processes, not on people.

Punitive systems MUST Not Be Used

"But you have to admit management's commitment to quality is working."
Metrics that Matter

ENGAGED EMPLOYEES

Employee Retention  + 44%
Safety  + 50%
Productivity  + 50%
Adherence to Budget  + 33%
Customer Metrics  + 56%

in probability of success when engagement is
Engagement is a Process

Pre-Hire
- Performance Based Interviews
- Culture up Front
- Myers-Briggs

New Employees
- Employee Orientation
- Code of the West
- Strengths-Finder

Annually
- Performance Appraisals
- Ethics Expectations
- Q12
- Team Participation

SAW, Environmental Scans, SPEED, Teams, Community Outreach
Pre-Hire

Performance-Based Interviewing

Assess Fit with Values
- Leadership
- Customer Service
- Safety
- Teamwork
- Continuous Learning

Define Culture
Styles: Myers-Briggs
On-Boarding

StrengthFinder©
• Development tool to help employees discover their Top 5 “signature themes”
• Consistent, near-perfect performance in a task = Strength
Strengths-Based Approach

• Pharmaceutical Expertise
• Hallmark of quality
• Organizational Strengths Are:
  ✦ Achiever
  ✦ Learner
  ✦ Responsibility
  ✦ Deliberative
  ✦ Relator
Daily Opportunities

Booth Duty

Hosting Visitors
Celebrations
Workforce Engagement

Grand Mean Score
Scale of 1 to 5

▲ Good

Center

- Overall 75th Percentile
- Sector 75th Percentile
Regular recognition is a key

“In the last seven days, I have received recognition or praise for doing good work” – Q04

EARS –
Employee Award & Recognition System
Employee recognition

Mean scores of QO4 survey statement
Scale of 1 to 5

EARS implemented
Innovation Results

- I have enough time to innovate and discuss creative ideas with my colleagues.
- My current job brings out my most creative ideas.
- I feed off of the creativity of my colleagues.
- My organization encourages new ideas that defy conventional wisdom.
- I have a friend at work with whom I share new ideas
Innovation Index

Mean Score of Innovation-Related Survey Statements

Scale of 1 to 5

<table>
<thead>
<tr>
<th>Year</th>
<th>Our Center</th>
<th>All CSP</th>
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The chart shows the mean score of innovation-related survey statements for the years 2006 to 2010, with a scale of 1 to 5. The scores for 'Our Center' and 'All CSP' are compared over these years.
Rational Loyalty

- **Passion**: View us as irreplaceable and an integral part of their lives.
- **Pride**: Feels good about us and about how use reflects on them.
- **Integrity**: Treats us fairly & resolves complaints or issues.
- **Confidence**: Customers believe we can consistently be trusted to deliver on our promises.

Overall Satisfaction.
Continue to use services.
Likelihood to Recommend.
Drivers

- PCC Staff always provides accurate & timely information about drug information & handling procedure changes.
- PCC Staff always provides the highest quality of communication to study team members.
- The information received from PCC is always timely.
- PCC Staff always provides the right amount of communication to study team members.
- The information received from PCC is always accurate.
- Drug/Device Accountability Forms are well-designed & easy to complete.
- PCC Staff is an exceptional source of pharmaceutical expertise at every phase in a study.
Overall Satisfaction: 2003 - 2009

Top Two Box Overall Customer Satisfaction
% of 4 & 5 Responses

▲ Good

projection
CE11 Customer Engagement

VA PCC exceeds Gallup 90th Percentile
Actively Engaged = 53%

2010

2011

Actively Engaged
Fully Engaged
Engaged
Not Engaged
Strategy based on Results

Increase repeat/referral business by identifying key factors to make us attractive to customers.

Increase Productivity through innovation and increased capabilities
Results: Service-Value Chain

Holistic Approach

Leadership

Solid Strategy

Great Employees

Constantly Improving Processes

Engaged Customers

Information, Knowledge, Learning

Great Results
Where Do We Go From Here?

– Future Plans

• Measures Integration Team (MIT) develop measures designed to track strategy. (WIGS….wildly important goals)
• Dashboards for all major committees.
• Continue selecting appropriate Measures by aligning to key committees.
• Seek better benchmarks and comparative measures. What is World-Class?
Questions and Discussion!