



JAPM / USP and Middle East/North Africa (MENA) Stakeholders 6th Science & Standards Symposium

Exploring the Latest Advances & Trends in Standards & Regulations

**October 10-11, 2010
Sheraton Amman Al Nabil Hotel & Towers
Amman, Jordan**

**Preliminary Agenda
(As of September 27, 2010)**

The *Jordanian Association of Pharmaceutical Manufacturers (JAPM)* and the *United States Pharmacopeial Convention (USP)* in collaboration with *Jordan Food and Drug Administration (JFDA)* are pleased to present the 6th Science and Standards Symposium (formerly called Annual Scientific Meeting in *Jordan*). This meeting supports a science-based dialogue to promote access to good quality medicines and dietary supplements/botanicals. Topics focus on the information related to regulatory requirements and compendial standards for drug products and their ingredients.

Topics:

- I. Supporting Drugs Registration
- II. Manufacturing Components
- III. Sterility Issues and Compendial Considerations
- IV. Quality of Manufactured Medicines
- V. Stability

The meeting is of interest to manufacturers of medicines and their ingredients, exporters and importers of pharmaceuticals; regulatory scientists, representatives of national drug control laboratories, professional and academic scientists, policy makers, and other interested parties.

SUNDAY, OCTOBER 10, 2010

- 8:00 – 8:30 a.m. **Registration / Welcoming Coffee**
- 8:30 – 9:00 a.m. **Opening Remarks**
- *Maher Kurdi, Chairman, JAPM*
 - *Moh 'd Rawabdeh, Director, Jordan Food & Drug Administration*
 - *Roger Williams, M.D., Chief Executive Officer, USP*
- 9:00 – 10:30 a.m. **Session I: Supporting Drug Registration**
- **ANDA Regulations Update**
Gordon Johnston, M.S., R.Ph., Vice President of Regulatory Sciences, Generic Pharmaceutical Association (GPhA)
 - **Reliance on Compendia / Pharmacopeial Discussion Group Update**
Roger Williams, M.D., Chief Executive Officer, USP
 - **Regulatory Considerations when Developing Biologics: Biosimilars**
Gordon Johnston, M.S., R.Ph., Vice President of Regulatory Sciences, GPhA
Roger Williams, M.D., Chief Executive Officer, USP
- 10:30 – 11:00 a.m. **Break**
- 11:00 a.m. – 1:30 p.m. **Session II: Manufacturing Components**
- **Cleanrooms & Controlled Environments**
Donald Singer, M.S., USP General Chapters – Microbiology Expert Committee Member
 - **Lean Approach to Clean In Place Systems**
Speaker To Be Announced
 - **Manufacturing Supply Chain Management**
Gordon Johnston, M.S., R.Ph., Vice President of Regulatory Sciences, GPhA
 - **GMPs / Quality Systems**
Nick Cappuccino, Ph.D., MBA, USP Monographs – Small Molecules 3 Expert Committee Member
- 1:30 – 2:30 p.m. **Lunch**
- 2:30 – 4:30 p.m. **Session III: Compendial Considerations**
- **USP Workplan: 2010-2015**
Roger Williams, M.D., Chief Executive Officer, USP
 - **Sterility Assurance**
Donald Singer, M.S., USP General Chapters – Microbiology Expert Committee Member
 - **Residual Solvents**
Samir Wahab, Ph.D., Director of ARD Laboratory, USP
 - **Compendial Approach to Inter-laboratory Testing**
Lawrence Evans III, Ph.D., MPH, Global Services and Standards Manager, USP
- 4:30 – 5:00 p.m. **Day One Q&A - Discussion**

MONDAY, OCTOBER 11, 2010

- 8:00 – 8:30 a.m. **Registration / Welcoming Coffee**
- 8:30 – 10:00 a.m. **Session IV: Quality of Manufactured Medicines – Part One**
- **ICH Q11 Guideline Update**
Nick Cappuccino, Ph.D., MBA, USP Monographs – Small Molecules 3 Expert Committee Member
 - **Drug Substance/API – Quality by Design**
Gordon Johnston, M.S., R.Ph., Vice President of Regulatory Sciences, GPhA
 - **Implementation of Quality by Design / Process Analytical Technologies**
Nick Cappuccino, Ph.D., MBA, USP Monographs – Small Molecules 3 Expert Committee Member
- 10:00 – 10:30 a.m. **Break**
- 10:30 – 12:00 p.m. **Session IV: Quality of Manufactured Medicines – Part Two**
- **Heparin Case Study**
Samir Wahab, Ph.D., Director of ARD Laboratory, USP
 - **Quality of Excipients: Case of Glycerin, Maltose**
Samir Wahab, Ph.D., Director of ARD Laboratory, USP
 - **Qualification of Manufacturers and Suppliers of Starting Materials**
Tom Buggy, Ph.D., International Quality Manager, DSM Anti-Infectives B.V.
 - **JFDA Updates on API Qualifications**
Dr. Lina Bajjali, Head of Registration Department, JFDA
Dr. Zakia Al Kurdi, Licensing Director, JPM, Jordan
- 12:00 – 1:00 p.m. **Session V: Stability**
- **Stability, Storage and Labeling Conditions**
Nick Cappuccino, Ph.D., MBA, USP Monographs – Small Molecules 3 Expert Committee Member
 - **Stability Issues**
Rania Kawar, Regulatory Affairs Manager, Hikma Pharmaceuticals-Jordan
- 1:00 – 1:30 p.m. **Day Two Q&A – Discussion**
- 1:30 – 2:30 p.m. **Summary, Closing Remarks, and Presentation of Certificates**
- *Maher Kurdi, Chairman, JAPM*
 - *Hanan Sboul, Ph, MBA, CAE, Secretary General, JAPM*
 - *Roger Williams, M.D., Chief Executive Officer, USP*
- 2:30 – 3:30 p.m. **Lunch**
- 3:30 p.m. **Adjourn**