Compendial Process Improvement Project Team (CPI PT) Update

USP P/NP Stakeholder Forum
18 October 2018

Phil Travis and Danita Broyles: Co-Chairs CPI PT
Presented by Barbara Ferguson – CPI PT Member
Agenda

- Background
- Supporting the 2015-2020 Cycle
- CPI PT Focus Areas
- CPI PT Recommendations
- Next Steps
- Acknowledgements
CPI PT Background

- **CPI PT**
  - Formed under the USP Prescription/Non-Prescription (P/NP) Stakeholder Forum
  - For over 4 USP cycles (more than 20 years)
  - Provide updates periodically at the P/NP
- **Charge**
  - Open a dialogue between Stakeholders and USP to determine ways in which improvements can be made to USP’s compendial processes, including:
    - Pharmacopeial Forum (PF) comment process
    - USP publication topics, including redesign of USP publications
    - Communication of USP initiatives to pharmaceutical manufacturers and other groups
- **Process**
  - CPI PT works with USP to identify areas for process improvements and develops recommendations to promote positive change
  - CPI PT submits recommendations to USP for discussion and approval
  - If approved, USP implements recommendations
Supporting the 2015-2020 Cycle

- USP Convention Take Home Messages
  - Shoulder to Shoulder (to Shoulder)
  - Making the USP Relevant
    - Modernization
    - Compendial Processes

- P/NP Stakeholder Message
  - Quality
    - Functional
    - Reliable
    - Adaptable/Flexible
Supporting the 2015-2020 Cycle

Start: Plan for Success

Continuous Improvement

Finish: Confirm Success

Relevance

Shoulder to Shoulder

Quality
CPI PT Focus Areas

2015 P/NP

- USP Publications
  - Accelerated Revision Guideline
  - USP 2020 Publication Nomenclature
  - USP online
  - USP Prospectus Process
  - General Chapter PF Briefings

- Special Topics
  - <476> Application to Monographs
  - Global Health Monographs

- Best Practices
  - USP Training – Impact of Compendial Changes on Regulatory Filings
  - Best Practices for Communications to Advance Development of Public Standards
  - Compendial Surveys

2018 P/NP
CPI PT Recommendations

USP Publications – Accelerated Revision Guideline

- Requested by: USP
- Purpose: Review USP’s proposed changes to the Accelerated Revision Guideline (primarily to incorporate FCC) and provide recommendations
- Status: Complete (31-Jul-2018)
- Recommendations:
  - Continue to simplify the Accelerated Revision process
  - Addition of FCC to Guideline is not problematic; clarify terms specific to USP-NF vs. FCC
  - Changes to new sections on “Reference Changes” and “Pending Monographs”
  - Provided specific wording changes for clarification throughout
CPI PT Recommendations

USP Publications – **USP 2020 Publication Nomenclature**

- **Requested by:** USP
- **Purpose:** Review USP’s proposed publication nomenclature for USP 2020 and provide recommendations on that issue as well as the annual print publication.
- **Status:** Complete (19-Sept-2018)
- **Recommendations:**
  - USP should justify/explain value of this change that would impact industry’s documentation systems
  - The timing of the change should be delayed to benefit from lessons learned from the new USP online
  - USP should provide sufficient notification to stakeholders prior to the change
  - The nomenclature should be based on the Official Date (not the publication date)
  - CPI PT do not see value in an annual print publication without change control
CPI PT Recommendations

USP Publications – New USP Online

- Requested by: USP
- Purpose: Provide input on the functionality of the New USP Online product during quarterly meetings with USP and as needed.
- Status: Ongoing
- Recommendations have been communicated directly to the USP online development team and many have been incorporated already
CPI PT Recommendations

USP Publications – **USP Prospectus Process**

- Requested by: Follow-up to USP’s P/NP Presentation
- Purpose: Review progress of USP’s Prospectus Process, determine if there is any value to stakeholders, and provide recommendations to USP
- Status: CPI PT is finalizing recommendations
CPI PT Recommendations

USP Publications – General Chapter PF Briefings

- Requested by: USP
- Purpose: Provide 10 examples of GC PF Briefings that could be improved. USP will select 5 for the team to go into more detail.
- Status: CPI PT is finalizing list
CPI PT Recommendations

Special Topics – Application of <476>* to Monographs

- Requested by: Follow-up to USP’s presentation at the Jan 2016 P/NP
- Purpose: Review USP’s proposed application of <476>
- Status: Complete (13-Jul-2016)
- Comments/Recommendations:
  - General Information on USP or ICH impurity expectations should be provided as guidance and not included in individual monographs
  - Hierarchy of Monographs and General Chapters needs to be maintained to ensure relevance and functionality of public standards
  - Monographs should have clear requirements and application of the chapters should support monograph content

*Control of Organic Impurities in Drug Substances and Drug Products
CPI PT Recommendations

Special Topics – Global Health Monographs (GHMs)

- Requested by: CPI PT
- Purpose: Comment on USP’s GHM process and reply to USP’s 13-Oct-2017 response to CPI PT’s 26-Apr-2017 comments
- Status: Complete (14-Aug-2018)
- Comments/Recommendations:
  - Application of GHMs outside US are not well defined
  - GHM program requires clarity and process development with respect to governance and the creation of new and revised standards
  - Location of GHMs in USP online needs to be clearly and adequately differentiated from USP monographs
  - Unclear what need (i.e., value to public health) is being met that can not be satisfied by other means
  - Concerns on lack of input from stakeholders on GHMs
CPI PT Recommendations

Best Practices – **USP Training - Impact of Compendial Changes on Regulatory Filings**

- Requested by: CPI PT and USP
- Purpose: Prepare and present a comprehensive training package for USP staff on the topic
- Status: Complete (19-Nov-2015)
- Recommendations:
  - USP should consider the regulatory impact of new and revised USP-NF monographs and chapters during development and prior to determining implementation plans and official dates
  - We encourage USP to use this training package for ongoing training of USP liaisons, staff and volunteers in order to raise awareness of the regulatory impact that USP revisions have on the industry
CPI PT Recommendations

Best Practices – **Best Practices for Communications to Advance Development of Public Standards**

- Requested by: CPI PT
- Purpose: Enhance the communication process that supports the development of public standards
- Status: Complete (31-Mar-2017)
- Major Recommendations:
  - Two-way communication assures critical issues and challenges are resolved prior to establishing official content
  - General Notices/Chapters may require more communication and step-wise or phased-in approaches
  - Comment Form can improve consistency, enhance organization and measure the impact of stakeholder comments
CPI PT Recommendations

Best Practices – Compendial Surveys

- Requested by: CPI PT
- Purpose: Provide best practices for Compendial Surveys
- Status: Complete (28-Aug-2018)
- Major Recommendations:
  - Surveys should:
    - Specify a clear purpose and intended audience/stakeholder
    - Be available on compendial website and/or sent from a recognized pharmacopoeial staff member/email address
    - Be respectful of stakeholder’s time
    - Include unambiguous questions
    - Have anonymous and aggregate responses
    - **Provide conclusions to those who took the survey (2-way communication!)**
  - Survey Ethics
    - Limited to compendial issues
    - Respectful of company’s confidentiality
    - No incentives should be provided
    - Purpose should never be to sell/promote a product
Next Steps

- Ongoing support and discussion on the current publication recommendations
- Continue discussions on best practices for the USP development process
- New topics as identified
Acknowledgements

- USP Staff
- CPI PT Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phil Travis (Co-Chair)</td>
<td>NJPQCA</td>
</tr>
<tr>
<td>Danita Broyles (Co-Chair)</td>
<td>MWCDG</td>
</tr>
<tr>
<td>Chuck Bates</td>
<td>MWCDG</td>
</tr>
<tr>
<td>Susan Beavis</td>
<td>CHPA</td>
</tr>
<tr>
<td>Barbara Ferguson</td>
<td>NJPQCA</td>
</tr>
<tr>
<td>Ranil Fernando</td>
<td>WCDG</td>
</tr>
<tr>
<td>Humcha Hariprakasha</td>
<td>FDA</td>
</tr>
<tr>
<td>David Klug</td>
<td>IPEC</td>
</tr>
<tr>
<td>Elisabeth Kovacs</td>
<td>AAM</td>
</tr>
<tr>
<td>Pallavi Nithyanandn</td>
<td>FDA</td>
</tr>
<tr>
<td>Sumit Sen</td>
<td>WCDG</td>
</tr>
<tr>
<td>Priscilla Zawislak</td>
<td>IPEC</td>
</tr>
</tbody>
</table>
Thank You