



Global Expertise
Trusted Standards
Improved Health

USP Excipients Stakeholder Forum
June 7, 2013
Rockville, Maryland

Pharmacopeial Education

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PE: One of the Four **Core** Pharmacoepial Programs at USP

- ▶ Publications
- ▶ Reference Standards
- ▶ Verification Programs
- ▶ Pharmacoepial Education (PE)

USP Quality Manual, May 2013

- ▶ Pharmacopeial Education (PE) program was created in 2000, when the USP Board of Trustees passed a resolution for establishing training and education programs:

“Establish education and training programs to support the appropriate use of U.S. Pharmacopeia and National Formulary standards and compendial methods.”

- ▶ *Provide opportunities for pharmaceutical, food and dietary supplement industries to interact directly with USP scientists*
- ▶ *Greatly enhance the ability of these industries to comply with government regulators (e.g., FDA)*

USP Quality Manual, May 2013

Key Characteristics (1)

- ▶ All Contents are Created and Taught by USP Subject Matter Experts - a combination of volunteers (leading experts in their field) and scientists who are the author of the **Unique** General Chapters and Monographs.
- ▶ More than 1000 volunteers worldwide. They are the leading experts in their respective fields and are selected for their knowledge of a topic and their contributions to related standards-setting activities during the year at USP. **Rich Content**
- ▶ All contents are approved and reviewed for accuracy and quality by the USP Scientific Liaisons and Regulatory Liaisons. **High Quality**
- ▶ Instructors are selected and approved by USP, and are infused with passion to teach.

Excipients Performance: half-day course

▶ *Learning Highlights*

- Understand the scope and context of < 1059> Excipient Performance
- Understand the role of the excipients in a QbD development environment
- Understand the link between ICH Q8 and <1059>

▶ *When: Sep. 17, 2013*

▶ *Where: at the USP Science and Standard Symposium, in Baltimore, MD.*

USP-NF Fat and Fixed Oil Excipient : half-day

▶ *Learning Highlights*

- Understand the related General Chapters <401> *Fats and Fixed Oils* and <1> *Injections*.
- Understand the role of the excipients in a QbD development environment
- Understand the issues associated with fat and fixed oil qualities and variability with examples

▶ *When: Spring 2014*

▶ *Where: USP Headquarter, in Rockville, MD.*

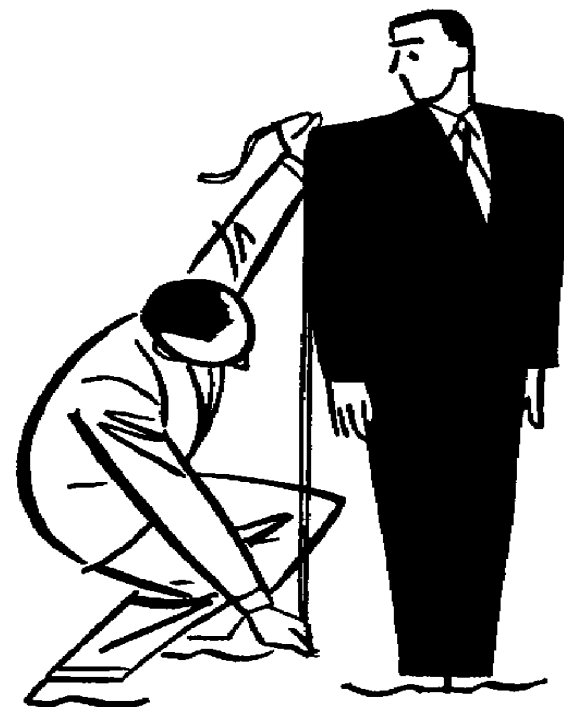
Tailored Content

Feedbacks from the students

Global Alliance

Marketing and Sales

Marketing Intelligence Analysis



Timely Information

Elemental Impurity Analysis: <232>, <233>

Pharmaceutical Compounding: <795>, <797>

Compounding - A Crisis

By Scott Gottlieb, M.D.

The tragic deaths of 55 Americans and sickening of more than 740, resulting from contaminated steroid injections that were shipped by a disreputable firm in Massachusetts, have focused public attention on a largely unfamiliar, but prominent part of our drug supply chain – the practice of pharmacy compounding. Observers are calling on Congress to give FDA more power over these firms.

Collaboration

Critical
Point

RAPS

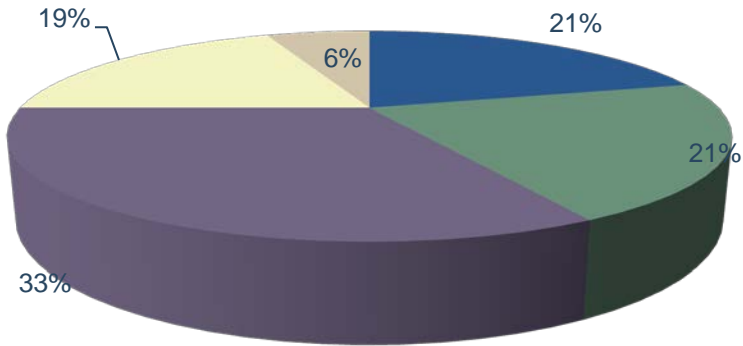
More.....



Key Characteristics (5): Global Presence

FY'12 Students Total

- Brazil
- China
- U.S.
- India
- E/ME/A



Student Profile

- Quality Control
- Research & Development
- Quality Assurance
- Regulatory Affairs
- Validation
- Reference Standards
- Formulation
- Government
- Academic

Americas and Far East	Total Number of Students
Dissolution: Theory and Best Practices	119
Analysis of Elemental Impurities	99
Essentials of Microbiological Testing	60

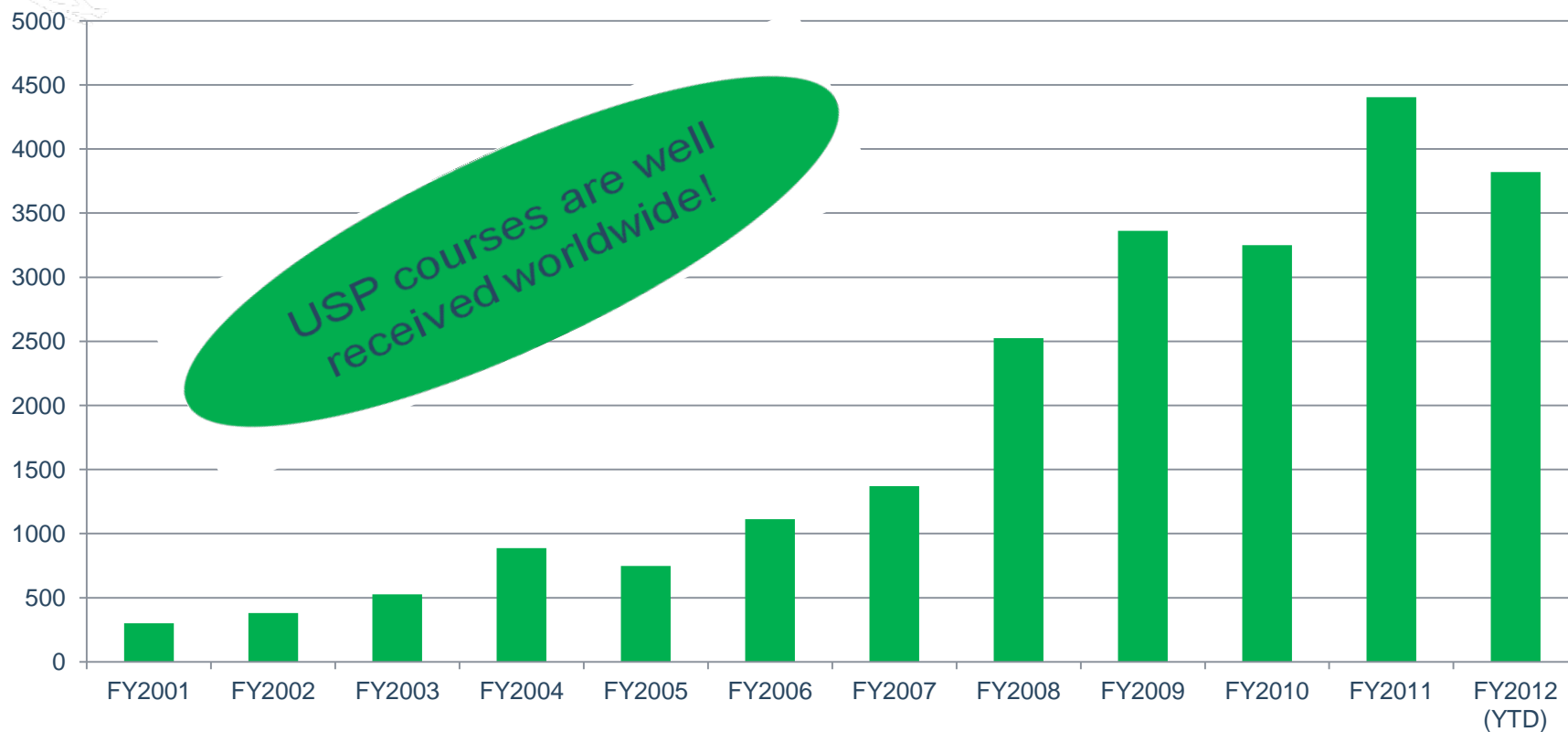
EMEA	Total Number of Students
Dissolution: Theory and Best Practices	135
Validation and Verification of Analytical Procedures	85
Analysis of Elemental Impurities	32

Brazil	Total Number of Students
Validation and Verification of Analytical Procedures	208
Dissolution	137
Pharmaceutical Stability	93

China	Total Number of Students
Essentials of Microbiological Testing	180
Preventing Medical Errors	157
Dissolution: Theory and Best Practices	153

India	Total Number of Students
USP's Perspective on Drug Product Performance Test (Dissolution)	291
Pharmaceutical Waters	163
Impurities in Drug Substances and Drug Products - A USP Approach	129

Number of Attendees at PE Courses and Webinars FY 2001 - 2012



<http://www.usp.org/meetings-courses/courses>

The screenshot displays the USP Courses website interface. At the top, there are language options (English, Español, 简体中文, Português) and a 'Log-in' dropdown menu. The USP logo and 'U.S. Pharmacopeial Convention' text are prominently displayed. Below this is a search bar and navigation links for 'Calendar', 'Support', and 'A to Z Reference Standards Index'. A horizontal menu lists various course categories, with 'Meetings & Courses' and 'Courses' highlighted. The main content area features a 'Registration & Payment' section, a 'Faculty & Staff' section, and a 'Featured Pharmacopeial Education Video' section. The video section includes a photo of Bernard Olsen, Ph.D., and details for three courses: 'USP Expert Committee Chair—USP Small Monographs 3', 'Methodologies and Procedures Training on Dissolution Testing in Republic of Korea', and 'Validation and Verification of Analytical Procedures in Republic of Korea'. Each course entry includes the date, location, and a 'REGISTER' button. A 'CONTACT INFORMATION' section lists 'USP Meetings', 'USP Courses', and 'All USP Contacts'. A 'RELATED RESOURCES' section lists various links like 'Directions to USP', 'Hotels & Transportation', and 'USP Catalog'. The browser's taskbar at the bottom shows several open applications, including 'Inbox - Micros...', 'RE: My slides...', '2013-05-22 AI...', 'Expicent Stak...', 'NISVisit June2...', 'Presentations', and 'USP Courses...'. The system tray shows the date and time as 1:14 PM.



Learning Management
System



July 2013

Better browsing
experience



Better registration
process



Better customer
service experience



Better feedback
system

PE Future Development: Media Lab



face-to-
face

video
clip

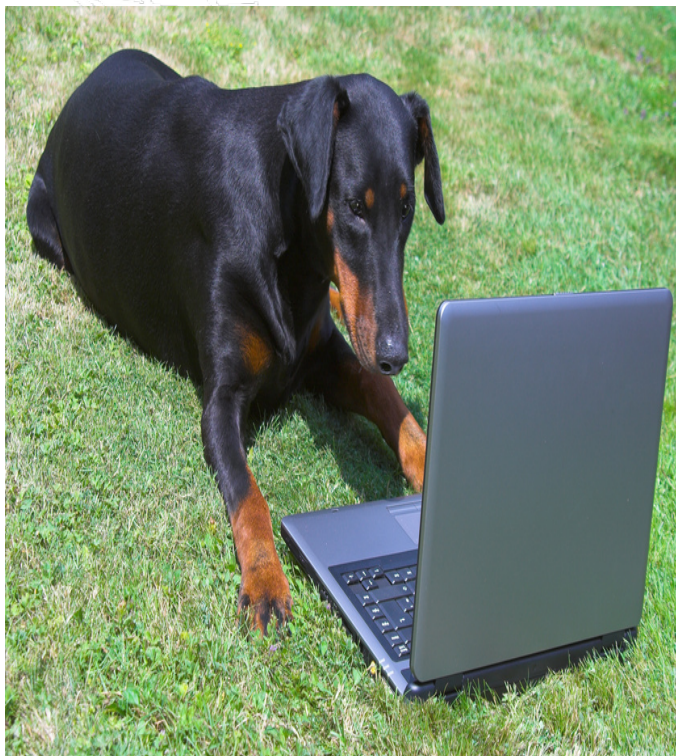
Training / Media Lab



September 2013

PE Future Development: E-learning

the flexibility
of e-learning



the tranquility
of e-learning





Global Expertise
Trusted Standards
Improved Health

www.usp.org

Thank You