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Committee E55
Manufacture of Pharmaceutical and Biopharmaceutical Products

NEWSLETTER

Introduction

ASTM XCELLERATE™ Healthcare: Leading the way through Innovation and Standardization

ASTM Xcellerate Team / John Logar – E55 Chair

Manufacturing technology within the healthcare space has recently evolved rapidly. The lack of standards for new technologies inhibits innovation in the healthcare biotechnology and biopharmaceutical manufacturing space. There is an increasing global demand to address these challenges.

In January 2023, ASTM International held an informal workshop to discuss the current challenges and needs space for biotechnology and biotechnology manufacturing.

Two brainstorming questions were posed and explored:

1. What challenges are slowing innovation and standards development in the biotech/biopharma manufacturing space?
2. What manufacturing/process control topics / transformative technologies would benefit most from ASTM's Research-to-Standards approach?

The workshop output resulted in the following focus areas:

CHALLENGES IN TECHNOLOGY AND PROCESS CONTROL – Process Control, Hardware and Equipment, and Advancement in Sensors and Monitoring

and

CHALLENGES TO STANDARDS DEVELOPMENT – Standardization and Certification of Hardware and Product Quality and Workforce Development

The insights from the discussion identified the needs for new standards to be developed across multiple categories in healthcare including new manufacturing technologies (hardware and software) and new standards for process controls and testing.

Next Steps / Recommendations

01 → Engage potential stakeholders to gauge interest and get community feedback

02 → Plan additional workshops for a greater number of stakeholders to identify gaps and priorities

03 → Identify possible members to lead a steering committee

04 → Form an ASTM International Administrative Collaboration Group to coordinate all planning activities and generate topics for discussion

05 → Develop a roadmapping activity to identify existing standards and identify gaps and research and standards needs

06 → Prioritize standards needed to fill gaps and engage relevant ASTM Committees

07 → Consider forming a new main ASTM Committee or create a sub-committee under an existing activity

ASTM E55 has been identified as one of the committees that can directly support this initiative for incorporating new standards that fall under our scope. For additional information or for a copy of the workshop output white paper, please contact John Logar (Jlogar8@its.jnj.com)

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Committee Updates

E55 Officers

Chair: *John Logar, Johnson & Johnson*
Vice-chair: *Don Kientzler, J-STAR Research*
Recording Secretary: *Jennifer Gray, LyoHUB, Purdue University*
Membership: *Claus Weisemann, BioPharma*

MQL Workshop: Accelerating Standards Development

John Logar – E55 Chair

In an effort to accelerate the creation of a new standard, ASTM E55 and the Kilmer Collaboration Teams are hosting a workshop Microbiological Quality Level (MQL) during the ASTM Committee Week on May 7th, 2024 at the Philadelphia Marriott in Philadelphia, PA.

KILMER FOR PASSION PATIENTS | DRIVING COLLABORATIVE INNOVATION

The concept of a Microbiological Quality Level (MQL) has been proposed as a mechanism that can be developed and used for:

Determining the acceptable level of microbial contamination permitted during the manufacturing of or on a finished pharmaceutical, biopharmaceutical or combination product.

- A level established based on critical microbiological quality attributes and acceptance criteria for the product (i.e. specifications)
- A level, when met, delivers a high degree of confidence in acceptability of the process step and/or product.

This workshop is intended to gain alignment and provide the guidance from industry on understanding the different levels of product and process controls, their impact on the microbiological quality and the ability to determine a level of confidence in the output of a process including:

- Understanding the Microbiological Quality Spectrum: from non-sterile to sterile and throughout the end-to-end manufacturing process.
- An integrated quality approach for process verification (end to end) and to support final product release (E.g., Food HACCP programs);
- Differentiating the level of microbiological control(s) as it proceeds from start to final release (e.g. sterility).
- A means of determining probability/quantification of microbial risk for each step and its contribution to the final product
- A standard approach for the determination and evaluation for each process critical control point and critical microbiological quality attribute.
- A standard approach for trending to support demonstration of a state of control.
- A mechanism to differentiate the microbiological quality of finished product.

Attendance is limited to the first 50 to register for the event. You can register for the event here:

https://www.linkedin.com/feed/update/urn:li:activity:7178406393505312769

https://twitter.com/ASTMIntl/status/1772641743499862107

If you are interested in supporting this effort but are unable to join us for the workshop, please reach out to John Logar at Jlogar8@its.jnj.com.

Fall Committee Week

The E55 committee met on November 8th and 9th in

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Washington, DC during the ASTM Committee week. We hosted a hybrid event where committee members were able to join in person and on-line. Thank you to all of those who attended in person and joined us for a group dinner. Looking forward to connecting with members in person at our May Committee meeting in Philadelphia!

Subcommittee Highlights

E55.11 Process Design

Richard Hall Hall

ASTM E55.11: *Clean by Design (WK78595)* was presented at the 2024 ISPE Facilities of the Future Conference in San Francisco on 29 January by Dawn Marshall, Sanofi and Kenneth Pierce, Hyde Engineering & Consulting and was well received by the 110 SMEs present.

The draft Clean by Design standard was also introduced on the Rattiinox booth in the exhibition area. Thomas Hartman (President & CEO, ISPE) was interested in the simple design ideas presented to improve the CIP-cleanability of manufacturing systems to increase pharmaceutical production efficiency using less water and energy. Thomas also plied Walter and John with a rather good local red wine – and introduced them to many conference attendees – Thank you Thomas!

(Pictured) John Swibes (CEO, Rattiinox USA), Thomas Hartman (President & CEO, ISPE) & Walter Ratti (CEO, Rattiinox S.r.l.)

E2537-16 *Standard Guide for Application of Continuous Process Verification to Pharmaceutical and Biopharmaceutical Manufacturing* is due for renewal this year. Please give your feedback on this standard – or express your potential interest in joining (or starting!) a work item – to Richard Hall Hall, Chair E55.11 Process Design subcommittee.

ASTM E55.11: *Clean by Design (WK78595)* will be presented by Richard Hall Hall at the AFI (Associazione Farmaceutici Industria) Cleaning Validation meeting at Milan University on May 15, 2024. For more information about this meeting and to register, visit: https://newaurameeting.it/prodotto/afi-cleanability-by-design-cybd/

E55.12 Process Applications

John Logar

E2656: Practice for Real-Time Release Testing of Pharmaceutical Water for the Total Organic Carbon Attribute: Went to ballot with revisions in April 2024

E3042: Standard Practice for Process Step to Inactivate Rodent Retrovirus with Triton X-100 Treatment: Went to ballot and was approved. Next version will be published this Spring.

E55.13 Process Evaluation & Controls

Sameer Talwar

E3077: Guide for Raw Material eData Transfer from Material Suppliers to Pharmaceutical and Biopharmaceutical Manufacturers: A task group is being formed in collaboration with BioPhorum. Anyone interested in this effort is welcome to join the team.

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E55.14 Measurement & Analysis

Daniell Willett

E3060: **Guide for Subvisible Particle Measurement in Biopharmaceutical Manufacturing Using Dynamic (Flow) Imaging Microscopy:** Went to ballot and was reapproved in October 2023

E2810: Practice for Demonstrating Capability to Comply with the Test for Uniformity of Dosage Units: Went to ballot and was reapproved in December 2023

E3177: Standard Guide on Sampling for Process Analytical Technology: Went for ballot in Dec. 2023 and received one persuasive negative, was revised with the help of Benoit Igne and sent back for re-balloting in February

New technical contact for **E2891 Standard Guide for Multivariate Data Analysis in Pharmaceutical Manufacturing Applications**: Daniel Willett

Still seeking technical contact for **E3263 Standard Practice or Qualification of Visual Inspection for Pharmaceutical Manufacturing Equipment and Medical Devices for Residues**

E55.05 Lyophilization

Arnab Ganguly

WK80172 Practice for Lyophilization Process Validation (Part 1): Went out to main committee ballot in April 2024 and anticipation for approval and publication later this year.

WK88962 Practice for Lyophilization Process Validation (Part 2): Is being drafted by the task group and preparing the draft for ballot later this year.

E55.06 Microbial Contamination

Scott Drummond

WK69826 Standard Guide for Standard Template for Environmental Monitoring (EM) Trend Analysis: New Technical Contact is needed for this work item. A task group restart and draft update is needed.

WK74412 Standard Guide for Critical Airflow Visualization: Document revised based on stakeholder meetings. Final reviews and updates will be presented to FDA prior to going to next ballot.

WK78574 Standard Guide for Best Practices for Microbial Control for Cell Therapeutics: Dieter Bachmann (Johnson & Johnson) has been appointed as the new task group leader for this standard.

E55.07 Single Use Systems

Jeff Carter & Weibing Ding

E3051: Guide for Specification, Design, Verification, and Application of Single-Use Systems in Pharmaceutical and Biopharmaceutical Manufacturing: Went to ballot in November 2023 resulting in negative comments. Those are being addressed and a new version will be balloted in the coming months.

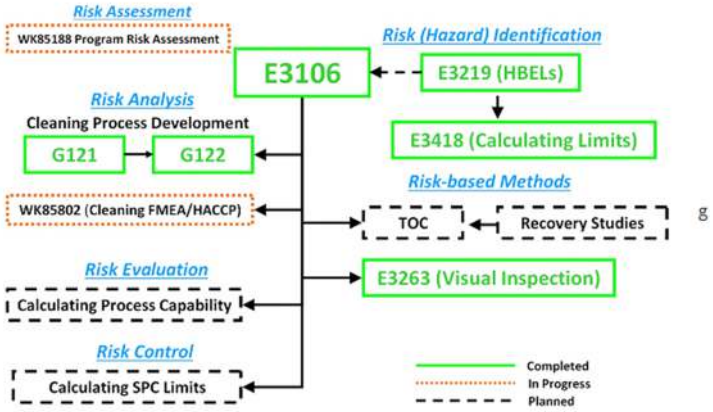
E55.91 Terminology

Alain Pralong

WK72293 Standard Guide for Standard Guide for Definition of Combination Products (Drug / Device / Biologic Combinations): Negative votes from the last ballot are being addressed and is targeted for a new ballot in mid 2024.

E55 in the News

E55's New ASTM E3418 ***Standard Practice for Calculating Scientifically Justifiable Limits of Residues for Cleaning of Pharmaceutical and Medical Device Manufacturing Equipment and for Medical Devices*** was recently featured in an article with Pharmaceutical Online. The article outlines the history leading up to the need for the standard, scope, the process by which the standard was developed through ASTM, its application and key points.



To read the full article, visit,

https://www.pharmaceuticalonline.com/doc/introduction-to-the-new-astm-e3418-standard-practice-for-calculating-scientifically-justifiable-limits-of-residues-for-cleaning-of-pharmaceutical-and-medical-device-manufacturing-equipment-0001

Membership

Welcome Aboard New Members

Name	Organization
Baek, Grace	*RheoSense, Inc.*
Bench, Nicola	*BD Diagnostics*
Chai, Yoke Leong	*STERIS Corporation*
Clark, Brett M	*Veolia Water Technologies and Solutions*
Deneux, Christophe	*Becton Dickinson*
Drosnock, Mary Ann	*Healthmark Industries*
Duhigg, Cindy	*Alcon*
Ellsaesser, Bryan	*cGMPnow LLC*
Graham, Brandon	*Saint-Gobain*
Horst, Kendall	*Qosina Corp.*
Miller, Kyle	*Valent BioSciences*
Morgan, James	*ASTM International*
Pierson, Dalton Q	*Performance Validation*
Roemer, Meike	
Scheler, Sebastian	*Innerspace GmbH*
Senica, David	*Novartis AG*
Shull, Steven A	*Quality Co*
Talwar, Sameer	*GlaxoSmithKline*
Tordik, Jacqueline	*Strahl & Pitsch. LLC*
VanBerschot, John	*PharmEng Technology*
Wabby, James P	*AbbVie, Inc.*
Whittaker, Mark	*Scientific Research Consortium Inc.*

E55 continues to attract members from all sectors of the Biopharma community, a testimony for the interest in our standards and for the need to define and harmonize emerging technologies and promote a science- and risk-based consensus-guidance for the Biopharma community. Following the drop last fall to 180 members our membership has increased 18% in the past six months. Our membership is currently at 215 members and remains in balance. Our 215 members come from "Big Pharma", Biotech, and mid-size pharmaceutical companies, from the service sector (CMOs, consultants, suppliers, laboratories), from Health Agencies and from Academia. This ensures a multitude of perspectives and viewpoints which are essential for the development of balanced and widely accepted standards. The subcommittee chairs continue to welcome new members as the transition to our new subcommittee structure continues to evolve.

As a reminder, you must renew your membership each year, so If you have not renewed your membership for 2024, please renew today so you remain active in our committee and activities.

Not a Member? Here's How to Get Involved

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

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Committee Awards Nominations Sought

***Don Kientzler**, Process Engineering Head for J-STAR Research, Inc., currently serves as the Vice-Chair for E55, and is the sub-chair for E55 Committee Awards.*

As a means of recognizing the outstanding contributions which our members deliver to the committee, ASTM International and our industry members, the executive team has approved the formation of two new awards. The details of the awards are as follows:

Founders Award: the highest award given by the E55 committee. Only one E55 Founders Award can be given per calendar year. The criteria for this award are as follows:

- Well-known in the field of pharmaceutical or biopharmaceutical manufacturing; and,
- Have made significant and sustained contributions to the advancement of the pharmaceutical or biopharmaceutical industries and community; and,
- Have demonstrated knowledge and expertise which has been shared throughout society through published papers, articles, seminars, mentoring, teaching, or coaching; and,
- The individual or organization shall have demonstrated admirable personal characteristics such as humility and commitment to purpose.

Lifetime Achievement Award: recognizes individual time, effort, and expertise throughout their career to the development of ASTM standards. The criteria for this award are as follows:

- Member of the E55 committee for > 20 years

and

- Served as Committee Officer *or*
- Served as a Subcommittee Chair *or*
- Contributed to a minimum of 10 standards *or*
- Led a committee symposia or workshop

Please reach out to Don Kientzler don.kientzler@jstar-research.com or Travis Murdock tmurdock@astm.org

Upcoming Events

Next Meeting – May 2024

The E55 committee will be meeting at the upcoming May Committee week being held in Philadelphia, PA at the Philadelphia Marriott. Registration is required for this meeting, and you can register via the ASTM Website at https://na.eventscloud.com/website/55251/E55/. ASTM has a room block of hotel rooms at a negotiated rate for their committee weeks and you can book your hotel room directly through the registration link. The agenda for the May Committee week can be found at the registration link above.

What to Expect at a Committee Week: For those not familiar with Committee Week, there is a welcome letter that members receive when going to a specific CW which highlights all of the activities going on during the week (e.g. training, Members Lunch, Annual Business Meeting, etc.) as well as a listing of all the committees' meetings that week. This creates a great opportunity for our committee and committee members to connect with other committee members who may be working in a similar industry or on similar standards.

Here is link to a video on attending a CW for the first time:

https://www.youtube.com/watch?v=kPgLQvpomUU. This provides insights into what to expect when you attend the meeting in person.

Future Committee Meetings and More:

2024

November 12th – 13th, 2024 – E55 Meeting (Nov Committee Week, Orlando FL)

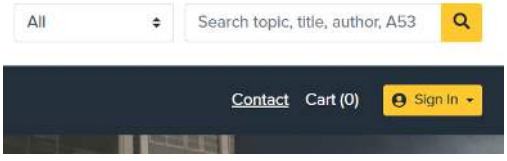
E55 will continue to meet at least twice per year and those meetings will continue to be a hybrid format for the immediate future to accommodate our membership. Although we value the added benefits of meeting in person, we recognize the limitations and challenges our members face in attending in person. Additionally, the executive committee recognizes the diversity of our international membership and is committed to continuing to host committee meetings internationally.

Effective Participation Tips

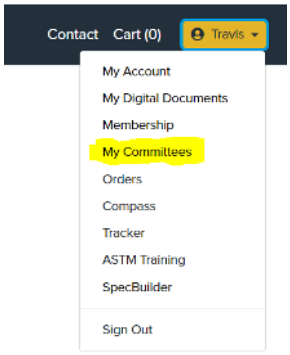
Joining a new subcommittee via the ASTM website

For those of you interested in joining the new E55 subcommittees, or who are just interested in learning about how to manage your membership with ASTM, here is how you can join or drop ASTM subcommittees.

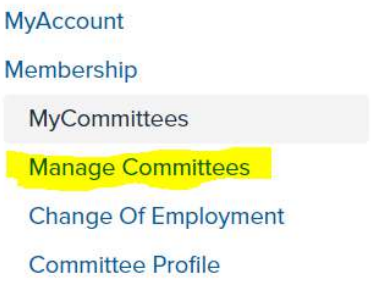
1. Log into your member account at www.astm.org using the Yellow Sign-In button on the top right of your screen



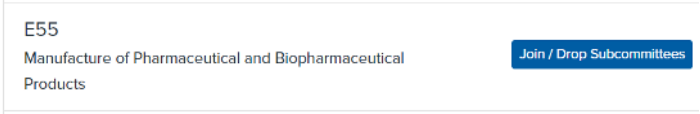
2. Click on the link to go to MyCommittees



3. On the left side of the screen, click on “Manage Committees”



4. Where E55 is listed, Click Join/Drop Subcommittees to the right



5. A pop-up will appear with an option to Join or Drop from any of the subcommittees within the group

ASTM staff recommends using Google Chrome when working with the new website, but it should work with most browsers. If you run into any trouble or need to make any other changes to your members, please contact the E55 staff manager at tmurdock@astm.org.

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.

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 using the link below.

www.astm.org/MEMBER_TRAINING

Voting

E55 members with official voting rights are encouraged to vote on all ballot items 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 Develop

Enhancing Communication

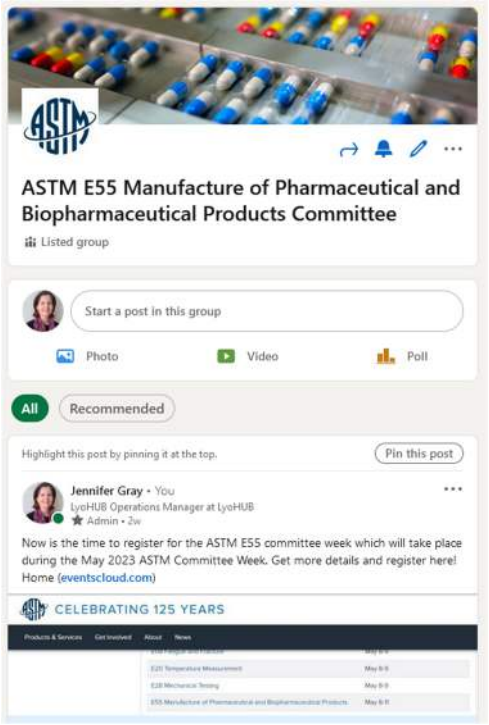
E55 would like to share your ASTM news!

Jennifer Gray, E55 Secretary

E55 has a Linked In Group specifically to share ASTM E55 news, https://www.linkedin.com/groups/12745359/.

We encourage all members of ASTM E55 to share news that would be of interest to members!

- Launch a new E55 standard?
- Discovered an interesting story on how an ASTM standard was used?
- Have a photo of yourself or a colleague presenting ASTM at a meeting or conference?
- Hosting a meeting or conference that may be of interest to your fellow ASTM members?
- Caber tossing at Highland games in your ASTM swag?



Help us show the many faces and facets of ASTM E55 by populating our Linked in site!

Please send items to Jen Gray at gray160@purdue.edu.