# Overview of USP's Research and Innovation Activities

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Director, Research and Innovation

# USP is committed to…

- Tailoring programs to address stakeholder priorities
- Fostering next generation of science and public health experts to volunteer with USP
- Measuring public health impact of USP's quality work
- Advocating for quality to advance public health and patient safety

# USP's Research & Innovation Vision

## 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.

# Research and Innovation Group at USP

Ding Ming Ph.D.  Vice President, R&I

Michael Ambrose Ph.D. Director, R&I

Christine Yu, MPH, Associate Program Manager,  R&I

Georganne Fok, Project Manager, Innovation Infrastructure R&I

# Looking to the Future: USP Research & Innovation Areas

| AREAS | PROJECTS |
| --- | --- |
| ***Future Quality***<br>*Strategic long-term Exploration for Quality/ Standard of the Future* | ▸ Defining Future Metrologic Standard<br>▸ Establishing Standards in new pharmaceutical development<br>– Continuous Manufacturing<br>– Digital Healthcare |
| ***New Technologies***<br>*Enabling Technologies to impact USP in the medium term* | ▸ DNA-based Analysis<br>▸ qNMR Technology<br>▸ Spectral Library Research<br>▸ Polymorphism Analysis<br>▸ …… |
| ***New Infrastructure***<br>*Establishing Innovation Infrastructure to produce immediate results* | ▸ Idea system: Idea generator from frontline workers<br>▸ Ignite system: Crowdsourcing platform for solutions<br>▸ …… |

# R&I ongoing Initiatives

- **Pharmaceutical Continuous Manufacturing**
- Quantitative NMR
- Innovative Infrastructure
- DNA Identification of Botanicals
- Digital Health

# Quality Standard Development in PCM Aligns with USP Strategy and Mission

- Unique opportunity for USP to establish itself as a thought leader on quality while maintaining a healthy and sustainable standards program
- USP has attained solid initial understanding of PCM space, received great interests from our consumers and customers, and established good alignment with PCM stakeholders and players from FDA, industries, and academics:
- Current efforts include:
  - Established Expert Panel for exploring PCM standards and guidance
  - Initiated standardization collaboration with PCM research community

# USP Formed a Quality Standards for Pharmaceutical Continuous Manufacturing (QSPC) Expert Panel

- Provide recommendations for a roadmap for the development and implementation of compendial quality standards for PCM
- Opportunities for such standards include, but are not limited to,
  - standardizing terms
  - material characterization
  - system validation/qualification
  - in-process control using statistical methods
  - real-time release testing
  - equipment standardization
- Other areas of relevancy include identification of technologies and control strategies for the physical characterization of materials used in PCM

# USP Hosts a Series of International PCM Workshops

**USP PCM Workshop for Generics Manufacturers** took place on May 16-17, 2017 in ***Mumbai, India*** with 109 attendees including 32 CEO/SVPs

**USP Pharmaceutical Technology Workshop** took place on Oct 5, 2017 in ***Sao Paulo, Brazil*** with approximately 150 pharmaceutical executives and scientists enrolled

**USP PCM Workshop for API and Contracting Manufacturers** is planning to take place on May 2018 in ***Shanghai, China***

# R&I ongoing Initiatives

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- **Quantitative NMR**
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# Nuclear Magnetic Resonance (NMR)

- NMR traditionally used as a means of structure elucidation of organic compounds due to exceptional sensitivity to molecular structure

  Quantitative NMR (qNMR) is a primary relative analytical methodology for quantifying compounds based on a combination of NMR measurements and advanced data analysis tools. Suitable for establishing purity of reference materials, as well as determination of residual solvents and impurities

  The resolving power of the technique is the response for all the constituent protons result in reliable and robust quantitation and is applicable to the vast majority of molecules of interest

- Signal analysis and interpretation is independent on instrument manufacturer and is adaptable across the range of the magnet field strengths

- Besides small molecules, NMR is increasingly a method of choice for complex mixtures such as botanical extracts common in dietary supplements and herbal medicines, and biopolymers such as complex carbohydrates, polyphenols, peptides and small proteins

# Implementation of qNMR technology involves both internal and external activities

## Recent Activities (FY16-FY17)

- USP and CENAPT-UIC co-sponsored the inaugural qNMR Summit
- USP participated in the qNMR Foundation Meeting – Cologne, Germany
- USP participation in Interlaboratory Comparison Study: “NMR for candidate RS Evaluation”

## Current Activities (FY17-FY18)

- NMR for Candidate Reference Standard Evaluation – UIC/NMR Solutions joint pilot study
  - Collaborators:
    - USP – R&I, Dietary Supplements and Herbal Medicines
    - University of Illinois – Chicago (UIC)
    - NMR Solutions (Finland)
- Bruce Yu (U of Maryland) to present at Novel Technology Seminar on September 6, 2017

## Future Activities (FY18-FY19)

- Identify USP Scientific Fellow to develop a program of integrating qNMR into routine USP RS characterization
- Participant in the 2018 Tokyo qNMR Summit

# R&I ongoing Initiatives

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| | USP Idea System Front-line Staff Ideation Tool | Ignite! Online Crowdsourcing Ideation Tool | MyVoiceBox Suggestion Box |
|---|---|---|---|
| **Usage** | Capture and implement front-line staff ideas and solutions within a specific team's control | Leverage crowds to ideate, prioritize or develop solutions for specific problems, strategic opportunities or for continuous improvement | Put forward ideas or suggestions on various topics;<br>Gather staff feedback on specific challenges or initiatives |
| **Audience** | Teams of 6-10 people within functional group | Cross functional and scalable from small groups to company-wide; External stakeholders; Global outreach | Open to all staff to submit ideas;<br>Used by project teams to solicit staff |
| **Timeframe** | Scheduled Idea Board meetings (45 minutes);<br>1 hour per week personal commitment | Time bound challenges take 1- 6 weeks;<br>1 Hour/1 Day/Always on options | Specific suggestions vary in time<br><br>Scheduled challenges take 3-4 weeks to solicit/analyze results |
| **Utility** | Idea Board; weekly team meetings | Web-based (desktop/mobile) crowdsourcing platform; 24/7 availability | Physical Box; Online Form; Survey Question |

# Global Participation

Research & Innovation

## The USP Idea System
## Implemented Ideas to (Sept 2017)

### ROCKVILLE

1. HQS
2. QA
3. DIST
4. ADMIN
5. CS
6. BBL
7. HRBP
8. PUBS 1
9. PUBS 2
10. CDL

### BRAZIL
Launched Jul 2017

1. RSL
2. Operations
3. Purchasing

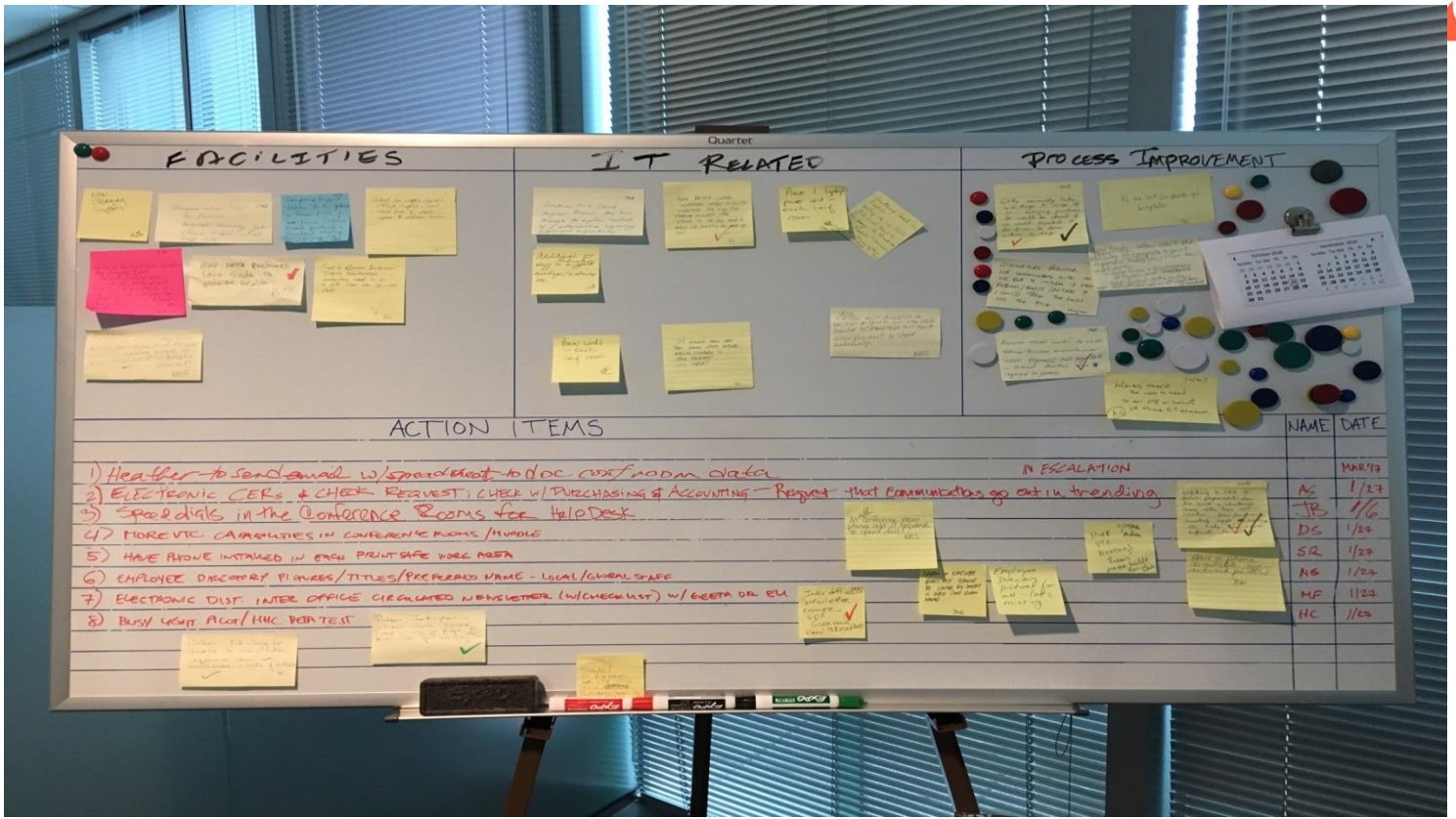

### INDIA

1. R&D
2. Synthetics
3. RS
4. SMEA

### CHINA
Launched Aug 2017

1. SMPO
2. RSL

# The Idea Board



# R&I Initiatives

- Pharmaceutical Continuous Manufacturing
- Quantitative NMR
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- **DNA Identification of Botanicals**
- Digital Health

# NY AG observations

**Gingko Biloba.** Negative. No gingko biloba DNA was identified. The only DNA identified was allium (x5), "oryza"(x4)(commonly known as rice), spruce, and asparagaceae. Nine of the tests revealed no plant DNA whatsoever.

**St. John's Wort.** Negative. No St. John's Wort DNA was identified. Of the 20-tests performed, only three identified any DNA, and it included allium, oryza, and dracaena (tropical houseplant).

**Ginseng:** Negative. No ginseng DNA was identified. The testing yielded identification of oryza, dracaena, pinus strobus, wheat/grass, and citrus spp., with 15 of the tests identifying no genetic material at all.

**Garlic:** Positive. All 20 tests yielded DNA from allium.

**Echinacea:** Negative. Five tests identified oryza DNA, one other yielded the DNA of pinus or ranunculacae. Fourteen tests detected no plant DNA of any sort in the product labeled Echinacea.

**Saw Palmetto:** Qualified negative. Only 6 of 20 tests did identify the presence of saw palmetto, but the positive results were principally from one sample. The results did not replicate in the three other samples. One sample demonstrated no plant DNA, another revealed the presence of asparagaceae, and oryza, while a fourth was positive for DNA from the primrose family as well as saw palmetto.

# USP Roundtables on DNA Methods for the Identification of Botanicals

- Guidelines to appropriately utilize DNA methods
- Library of vouchers of plants (“safe sets”) commonly used in dietary supplements.
- Near Completion: Visiting Scientist -Pilot studies for a set of standard methods for identifying specific botanicals, such as ginseng and others, to include in the compendium.
- Guidance for DNA methods to complement chemical methods.
- Consolidate DNA libraries into a single repository targeted for dietary supplements
- USP Fellow starting in January 2018

# R&I Initiatives

- Pharmaceutical Continuous Manufacturing
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- **Digital Health**

# What is Digital Health?

Broad definition of the digital health system:

**The confluence of digital technology integration and health care system (HCS) transformation**

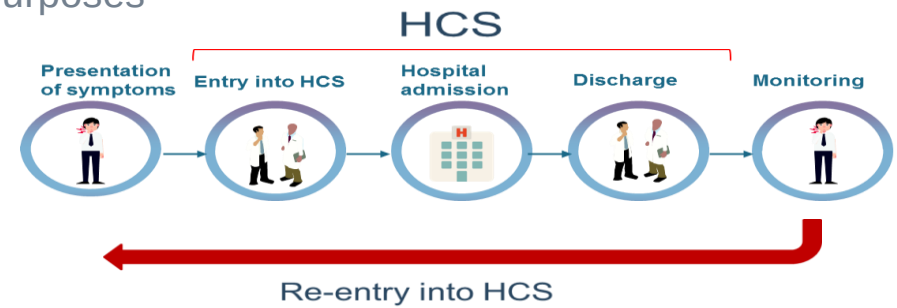
# Standards Developing in Digital Healthcare

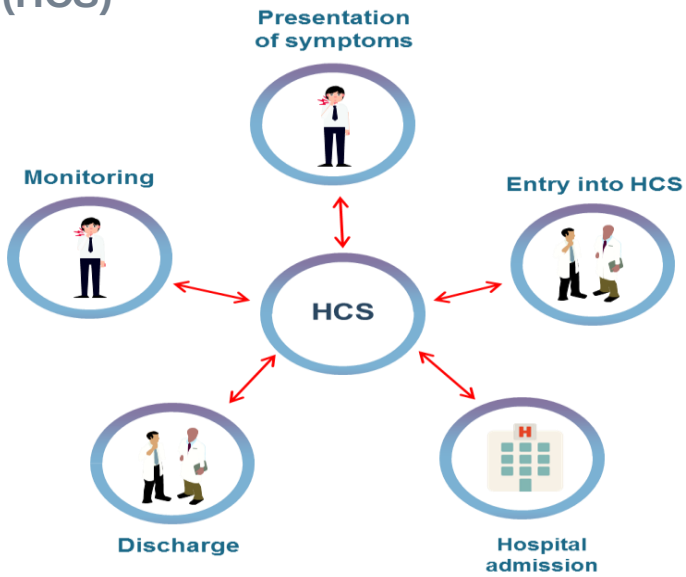
- Advance thinking on quality standards in dHealth and Patient Care
- Enable USP to continue mission of Improving patient care in an increasing patient-centric landscape
- Increase visibility and leadership position through engagement of top experts in the field
- Continue to enable innovation in healthcare through standards

# Transformation of the Healthcare System by Digital Health

- Broad definition of the digital health system: **The confluence of digital technology integration and health care system (HCS) transformation**

*Variations in the definition depending on specific needs and purposes



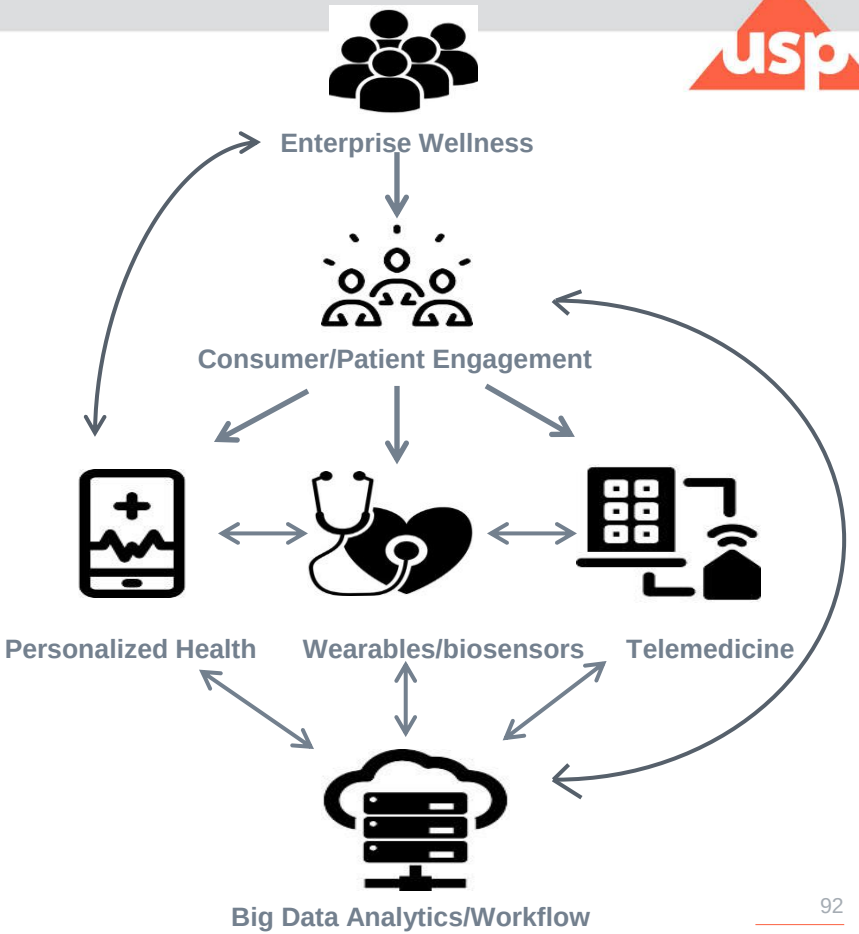

**Linear Pathway**
**(product focused)**

**System Integration**
**(patient-centric; service focused)**

# Dhealth attributes intertwined and complex

## Major attributes/segmentations

- **Consumer/Patient Engagement** with $2.8B total raised YTD and 163 deal counts in 2016
- **Personalized Health** with $1.0B total raised YTD and 45 deal counts in 2016
- **Big Data Analytics/Workflow** with combined 1.2B total raised YTD and 143 deal count
- **Digital wearable device/biosensors** with $713M total raised YTD and 53 deal counts in 2016
- **Telemedicine** with ~6% of US population getting some kind of virtual care
- **Enterprise wellness** with $1.0B total raised YTD and 45 deal counts in 2016



# USP Activities in Dhealth

- Current Activities
  - Landscape assessment of Digital Drug Device Combination products
  - Network with Thought leaders to increase USP understanding of the area
  - Network with DTX providers to identify potential role of USP
  - Interaction with the FDA to understand FDA roadmap and vision and identify alignment and synergies
- Next Steps
  - Roundtable/blue-sky focus groups

# Thank You


Empowering a healthy tomorrow