U.S. PHARMACOPEIA
The Standard of Quality℠

USP 2010–2015 Council of Experts
Expert Committee Orientation

General Chapters Overview

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General Chapters Overview

General Chapters can be

- Required (numbered below <1000>)
- Informational (numbered <1xxx>)
- Specific for dietary supplements (numbered <2XXX>)

Required Chapters (Below <1000>)

- When referenced in monographs, are procedures used by the FDA to demonstrate compliance to a specification
- Typically are procedures referenced in multiple monographs
  - Chapter status avoids duplication and simplifies updating
- Typically consist of method and procedure
  - Acceptance criteria – in the General Chapter or the monograph
- Can apply to monographs even if not specifically called out in the monograph
- Tests need to be verified by users for their applications

Informational Chapters (<1xxx>)

- Provide information or guidance
- Are not intended to be required by regulatory agencies
  - Some countries enforce the entire *USP–NF*
  - FDA reserves the right to require at their discretion
- Should be devoid of acceptance criteria to minimize misunderstandings
- May become required if referenced without disclaimer in a monograph or General Chapter numbered below <1000> (very rare)

General Chapters and Reference Materials

- Reference materials are in a minority of General Chapters.
- Typically used to confirm identity or instrument performance verification
- When they occur, they are often high impact
  - <711> Dissolution (Prednisone tablets)
  - <467> Residual Solvents
  - <90> Bovine Serum – Quality Attributes
  - <130> Protein A Quality Attributes
- May be proposed by staff, committee, panel, or an external source
- Evaluated via testing protocols similarly to reference materials in monographs
- Developed in parallel with documentary standard

Impact of General Chapters

- General Chapters have broad industry impact
  - Some are required testing in monographs
  - Some provide guidelines that are enforced outside the U.S. or are broadly applied in the U.S. even if not required
- Broad-based input is typically needed and provided
- For chapters with high impact, training may be needed
  - Pharmacopeial education courses
  - FAQs
  - Guidebooks
- Much of this material is developed through the appropriate Expert Committees

General Notices, General Chapters, and Monographs

- General Notices contain requirements applicable throughout *USP–NF* unless superseded by a chapter or monograph
- General Chapters contain requirements applicable to monographs to which they apply
  - General Chapter requirements supersede General Notice requirements in case of conflict
- Monograph requirements are specific to the monograph in which they appear
  - Monograph requirements supersede General Notice and General Chapter requirements in case of conflict

General Chapter Development

New Chapters or Major Revisions

- Proposal for new General Chapter or major revision comes from staff, committee member, or external source
- Committee, sub-committee, or panel evaluates idea and develops a *Pharmacopeia Forum (PF)* proposal
- Public comment solicited
  - Stimuli Article (common for new General Chapter) or draft chapter published in *PF*
  - "Design phase" of workshop or other public meeting scheduled for "high-impact" chapters (required chapters with broad industry impact)
- Comments collected from public forums and shared with committee/panel

General Chapter Development

New Chapters or Major Revisions

- Committee/panel develops updated proposal
  - Another Stimuli Article in *PF*
  - Draft General Chapter in *PF*
  - Final General Chapter in *USP–NF* with commentary addressing comments
- Timing
  - From inception to first *PF* publication often 12–18 months
  - Timing for final implementation of informational chapters typically shorter than for required chapters
  - For a high-impact chapter, timing from inception to final chapter can be five years or more (e.g., elemental impurities)

General Chapters – Current Status

- Chapters have been
  - Written and updated over many years
  - Under the auspices of many Expert Committees
  - Updated without vision for style and content
- Styles, formats, and information content depend on
  - Committee and USP norms at the time
  - Maturity of technology at time of updating

Vision for General Chapters

- Required chapters
  - Current technology
  - Easy to read, understand, execute
  - Clear acceptance criteria – latitude for procedural changes
- Informative chapters
  - Current guidance, no acceptance criteria
  - Context for enforceable chapters
  - Forward looking
  - Relevant to real-world pharmaceutical issues
- All look and read as if edited by one person
- Summarized in *PF* 35(5) Sept/Oct 2009 Stimuli Article

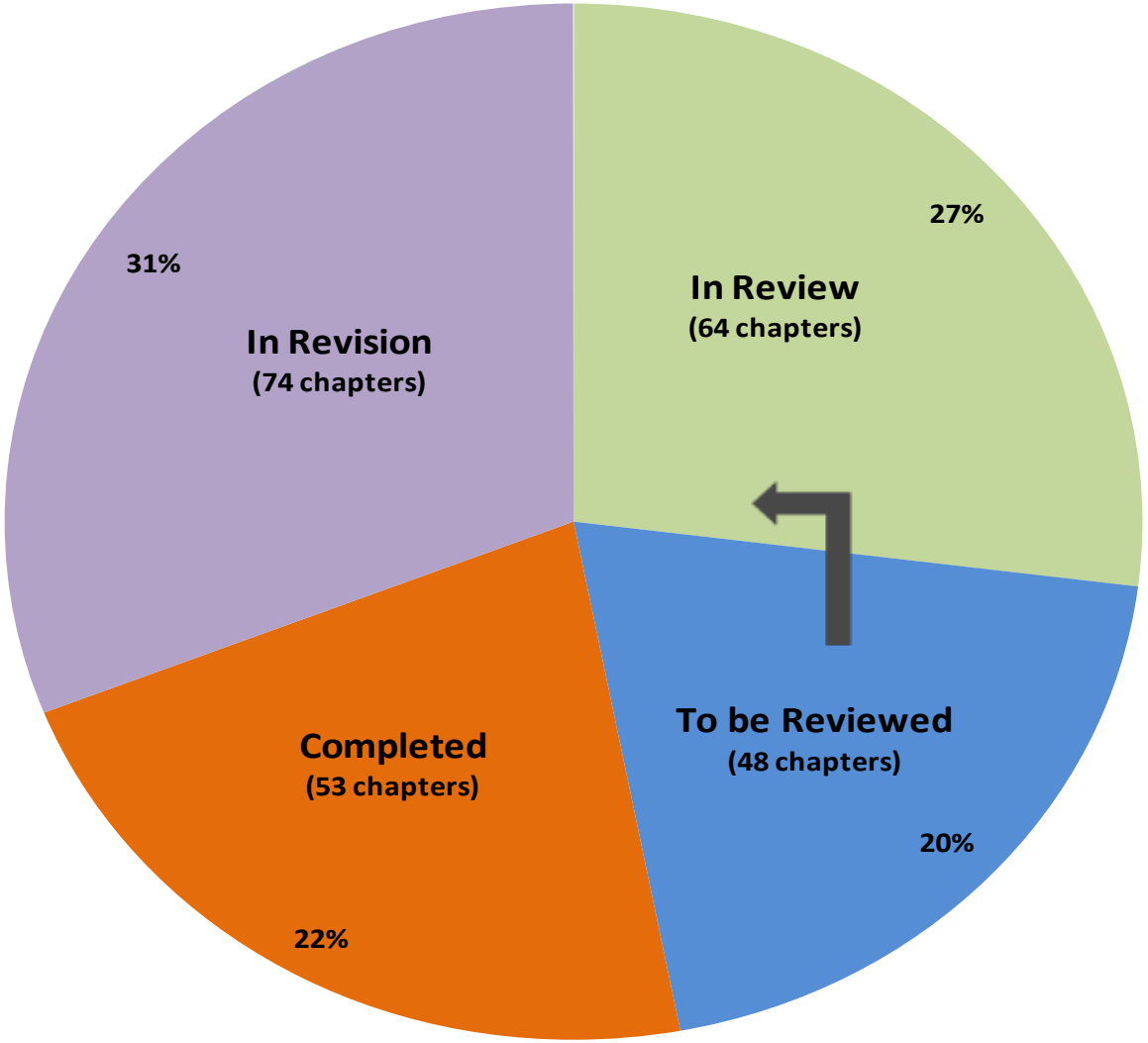
Why is This Important?

- Should represent standard industry practice
  - Current technology and acceptance criteria
  - Meaningfully assess quality attributes
- Used across the globe
  - Clear
  - Concise
  - Well-defined acceptance criteria
- Some countries enforce the whole book
  - Some informational chapters contain enforceable sections
  - Confusion, missed expectations, approval delays
- Harmonization – Clear, concise wording is critical

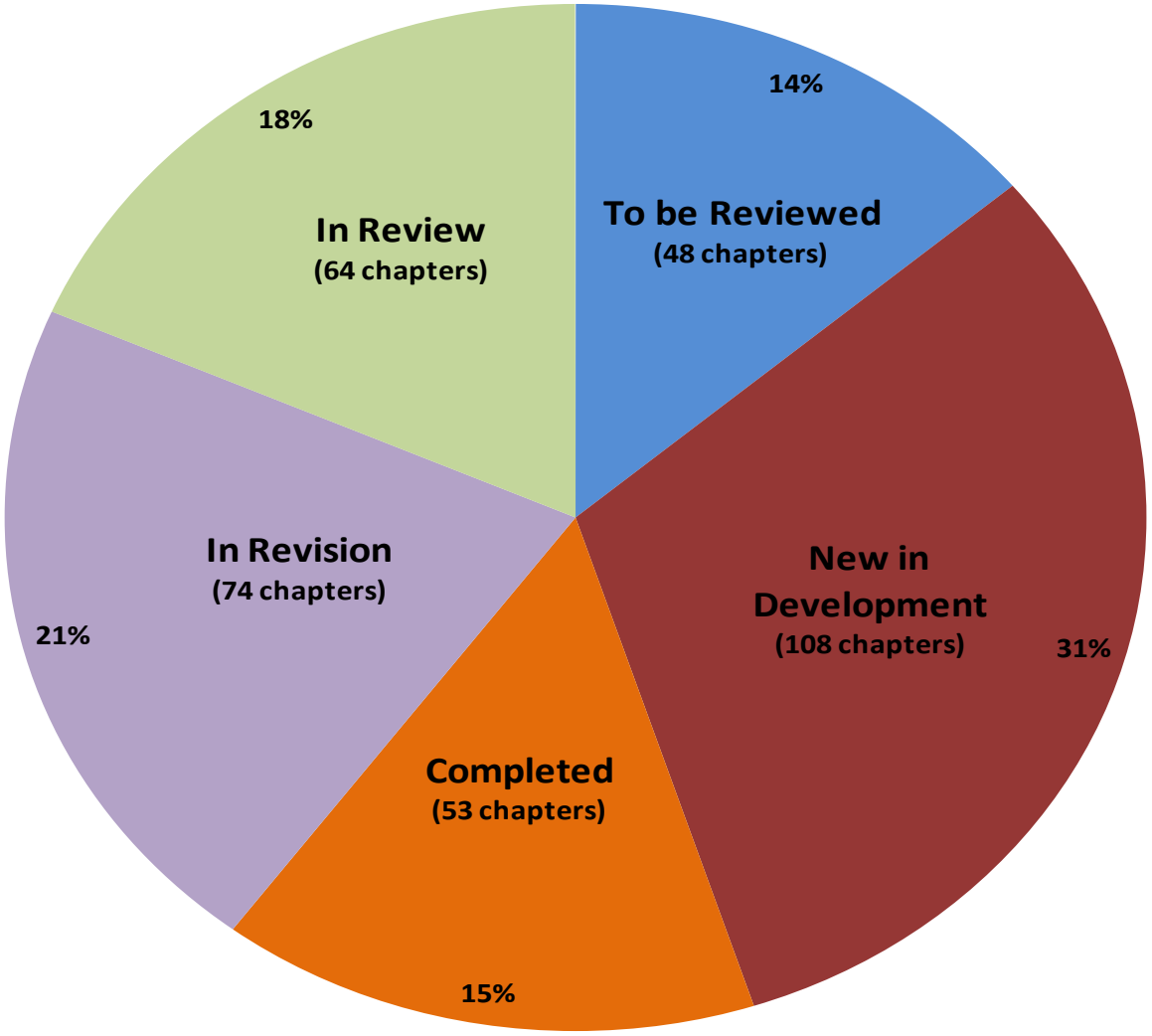
Objective for the 2010-2015 Cycle

- Review the approximately 240 current chapters for content and format
- Prioritize the updating of those that need it using the appropriate committee, subcommittee or panel
- Develop and write new chapters as determined by each committee
- Collect broad-based stakeholder input for high-impact chapters

Official General Chapters in 2010-2015 CoE Cycle



New & Official General Chapters, 2010-2015 CoE Cycle



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Thank You