Engagement throughout the Commenting Cycle

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What we’ve heard from Stakeholders
Stakeholder input

- Compendial Process Improvement Project Team has provided recommendations to USP throughout its history
- Multiple surveys
  - USP customers, PNP attendees, PF users, USP-NF users
- FDA Quarterly meetings
- Customer Advisory Board
- Prescription/Non-Prescription Stakeholder Forum
  - Industry presentations
  - Breakouts
- User interviews
Stakeholder input

- How to have an impact on standards—early in the process and during PF
- Want to know more about commenting
  - How to comment effectively
  - Understand the comment process
  - Dispensation of comments
- Desire for transparency in the standards-setting process
- Implement a standardized comment form
- Incorporate line numbers in PF
- Want more opportunities to communicate with Expert Committees and more feedback on comments
Understanding user needs

- USP worked with Designit, an ethnographic research and design thinking firm, to understand user needs throughout the commenting process.
  - Under their previous name, Cooper, they worked with us to redesign USP–NF

- Compiled all the input received and provided that as foundational information to build off

- Designit interviewed stakeholders and staff to understand how they interact with the standards-setting process
Synthesis

08 iterations
02 weeks

Gathered all the information collected and laid out the data in a “war room.” Multiple brainstorming sessions and data reformatting lead to certain core insights and journey maps for the teams involved.
Insights and findings

Awareness and education about USP and the PF greatly determine engagement.

Transparency builds trust in the process and the brand.

Clarity of communication greatly affects the detail and speed of commenting.

Orchestrating the commenting process takes up most of a compendial liaison’s time.

Industry comments are prioritized and shaped by assessing both science and operations.

Compendial Liaisons rely on their professional community for context, knowledge sharing, and development.
Commenting Process and Timelines
Basic stakeholder engagement

New and regular revisions baseline engagement requirements per the Rules and Procedures of the Council of Experts

Pharmacopeial Forum

Commentary
Comprehensive engagement via the SEM

Stakeholder engagement model pulls engagement forward:

Expert engagement examples:
- Expert Committee
- Expert Advisor
- Working group
- Subcomm/joint
- Expert Panel

Stakeholder engagement examples:
- **Collect information**
  - Survey
  - Open Mic
  - Knowledge Hub
  - Company trade org outreach
- **Convene stakeholders**
  - Project Team
  - Open Forum
  - Round Table
  - Stakeholder Forum
  - Workshop
- **Formal communications**
  - Prospectus
  - Compendial Notice
  - Stimuli Article
  - Forum Briefing
  - Journal Article
- **Informal communications**
  - eNews-letter
  - Social Media Post
  - Blog Post
  - White Paper
- **Share information**
  - Education course
  - Open Mic meeting
  - Meeting Observer

**PF**

**Commentary**
Comprehensive engagement example and timelines

Example standard goes through one PF publication, moves to ballot, and is approved at ballot

*these decisions are made following Robert's Rules
**changes must adhere to Rules and Procedures of the CoE
Why aren’t my comments in commentary?

There are only two reasons

- When initial PF publication is followed by another round of PF publication

  - Initial proposal published in PF
  - EC considers comments, incorporates comments into standard, Changes necessitate republication
  - Updated proposal published in PF
  - EC considers comments and decides to move proposal to ballot
  - EC approves
  - Publication in USP-NF and commentary

- Comment on a section NOT under revision

- CoE Rules 9.05(e) Commentary
  - Where a proposal appears in the PF and is approved for publication in the USP-NF, a summary or abstract of each significant type of comment received and a succinct response to the comment from the Expert Committee or CoE Chairperson shall be posted on USP’s website and called Commentary.
  - Comments received on text that are not the subject of a proposed revision generally are not considered for inclusion in the Commentary unless the comments result in a change to the text.

- Otherwise, your comments are in commentary and are summarized very succinctly
**USP-NF: Current State**

- **Pharmacopeial Forum (PF):**
  - Batched publication 6 times per year
  - 90 day comment collection for all proposals

- **PF to Compendial Publication Ratio:**
  - Two PFs per Compendial Publication, 2:1
  - 6 PFs to 3 Compendial Publications per year, 6:3

- **Official Publication Schedule:**
  - 3 Compendial Publications: November, February, June
    - Uneven spacing between (3, 4, 5 months)
  - 12 Accelerated Revisions: monthly (last Friday of month)

- **Deferrals and Cancelations**
  - Based on comments received, some proposals are either
    - Deferred: held from upcoming ballot, still eligible to ballot later
    - Canceled: proposal is withdrawn, no longer eligible for ballot
  - Lists of these are available on uspnf.com
Effective Commenting

**Goal:** Provide scientifically supported and patient-focused recommendations

**Effective:**
- Comments supported by scientific rationale and/or data
- Comparing proposed method to in-house method and including details of the comparison
- Comments on sections that are not under revision

**Less Effective:**
- Questions
- Comments that don’t reference a specific section of the standard
- Comments on sections that are not under revision
- This is better sent as a “Request for Revision”
- Include the section name

Provide reasoning and desired outcome

Less Effective:
- Commenting that you don’t like a revision, but not stating why.
- Commenting that your in-house method is different

This is better sent as a “Request for Revision”
Resources

- Rules and Procedures of the Council of Experts
- Request for Revision information and guidelines
- Commentary location and schedules
- Overview of the USP-NF training webinar (free, 49 minutes)
Thank You

Empowering a healthy tomorrow