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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 that will help drive new innovations in pharmaceutical and biopharmaceutical manufacturing and process control. As a member of Committee E55, you'll contribute to an industry-driven standards effort that will directly impact the pharmaceutical industry for generations to come.

E55 members will develop standardized language and definitions of terms, recommended practices, guides, test methods, specifications, and performance standards for pharmaceutical application of process analytical technology.

www.astm.org/COMMITTEE/E55

An Industry in Need of New Processes & Techniques

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 regulations in drug manufacturing, the first such overhaul in 25 years.

Recognizing that the industry was in need of new processes and techniques in manufacturing, the FDA created "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.

200 Members

20 Standards

14.05 Volume, E55 Book of Standards

Following the introduction of PAT, the industry's needs have evolved toward defining and developing process-based "best practices" to advance a 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.

ASTM standards have already improved the 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. Cost savings is achieved by the elimination of a variable and expensive reference standard.

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).

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Subcommittee E55.01

Process Understanding and PAT System Management, Implementation, and Practice

Subcommittee E55.01 develops principles for pharmaceutical process understanding, process design, control, and optimization and the implementation and practice of process analytical technology. The subcommittee covers the PAT system management, implementation and practice, allowing it to be maximally responsive to industry needs.

Approximately 80 volunteer members managesstandards related to process design, process understanding, risk assessment, risk control, verification, validation, and multivariate data analysis. Sampling and continuous processing guidance is also under their purview.

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

Complete active and draft standards available at
www.astm.org/COMMIT/SUBCOMMIT/E5501

Subcommittee E55.03

General Pharmaceutical Standards

Over 150 stakeholders collaborate to develop standards related to manufacturing pharmaceuticals. The breadth of work under this subcommittee is not limited in scope, meeting a wide range of industry needs to manage quality of pharmaceuticals worldwide.

Although the work of the subcommittee is broad they have successfully 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. The work expands into 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
- **F838** Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration

Complete active and draft standards available at
www.astm.org/COMMIT/SUBCOMMIT/E5503

Standards Roadmap: E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products

GENERAL TOP-LEVEL STANDARDS
- General Concepts
- Common Requirements
- Generally Applicable

CATEGORY STANDARDS
- Specific to material or process category

SPECIALIZED STANDARDS
- Specific to material, process or application

QUALITY MANAGEMENT

- ISO 9001: 2015
- ISO 9004: 2009

TERMINOLOGY

- ASTM E2363

REGULATION

- FDA
- EMA

PROCESS DESIGN
- Chemo-Metric Modeling
- Continuous Processing
- Critical Control Parameters
- PAT
- Process Understanding
- Risk Management
- RTR
- Sampling
- Scaling Methodologies
- Small-Scale Mfr & Predictive Models
- Technology Platform Methodologies
- Unit Operations

PROCESS QUALIFICATION AND LIFECYCLE MANAGEMENT
- Automatic Control
- Engineering Control
- Fault Analysis
- Information Management
- Process Understanding
- Process Verification
- Risk Management
- Sampling
- Trend Monitoring

PRODUCT DESIGN
- Bioavailability
- Chemical & Physical Stability
- Critical Quality Attributes
- Design Specifications
- Drug Substance, Product Properties
- Excipients & Container-Closure Components
- Functional Properties of Mtls
- Functional Requirements
- In-vivo Performance

CHARACTERIZATION OF MATERIALS
- Biological
- Chemical
- Extractables
- Leachables
- Methods for Bulk Measurement
- Molecular Properties
- Structural
- Particle Size and Shape
- Physical Characterization
- Surface Properties

A Roadmap for the Future (E55.95)

Industry and science are ever-evolving.The “Roadmap subcommittee helps predict A standards roadmap is aimed at predicting and meeting the needs of industry proactively. It also aids experts in ensuring their work to complements - not contradicts or duplicates - existing standardized frameworks already adopted by industry. The roadmap serves as an intricate and feasible puzzle of functioning guidance to ultimately ensure product safety and quality.

Roadmapping ensures that standards can encompass broad topics, address specific subject areas, cross-reference each other to ensure detailed coverage of content, and more.

Subcommittee E55.04

Subcommittee on General Biopharmaceutical Standards
Subcommittee E55.04 is one of the newest, with approximately 100 members. It was formed in response to the growth in biopharmaceutical science. Its standards meet emerging needs of this market.

Topics include:
- Determining and characterizing extractables from materials used in single-use applications
- Characterizing particulates burden from single-use systems (vendor and end-user)
- Testing and controlling integrity of single-use systems
- Applying single-use systems in manufacturing
- Inactivating enveloped viruses using detergent
- Removing viruses by filtration

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

Note
All biopharmaceutical related standards work is conducted under E55.04, not Committee E48 on Biotechnology

Complete active and draft standards available at
www.astm.org/COMMIT/SUBCOMMIT/E5501

E55.04 Fun Fact

The first standard approved under E55.04 was E2888, only 6 months after its formation!

Subcommittee E55.91

Subcommittee on Terminology
One of the most critical tasks of all standards committees is to develop common terminology to eliminate the chances of standards contradicting each other or creating an unsafe marketplace. E55.91 maintains terminology standard E2363. The subcommittee also works to harmonize terminology on a global scale to ensure international application of E55 standards.

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

Subcommittee E54.94

Subcommitte on Outreach and Education
The best way to ensure continued effectiveness of standards is to be aware of industry happenings and to foster strategic relationships. E55.94 implements a strategy to promote the understanding and usage of E55 standards by developing relationships and liaisons between E55 and key stakeholders in the industry. The work of this subcommittee includes identifying, establishing and supporting contacts in relevant organizations, developing promotional materials, and providing outreach and education recommendations to the committee.

Timeline

2003

December 10
- **E55** on Pharmaceutical Application of Process Analytical Technology orgainized
- Subcommittees **E55.01** PAT System Management and **E55.02** on PAT System Implementation and Practice formed

2004

January 12
- **E55.91** Terminology Subcommittee formed

July 1
- First standard **E2363** on Terminology approved

August 1
- Lawrence Hecker received the Distinguished Service Award for **E2363**

2005

September 8
- Subcommittee **E55.92** on Awards formed

2006

August 1
- **Donald Marlowe** received the Outstanding Leadership Award

November 1
- **E2474** on Pharmaceutical Process Design Utilizing Process Analytical Technology approved

November 15
- **Gerd Fischer** received the Standards Excellence Award for E2474.
- **Bruce Davis** received the Award of Appreciation for promotion of E55 to the European Medicines Agency (EMEA)

2007

March 15
- **E2503** Practice for Qualification of Basket and Paddle Dissolution Apparatus approved

June 1
- **E2500** Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment approved

2008

January 1
- **E2537** Guide for Application of Continuous Quality Verification to Pharmaceutical and Biopharmaceutical Manufacturing approved

2009

May 15
- **E2476** Guide for Risk Assessment and Risk Control as it Impacts the Design, Development, and Operation of PAT Processes for Pharmaceutical Manufacture approved

2010

August 1
- Gawayne Mahboubian-Jones received the Standards Excellence Award for **E2476**

April 15
- E2475 Guide for Process Understanding Related to Pharmaceutical Manufacture and Control approved

August 1
- **E2656** Practice for Real-time Release Testing of Pharmaceutical Water for the Total Organic Carbon Attribute approved

2011

August 4
- Subcommittees **E55.94** on Strategic Planning and Resource Development and E55.95 on Roadmap for Standards Development formed

April 15
- **E2629** Guide for Verification of Process Analytical Technology (PAT) Enabled Control Systems approved

October 1
- **E2810** Practice for Demonstrating Capability to Comply with the Test for Uniformity of Dosage Units approved

2012

February 15
- Subcommittee **E55.04** on General Pharmaceutical Standards was formed. 16 biopharmaceutical standards transferred from E48 to E55.04

April 16
- **E55.02** merged under newly titled E55.01 on PAT System Management, Implementation and Practice

August 1
- **E2888** Practice for Process for Inactivation of Rodent Retrovirus by pH approved

2013

June 19
- **F838** Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration transferred to E55.03

November 1
- **E2891** Guide for Multivariate Data Analysis in Pharmaceutical Development and Manufacturing Applications approved
- **E2898** Guide for Risk-Based Validation of Analytical Methods for PAT Applications approved

2014

February 19
- **E55.94** retitled and scoped to Outreach and Education

April 29
- Awards of Appreciation presented to **Sabra Seyer** (E2537 & E2500), **Bruce Davis** (E2629), **Richard Godec** (E2656), and **Trevor Page** (E2968)

May 21
- Awards of Appreciation presented to **Chun Cai** (E2891), **James Rydzak** (E2898), **Robert Steininger** and **Ali Afran** (E2888), **Alex Viehmann** and **Thomas Murphy** (E2810). Outstanding Service and Leadership awards presented to **Duncan Low, Martin Warman, Russell Madsen, among others**

September 24
- ASTM Committee on Technical Comittee Operations (COTCO) approved and revised **E55 by-laws**; E55 renamed to include Biopharmaceutical

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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