



Global Expertise  
Trusted Standards  
Improved Health

# USP Research & Innovation Program

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United States Pharmacopeial Convention (USP)

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# USP Programs and Products Impact Millions Worldwide Each Year and Every One of Them Has a Stake in USP



Our standards help ensure that over **300MM<sup>1</sup>** people worldwide have access to high quality prescriptions medications – with our reach extending well beyond “Rx,” through our food, dietary supplement, herbal and OTC standards:

- Over **5,900 monographs** published, covering pharmaceuticals, food ingredients, herbal medicines and dietary supplements
- **More than 3,500 reference standards** available in the catalog
- Standards **used in 140+ countries** and legally recognized in 39+



Through our PQM, TAP and CePAT programs, we have **increased access to quality medicines in 35+ countries**



**Our education programs train over 6,000 professionals WW per year**



**We have continued to innovate to support our mission**, examples include:

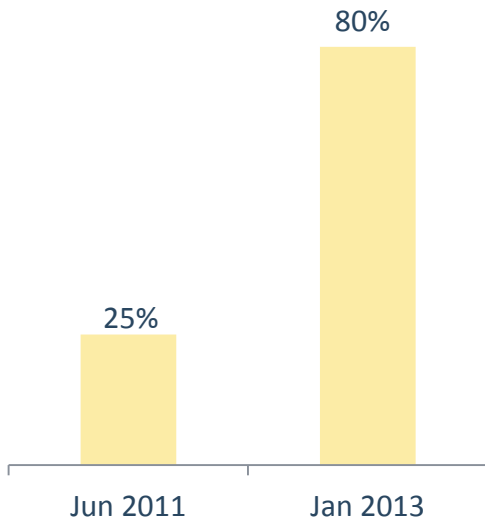
- Launch of **Compounding Compendium – A Guide for the Compounding Practitioner**
- **Release of the first monograph for a patient-individualized cell therapy**
- Creation of the **Food Fraud Database**

1. Assumptions: totaled population of countries that legally recognize USP’s standards, reduced by the percent that takes prescription drugs, the generics penetration rate, and USP’s coverage rate of generic drugs within the top 200 drugs sold. For non-U.S. countries, affected population was further adjusted to reflect USP’s reduced penetration

Category	Key Trend	USP Implications
Continued growth in generics market	Generics (Gx) market to grow at ~7% annually through 2023, driven by 10% growth in BRIC countries and key patent expirations of blockbusters	Positive growth outlook for USPs chemical standards business, which has historically outpaced the generics market and is expected to continue to do so
Robust biosimilar growth	Biosimilars market to grow from \$5 to \$24 BN over next 5 years, driven by unit growth coupled with premium pricing	Biosimilars an attractive opportunity, provided USP adjusts strengthens alignment with regulatory/ industry, adjusts pricing model to support sustainability
Supply chain globalization	Over 2/3 of pharmaceuticals sold in the US are manufactured abroad, with 94% of API manufacturers outside the US; FDA focusing increasing regulatory scrutiny abroad	USPs role as an advocate of standards adoption globally remains critical, with opportunity to partner with regulators and industry in U.S. and abroad to support quality continuing to grow
Manufacturing process innovation	Strong regulatory support and increasing cost pressures encouraging Gx companies to innovate in manufacturing	Further review critical to understand implications of manufacturing process changes on USP standards utilization and to uncover new related opportunities
Digitization/ health informatics	Technology transforming areas like Electronic Health Records, where 3 of 5 implemented services are related to drugs and drug safety.	Opportunity to translate current USP offerings to new technologies , evaluate the need for new standards related to emerging informatics areas
Consumerism	Patients taking more holistic role in health management, with 70%+ proactively seeking information on medications, chronic conditions	Opportunity to leverage grassroots consumer voice to drive pull-through demand in high consumer interest areas (e.g., dietary supplements)

## QbD appears to be gaining traction, though extent of “true” adoption remains uncertain

% of generic companies claiming to use QbD when submitting to FDA



As of January 2013, FDA expects use of QbD for all generics manufactures

## As a result, industry is focused on identifying QbD-related opportunities that drive value

**Continuous Manufacturing (CM)**- CM can enable capacity utilization of 80+% (versus 35% for batch process), but traceability for CM as raw materials change is a challenge

**Process Analytical Technologies (PAT)**- Advances in PAT can lead manufacturers to examine new technologies and production that further enable efficiencies, but manufacturers are challenged with proactively increasing PAT as part of process control, versus retroactively fixing issues

**Replacing Manually-Intensive Processes with Automation** – Use of automation can improve efficiency. The shift to Biologics (with different manufacturing needs) is also a driver. Manufacturers have been slow to modernize due to initial investment costs.

### USP must study and monitor manufacturing innovations to understand their impact, maintain relevance

- QbD shifts the focus from post-production testing to continual improvements. How does this impact how much our products are used? How might this impact FDA regulatory requirements?
- FDA is continuing to release guidance in support of QbD. How can USP best partner with the FDA on this?
- Larger players are better equipped to innovate with QbD. How does this impact our own customer landscape?



# INCREASING OUR IMPACT GLOBALLY

AND REMAINING SELF-SUSTAINING  
OVER THE NEXT FIVE YEARS

## Insight to Action 2020 Ambitions

- 1 Continuously modernize and strengthen USP-NF and eliminate backlog of standards requiring modernization.
- 2 Add an overall annual 6.5% operating margin, while diversifying our portfolio with surplus-generating programs.
- 3 Tailor programs to ensure impact and responsiveness to the unique needs of their stakeholders.
- 4 Define, measure, and publicly report our global public health impact.
- 5 Be a leading advocate for the use of quality standards throughout the world.
- 6 Identify, recruit, develop, and retain the next generation of volunteers.
- 7 Develop, engage, and empower our staff while promoting a culture of high performance.



## MISSION

To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and food.

## VISION

USP envisions a world in which all have access to high-quality, safe, and beneficial medicines and foods.

# Circles back to Stakeholders: The Convention Resolutions Support this New Strategy

## 2015 – 2020 Resolutions:

1. Collaboration with the U.S. Food and Drug Administration
2. USP–NF Monograph Modernization
3. Globally Harmonized Standards
4. USP’s Quality Systems
5. **Research and Innovation Within USP**
6. Standards for Biological Medicines
7. Quality Standards for Compounded Medicines
8. Healthcare Quality Standards
9. Quality Standards for Dietary Ingredients and Dietary Supplements
10. Food Quality and Integrity
11. USP’s Global Health Impact

**InSight2020**  
Define the path • Shape the future

**Action2020**  
Shape the Future • Maximize Our Impact



## RESOLUTION 5—RESEARCH AND INNOVATION WITHIN USP

USP will cultivate a collaborative, robust research and innovation culture that will allow USP to continuously assess new technologies and capabilities relevant to its standards-setting activities.

### **Vision**

To drive long term growth of USP standard setting activities and related programs and services, responding to the needs of USP's stakeholders and customers.



## USP Research & Innovation areas

- ▶ **Exploring Standards of the Future**
  - Digital standards
  - Quality by Design
  - New manufacturing techs (Continuous manufacturing, 3D printing)
  - Standard development for other emerging technologies
- ▶ **Enabling new technology for standard development**
  - qNMR
  - DNA technology
  - Other novel analytical technologies
- ▶ **Building an Innovation infrastructure to leverage the power of frontline workers**
  - Idea system
  - Innovation incubator

# 1. Strategic Exploration for Quality/ Future Standard

## □ Defining future standard

- What is a compendial standard in the future (Quality identity, strength and purity)
- Standard as a metrology tool--- the future of compendial measurements (chemical, physical, functional, and others)
- Future standard use issues (development vs testing)

## □ Standard setting in future pharmaceutical development

- Continuous Manufacturing
- Personalized Medicine
- eHealth

## ❑ USP internal taskforce

- ❑ An internal taskforce will be assembled to prepare and organize existing data, evaluate organizational readiness, and identify development opportunities and priorities. All Program Units will be involved in this step.

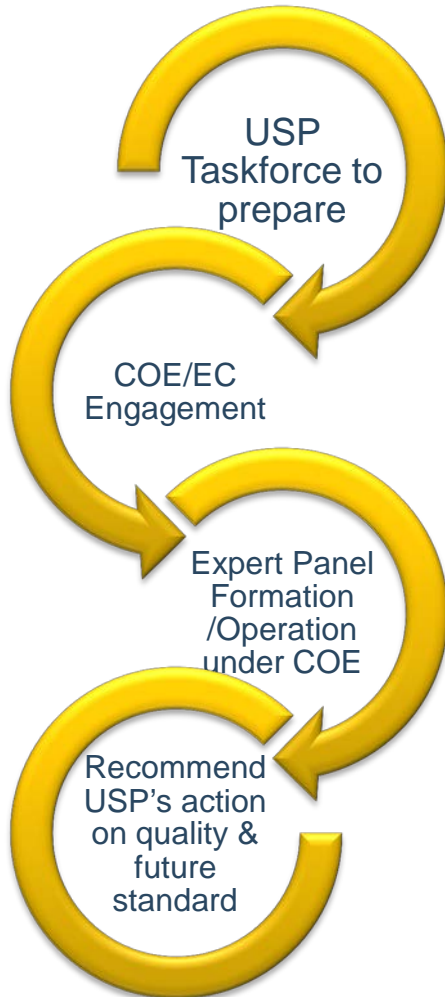
## ❑ Strategic landscape mapping & gap assessment

- ❑ Based on the internal taskforce assessment, to commission a research project in exploring specific future quality related industrial development, academic research progress, and regulatory thought process, assessing their impact on USP, and recommending corresponding actions and roadmaps for USP.

## ❑ Expert engagement in action

- ❑ CoE members, Expert Committee members, and other Expert Volunteers will be involved to help explore all aspects of the quality/future standard development focusing on pharmaceuticals initially. The ultimate goal is to build a solid foundation to justify USP's vision, roadmap, and work streams for preparation, participation, and proactive leadership role in the Future Quality development.

## Process



## Purpose

**EP will explore all aspects of the quality/future standard development focusing on pharmaceuticals initially**

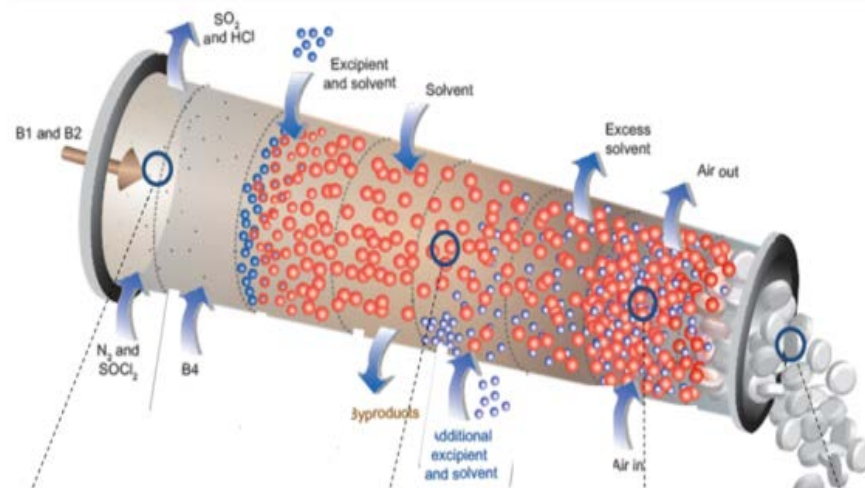
**EP will recommend USP's vision, roadmap, and work streams for preparation, participation, and proactive leadership role in the quality/future standard development.**

## Scope of Work

- 1. Explore and summarize industrial and regulatory landscape in quality development and future standard**
- 2. Identify knowledge gaps and set up directions and further assessment work scope for external strategic assessment**
- 3. In combination with the external assessment and recommendations, conclude the current and future impact on USP, and recommend USP's vision, roadmap, and work streams for preparation, participation, and proactive leadership role in the development of quality and future standard.**

# Quality Standard Development in Pharmaceutical Continuous Manufacturing

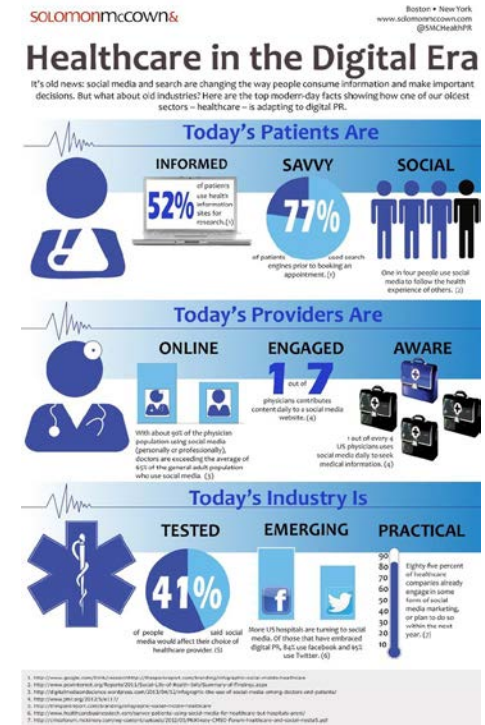
- ▶ CM represents a great opportunity for USP to establish itself as a thought leader on quality while maintaining a healthy and sustainable standards program
- ▶ USP has attained a solid initial understanding of CM space
- ▶ R&I and Chem Meds have established good stakeholder engagement
- ▶ Strong interest from FDA and industry
- ▶ USP will invest in further understanding and impact assessment
- ▶ Immediate next steps:
  - ▶ Establish USP Collaboration/Partnership opportunities with academia and industry
  - ▶ Research and training collaboration with Rutgers University
  - ▶ Form Expert Panel - stimuli articles and General Chapters





# Standards Development in Digital Healthcare: project aspirations

- **Advance the thinking** on quality standards in digital health and patient care
- **Enable USP to continue mission of improving patient care** in an increasingly patient-empowered landscape
- **Increase visibility and leadership position** through engagement with top experts across digital health
- **Continue to enable innovation** in healthcare through standards



## ***2. The state of industry technology development programs (USP “Novel Technologies Series”)***

- New testing technologies beyond and above the traditional chemical and biological testing approaches
- New identification technologies
- Highly integrated analytical technology for an E2E operation
- More

## ▶ “Novel Technology Series” Workshop (FY15-16)

- DART-MS\*<sup>1</sup> Technology
- 3D Printing Technology
- Nanotechnology
- DNA-based Method for Plant Material Identification
- Continuous Manufacturing
- LIBS\*<sup>2</sup>
- Precision Medicine
- Process development for PCM
- Process Analytical Technologies

\*1: Direct Analysis Real Time – Mass Spectroscopy (DART-MS)

\*2: Laser Induced Breakdown Spectroscopy (LIBS)

Project	Who-Project Team	What-Delivery	How-Operation
<b>1. DNA based Technologies</b>	<u>Project Lead: Macy Ma</u> Nandakumara Sarma , Ding Ming, Gabriel Giancaspro , Bei Ma	<ul style="list-style-type: none"> <li>• Develop USP roadmap for DNA based technology through a round table discussion of DNA technology for identifying botanical ingredients</li> <li>• Explore collaborative research with Dr Newmaster to establish a complementary approach of combining chemical and DNA analysis synergistically</li> </ul>	Round table for identifying botanical ingredients (May 26, 2016) Collaboration with Dr Newmaster is in discussion
<b>2. qNMR Technologies</b>	<u>Project Lead: Anton Bzhelyansky</u> Horacio Pappa, D. Ming, B. Ma	<ul style="list-style-type: none"> <li>• Pilot of Developing qNMR Method for Complex Compounds</li> <li>• Pilot of Developing qNMR Method for Full Characterization of Selected Reference Standards</li> <li>• Stimuli Article on qNMR application</li> </ul>	Round table on qNMR (October 6-7, 2016)
<b>3. Spectral Library</b>	<u>Project Lead: Horacio Pappa</u>	<ul style="list-style-type: none"> <li>• Stimuli Article &amp; peer reviewed publications on Spectral Library</li> <li>• General Informational Chapter on Spectral Library</li> </ul>	Complete the <197> Revision Establish Expert Panel

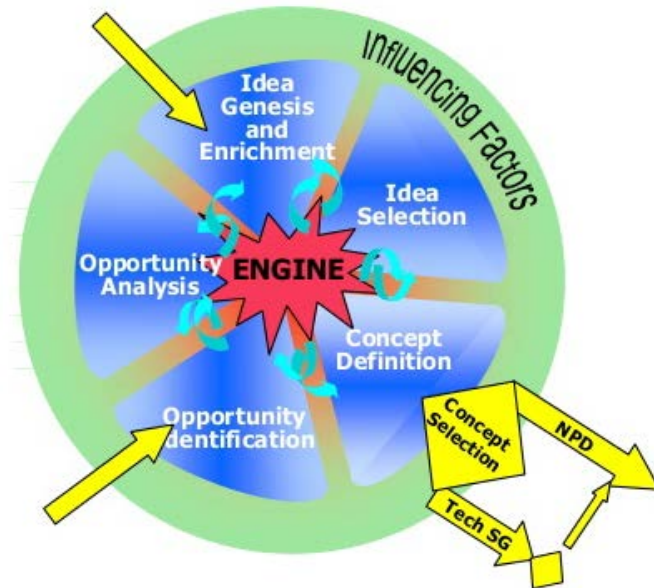
## 3. Innovation Infrastructure

### □ USP Idea System

- Developing a formal corporate process to manage the lifecycle of innovative ideas across USP
- Completing a pilot program and make a recommendation to optimize organizational rollout

### □ USP Innovation Incubator

- Facilitating various innovative idea initiation, evaluation, communication, and implementation
- Promoting creative and measured destruction/innovation cycle by fellow/special grant systems
- Providing training in the process of innovation at USP
- Operation of organizational innovation agenda to meet the expectation of stakeholders/ET/COE/Board.







Idea System is a *Systematic Approach* to  
**Capture and Implement Front-line Ideas and Solutions,**  
resulting in  
**Improved Performance** at USP

# The Idea-Driven Organization: Introducing an Idea System at USP

Please join Research and Innovation (R&I) in welcoming Dr. Alan G. Robinson and learning about his work studying “idea systems” in high-performing organizations.

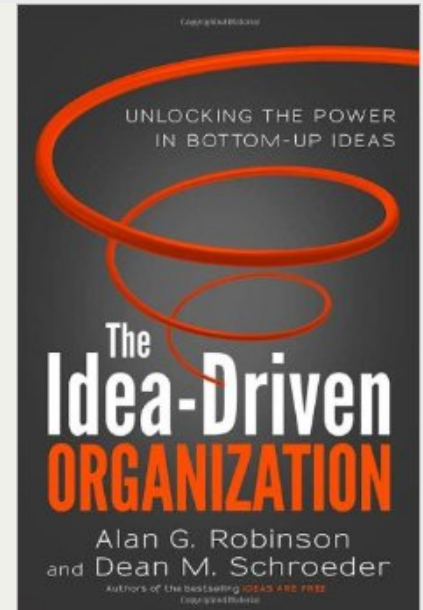
Dr. Robinson is advising R&I in the development of a USP idea system to engage front-line workers in USP’s improvement and innovation efforts. In this session, you will learn:

1. Why front-line employees engage in idea system activities?
2. How mid-level managers facilitate front-line involvement?
3. Why high-level executives pay attention to the performance of their idea systems?

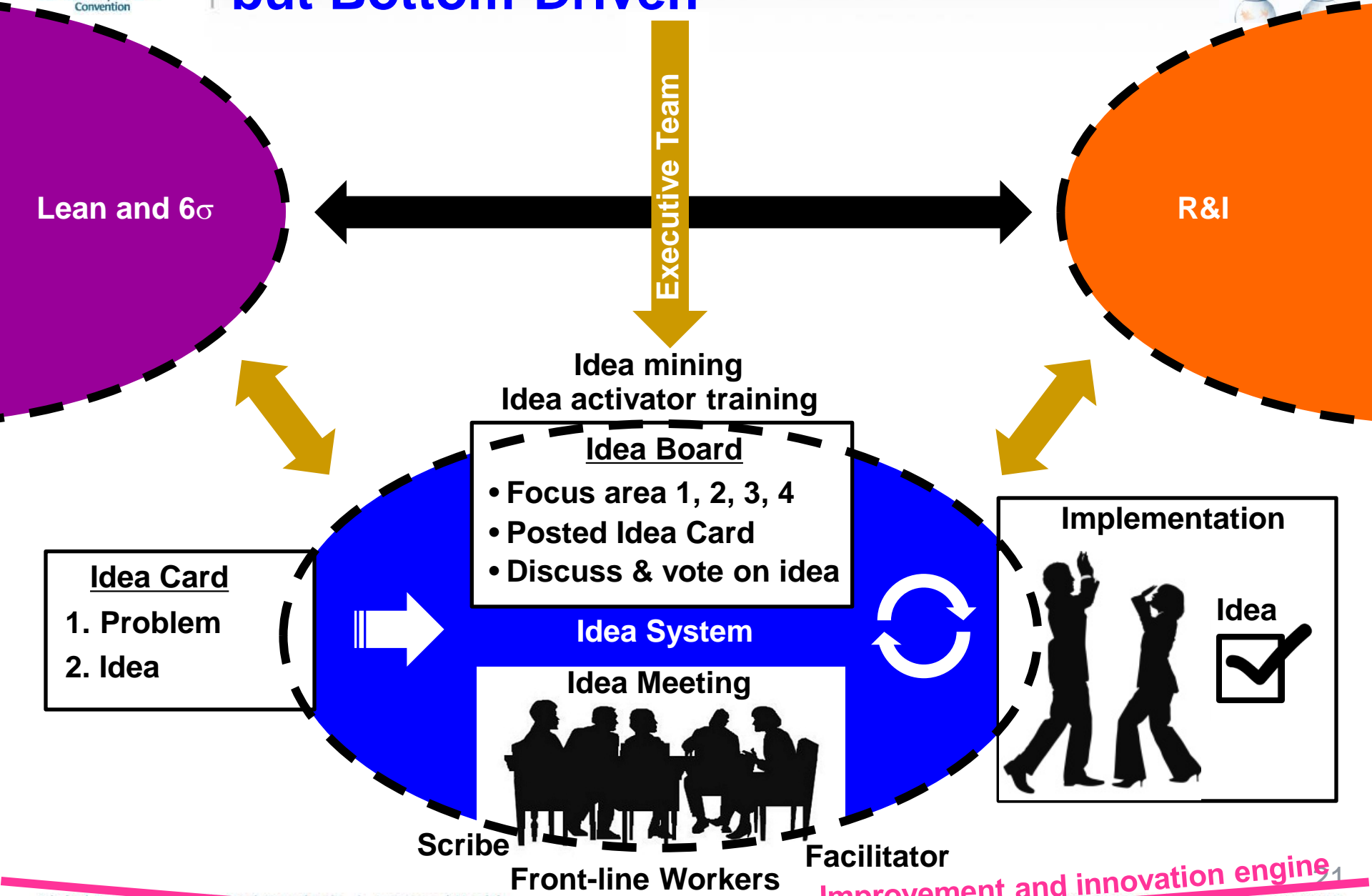
Dr. Robinson is an award winning author and co-author of six books, including his most recent collaborative work, *The Idea-Driven Organization*. Dr. Robinson has worked with more than 200 organizations around the world to improve their creative output.



**“Front-line employees see a lot of problems and opportunities that their managers don’t. Their ideas represent some 80 percent of an organization’s improvement potential.”**

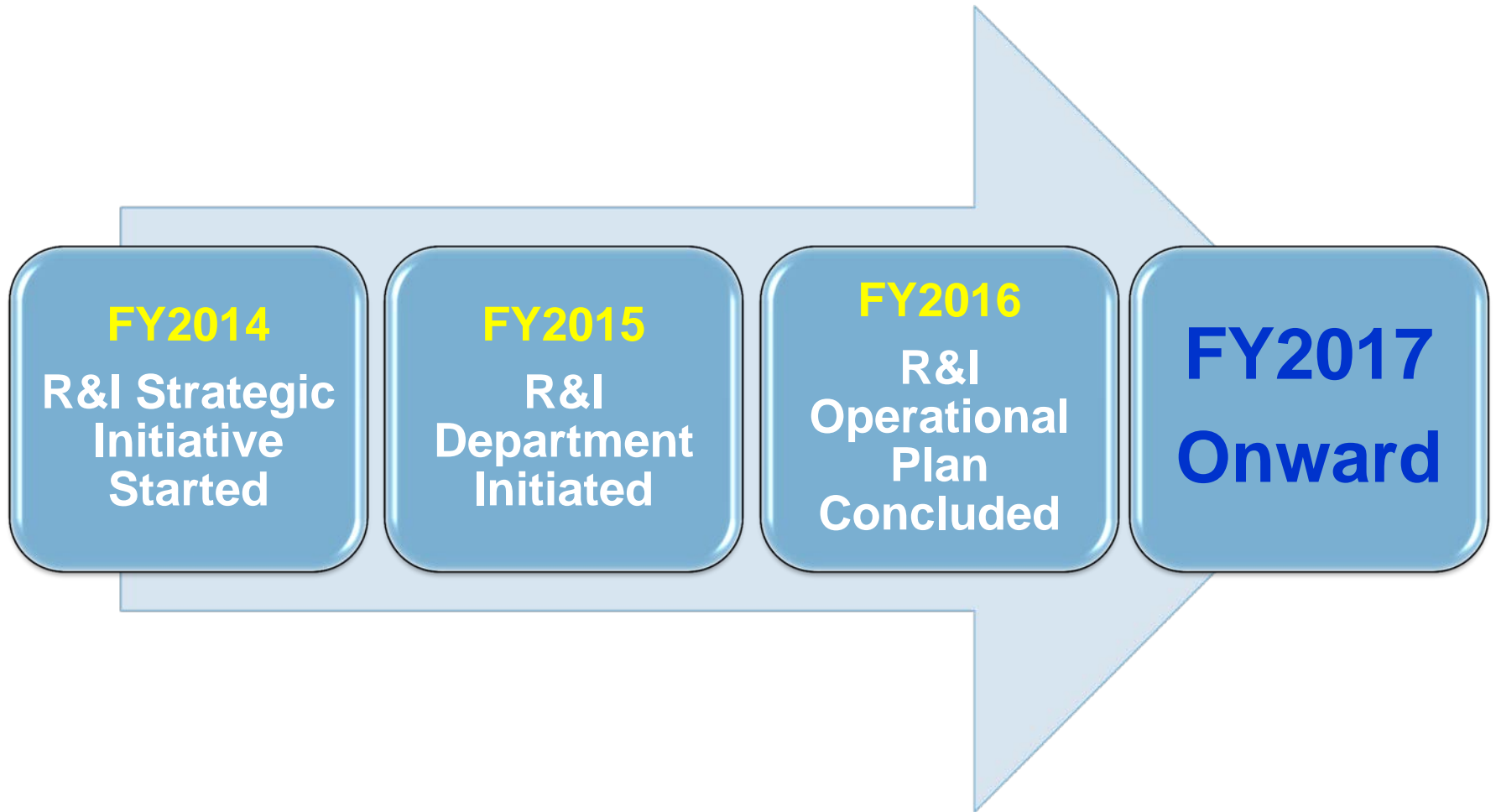


# Idea System: Management-Directed but Bottom-Driven



CATEGORY	PROJECTS
<p><i>Future Quality</i></p> <p><i>Strategic long-term Exploration for Quality/ Standard of the Future</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Defining future standard metrologically               <ul style="list-style-type: none"> <li><input type="checkbox"/> USP internal taskforce, CoE/EC engagement, and strategic assessment</li> </ul> </li> <li><input type="checkbox"/> Establishing Standards in new pharmaceutical development               <ul style="list-style-type: none"> <li>➤ Continuous Manufacturing</li> <li>➤ eHealth</li> </ul> </li> </ul>
<p><i>New Technologies</i></p> <p><i>Enabling Technologies to impact USP in the medium term</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> DNA-based Analysis</li> <li><input type="checkbox"/> qNMR Technology</li> <li><input type="checkbox"/> Spectral Library Research</li> <li><input type="checkbox"/> SFC Technology</li> <li><input type="checkbox"/> Polymorphism Analysis</li> <li><input type="checkbox"/> .....</li> </ul>
<p><i>New Pipeline</i></p> <p><i>Innovation Infrastructure</i></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Idea System               <ul style="list-style-type: none"> <li><input type="checkbox"/> Innovation infrastructure allows USP to quickly evaluate, develop and implement new standards &amp; technologies</li> </ul> </li> </ul>

# R&I Development Journey





# Any Questions?





Global Expertise  
Trusted Standards  
Improved Health

A light gray world map is centered in the background of the slide, showing the continents of North America, South America, Europe, Africa, Asia, and Australia.

# Thank You