

中国医药包装协会

药包秘字【2017】第008号

关于美国药典委员会玻璃和弹性体组件-包装标准化 研讨会开放注册的通知

各有关单位：

美国药典（USP）包装标准越来越受到全球制药厂商和包装厂商的关注。日前，美国药典（USP）药用玻璃和弹性体组件标准正在修订中。为配合标准的修订，美国药典委员会玻璃和弹性体组件-包装标准化研讨会（USP Workshop on Modernization of USP Packaging Standards for Glass and Elastomeric Components）于2017年6月19-20日在 USP 总部美国马里兰州罗克维尔举行，并已开放注册报名。该研讨会主要讨论内容有：

- 1、USP 对于医药包装系统结构材料（玻璃、弹性体及其他）的要求的关键问题
- 2、用于药物产品的玻璃组分和弹性体组件系统适用性的监管预期；

3、修订两个现有的 USP-NF 章节：<381>注射用弹性体密封件和<660>容器-玻璃（<381> Elastomeric Closure for Injections and <660> Containers—Glass）；

4、同时提出三个新章节：<1381>用于药物包装/运输系统的弹性体组件的评价、<382>注射药物包装/运输系统中的弹性体密封功能和<1382>注射药物包装/运输系统中弹性体密封功能的评估。（<1381> Evaluation of Elastomeric Components Used in Pharmaceutical Packaging/Delivery Systems, <382> Elastomeric Closure Functionality in Injectable Pharmaceutical Packaging/Delivery Systems and <1382> Assessment of Elastomeric Closure Functionality in Injectable Pharmaceutical Packaging/Delivery Systems.）

有意参加该研讨会的人员请至 USP 官网（www.usp.org）自行报名注册并查阅更多详细相关信息（注：会议全程英文无翻译）。协会秘书处将派人员参加该研讨会，如有问题可联系协会秘书处。

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附件：研讨会日程



**USP Workshop on
Modernization of USP Packaging Standards for
Glass and Elastomeric Components
June 19-20, 2017
USP Meetings Center, Rockville, MD USA**

**Draft Agenda
(as of January 30, 2017)**

**DAY ONE: Monday, June 19, 2017
Glass Containers**

8:00 – 8:30 a.m.	Registration & Coffee
8:30 – 8:50 a.m.	Welcome and Overview of Key Issues for the Revision of <660> and <1660> <i>Michael Eakins Ph.D., Vice-Chair Packaging & Distribution Expert Committee Co-Chair <660> Expert Panel</i>
8:50 – 9:10 a.m.	Revision of the Autoclave Cycle for Glass Grains and Surface Tests: Key Issues and Changes (<660> and <1660>) <i>Holger Roehl, Member of <660> Expert Panel</i>
9:10 – 9:25 a.m.	Use of Autotitrators for Glass Grains and Surface Tests Titration Methods <i>David Lisman, Nipro</i>
9:25 – 9:55 a.m.	Glass Particles and Flakes: Description, Origin and Detection <i>Daniel Haines, Member of <660> Expert Panel</i>
9:55 – 10:10 a.m.	Q&A
10:10 – 10:30 a.m.	Break
10:30 – 10:50 a.m.	Chinese Perspective on Pharmaceutical Glass <i>Yonghua Gao, Packaging & Distribution Expert Committee Co-Chair <660> Expert Panel</i>
10:50 – 11:10 a.m.	Japanese Pharmacopeia Perspective on Pharmaceutical Glass <i>Yukio Hiyama PhD., National Institute of Health Sciences, The Ministry of Health Labour and Welfare, Japan</i>
11:10 – 11:40 a.m.	Glass Materials and Their Use in Packaging Systems: Regulatory Expectations <i>TBA, U.S. Food and Drug Administration</i>
11:40 a.m. – 12:00 p.m.	Q&A/Panel Discussion
12:00 – 1:00 p.m.	Lunch

- 1:00 – 1:30 p.m.** **Approach to Elemental Impurities in Glass Containers**
TBA, U.S. Food and Drug Administration
- 2:00 – 2:20 p.m.** **Borosilicate Glass Formulations with Enhanced Chemical Stability**
Bettine Boltres Ph.D., Member Packaging & Distribution Expert Committee
Co-Chair <660> Expert Panel
- 2:20 – 2:40 p.m.** **Aluminosilicate Glass Formulations with Enhanced Chemical Stability**
TBA
- 2:40 – 3:00 p.m.** **Q&A/Panel Discussion**
- 3:00 – 3:20 p.m.** **Break**
- 3:20 – 3:40 p.m.** **Proposed Revision of Spectral Transmission Test**
TBA
- 3:40 – 4:00 p.m.** **Inner Surface Hydrolytic Test: New Approaches**
Carol Flynn, Member of <660> Expert Panel
- 4:00 – 4:20 p.m.** **Glass Delamination: Predictive Screening Methods**
Michael Akers, Amgen, Member of <660> Expert Panel
Daniele Zuccato, Ompi
- 4:20 – 4:50 p.m.** **Q&A/General Discussion**
- 4:50 – 5:00 p.m.** **USP Summary: Next Steps**
Bettine Boltres Ph.D., Member Packaging & Distribution Expert Committee
Co-Chair <660> Expert Panel
- 5:00 p.m.** **Workshop Adjourns**

DAY TWO: Tuesday, June 20, 2017

Elastomeric Components Used in Pharmaceutical Packaging/Delivery Systems

- 8:00 – 8:30 a.m.** **Registration & Coffee**
- 8:30 – 9:00 a.m.** **Welcome and Overview of Key Issues for the Revision of <381> and Future Revision Topics**
Michael Eakins Ph.D., Vice-Chair Packaging & Distribution Expert Committee
Member <381> Expert Panel
- 9:00 – 9:30 a.m.** **<381> Elastomeric Components Used For Injectable Drug Products Packaging/Delivery Systems**
Diane Paskiet, Member Packaging & Distribution Expert Committee
Chair <381> Expert Panel
- 9:30 – 10:00 a.m.** **Elastomeric Materials and Their Use in Packaging Systems; Regulatory Expectations**
TBA U.S. Food and Drug Administration

10:00 – 10:30 a.m.	Data Supporting Elemental Impurities Extraction Conditions & Data Analysis for <381> <i>Diego Zubriggen, West Pharmaceuticals</i>
10:30 – 10:50 a.m.	Break
10:50 – 11:30 a.m.	<1381> Evaluation of Elastomeric Components Used in Pharmaceutical Packaging/Delivery Systems <i>Renaud Janssen, Member Packaging & Distribution Expert Committee</i> <i>Member <381> Expert Panel</i>
11:30 a.m. – 12:00 p.m.	Round Table Discussion: Audience Q&A
12:00 – 1:00 p.m.	Lunch
1:00 – 1:45 p.m.	<382> and <1382> Elastomeric Closure Functionality in Injectable Pharmaceutical Packaging/Delivery Systems <i>Dana Guazzo Ph.D., Member Packaging & Distribution Expert Committee</i> <i>Member <381> Expert Panel</i>
1:45 – 1:55 p.m.	Vendor: Perspective on <381>, <1381>, <382> and <1382> <i>Heinz Kirchmeyer, Consultant, Member <381> Expert Panel</i> <i>Philippe LeGall, Aptar, Member <381> Expert Panel</i>
1:55 – 2:05 p.m.	Drug Manufacturer: Perspective on <381>, <1381>, <382> and <1382> <i>Lisa Yoest, GSK, Member <381> Expert Panel</i> <i>Doug Kiehl, Lilly, Member <381> Expert Panel</i>
2:15 – 3:15 p.m.	Round Table Discussion: Audience Q&A
3:15 – 3:40 p.m.	Break
3:40 – 4:45 p.m.	Round Table Discussion: Audience Q&A (Cont'd)
4:45 – 5:00 p.m.	Workshop Summary <i>Desmond Hunt, Ph.D. Scientific Liaison, USP</i>
5:00 p.m.	Workshop Adjourns