



U.S. Pharmacopeia
The Standard of Quality™

USP Enzyme Workshop July 08 - 09, 2009 The Spalding Auditorium USP Headquarters, Rockville, Maryland

Agenda

Day 1: Wednesday, July 8, 2009:

- 8:00 a.m. Registration and Information, Continental Breakfast
8:30 a.m. Opening and Welcome Roger Williams, USP

Session I: Enzymes in the Pharmaceutical Area

Chair: William Koch, USP Chief Metrology Officer

- 8:45 a.m. Introduction – Implications for Enzymes as Pharmaceuticals Roscoe Brady, NIH
9:15 a.m. Enzyme Replacement Therapies: Changes in the Regulatory Environment Emanuela Lacana, FDA
9:45 a.m. Special Challenges for Enzymatic Assays Charles Craik, UCSF
10:15 a.m. Break

Session II: Enzymes in Foods and Dietary Supplements

Chair: Janet Balson, Chr. Hansen Inc.

- 10:30 a.m. Role of the Compendia and Standards William Koch, USP
11:00 a.m. Enzymes as Dietary Supplements Nena Dockery, ETA
11:30 a.m. Enzymes in Food Manufacturing Christopher Penet, Bio-CAT
12:00 p.m. Morning Wrap-Up Discussion and Panel
12:30 p.m. Lunch

Session III: Enzyme Scientific Issues

Chair: Gibbes Johnson, FDA

- 1:30 p.m. Unit Assignment and Maintenance Reference Materials and International Unit Harmonization Tina Morris, USP
2:00 p.m. JP Perspective Teruhide Yamaguchi, JP

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2:30 p.m.	European Perspective	Anne Theobald, EFSA
3:00 p.m.	Industry Perspective	Gary Yingling, ETA
3:30 p.m.	Break	

Session IV: Enzyme Scientific Issues – Continued

Chair: Jo Demeester

4:00 p.m.	Industry Perspective	Jennifer Baker-Malcolm Genzyme
4:30 p.m.	Challenges in Therapeutic Enzyme Manufacturing	Gibbes Johnson, FDA
5:00 p.m.	Afternoon Wrap-up Discussion and Panel	
5:30 p.m.	Adjourn to Reception, Corridor of the Volunteers	

Day 2: Thursday, July 9, 2009

8:00 a.m. Continental Breakfast

8:30 a.m. **Keynote: Celiac Disease** Pawan Kumar
Alvine Pharmaceuticals

Session V: Enzyme Special Topics - Pancrelipase

Chair: Tina Morris, USP

9:00 a.m. Lipases – Measurement and Substrate Challenges Jo Demeester, U. of Gent

9:30 a.m. Pancrelipase Analytical Updates:
Industry Perspective T. Andrew Halton
Digestive Care, Inc.

10:00 a.m. USP Pancrelipase Update Alexey Khrenov, USP
Mary Crivellone USP

10:30 a.m. Break

Session VI: Enzyme Special Topics – Proteases

Chair: Charles Craik

11:00 a.m. Proteases in Food Industry Peter Birschbach, Danisco

11:30 p.m. Use of Enzymes as Ancillary Materials
Regulatory Perspective Julia Goldstein, NIH
Enzymes Used in Cell Manufacturing David Scharp, Prodo

12:30 p.m. Proteases in Peptide Mapping/Proteomics David Bunk, NIST

1:00 p.m. Lunch

Session VII: Enzyme Special Topics - Pepsin as *Case Study* for Method and Unit Harmonization

Chair: Teruhide Yamaguchi

2:00 p.m. Pepsin – Industry Perspective Tom Langdon
American Laboratories, Inc.

2:45 p.m. Pepsin – Standardization Challenges Alexey Khrenov, USP

3:30 p.m. Meeting Closing Remarks Roger Williams, USP

4:30 p.m. Adjourn