Compendial Process Improvement Project Team (CPI PT) Update

USP P/NP Stakeholder Forum
24 October 2019

Phil Travis: Chair 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 and quality systems (recently added to focus), 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 and quality improvements and develops recommendations to promote positive change
  - CPI PT submits recommendations to USP for discussion and approval
  - If approved, USP implements recommendations
CPI PT Background

- Major CPI PT recommendations prior to this cycle:
  - Change the implementation date for official changes from 6 weeks to 6 months
  - Limit the types and number of Accelerated Revisions
  - Ensure that there is historical traceability for all official revisions, including Accelerated Revisions
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
- Working Together “3-legged stool”
  - Compendia (USP), Regulatory (FDA), Industry
Supporting the 2015-2020 Cycle

Start: Plan for Success

Continuous Improvement

Finish: Confirm Success

Relevance

Shoulder to Shoulder

Quality
CPI PT Focus Areas

- **USP Publications**
  - Accelerated Revision Guideline (7/31/2018)
  - USP 2020 Publication Nomenclature (9/19/2018)
  - USP online (2018 - ongoing)*
  - USP Prospectus Process (10/18/2018)*
  - General Chapter PF Briefings (1/24/2019)*

- **Special Topics**
  - Application to Monographs (7/13/2016)
  - Global Health Monographs (4/26/2017 and 8/14/2018)
  - PDG Deharmonization Procedure (8/27/2019)*
  - Monograph Modernization (5/6/2019)*

- **Best Practices**
  - USP Training – Impact of Compendial Changes on Regulatory Filings (11/19/2015)
  - Best Practices for Communications to Advance Development of Public Standards (3/3/2017 and 8/27/19)*
  - Compendial Surveys (8/28/2018)

*Activity since 2018 P/NP
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:
  - Communicated directly to the USP online development team
  - Many recommendations have been incorporated already – thank you!
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: Complete (18-Oct-2018)
- Recommendations:
  - Prospectus Process does not add value because it does not contain sufficient detail for reviewers to provide value-added feedback
  - Utilize PF process instead
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: Complete (24-Jan-2019), Awaiting next steps from USP
- Recommendations:
  - CPI provided examples of helpful and insufficient PF Briefings
  - Highlight major changes to content and scope with explanation(s)
  - List minor and editorial changes
  - Include rationale/justification for revisions and new requirements
  - Include rationale if revision deviates from regulatory guidance or PDG harmonization
  - For new chapters, include intended application
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 (27-Aug-2019 – 2nd CPI PT Response)
- 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
  - Stage-gate (escalation) for unresolved critical comments
  - QA review of USP-NF revisions – right first time, every time
CPI PT Recommendations

Special Topics – Monograph Modernization Process

- Requested by: CPI PT
- Purpose: Recommend USP process expectations to modernize product monographs
- Status: Complete (06-May-2019)
- Recommendations:
  - Public standard must be based on FDA-approved criteria, and not be in conflict with that criteria
  - Appropriate process and communications can maximize USP and industry resources
  - USP process must be accountable for complete/credible PF proposals
  - After PF, appropriate public review processes (CPI Best Practices) should be followed to complete development
  - Process Overview in next slide
CPI PT Recommendations

Special Topics – Monograph Modernization Process –
Figure 1: Process Overview

1. USP request for Industry (stakeholders registered in FDA orange book) to support new modernization project

2. FDA Criteria Confirmed by A/NDA Holder

3. USP issues modernization prospectus indicating FDA approved acceptance criteria

4. USP proceeds with monograph development and public review

NO: Work does not advance until valid criteria is available
Special Topics – **PDG Deharmonization Process**

- Requested by: CPI PT
- Purpose: Request Deharmonization Procedure
- Status: Complete (27-Aug-2019)
- Recommendations:
  - Establish PDG deharmonization procedure
  - Include justification and plan for deharmonization proposals
  - Allow for public review and comment
  - Retain harmonization until official deharmonized revision is published
Next Steps

- Ongoing support and discussion on the current publication recommendations
- Continue discussions on Best Practices for the USP development process
- Provide further feedback on USP’s PF Briefing project

- New process/quality topics as identified by CPI:
  - Undocumented USP changes
  - Posting unofficial content in official online content
  - ICH Q3A/B for Identification and Reporting Threshold
Food for Thought

• How can USP:
  • processes support two-way communication
  • simplify processes and types of changes
  • consider impact and implementation timeframes for proposals
  • ensure that all changes are transparent to users

• How can USP be more transparent in:
  • proposing changes
  • USP processes
  • application/hierarchy of official content
  • including intended application for new chapters

• How can industry be more involved in:
  • reviewing and commenting on proposals
  • USP Expert Committees and Expert Panels
Acknowledgements

- USP Staff
- Current CPI PT Members
- Former CPI PT Members this cycle
  - Chuck Bates (MWCDG)
  - Danita Broyles (MWCDG)
  - Elisabeth Kovacs (AAM)

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<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Phil Travis (Chair)</td>
<td>NJPQCA</td>
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<tr>
<td>Susan Beavis</td>
<td>CHPA</td>
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<tr>
<td>Anne Cook</td>
<td>MWCDG</td>
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<tr>
<td>Lisa Eichler-Johnson</td>
<td>MWCDG</td>
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<tr>
<td>Barbara Ferguson</td>
<td>NJPQCA</td>
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<td>Ranil Fernando</td>
<td>WCDG</td>
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<td>David Klug</td>
<td>IPEC</td>
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<td>Ruth Miller</td>
<td>PDA</td>
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<td>Pallavi Nithyanandan</td>
<td>FDA</td>
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<td>Humcha Hariprakasha (alt.)</td>
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<td>Sumit Sen</td>
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<td>Priscilla Zawislak</td>
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Thank You