Innovation

What a neat idea!

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Presentation contents

- Thoughts on innovation
- Key aspects of innovation
- Innovation and culture
- Drivers and challenges in innovation
- Case studies for innovation in Pharma
- Final thoughts

"Innovate, Change, Adjust???
-What are you talking about, we're doing good!!!"

What is it?

- Innovation is an insight that inspires change that creates value
- Not simply an idea, an invention, an improvement, or creativity
- A process, not simply an end-result
- Requires preparation, insight, change, opportunity recognition
- How do we get it?
  - Be open-minded
  - Encourage diversity
  - Learn to trust
  - Encourage experimentation
  - Encourage language of innovation
  - Forgive mistakes

The most important thing about Innovation I can share with you

"Innovation should not be an end on to itself but have a focused objective directed to bring a tangible benefit that can be recognized and quantitated"

Key characteristics of innovators

- They are intense observers
- Ask a lot of questions (i.e., inquisitive)
- Are comfortable thinking differently
  - ✓ power of association to find surprising connections
- Networkers
  - ✓ link ideas in own are of knowledge with those playing in a different box
- Like to experiment

Well-known Breakthroughs

The Microwave - Percy L. Spencer

From *Ice to the Eskimos* by Jon Spoelstra

The "So What" on Innovation

The following things about innovation are clear….

- *Our ability to innovate is ABSOLUTELY VITAL to sustained success (and to the lives of the patients whom we touch)*
- *Executive's success should be measured against their ability to be innovative and to drive innovation in their organizations*
- *We should ask our employees to measure how we are doing to foster innovation*
- *Innovation management should be built into our Leadership Competency Models, and incorporate this competency in Leadership curricula*

Critical aspects for innovation success

- Reality checks with the people impacted by the change at intervals throughout implementation
- Test ideas in a sandbox environment prior to global implementation
- Emphasis on the process of implementation, not on the timeline for implementation
- Be prepared to adjust along the way
- Manage expectations
- Ensure effective communication plans, not just about changes, but also about the rationale

X-Rays - Wilhelm Roentgen

What does it look like?

The "SOKKET" Ball

Innovation in a regulated environment

Innovation is a differentiating factor

Ample environment for potential to innovate with high business-impact results

Innovation offers a great opportunity for pharmaceutical professionals to lead by driving improvement in the quality of business, including profitability

Drivers For Innovation in Pharma

Increasing Complexity

- Need for increased responsiveness and flexibility
- Need to respond quickly to investigations both internally and externally

Manage Risk

- Need to adjust quickly to the unanticipated
- Impact of negative regulatory action on contract manufacturers
- Redundancies needed for analytical methods or reagents
- Manage unanticipated spikes in volume

Need for Flexibility

- Support paradigm must adjust with changes in manufacturing strategies
- Adjust to opportunities and growth in product pipeline
- Need for seamless level-loading of resources across the spectrum of capabilities and strengths

Global Requirements

- Expectations and requirements change
- Requirement to manage differing specifications across different countries
- Quality Units geographical locations need to operate as a integrated unit
- Changing regulatory expectations

Innovation and efficiency can live comfortably alongside a direction toward Sustainable Compliance

"…thinkers who exploit opposing ideas to construct a new solution enjoy a built-in advantage over thinkers who can consider only one model at a time.

"…the most successful thinkers 'embrace the mess' in that they allow complexity to exist, at least as they search for solutions, because complexity is the most reliable source of creative opportunities."

- from Roger Martin's research and book "The Opposable Mind" (Brown, Change by Design, 2009, p. 85)

"I'll be happy to give you innovative thinking. What are the guidelines?"

The Challenge

- What is less clear is HOW to describe what it is to ***innovate…what does innovation really mean to us?***
- If, indeed, we have a definition of what it means to innovate, it is often ***not a shared definition***
- ***How to most effectively and efficiently build the capacity to innovate*** (i.e., what are ***the specific skills that can be taught or coached)?***
- ***How to*** systematically ***build it into our culture and then to reinforce it?***

Play-Doh : Kutol Products

Questions to consider on culture

- ***Does our organization have a shared definition and understanding of what it means to innovate (beyond thinking creatively)?***
- ***Can we identify and have general agreement on where the innovation challenges reside in our culture?***
- ***How do we teach the skill / competency of innovation? How is it reinforced?***
- ***What other fields might be able to yield fresh "lenses" for those in leadership as they coach and reinforce innovation in their respective organizational cultures?***

Begin with establishing a framework for transformational opportunities

- Advances in technology, logistics, and process excellence opens the possibility for a strategic direction that results in improved compliance and unprecedented efficiencies, while driving down costs
- Analytical Technology is allowing a greater degree of automation, the possibility for real-time testing, and parametric release
- Advances in transportation infrastructure allows for overnight shipment of samples at controlled conditions to virtually anywhere in the globe and eliminates restrictions based on site location
- Modernization of the Laboratory Information System will permit seamless data exchange globally and full instrument integration
- Globalization trends require an integrated matrix model that removes dependency from site-specific support in lieu of a network of internal and external laboratories that can respond quickly to changes in demand and expectations

Innovation should be intentional

Optimal leveraging of data and information

Fostering difference in perspectives

Efficient change management process

Enablers for Innovation

Defined process for innovation with governance

Empowerment

Velcro - George de Mestral

CASE STUDIES

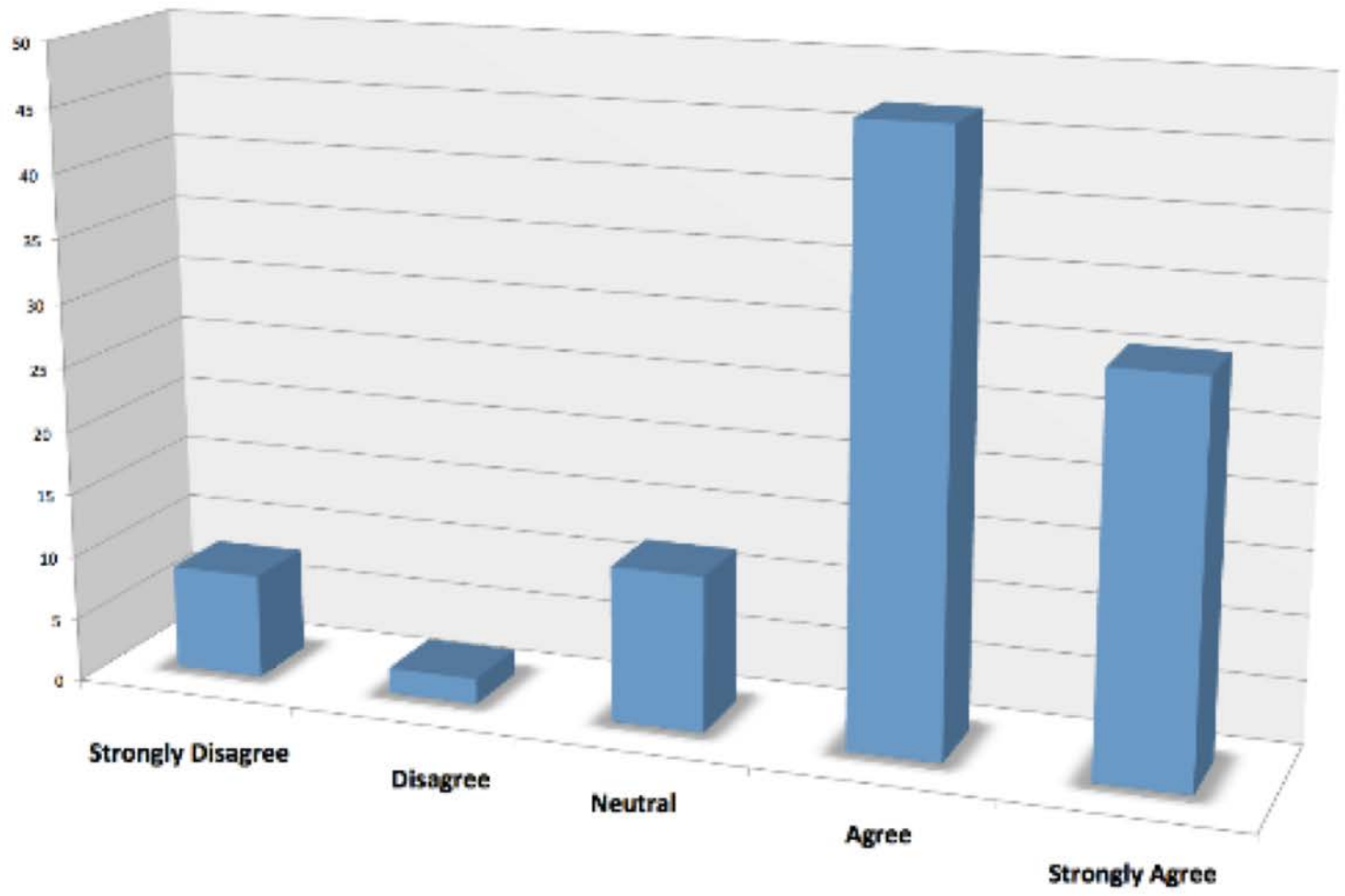
New ideas IN TRAINING SYSTEMS

Approaches to Learning Management

eLearning Technologies

- Webinar
- Video
- Interactive Courseware
- Simulation
- Gaming
- New Technologies

*Completing this e-learning tool makes me feel more **CONFIDENT** about performing a similar task in a real laboratory.*



Webinars

http://www.ncbionetwork.org/bioforum-events

Multimedia Approaches

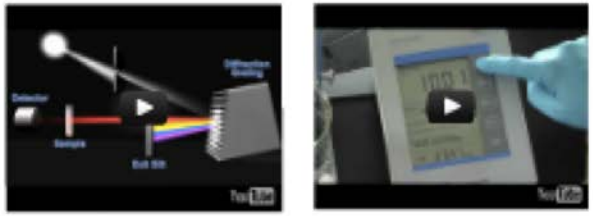
Science Concepts

Video

YouTube BioNetwork

http://www.youtube.com/bionetwork

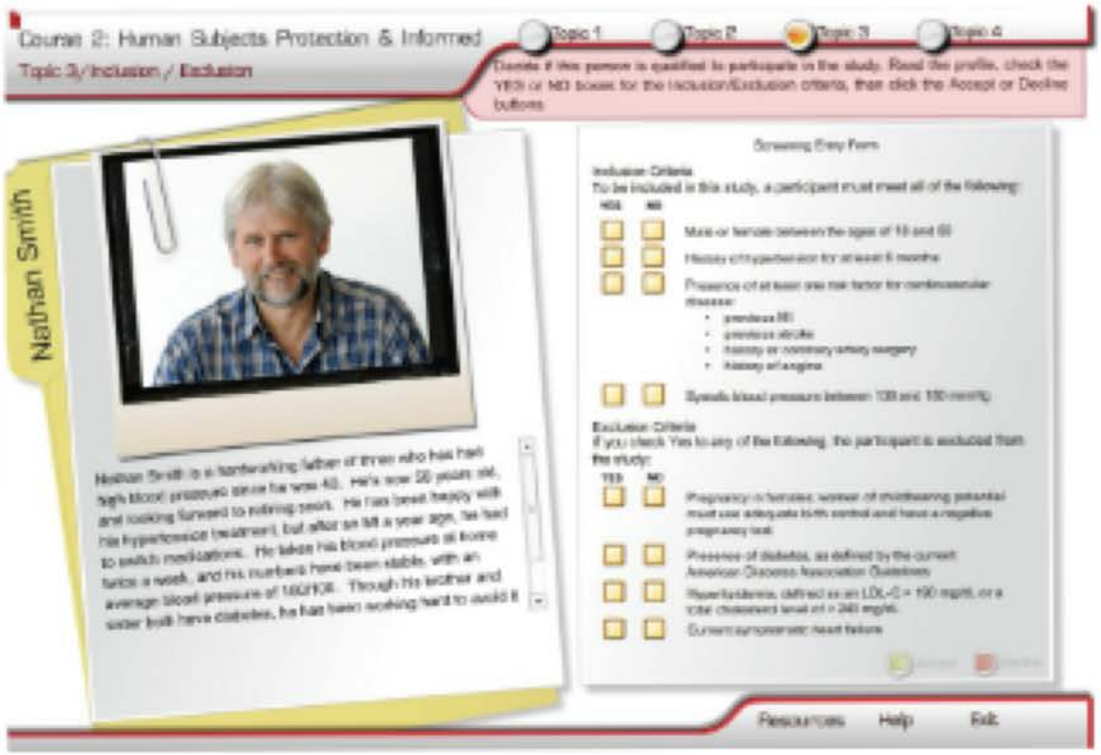
Hands-On Demos



Lab Procedures

Animations

Interactive Courseware



Foundations of Clinical Research

Spectrophotometer

Lab Safety

Lab Safety

Lab Safety

COMMUNICATOR
AWARDS
Interactive
DISTINCTION

ENVIRONMENTAL MONITORING
PERSONNEL MONITORING
Click the three sources of personnel contamination.
We've been having problems with cleanroom contamination. Can you help us identify the sources of contamination?
TIP: Check the reference on cleanroom behavior.
EXPERIENCE
CHECK ANSWERS
STATION ONE
100
STATION SCORE
1200
SCORE TO BEAT
1500
MAXIMUM SCORE
PROGRESS
© 2010 NCCCS BioNetwork
Help us improve this exercise. Take the 7 Question Survey.
SHARE

Games

http://www.futurefactorygame.com

Future Technologies

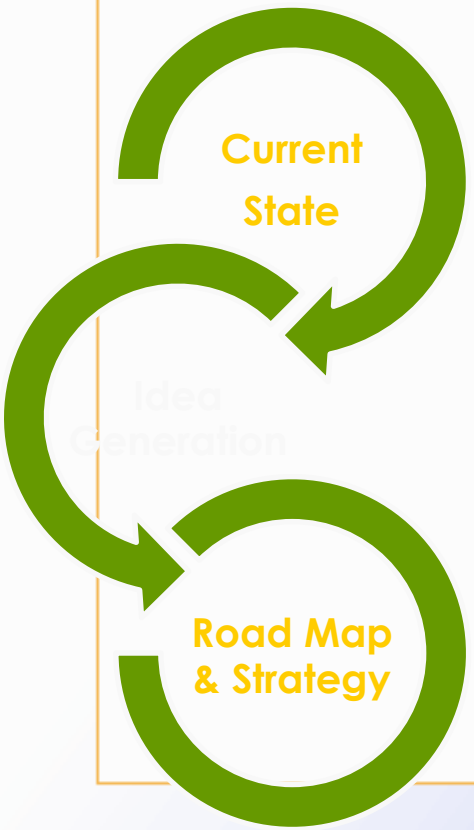
Motion Tracking & Voice Recognition

Flow Hood Trainer

ANALYTICAL INNOVATION

Direction

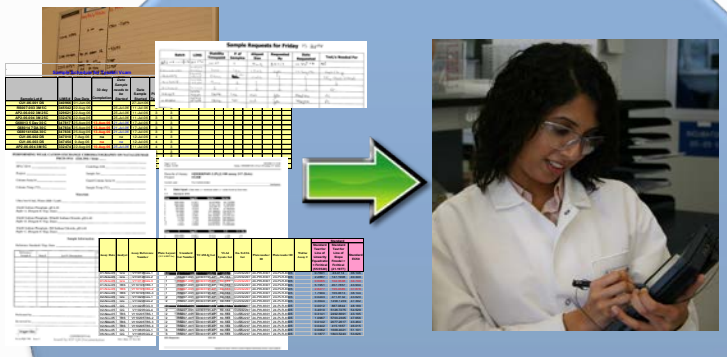
What are the key steps and requirements to enable QC to be successful and meet near and long-term challenges.



Driving compliance and efficiency through Innovation & Technology

Data Management Options

- Wireless
- Paperless QC testing, calculations and CoA
- Fundamental increase in efficiency
- Improved Compliance



Analytical Solutions

- Immediate on-floor test results for faster decisions
- Improved analytical method efficiency and accuracy

Handheld LAL

QC Systems Innovation

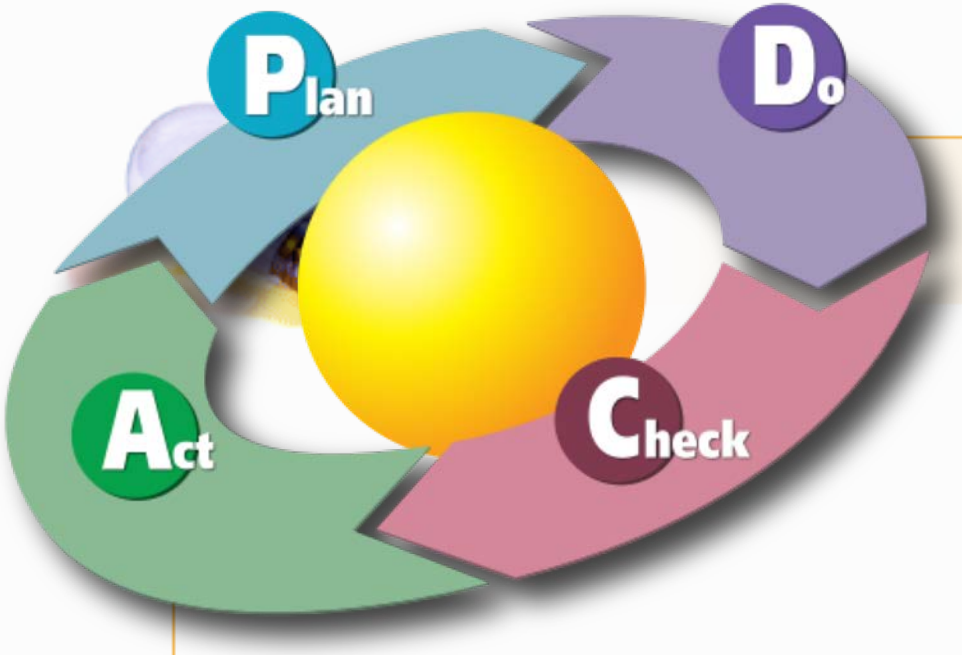
discoverant

ISOtrain

TRACKWISE

The Ultimate Quality Management Software

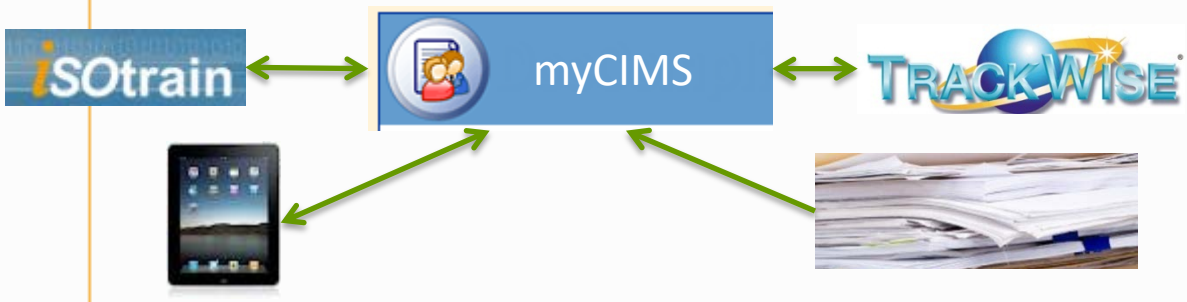
- Driving value while decreasing bureaucracy
- Paperless change control, deviations and training processes
- Enhanced compliance
- Increased responsiveness through real-time product quality trending



QUALITY SYSTEMS INNOVATION

Access To Controlled Documents

Implement an intuitive and accessible interface to Controlled Documents; replace and streamline review with an interactive and collaborative process



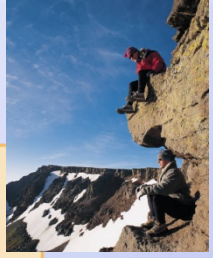
Measures:

- Repurpose personnel currently keeping up paper copies of docs
- Reduce time required to review and approve documents
- Make paper controlled document available online
- Automatically synchronize platforms

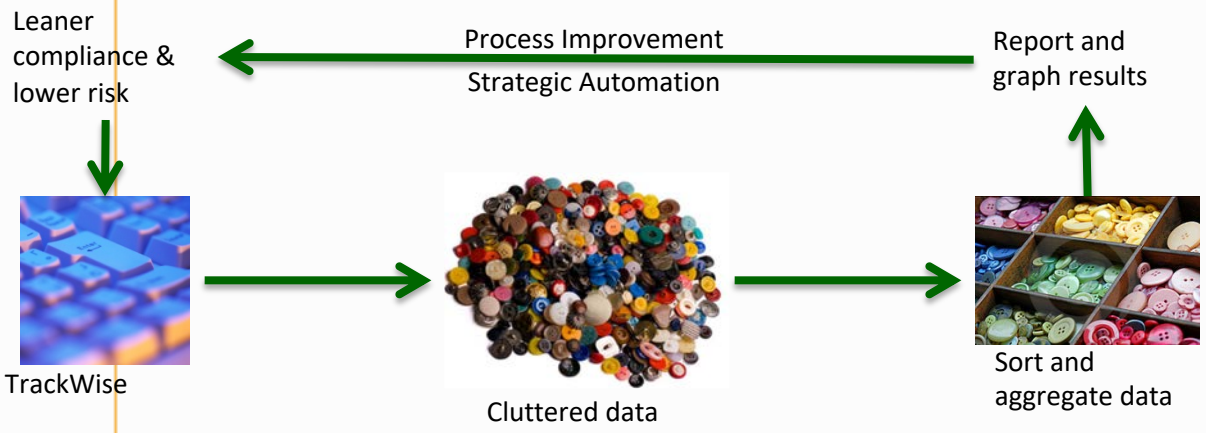
Approach:

- Create an intuitive interface for electronic documents
- Make controlled documents available online in areas like manufacturing through the use of mobile devices
- Import scanned vital records
- Replace serial document review with a collaborative parallel process

“Lean” Compliance



Benefit Statement: Provide the ability to analyze Quality Data for trends, patterns and also generate regulatory reports like APRs and overall Quality metrics more efficiently



Measures:

- Reduction in number and frequency of errors and deviations
- Number of process improvements identified
- Improved compliance with less manual and menial labor
- Reduce use of spreadsheets and databases

Approach:

- Extract data from platform systems and make it available for searching and reports.
- Use text analytics or similar technology to look for patterns, trends, and recurring issues.
- Automate reports
- Analyze output for innovative solutions, possible automation targets and business improvement opportunities

Clinical Transformation

Possibility Statement

Clinical transformation makes a new operating model possible, where an ***accelerated approach for early phase drug development is realized.***

It is a model that ***dissolves the existing functional operating boundaries*** *in the transition of clinical programs from R&D to patients.*

FROM	TO
Conventional tech transfer	*Seamless knowledge transfer*
"Line function centric" approach	*Nimble "product centric" approach*
Multiple hand-offs	*Minimal hand-offs*
Application of commercial-centric systems for all programs	*Adopting flexible/simplified systems for clinical programs*

A few take-home messages

- Smaller changes applied consistently equal sustainability
- Integrate value checks in implementation plans
- Innovation is a process of generating new ideas and not just a set of deliverables
- Innovation always involves an element of courage and a need for nurturing
- Innovation must be intentional
- Innovation can and should become an identifier for Quality organizations

Slinky - Richard James