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Committee E55
Manufacture of Pharmaceutical and Biopharmaceutical Products

www.astm.org/COMMITTEE/E55

Manufacture of Pharmaceutical and Biopharmaceutical Products

ASTM Committee E55 brings together hundreds of technical experts from the public and private sectors to write voluntary consensus standards designed to drive new innovations in pharmaceutical and biopharmaceutical manufacturing and process control. As a member of Committee E55, you'll contribute to an international, industry-driven standards effort that will directly impact the pharmaceutical and biopharmaceutical industry for generations to come.

E55 members develop standardized language and definitions of terms, recommended practices, guides, test methods, specifications, and performance standards necessary to the manufacture of pharmaceutical and biopharmaceutical products.

Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products was formed in 2003 following an overhaul of U.S. Food and Drug Administration (FDA) regulations in drug manufacturing, the first such overhaul in 25 years.

Recognizing the industry needed new processes and techniques in manufacturing, the FDA created "Process analytical technology (PAT) - A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance." PAT was the first step in supporting the development, implementation, and regulation of manufacturing processes based on fundamental process understanding.

Following the introduction of PAT, industry needs have evolved toward defining and developing process-based best practices to an advanced scientific approach toward process understanding and flexible manufacturing.

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 drafting these practices through consensus and broad-based stakeholder representation and input. ASTM International took a leadership role in making it all happen.

200
Members Globally

20+
Approved Standards

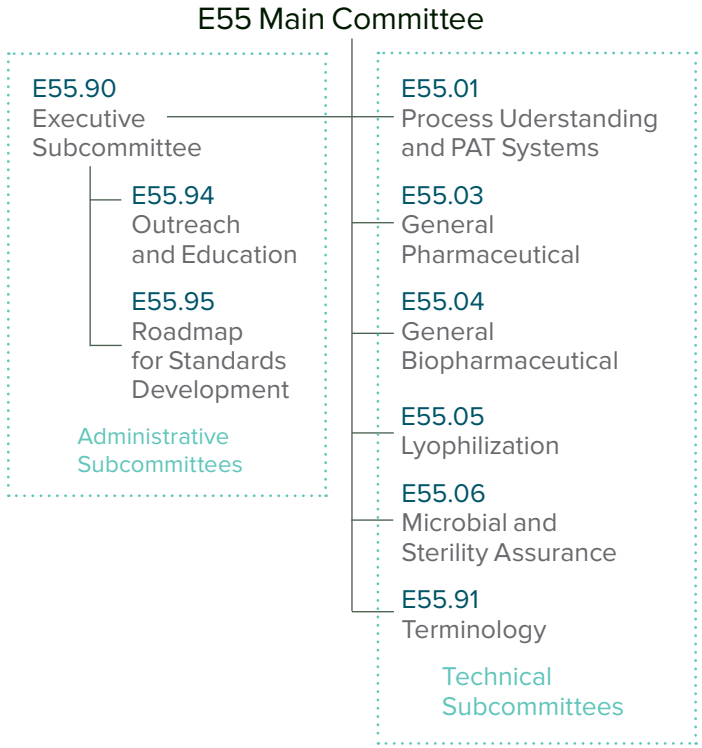
14.05
Volume Annual Book of Standards

Committee Scope and Structure

The scope of E55 is to develop standard nomenclature and definitions of terms, test methods, specifications, and performance standards for the manufacture of pharmaceutical and biopharmaceutical products. The Committee also encourages research and sponsors symposia, workshops, and publications to facilitate the development of such standards.

The work of E55 is distributed across several subcommittees that handle either technical development of standards in different areas of the industry or specific administrative functions of the committee.

Committee structure:



Subcommittee E55.01

Process Understanding and PAT System Management, Implementation, and Practice

Subcommittee E55.01 develops standards focused on pharmaceutical process understanding, process design, control, and optimization as well as the implementation and practice of process analytical technology. The subcommittee covers PAT system management, implementation and practice, allowing it to be highly effective in response to industry needs.

Approximately 80 volunteer members drive the work of drafting and revising standards related to process design, process understanding, risk assessment, risk control, verification, validation, and multivariate data analysis. Sampling and continuous processing guidance is also under the purview of E55.01.

ACTIVE STANDARDS

E2474 - Practice for Pharmaceutical Process Design Utilizing Process Analytical Technology

E2475 - Guide for Process Understanding Related to Pharmaceutical Manufacture and Control

E2476 - Guide for Risk Assessment and Risk Control as it Impacts the Design, Development, and Operation of PAT Processes for Pharmaceutical Manufacture

E2629 - Guide for Verification of Process Analytical Technology (PAT) Enabled Control Systems

E2891 - Guide for Multivariate Data Analysis in Pharmaceutical Development and Manufacturing Applications

E2898 - Guide for Risk-Based Validation of Analytical Methods for PAT Applications

E2968 - Guide for Application of Continuous Processing in the Pharmaceutical Industry

E3177 - Guide on Sampling for Process Analytical Technology

Subcommittee E55.03

General Pharmaceutical Standards

Over 100 stakeholders collaborate to develop standards related to pharmaceutical manufacturing beyond PAT. The breadth of work under E55.03 is not limited in scope, meeting diverse industry needs to manage quality of pharmaceuticals worldwide. As a result, the subcommittee continues to be successfully in standardized the design and verification of manufacturing systems and equipment, continuous quality verification, real-time release testing, testing of uniformity of dosage units, and qualification of basket and paddle apparatus. E55.03 also covers science and risk-based cleaning processes, particle analysis, and single-use system design and verification.

ACTIVE STANDARDS

E2500 - Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment

E2503 - Practice for Qualification of Basket and Paddle Dissolution Apparatus

E2537 - Guide for Application of Continuous Quality Verification to Pharmaceutical and Biopharmaceutical Manufacturing

E2656 - Practice for Real-time Release Testing of Pharmaceutical Water for the Total Organic Carbon Attribute

E2810 - Practice for Demonstrating Capability to Comply with the Test for Uniformity of Dosage Units

E3051 - Guide for Specification, Design, Verification, and Application of Single-Use Systems in Pharmaceutical and Biopharmaceutical Manufacturing

E3060 - Guide for Subvisible Particle Measurement in Biopharmaceutical Manufacturing Using Dynamic (Flow) Imaging Microscopy

E3077 - Guide for Raw Material eData Transfer from Material Suppliers to Pharmaceutical & Biopharmaceutical Manufacturers

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

F838 - Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration

Subcommittee E55.04

General Biopharmaceutical Standards

Formed in response to the growth in biopharmaceutical science, Subcommittee E55.04 covers emerging needs specific to bioprocessing, biologics, and biotherapeutics. With a roster of 100 members and counting, E55.04 explores topics such as, but not limited to, single-use systems application, integrity, and testing; characterization of particulates; viral filtration; handling of biological material; and stability.

ACTIVE STANDARDS

E1564 - Guide for Design and Maintenance of Low-Temperature Storage Facilities for Maintaining Cryopreserved Biological Materials

E1565 - Guide for Inventory Control and Handling of Biological Material Maintained at Low Temperatures

E1566 - Guide for Handling Hazardous Biological Materials in Liquid Nitrogen

E2097 - Guide for Determining the Impact of Extractables from Non-Metallic Materials on the Safety of Biotechnology Products

E2888 - Practice for Process for Inactivation of Rodent Retrovirus by pH

E3042 - Practice for Process Step to Inactivate Rodent Retrovirus with Triton X-100 Treatment

Subcommittee E55.05

Lyophilization

Subcommittee E55.05 is dedicated to developing standards on the use of lyophilization (freeze-drying) in pharmaceutical manufacturing processes. Championed by the Advanced Lyophilization Technology Hub (LyoHub) industry group, and with the support of the U.S. National Institute of Standards and Technology (NIST) and the FDA, the subcommittee is currently exploring aspects of lyophilization process and equipment design, operation and qualification, quality assessment, process understanding and control of parenterals and other pharmaceutical and biological products.

Subcommittee E55.06

Microbial and Sterility Assurance

Continued growth of E55 has led to the formation of its newest subcommittee, E55.06, which takes deeper dive into aspects of microbial and sterility assurance of pharmaceutical and biopharmaceutical products. The initial work of the subcommittee will consider topics such as post sterilization filter testing, contamination control strategy, release testing strategies, single-use system leak testing post use, integrity testing, and garment controls.

Subcommittee E55.91

Terminology

One of the most critical tasks of all ASTM technical committees is to develop common terminology to eliminate contradicting definitions across standards that may lead to confusion when used in industry. Subcommittee E55.91 is tasked with maintaining terminology that may be referenced by other E55 standards and beyond. The subcommittee also works to harmonize terminology on a global scale to ensure international application of all industry relevant ASTM standards.

ACTIVE STANDARDS

E2363 - Terminology Relating to Process Analytical Technology in the Pharmaceutical Industry

Subcommittee E55.90

Executive

All ASTM technical committees have an Executive Subcommittee, led by a selection of elected member officers, to oversee the duties and responsibilities within the committee. The E55.90 Executive Subcommittee is primarily responsible for the formation of all E55 subcommittees, maintaining E55 committee by-laws, conflict resolution, and strategic planning. This group routinely meets to discuss main committee and subcommittee operations, status of standards development projects, trends and challenges within industry, and new opportunities. The Executive Subcommittee will often delegate administrative responsibilities to members, establish specific task groups, or to one of the following existing administrative subcommittees.

Subcommittee E55.94

Outreach and Education

To ensure continued effectiveness of standards is to be aware of industry happenings and to foster strategic relationships. Subcommittee E55.94 defines and implements strategies to promote awareness and usage of E55 standards by establishing relationships with key stakeholders, developing promotional material to keep the industry informed, and providing education for new members. E55.94 continuously seeks and relies heavily on the feedback of members and observations of the industry. Such information has led to the creation of the E55 Committee Newsletter, increased participation from regulators and academics, and the continued recruitment of targeted industry experts to address specific needs of current and future E55 standards.

The E55 Committee Newsletter is published semi-annually, opposite E55 committee meetings, and is a great way to stay current with updates on open projects, meeting recaps, upcoming events, feature articles, and other general announcements. It is available for free on the E55 section of the ASTM website.

The latest copy of the E55 Newsletter is available at **www.astm.org/COMMITTEE/E55**

Subcommittee E55.95

Roadmap for Standards Development

The industry, along with the underlining science and technology, is ever-evolving. In response of this, the focus of the E55.95 Roadmap Subcommittee is to formulate and maintain a standards roadmap aimed at predicting and proactively meeting the needs of pharmaceutical and biopharmaceutical manufacturing. This group also aids experts in ensuring their work complements or advances – not contradicts or duplicates – existing standardized frameworks already adopted by industry. The goal of E55.95 is to help the committee and the industry navigate an intricate puzzle of existing standards, current and potential regulations, process innovations, and emerging technologies. As a result, the subcommittee can provide guidance for determining priorities, opportunities, and resource requirements needed to ensure the work of E55 provides product safety and quality as well as process efficiency.

For more detail on the past, present, and future work of the committee, check out the Committee E55 Roadmap brochure available at **www.astm.org/COMMITTEE/E55**

Timeline

2003

ASTM Committee E55 on Pharmaceutical Application of Process Analytical Technology established

Subcommittees E55.01 PAT System Management and E55.02 PAT System Implementation and Practice formed

2004

Subcommittee E55.91 Terminology formed

First E55 standard E2363 on Terminology Relating to PAT approved

2005

E55 scope updated and renamed to Manufacture of Pharmaceutical Products

Subcommittee E55.03 General Pharmaceutical formed

2006

E2474 Practice for Pharmaceutical Process Design Utilizing PAT approved

2007

E2500 Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment and **E2503** Practice for Qualification of Basket and Paddle Dissolution Apparatus approved

2008

E2537 Guide for Application of Continuous Process Verification to Pharmaceutical and Biopharmaceutical Manufacturing approved

2009

E2476 Guide for Risk Assessment and Risk Control as it Impacts the Design, Development, and Operation of PAT Processes approved

2010

E2475 Guide for Process Understanding Related to Pharmaceutical Manufacture and Control and **E2656** Practice for Real-time Release Testing of Pharmaceutical Water for the Total Organic Carbon Attribute approved

2011

ASTM Committee E55 on Pharmaceutical Application of Process Analytical Technology established

Subcommittees E55.01 PAT System Management and E55.02 PAT System Implementation and Practice formed

2012

Subcommittee E55.91 Terminology formed

First E55 standard E2363 on Terminology Relating to PAT approved

2013

E55 scope updated and renamed to Manufacture of Pharmaceutical Products

Subcommittee E55.03 General Pharmaceutical formed

2014

E2474 Practice for Pharmaceutical Process Design Utilizing PAT approved

2015

E2500 Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment and **E2503** Practice for Qualification of Basket and Paddle Dissolution Apparatus approved

2016

E2537 Guide for Application of Continuous Process Verification to Pharmaceutical and Biopharmaceutical Manufacturing approved

2017

E2476 Guide for Risk Assessment and Risk Control as it Impacts the Design, Development, and Operation of PAT Processes approved

2018

E2475 Guide for Process Understanding Related to Pharmaceutical Manufacture and Control and **E2656** Practice for Real-time Release Testing of Pharmaceutical Water for the Total Organic Carbon Attribute approved

Helping our World Work Better
Committed to serving global societal needs, ASTM International positively impacts public health and safety, consumer confidence, and overall quality of life. We integrate consensus standards – developed with our international membership of volunteer technical experts – and innovate services to improve lives... Helping our world work better.

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www.astm.org/JOIN

Attend a meeting
www.astm.org/MEETINGS

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