IPEC FEDERATION
A journey update

Patricia Rafidison, Chair
Janeen Skutnik-Wilkinson, Vice-Chair

May 9th 2011 – IPEC Americas 20th Anniversary

IPEC Federation
Promoting the quality, safety and functionality of pharmaceutical and related healthcare products worldwide
IPEC Federation

• Recognition that the drug market is global, including excipient sourcing
• Increased regulatory developments from multiple fronts and geographies
• Need for an industry speaking as one voice for common global issues
• Building on «unique » IPEC set up: users and producers of excipients sharing the same «quality and safety » vision to benefit patient

IPEC Federation: What is it?

• Concept was born in 2009
  – Evolved from TriPEC
    • Meetings with Pharmacopoeia discussion group (PDG)
    • General regulatory update sharing (PECs)
    • IPEC foundation: IPEC Americas, IPEC Europe, JPEC
    • Linked with ICH venues

• The need
  – Formalize interactions between PECs
  – Provide a mechanism for developing consensus based positions across regions
  – Set priorities for issues that interest/affect members globally
IPEC Federation setup

- Federation statutes
  - Not for Profit association based in Belgium (ASBL)
  - Membership:
    - Full members: IPEC Americas, IPEC Europe, IPEC Japan and IPEC China
    - Associate members (for new PEC)

- Operations
  - One « assemblée générale » per year
  - 2 Meeting per year linked with PDG
  - Governance principles per Quality manual

IPEC Federation: Policy Manual

- Purpose: Outline the policies and procedures of Federation
- Content:
  - Governance principles, and Board members duties
  - Prioritization and subjects escalation process, including conflict resolution
  - Stakeholder Management
  - Policy for working with Standard Development Organizations (ISO, ANSI)
  - Communication Policy

Individual PECs are still expected to address national needs and collaborate with local governments and regulators to address local issues.
IPEC Federation Board

Federation sign-off – Cannes 2010 - France

IPEC Federation Team
IPEC Federation priorities

- Key objectives:
  - Managing global regulatory expectation
  - Harmonisation of standards
  - Promoting supply chain security
  - Third-party certification

- 2011 Priorities:
  - Harmonisation of excipients monograph globally
  - Excipients certification programme (Excipact/IPEA)
  - Risk management/assessment of excipients
  - Elemental analysis ICH Q3D
  - Excipients Master files
  - Atypical excipients appropriate GMPs
IPEC Federation Projects

- Sponsorship
  - Single point of Contact
- Project Charters & Action Plans
  - Consistency
  - Drive to Action
  - Followup
- Targets and Timelines
  - Accountability

Harmonisation

- Further the work of excipient harmonisation
  - Continued partnership with PDG
  - Considering new pathways forward to speed up process
  - Prospective harmonisation of new excipient monographs
Excipient Risk Assessment

• Develop a Federation guidance document on performing excipient risk assessment
  – Excipient Risk Analysis and Evaluation
    • Considerations for and Perspective of Excipient Maker
    • Considerations for and Perspective of Excipient User

Other Projects

• ICH Q3D Elemental Impurities
  – IPEC’s first entry into ICH
• Excipient Certification
  – IPEA & EXCIPACT
• Foreign Matter
  – Position/White Paper development
<table>
<thead>
<tr>
<th><strong>IPEC Americas:</strong></th>
<th><strong>IPEC Europe:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Committee</td>
<td>Harmonisation Committee</td>
</tr>
<tr>
<td>GMP</td>
<td>Excipient Certification Committee</td>
</tr>
<tr>
<td>Excipient Qualification (EQ)</td>
<td>Regulatory Affairs &amp; Quality Committee</td>
</tr>
<tr>
<td>Compendial Review/Harmonisation (CRC)</td>
<td>GDP Committee</td>
</tr>
<tr>
<td>Regulatory Affairs</td>
<td>Risk Assessment Committee (recent)</td>
</tr>
<tr>
<td>Quality by Design (QbD)</td>
<td></td>
</tr>
<tr>
<td>Excipient Composition</td>
<td></td>
</tr>
<tr>
<td>(Subgroups: Supply Chain, Validation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>IPEC Japan:</strong></th>
<th><strong>IPEC China:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>GMP Committee</td>
<td>Regulatory Committee</td>
</tr>
<tr>
<td>Guideline Committee</td>
<td></td>
</tr>
<tr>
<td>Committee on the Specifications and Testing Method</td>
<td></td>
</tr>
<tr>
<td>Safety Committee</td>
<td></td>
</tr>
<tr>
<td>Administration Committee</td>
<td></td>
</tr>
<tr>
<td>International Committee</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Science</th>
<th>GMP/ Quality</th>
<th>Advocacy</th>
<th>Harmonisation</th>
</tr>
</thead>
</table>

5/19/2011