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Committee E55 Manufacture of Pharmaceutical and Biopharmaceutical Products

www.astm.org/COMMITTEE/E55

Roadmap

Areas of Focus for Standards Development and Innovation

Manufacture of Pharmaceutical and Biopharmaceutical Products

ASTM Committee E55 develops industry driven consensus standards that directly impact the manufacturing aspects of the pharmaceutical and biopharmaceutical industries. The Committee formed in 2003 following an overhaul of the U.S. Food and Drug Administration (FDA) regulations on drug manufacturing. Recognizing the industry needed new processes and techniques for manufacturing, the FDA began a series of efforts to encourage the use and implementation of new systems, such as Process Analytical Technology (PAT), which focuses on fundamental process understanding.

To establish the foundation for PAT implementation and to lend credence and acceptance to new best practices, the FDA encouraged the pharmaceutical industry to take an active role in generating these practices through a consensus standards developer, such as ASTM International. Thus, E55 was established with an initial focus on developing standards to support PAT implementation.

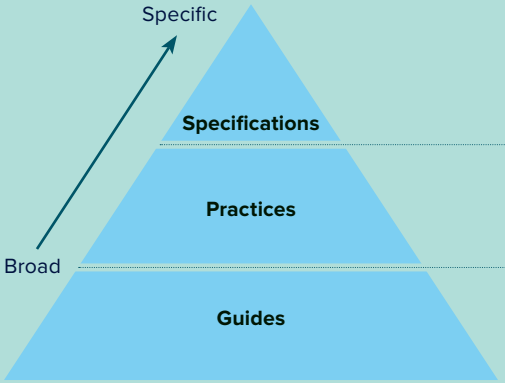
However, the committee soon discovered a wider need for standards within pharmaceutical and biopharmaceutical manufacturing and broadened its scope as a result. Through the ASTM process, approved standards hold the potential to not only be accepted or adopted by regulatory bodies, but also be developed in conjunction with regulators. Thus, E55 standards allow companies to move forward with standards that are broadly accepted and respected.

200
Members Globally

20+
Approved Standards

14.05
Volume Annual Book of Standards

Three Primary Types of E55 Standards



ASTM defines a standard specification as an explicit set of requirements to be satisfied by a material, product, system or service. For E55 purposes, specifications provide the most specific guidance for performing a task.

A standard practice provides a set of instructions for performing one or more specific operations that does not produce a test result. Practices offer a high level of detail over standard guides.

Standard guides are an organized collection of information or a series of options that recommend a specific course of action, giving the user flexibility in achieving the intended outcome.

Additional ASTM standards types within E55 include:

Terminology: a standard document composed of terms, definitions of terms, descriptions of terms, nomenclature, and explanations of abbreviations, acronyms, and symbols. Terminology standards allow E55 to set a single definition that may be used and referenced across multiple standards.

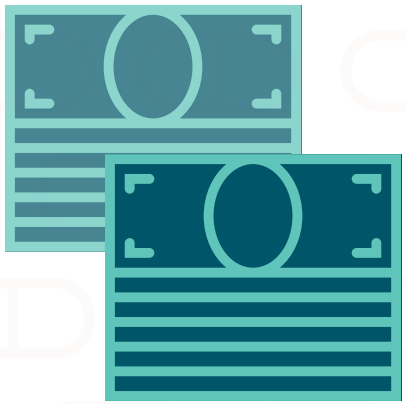
Test Methods: a definitive procedure that produces a test result, providing stricter guidelines below those found within standard practices and guides.

E55 standards aim to improve efficiency and cost-effectiveness of manufacturing processes

The Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment (E2500) has streamlined the qualification and validation of equipment, processes, and associated systems.

The Practice for Qualification of Basket and Paddle Dissolution Apparatus (E2503) has provided cost savings by standardizing the dissolution apparatus and reducing variability of data generated by testing.

The Practice for Demonstrating Capability to Comply with the Test for Uniformity of Dosage Units (E2810) helps manufacturers assess dosage uniformity, thereby reducing product variability and increasing safety. This practice can be used as an element for process demonstration or validation, continuous process verification, in-process testing, or lot release (acceptance).



Initial Development of PAT Standards

Since the formation of E55, the committee has produced several ASTM International standards across a wide range of subjects designed to help the industry become more efficient, streamline regulatory compliance, and improve product quality and safety. While today the committee supports the development of standards on technical topics across both pharma and biopharma manufacturing, its origins in helping the industry adopt Process Analytical Technology set the stage for success within E55.

E55 Collection of PAT Standards

E2475

Process Understanding Related to Pharmaceutical Manufacture and Control

E2891

Multivariate Data Analysis in Pharmaceutical Development and Manufacturing Applications

E2363

Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry

E2474

Pharmaceutical Process Design Utilizing Process Analytical Technology

E2476

Risk Assessment and Risk Control as it Impacts the Design, Development, and Operation of PAT Processes for Pharmaceutical Manufacture

E2629

Verification of Process Analytical Technology (PAT) Enabled Control Systems

E2898

Risk-Based Validation of Analytical Methods for PAT Applications

E3177

Standard Guide for Sampling for Process Analytical Technology

Broadening the Scope of E55

Once the initial PAT based standards were approved, Committee E55 adopted an expanded scope encompassing both pharmaceutical and biopharmaceutical manufacturing. One of the first standards developed and approved under this new charter was E2500 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment. E2500 was encouraged by regulatory bodies in response to ICH guidance on risk-based qualification and is currently the committee's most popular standard to date. This expansion of E55 also led to the development of several other new standards, encompassing a wide variety of subjects, reflecting the growing desire for new standards within the industry. Shown here is a collection of standards developed and maintained by E55.

E1564

Standard Guide for Design and Maintenance of Low-Temperature Storage Facilities for Maintaining Cryopreserved Biological Materials

E1565

Standard Guide for Inventory Control and Handling of Biological Material Maintained at Low Temperatures

E1566

Standard Guide for Handling Hazardous Biological Materials in Liquid Nitrogen

E2500

Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment

E2503

Standard Practice for Qualification of Basket and Paddle Dissolution Apparatus

E2537

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

E2656

Standard Practice for Real-time Release Testing of Pharmaceutical Water for the Total Organic Carbon Attribute

E2810

Standard Practice for Demonstrating Capability to Comply with the Test for Uniformity of Dosage Units

E2888

Standard Practice for Process for Inactivation of Rodent Retrovirus by pH

E3042

Standard Practice for Process Step to Inactivate Rodent Retrovirus with Triton X-100 Treatment

E3060

Standard Guide for Subvisible Particle Measurement in Biopharmaceutical Manufacturing Using Dynamic (Flow) Imaging Microscopy

F838

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

Response to New Manufacturing Techniques and Challenges

As the industry continues to grow and evolve, so do the standards produced by E55. Examples of this change can be seen in the rapid growth of Single-Use Technology (SUT), as well as the introduction of continuous manufacturing processes, which have spawned a new round of E55 standards that support the innovation and industry adoption of these technologies.

E55 Standards Covering Modern Manufacturing

E2097

Determining the Impact of Extractables from Non-Metallic Materials on the Safety of Biotechnology Products

E2968

Standard Guide for Application of Continuous Processing in the Pharmaceutical Industry

E3051

Standard Guide for Specification, Design, Verification, and Application of Single-Use Systems in Pharmaceutical and Biopharmaceutical Manufacturing

E3077

Standard Guide for Raw Material eData Transfer from Material Suppliers to Pharmaceutical and Biopharmaceutical Manufacturers

E3106

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

E55 Standards Currently in Development

Committee E55 has several open projects addressing industry needs to further the introduction and use of SUT, as well as continuous manufacturing, with the goal of creating standards that move from general guidance to more prescriptive practices and specifications. Through the ASTM consensus process, these standards are being developed by teams comprised of subject matter experts representing companies in industry, regulatory agencies and academia, and are open to all interested stakeholders. Additionally, E55 regularly hosts meetings and workshops designed to inform everyone about what work is currently underway, what challenges the industry is facing, what solutions may be available, and how all these pieces align to shape new and existing standards that help bring forth new technologies and manufacturing science.

Standards currently under development or revision are commonly known as Work Items. For the most up-to-date information on all open Work Items visit the E55 website: www.astm.org/COMMITTEE/E55

WK41265 - New Standard Practice for Sampling Plans and Considerations

WK43741 - TNew Standard Practice for Testing Integrity of Single-Use Systems at Suppliers Manufacturing Facilities

WK43742 - New Standard Practice for Characterizing Particulate burden from Single-Use Systems for End-user mpact Assessment

WK59975 - New Standard Guide for Derivation of Health Based Exposure Limits (HBELs)

WK63507 - New Standard Practice for Process Monitoring Instrumentation in Pharmaceutical Freeze Drying

WK63854 - New Standard Practice Material Biocompatibility

WK64140 - New Standard Guide for Sampling for Process Analytical Technology

WK64938 - New Standard Practice for Calculation of Cleaning Validation Limits

WK64975 - New Standard Test Method for Microbial Ingress Testing on Single-Use Systems

WK64991 - New Standard Practice for Stability of Biotherapeutics Products

Note:

Work Item designations are assigned to every standards action to track it through the ASTM processes. When the standard is approved, or the project is withdrawn, the Work Item number expires. WK numbers are subject to change, so if you are interested in any of these projects, be sure to check the website or contact ASTM staff for the most accurate designation and status.

Areas of Focus for Future Standards

For E55 to act on its mission of addressing pharma and biopharma industry needs through the development of relevant and impactful consensus-driven international standards, the Committee routinely explores new topics and as seeks out stakeholders with expertise willing to contribute. Through membership surveys, discussions at E55 and industry events, and other means of communication, committee leaders are continuously looking towards, and planning for, what lies ahead. These new aspects are a constant reminder of the rapid changes and challenges that are ever present within industry, and the reason why E55 maintains a proactive approach to standardization. This active engagement with industry experts has led to the consideration and creation of new Work Items and subcommittees dedicated to topics such as the expansion of single-use technology components, aseptic filling, lyophilization, microbial and sterility assurance, gene and cell therapies, and much more.

Example topics E55 is currently exploring:

- Reference Standards for Amino Assays and antibody titers
- Process Validation for Gene Therapy
- Viral reduction in Continuous Manufacturing Processes
- Pre/Post use Integrity Testing of Single-use Components
- Sterility Assurance of Sterile Filtration
- Best Practices for Freeze Dryer Instrumentation
- Guide for Rubber Stopper Height
- Use of Pre-Sterilized Chromatography Columns
- Assays and Critical Quality Attributes (CQA) for Gene Therapy
- Standard Practices for PAT Multi-Attribute Measurement (MAM)

Membership in Committee E55 is open to all interested stakeholders with expertise in pharmaceutical and biopharmaceutical manufacturing. If you would like to learn more about any of the topics mentioned, request new topics not listed for consideration, or join to and participate in the Committee, contact ASTM International staff using the information provided.

Helping our World Work Better
Over 12,000 ASTM standards operate globally. Defined and set by us, they improve the lives of millions every day. Combined with our innovative business services, they enhance performance and help everyone have confidence in the things they buy and use - from the toy in a child's hands to the aircraft overhead.

Working across borders, disciplines, and industries we harness the expertise of over 30,000 members to create consenus and improve performance in manufacturing and materials, products and processes, systems and services. Understanding commercial needs and consumer priorities, we touch every part of everyday life: helping our world work better.

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