

Role and Purpose of P3-A Standards

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Why was the P3-A effort Started?

- Increased scrutiny on API Manufacturing in recent years drove the need for Cleaning Validation of API Equipment.
- It is costly for each company to have API equipment manufacturers make specific changes to make equipment easier to clean – is there a consensus on required changes?

Why was the P3-A effort Started?

- No suitable industry standards existed for the design of cleanable API Equipment.
- The Existing 3-A Standards were not suitable for most API Equipment.
- The ASME BPE Standards were not suitable for many types on API Equipment

Why not use ASME BPE Standards?

ASME BPE Standards deal with the requirements of the bioprocessing, pharmaceutical, and personal care product industries as well as other applications with relatively high levels of hygienic requirements, covering directly or indirectly the subjects of materials, designs, fabrication, pressure systems (vessels and piping), examinations, inspections, testing, and certifications.

Why was the P3-A effort Started?

- Existing benchmarking effort among several API manufacturers was expanded to include the development of Standards for Cleanable Design of API equipment.
- Started working with 3A-SSI as the umbrella organization for the Standards development.

Why was the P3-A effort Started?

- During the process it was determined there was also a need for Standards for downstream process equipment:
 - API conversion to dosage form (manufacturing)
 - Final Packaging

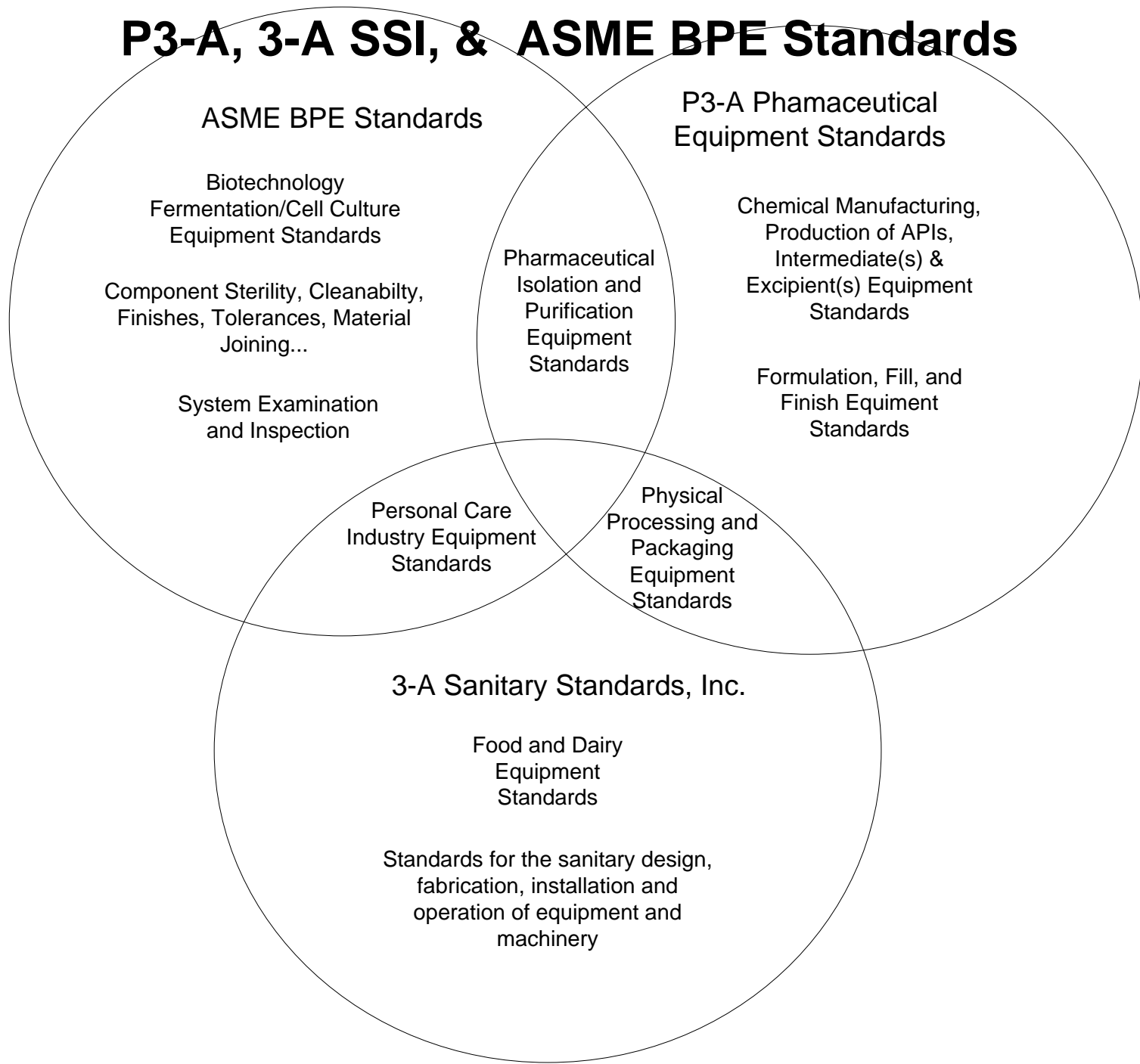
What is Included in P3-A Scope?

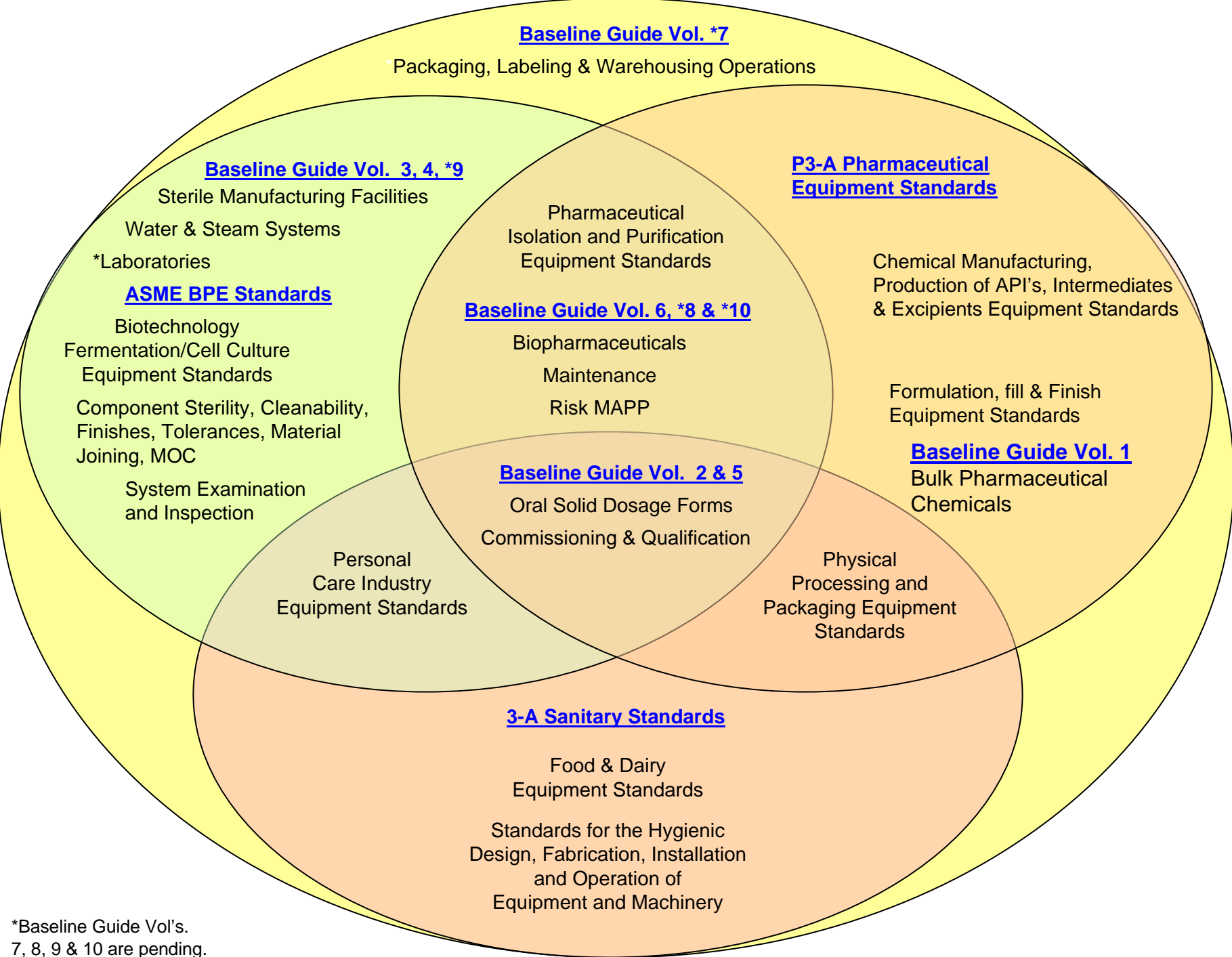
- In general, chemical pharmaceutical manufacturing involving small molecule manufacturing and purification
- These processes are usually solvent based, with highly acidic or basic pH conditions that inhibit microbial growth and contamination.
- Sterile and aseptic design is less critical.

What is Excluded from P3-A Scope?

- In general, biopharmaceutical manufacturing involving large molecule manufacturing and purification.
- These processes are usually aqueous based with normal pH conditions which promote microbial growth and contamination.
- Hygienic design is critical. Includes high purity water and clean steam systems.

P3-A, 3-A SSI, & ASME BPE Standards





*Baseline Guide Vol's.
7, 8, 9 & 10 are pending.