ASTM INTERNATIONAL
Helping our world work better

Committee E55
Manufacture of Pharmaceutical and Biopharmaceutical Products

NEWSLETTER

Introduction
New Vision

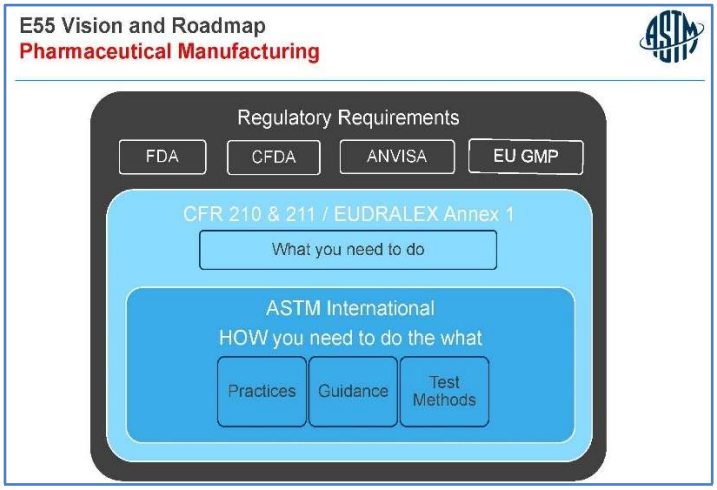
E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products
Chair: *John Logar, Johnson & Johnson*
Vice-chair: *Don Kientzler, J-STAR Research*
Secretary: *Jennifer Gray, LyoHUB, Purdue University*
Membership: *Claus Weisemann, NGM Biopharmaceuticals*

It is hard to believe the first half of 2022 is already over and to say we, the officers of ASTM Committee E55, have been busy, is an understatement. As a (mostly) new group of committee officers, we kicked off the year gathering member feedback and discussing the current state of the committee and quickly realized the strategies and objectives implemented by the previous leadership team has created a very solid foundation and will enable our committee to grow rapidly in the near future.

As a result of the feedback we received, we identified a few immediate opportunities that we believe can accelerate our position, involvement, and contributions in several critical areas of the pharmaceutical and biopharmaceutical industries. To socialize these areas, a strategic vision was created and shared at our April committee meeting. The tenets of this vision are as follows:

Establish Our Swim Lane: To enable our vision, will need to engage our industry partners and standards organizations, socialize our E55 roadmap and determine where our committee can 'take a lead' or where we can become a partner and 'complement existing activities and standards'. A shift in the focus of our output will play an important part of how our standards are viewed and used.

For example, if we focus on writing standards that describe "How" to do the "What" (or requirements described in regulations) and provide more detailed guidance, our standards become more valuable to new users and will ultimately attract new members (i.e. the next generation).



Restructure Sub-committees: First, we need to evaluate our current structure, titles, and standards for each subcommittee to ensure they are intuitive to the members and industries we represent and update them as needed.

Second, we should establish new 'specific' subcommittees (SUS, Cell Therapy, etc.) to align with and compliment the work being done by other stakeholder organizations.

Finally, we will then re-arrange our existing standards to align with the new subcommittees and/or subcommittee titles.

Drive Education, Outreach, Liaisons: Training on how to use our standards will become a critical component of increasing their utilization but also as a mechanism to bring new / next generation users into our ASTM community. This training can be in the form of webinars, workshops, or conferences.

Additionally, creating a strategic roadmap for outreach will enable connections and forums to socialize our current activities, share our strategies and focus areas as well as attracting students and regulatory agencies to engage in our activities. This includes a focus on the ASTM International 'Research 2 Standards' initiative through our partnerships.

Finally, establishing strategic liaisons with key stakeholder organizations will establish trusted partnerships, and deliver mutually beneficial value while advancing standardization in the pharmaceutical and biopharmaceutical industries.

Culture: It goes without saying that culture drives success. ASTM provides the opportunities for individuals to participate and develop their own intellectual property while returning their company's investment (of their time and knowledge). It is imperative that we continue to host and build a welcoming/inviting forum for industry collaboration.

Every voice matters regardless of the years of experience, the company one represents, or the origin of their expertise. This culture will enable our members to be their best and in return will produce critical standards for our industry.

Committee Updates
Building for the Future

Change in Bylaws: A review of our bylaws identified the opportunity to provide minor updates including adding the responsibility for committee awards to the Committee Vice-Chair role and including the immediate past chair to the executive committee. The updated bylaws have been approved by both the executive committee and the committee and will go out for approval by COTCO this fall.

Executive Subcommittees Combined: E55.94 and E55.96 have been combined into E55.94 with the following proposed scope:

The scope of the subcommittee is the establishment and management of committee education programs, outreach opportunities, and liaison activities for engagement and interaction with key stakeholders, regulatory agencies and industry organizations directly connected to the pharmaceutical and biopharmaceutical industries.

Education: The subcommittee will facilitate, standardize, and support the development and execution of educational programs and workshops focused on the interpretation, use, and application of standards applicable to and used in the manufacture of pharmaceutical and biopharmaceutical products.

Outreach: The subcommittee will solicit, engage, and promote interaction with pharmaceutical and biopharmaceutical companies, academic institutions, regulatory agencies and notified bodies, and complimentary industry organizations through focused outreach events, publicity on social media and collaboration on strategic platforms.

Liaisons: The subcommittee will provide governance for E55 committee liaisons who will serve as ambassadors of the committee E55 mission and promote a complementary vision for collaboration to build a mutually beneficial partnership and value proposition that benefits the individuals, companies, and industries the partner's support.

We are happy to report that Christine Farrance, PhD (Charles River) was nominated and approved to lead this executive committee. Congratulations Christine.

Industry Collaboration
Accelerating Innovation

MOU Signed with BioPhorum: In October 2021, ASTM International and BioPhorum signed a memorandum of understanding (MOU) to enable alignment, acceleration, and adoption of innovative and standardized practices for the biopharmaceutical industry. This collaborative framework will enable the two organizations to work in tandem on key priorities and drivers by leveraging the strengths of both organizations.

The groups are planning a series of meetings to establish and align on targeted areas to pilot bringing industry innovation (through BioPhorum) to standardization (through ASTM). The first meeting, to review the ASTM process and structure, is scheduled for late July and the second meeting,

to review the list of targeted BioPhorum focus areas is planned for mid-August. Following the initial meetings, independent meetings will be scheduled for each of the agreed upon areas.

Memorandum of Understanding
Between

ASTM International 100 Barr Harbor Drive PO Box C700 West Conshohocken PA 19428-2959, USA	and	**BioPhorum Operations Group Limited** 5 Westbrook Court Sheffield S11 8YZ England, United Kingdom

1. Introduction

This Memorandum of Understanding (MOU) is dated 18 October 2021 and sets out the understanding between; ASTM International (**ASTM**) and the BioPhorum Operations Group Limited (**BioPhorum**) (together the "Parties").

2. Purpose

2.1. Establish a formal relationship by which ASTM and BioPhorum can collaborate to help accelerate the rate of progress of the standards and standardization within the biopharmaceutical industry.

3. Desired Outcomes

3.1. Alignment of industry, agency, and standards body (industry stakeholder) strategies and priorities.

3.2. Acceleration of guidance and standards development.

3.3. Technical alignment and accelerated adoption of regulatory guidance and standards, within the biopharmaceutical industry.

Voice of Customer
Building Trusted Partnerships

Committee Liaison Opportunities: In support of the scope of E55.94 and the focus on liaisons, a list of pharma/biopharma industry organizations was created to open the door for 2-way sharing of information and mutually beneficial opportunities through the establishment of committee liaisons. The list includes the following organizations:

- ASTM F04 - Medical and Surgical Materials and Devices
- BioPhorum
- International Society for Pharmaceutical Engineering (ISPE)
- American Society of Mechanical Engineers-Biopharm Process Equipment (ASME-BPE)
- Bio-Process Systems Alliance (BPSA)
- LyoHUB
- STANDARDS COORDINATING BODY (SCB)
- Pharmaceutical Inspection Co-Operation Scheme (PIC/S)
- Parenteral Drug Association (PDA)
- US Pharmacopeia (USP)
- ISO TC/198 WG9 - Aseptic Processing
- Institute of Environmental Sciences and Technology
- International Society for Cell & Gene Therapy (ISCT)
- ISO TC/209 - Cleanrooms and Associated Controlled Environments
- US FDA
- European Medicines Agency (EMA)
- Association for Clean and Parenteral Products (A3P)

We are looking to identify, appoint and empower E55 committee members to act as official liaisons to these organizations. If you are interested, please reach out to John Logar or Christine Farrance.

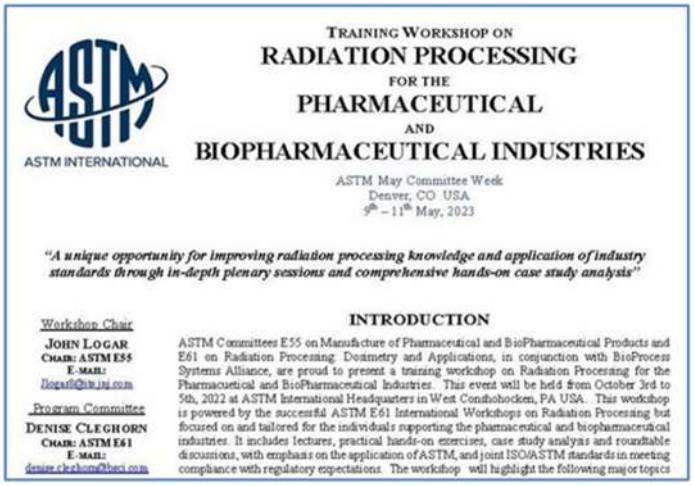
Academic Forum: Committee leaders hosted another meeting of the ASTM E55 Academia Forum on Thursday May 9th, 2022. This was the 6th meeting of this group since it was formed in 2019. There were six presentations from Academia Professors which were identified as areas for further collaboration. This forum continues to be a great avenue to review current research and innovation. Thank you to all of the professors who shared their work.

Industry Forum: This spring, we did not hold an industry forum, but we took the opportunity to re-evaluate the benefits

of this type of interaction and determined that we needed a different mechanism to gather input from key industry stakeholders. We will be creating an industry advisory board (IAB) and will solicit technical thought leaders and senior industry executives from member companies to ensure we are staying current with industry trends, technologies, and changes. The announcement of this board will be issued this fall.

Training & Education
Competency Development

Collaborative Workshop Planned: The E55 committee, in conjunction with ASTM E61 on Radiation Processing and support from BPSA, will host a training workshop May 9th – 11th at the 2023 ASTM Committee Week in Denver, CO. The workshop is planned to be a two-day event that will be focused on and tailored for the individuals supporting the pharmaceutical and biopharmaceutical industries.



ASTM INTERNATIONAL

TRAINING WORKSHOP ON
RADIATION PROCESSING
FOR THE
PHARMACEUTICAL
AND
BIOPHARMACEUTICAL INDUSTRIES

ASTM May Committee Week
Denver, CO USA
9th – 11th May, 2023

"A unique opportunity for improving radiation processing knowledge and application of industry standards through in-depth plenary sessions and comprehensive hands-on case study analysis"

Workshop Chair
JOHN LOGAR
CHAIR: ASTM E55
E-MAIL:
jlogar8@its.jnj.com

Program Committee
DENISE CLEGHORN
CHAIR: ASTM E61
E-MAIL:
denise.cleghorn@baci.com

INTRODUCTION

ASTM Committees E55 on Manufacture of Pharmaceutical and BioPharmaceutical Products and E61 on Radiation Processing: Dosimetry and Applications, in conjunction with BioProcess Systems Alliance, are proud to present a training workshop on Radiation Processing for the Pharmaceutical and BioPharmaceutical Industries. This event will be held from October 3rd to 5th, 2022 at ASTM International Headquarters in West Conshohocken, PA USA. This workshop is powered by the successful ASTM E61 International Workshops on Radiation Processing but focused on and tailored for the individuals supporting the pharmaceutical and biopharmaceutical industries. It includes lectures, practical hands-on exercises, case study analysis and roundtable discussions, with emphasis on the application of ASTM, and joint ISO/ASTM standards in meeting compliance with regulatory expectations. The workshop will highlight the following major topics

It includes lectures, practical hands-on exercises, case study analysis, and roundtable discussions, with emphasis on the application of ASTM standards in meeting compliance with regulatory expectations.

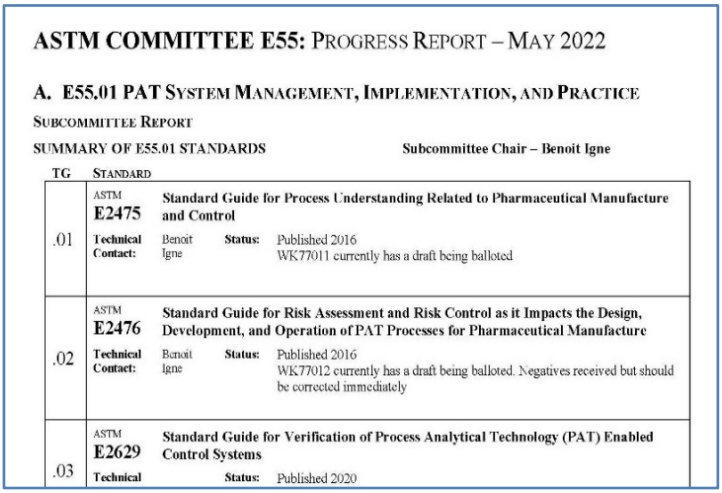
The workshop will highlight the following major topics during all plenary and hands-on sessions:

- X-ray, Gamma, and E-beam
- Equipment/Technology/Conveyance
- Mathematical Modeling

This workshop is intended for those individuals responsible for their organization's components, systems, or products that require radiation sterilization. Attendance will be limited to the first 50 participants who register.

Enhancing Communication
Progress Report Tracker

New Committee Activity Report: In an effort to keep our membership informed of critical committee activities, a new 'progress report' was created and will be issued periodically to the membership.



ASTM COMMITTEE E55: PROGRESS REPORT – MAY 2022

A. E55.01 PAT SYSTEM MANAGEMENT, IMPLEMENTATION, AND PRACTICE

SUBCOMMITTEE REPORT

SUMMARY OF E55.01 STANDARDS — Subcommittee Chair – Benoit Igne

TG	STANDARD	
.01	ASTM E2475	**Standard Guide for Process Understanding Related to Pharmaceutical Manufacture and Control** Technical Contact: Benoit Igne — Status: Published 2016 WK77011 currently has a draft being balloted
.02	ASTM E2476	**Standard Guide for Risk Assessment and Risk Control as it Impacts the Design, Development, and Operation of PAT Processes for Pharmaceutical Manufacture** Technical Contact: Benoit Igne — Status: Published 2016 WK77012 currently has a draft being balloted. Negatives received but should be corrected immediately
.03	ASTM E2629	**Standard Guide for Verification of Process Analytical Technology (PAT) Enabled Control Systems** Technical — Status: Published 2020

The report is designed to provide updates on the following items:

- Subcommittees: Chair, title, and standards under its jurisdiction
- Existing Standards: Task Group #, last publication date, technical contact, and ballot activity (if any)
- New Work Items: WK number, technical contact, and ballot activity
- Liaison Activity: Organization, E55 liaison, current activities, and opportunities
- Outreach Events: Event, Date and Time, Focus, and Scope

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Next Generation Talent
Emerging Professionals

ASTM Emerging Professional Program: E55 would like to identify and nominate an emerging professional from our industry who is in their first 5 years of membership. The program enables a new member to get a unique immersion experience into the ASTM process and insights how to become an effective member.

This program has been in place for several years and has quickly become valuable for task group, sub-committee and committee succession planning as leaders have emerged from the program and transitioned into key leadership positions in multiple committees.

If you nominate a colleague and they are selected for the program, they will receive some travel assistance to attend a future meeting and be included in all training opportunities. For more information, visit NextGen: Emerging Professionals Program, Scholarships, and More | ASTM Standardization News

Subcommittee Reports
Delivering Standards

Under the direction of the Executive Subcommittee and through the input of our members, E55 continues to make significant progress towards revising and expanding its catalog of international standards. This section covers subcommittee reports highlighting the accomplishments and ongoing efforts in standards development. All members and interested industry stakeholders are encouraged to contribute to any of these efforts by reaching out to the subcommittee chairs.

E55.01 Process Understanding and PAT System Management, Implementation and Practice
Chair: Benoît Igne, Vertex Pharmaceuticals

The E55.01 subcommittee activities have focused on addressing negative ballot comments to **E2968-14** Standard Guide for Application of Continuous Processing in the Pharmaceutical Industry, and balloting **E2475-10(2016)** Guide for Process Understanding Related to Pharmaceutical Manufacture and Control, and **E2476-16** Guide for Risk Assessment and Risk Control as it Impacts the Design, Development, and Operation of PAT Processes for Pharmaceutical Manufacture following document updates.

WK76297 Proposed Standard Guide on Advanced Process Control (APC) to develop a new standard on the use of Advanced Process Control in the pharmaceutical industry is progressing. A draft document was shared with the E55 committee ahead of the semi-annual meeting and the authoring team is working towards submitting the standard for ballot in 2022, A second draft for **WK74957** Proposed Standard Guide PAT System Applications in Biopharmaceutical **Industry** was shared by the authoring team and the document is being updated following input from the committee. Anyone interested in joining either of these drafting/reviewing efforts are welcome to contact E55.01 sub-chair Benoit Igne, benoit_igne@vrtx.com.

E55.03 General Pharmaceutical Standards
Chair: Paul Gil, Consultant

Subcommittee E55.03 currently has multiple standards and development projects underway, covering a range of topics within the industry. The subcommittee has been addressing comments on the revision of **E3106** Standard Guide for Science-Based and Risk-Based Cleaning Process Development and Validation and will ballot a "Not Persuasive" motion concurrently in the coming weeks to resolve the outstanding comments that are unable to be resolved. In addition, the Clean by Design (WK78595) task group has been meeting on a weekly basis. The work has been divided up into 5 sub-groups within.

WK73465 Standard Guide for Accelerated CMC development, manufacture and supply of therapies and vaccines for use in pandemics such as COVID-19 has been withdrawn. Drafts have been saved should anyone wish to convert the info into a journal article, white paper, or technical report.

Finally, the Combo Product task group has issued the next version of WK72293 New Guide for Standard Guide for Definition of Combination Products (Drug / Device / Biologic Combinations) for ballot. The group plans to register another work item on "cGMP Best Practices for Combined Use Systems (medicinal product-device)"

E55.04 General Biopharmaceutical Standards

Chair: Jeff Carter, Cytiva

The E55.04 subcommittee houses nine standards. The committee is working on several standards. Notably, between E55.04 and E55.03, they are developing a suite of standards directly relevant to single use biomanufacturing. E55 has become very active in this space and is now a go-to resource for standards in this area.

Building off **E3051-16**, Standard guide for specification, design, verification, and application of single-use systems, where are now standards on integrity assurance and microbial ingress. A new standard on integrity testing (**E3336-22**) has just been accepted for imminent publication. The standards on integrity assurance and microbial ingress will be revised to harmonize definitions of terms. Likewise, there are standards for extracting and for measuring particulates in single use items. New work items on additional measurement methods and reporting and classifying particulate cleanliness are underway. Lastly, E55.04 houses a standard on how to assess the impact of single use items on cell culture.

Beyond single use, E55.04 has a draft standard on removal of large viruses by using small-virus retentive filters, which is aimed at speeding early clinical trials by reducing the need for filter validation studies. A draft standard describing principles for continuous manufacturing in the biopharmaceutical space has undergone multiple ballots and is in the final stages of revision before final balloting.

The committee is still not resolved on the work item **WK64991** Practice for Stability of Early Phase Protein Products, which is intended to reduce validation needs for proteins in early clinical trials: one negative vote remains unreconciled.

E55.05 Lyophilization

Chair: Arnab Ganguly, Amgen

The scope of this sub-committee is to develop, disseminate, and educate standard practices and guides relevant to lyophilization of parenterals and other pharmaceutical and biological products. The work of the subcommittee will cover all aspects of process and equipment design, operation and qualification, quality assessment, process understanding, and control.

Work items in Process

In January 2022, work item **WK80172**, Standard Practice for Lyophilization Process Validation: Part 1 was drafted and sent to the working group for comments/edits. All received edits and comments have been consolidated, and the working draft will incorporate them prior to balloting in summer of 2022.

The content for the consensus standard will be based on the recently published Best Practice Document (Jameel, F., Alexeenko, A., Bhambhani, A. et al. Recommended Best Practices for Lyophilization Validation—2021 Part I: Process Design and Modeling. AAPS PharmSciTech 22, 221 (2021). https://doi.org/10.1208/s12249-021-02086-8). This work describes lyophilization process validation and consists of two parts. Part I focuses on the process design and is described in the above cited paper, while part II is devoted to process qualification and continued process verification. The intent of these articles is to provide readers with recent updates on lyophilization validation in the light of community-based combined opinion on the process and reflect the industrial prospective. Through this effort, the group will be looking to convert the Best Practice document into Consensus Standards. Interested members are invited to reach out and contribute to the working group.

E55.06 Contamination Control

Chair: Scott Drummond, Bristol Myers Squibb

Subcommittee E55.06 is changing its name to Contamination Control. Following feedback from several members and partner industry organization, E55.06 decided to align the subcommittee title with the term most recognized in the industry. The former title, Microbial/Sterility Assurance for Pharmaceutical and Biopharmaceutical Products, although appropriate, did not resonate as well as hoped. The subcommittee believes that the new title will clearly convey the focus and scope of the subcommittee.

Subcommittee E55.06 on Microbial/Sterility Assurance for Pharmaceutical and Biopharmaceutical Product aims to address an unmet industry need to develop practice and guidance documents in support of the microbiological quality and sterility assurance of pharmaceutical products.

Membership of E55.06 currently is 56 members. During the April meeting, the subcommittee discussed progress on the active standards. **WK74412**, Guide for Critical Airflow Visualization was issued for subcommittee comments and received two negative votes, one was a

request to the include guidance when using tracer gas as a visual medium. The Subcommittee agreed to include details for the tracer gas method, because use of tracer gas is new to the industry and inclusion will drive innovation for airflow visualization. The second negative was from a comment that the scope is too broad. The subcommittee will work with the commenter to attempt to resolve their comments. Dawn Nestola the technical lead for from Cleanroom Gowning Selection and Use provided the update on the great progress for this standard where leaders from single use and reusable gown suppliers are collaborating for this standard. **WK78574** New Guide for Best Practices for Microbial Control for Cell Therapeutics is the newest standard in progress and has very active interest.

For any questions or to participate in standards development please reach out to either Scott Drummond Bristol Myers Squibb or Martin Muellner at Boehringer Ingelheim.

Upcoming Events
Future Meetings

E55 will continue to meet at least twice per year and those meetings will continue to be a hybrid format for the immediate future to accommodate our membership. Although we value the added benefits of meeting in person, we recognize the limitations and challenges our members face in attending in person. Additionally, the executive committee recognizes the diversity of our international membership and are committed to continue to host committee meetings in Europe. To facilitate these meetings, we will work with our members and partner organizations to identify hosts and venues that can accommodate our committee with the intention of hosting an international meeting every other year.

As we reviewed our upcoming meetings, we identified the opportunity to leverage the ASTM Committee weeks and align with key stakeholder committees such as F04 on Medical Devices. Thus, starting in 2023, we will be holding our semi-annual committee meetings during the ASTM May and November committee weeks unless an alternate international location is identified and scheduled.

New CPI MMIC Facility set for Oct 2022 Meetings

Planning is currently underway for the October 2022 full committee meeting, which will be held at the brand-new Medicines Manufacturing Innovation Centre (MMIC) in Scotland. The state-of-the-art facility comes as a result of collaboration between the Centre for Process Innovation Limited (CPI), University of Strathclyde, UK Research & Innovation, Scottish Enterprise and founding industry partners, AstraZeneca, and GSK. The meeting is tentatively set for October 19-20, 2022 and will include a tour of the new facility and help to build new and existing relationships in the region. Stay tuned for updates as they are made available.

Committee Meetings and More:

Mark your Calendars:

2022

October 19th – 20th E55 Committee Meeting (MMIC – Scotland)

2023

May 8–9 ASTM May Committee Week (Denver, CO USA)

May 10–11 Training Workshop on Radiation Processing – ASTM Committee Week (Denver, CO USA)

November 8–9 ASTM November Committee Week (Washington DC, USA)

Membership
Welcome Aboard

NAME	ORGANIZATION
Adam C Whaites	*Cytiva*
Noel M Long	*Cytiva*
Cavon Cormack	*Saint-Gobain Life Sciences*
John Deaton	*Deerland Probiotics and*
Suzy Floyd	*Scriis Technologies*
Maria B Gautier	*LeeSar*
Brett Howard	
Matthew S Spink	*JM Canty Inc*
David A Vaillencourt	*The GMP Collective*
Christine Farrance	*Charles River Laboratories*
Dawn Tavalsky	*Sanofi*
James Hoffman	*Poseida Therapeutics*
Stephen Sadler	*Cytiva*

NAME	ORGANIZATION
Rafael Rodriguez	*Cytiva*
Dan A Klein	*Steris Corp*
Joann Lau	*Genentech*
Frederic B Ayers	*Eli Lilly And Company*
Craig Brodersen	*Seltec Inc*
Denis M Kluba	*Kinetics Process Consulting, Inc.*
Kathleen A May	*Triskele Quality Solutions*
Michael Lloyd	*OsecoElfab*
Michael J Rataj	*Aramark Cleanroom Services*
Giorgio Cesare Bruno	*Associazione Farmaceutici Industria - Società Scientifica*

ASTM Committee E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products currently has 208 members, up by about 10% since the beginning of the year. This reflects the continued interest of industry, service providers, and regulators and the continued need for consensus standards in this field. While there has been fluctuation in individual members the overall ratio of Producers, Users, and General Interest has been constant with about equal shares for the three groups. Currently there are 73 Producers, 61 Users, and 73 General Interest as well as one Consumer. The membership represents the full breadth of our industry, with members from large companies, small companies, service and equipment providers, and Health Authorities. This results in a tremendous knowledge base that can be leveraged for the development of future standards that facilitate effective and compliant processes in our industry.

Not a Member? Here's How to Get Involved

Any individual or organization from any country with interests in the pharmaceutical and biopharmaceutical industry are welcome to join Committee E55 and share your ideas. Existing ASTM International members can join E55 via their MyASTM account page. If you are not already an ASTM member, all you need to do is complete an application at https://www.astm.org/MEMBERSHIP/. Should you ever have any questions regarding the organization, the Committee, or standards in general, do not hesitate to contact our E55 Staff Manager, Travis Murdock, at tmurdock@astm.org.

Effective Participation Tips
Maximize Your Investment

After joining your committee(s), we encourage you to be proactive – build a foundation of knowledge and engage with the committee leadership. Here is some key information to get you started:

ASTM Member Specific Training

We offer live online training year-round, as well as face-to-face training at most technical committee meetings. The sessions provide information on navigating our website and the standards development process and include situational questions and solutions. View member training topics and upcoming sessions at www.astm.org/MEMBER_TRAINING

Voting

E55 members with official voting rights are encouraged to vote on all ballot items in order to maintain voting rights and help ballots meet the necessary response requirements. Voters not familiar with an item can vote abstain to help the item move forward in the approval process. If you have any questions about an item on ballot, you can always contact the technical contact of the item or the E55 Staff Manager.

Additional Information

Other Tools: ASTM Regulations
ASTM Form & Style Manual
How Standards Get Developed