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# ASTM International Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products

## SCOPE

The scope of the Committee shall be the development of standardized nomenclature and definitions of terms, test methods, specifications, and performance standards for the manufacture of pharmaceutical and biopharmaceutical products. The Committee will encourage research in this field and sponsor symposia, workshops, and publications to facilitate the development of such standards. The Committee will promote liaison with other ASTM Committees and other organizations with mutual interests.

## TECHNICAL SUBCOMMITTEES

- **E55.05** Lyophilization
- **E55.06** Microbial Contamination Control
- **E55.07** Single Use Systems
- **E55.08** Pharmaceutical and Biopharmaceutical Manufacturing Sustainability
- **E55.11** Process Design
- **E55.12** Process Applications
- **E55.13** Process Evaluation and Control
- **E55.14** Measurement Systems and Analysis
- **E55.90** Executive
- **E55.91** Terminology
- **E55.94** Outreach and Education
- **E55.95** Roadmap for Standards Development

## KEY DOCUMENTS

**E2500** — Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment Science and Risk Based Approach

**E2537** — Standard Guide for Application of Continuous Process Verification to Pharmaceutical and Biopharmaceutical Manufacturing

**E3106** — Standard Guide for Science-Based and Risk-Based Cleaning Process Development and Validation

**E3177** — Standard Guide on Sampling for Process Analytical Technology

**E3263** — Standard Practice for Qualification of Visual Inspection of Pharmaceutical Manufacturing Equipment and Medical Devices for Residues

**E3418** — Standard Practice for Calculating Scientifically Justifiable Limits of Residues for Cleaning of Pharmaceutical and Medical Device Manufacturing Equipment and for Medical Devices

**F838** — Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration



## QUICK FACTS

**Established** 2003

**Number of Members** 200+

**Number of Standards** 40+

**Global Participation**

21 countries represented

**The standards are available in**  
Volume 14.01 in the *Annual Book of ASTM Standards*

**Meetings** E55 meets twice annually  
in May and November

## STAFF MANAGER

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