

# Committee E55

## Manufacture of Pharmaceutical and Biopharmaceutical Products

NEWSLETTER

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## Introduction

### E55 Newsletter

#### E55 on Manufacture of Pharmaceutical and Biopharmaceutical Products

*Chair: Ferdinando Aspesi, Bridge Associates International*  
*Vice-chair: Russell Madsen, The Williamsburg Group, LLC*

Welcome to Spring 2021 edition of the ASTM Committee E55 Newsletter.

This issue comes following the recent E55 Spring 2021 Meeting, which was held virtually on April 21 and 22. This issue of the Newsletter contains updates and details on new activities of the Committee since back in October 2020. As announced at the last meeting, we have taken several initiatives to reach out to our Stakeholders.

We held the first ASTM E55 Industry Forum on December 12, 2020. That Forum identified eight areas that are currently important to the Industry. Out of these areas we have met with Industry representatives and the Subcommittee E55.06 (Microbiological and Sterility Assurance) Chair and Vice Chair and created a small team that will work on "Sterility Assurance in Cell and Gene Therapy Manufacturing." The next team meeting is set for June 18, 2021. Anyone interested in joining in this effort is encouraged to contact E55.06 chair Scott Drummond at [sdrummon@ITS.JNJ.com](mailto:sdrummon@ITS.JNJ.com).

Leaders of the committee also took part in the April 19<sup>th</sup> ASTM E55 Academia Forum. This was the 4<sup>th</sup> meeting of this group since it was formed in 2019. There were four presentations from Academia Professors from which we could identify in the future areas for potential consensus Standards. They presented the following:

- Prof. Blair Johnston – CMAC University of Strathclyde (UK) presented on "Data driven manufacturing at CMAC"

- Martin Warman – MMIC University of Strathclyde (UK) presented on "Medicine Manufacturing Innovation Center Update- Grand Change 1 to 3"
- Carl W. Lawton – Director of Massachusetts Manufacturing Center – University of Massachusetts Lowell (US) presented on "PAT and Biosensors in Biotechnology Manufacturing"
- Prof. Andrea Gazzaniga – University of Milan Institute of Pharmaceutical Technology (Italy) presented on "Oral Drug Delivery – Prolonged Release -3D and 4 D printing"

As part of our European Strategy, we started contacts with Swiss Academia, Italian Pharmaceutical Association (AFI), Biopharmachem Ireland and PIC/S. We will report the outcomes in the Fall 2021 Newsletter.

We wish also to report the first approved ASTM Standard from the E55.05 Subcommittee on Lyophilization. The new standard has been approved as **E3250-21 Standard Practice for Product Temperature and Equipment Pressure Instrumentation in Pharmaceutical Freeze Drying**. Congratulations to Arnab Ganguly and his team for all their hard work.

Benoit Igne and Pete Shi (E55.01 Subcommittee) are working to identify the opportunity to develop PAT Standards that could be useful in Biotechnology Development and Manufacturing particularly on Cell and Gene Therapy as well as in Vaccines. Anyone who is interested in contributing please feel free to contact Benoit Igne.

In February we agreed to add the Subcommittee E55.96 led by John Logar (J&J) on "Liaison with other Standard Development Organizations." The focus of this Subcommittee is to establish Committee Liaisons with other SDO's to build a mutually beneficial partnership.

Also please mark your calendar for the next E55 Meeting currently scheduled for October 6-7, 2021, still planned as virtual meeting.

And as always, everyone is invited to contact the E55 ASTM Staff Manager, Travis Murdock ([tmurdock@astm.org](mailto:tmurdock@astm.org)) with any questions or feedback on the Newsletter.

## Subcommittee Reports

# Path to Success

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, in these early months of 2021, have been on addressing comments to **E2968-14** *Standard Guide for Application of Continuous Processing in the Pharmaceutical Industry*. The standard will shortly go out for ballot after its withdrawal was voted down.

Since the last meeting, two new task groups have been established: **WK76297** *Proposed Standard Guide on Advanced Process Control (APC)* was initiated to develop a new standard on the use of Advanced Process Control in the pharmaceutical industry; **WK74957** *Proposed Standard Guide PAT System Applications in Biopharmaceutical Industry* is progressing as a first draft has been completed by the drafting team. Anyone interested in joining either of these drafting efforts should be welcome to contact E55.01 sub-chair Benoît Igne, [benoit\\_igne@vrtx.com](mailto:benoit_igne@vrtx.com).

Additional work of the subcommittee will include reapproval ballot items for **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* that are anticipated for ballot in the coming months.

### E55.03 General Pharmaceutical Standards

*Chair: Paul Gil, Consultant*

Subcommittee E55.03 has made significant progress with multiple standards projects in recent. Activity around Cleaning Validation continues on with revisions to **E3106-18e1** *Standard Guide for Science-Based and Risk Based Cleaning Process Development and Validation* (**WK73120**); revisions to **E3263-20** *Standard Practice for Qualification of Visual Inspection of Pharmaceutical Manufacturing Equipment and Medical Devices for Residues* (**WK75248**); and new standard **WK64938** *Standard Practice for the Calculation of Cleaning Validation Limits*. The task group plans to issue ballot items throughout the remainder of 2021.

Another project within E55.03 deals with Combination Products. Under the leadership of Manfred Maeder of Novartis, a task group was established and held several virtual meetings since Q1 2020. As a result, the group has made considerable progress on **WK72293** *Standard Guide for Definition of Combination Products (Drug, Device, Biologic Combinations)*. The task group expects to send their first draft out for ballot later in 2021.

Finally, stemming from discussions held during the October 2020 E55 Committee Meeting, a new task group has been formed for **WK74514** *Proposed New Practice for Measurement of Particulate Matter in Pharmaceuticals using Automated Membrane Microscopy*. The task group has been making great progress and continues to meet on a monthly basis. Those interested in this topic are encouraged to contact E55 member Klaus Wormuth, [klaus.wormuth@sartorius.com](mailto:klaus.wormuth@sartorius.com).

### E55.04 General Biopharmaceutical Standards

*Chair: Jeff Carter, Cytiva*

The E55.04 subcommittee is currently responsible for 10 standards under E55. Of these, two are up for re-ballot. **E3042-16** *Standard Practice for Process Step to Inactivate Rodent Retrovirus with Triton X-100 Treatment* has been re-balloted with one negative vote under consideration. **E2097-00(2014)** *Standard Guide for Determining the Impact of Extractables from Non-Metallic Materials on the Safety of Biotechnology Products*, will be put to a ballot for withdraw due to its general lack of use in the industry.

In addition, the subcommittee has three active work items in progress. **WK65428** *New Standard Guide for the*

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*Application of Continuous Processing in the Biopharmaceutical Industry* is a comprehensive guide on the topic. An initial draft has been generated and balloted within the E55.04 subcommittee. However, the task group is team is looking for more member participation and perspective needed to complete the draft. **WK64991 New Standard Practice for Stability of Early Phase Protein Products** will reduce validation needs for proteins in early clinicals. It has been balloted and the one negative vote is currently being considered. **WK74440 New Standard Test Method for Physical Integrity Testing of Single-Use Systems** has an active team that plans to submit a draft for ballot in the coming months.

Lastly, we are evaluating the possibility of initiating one or more work items on virus clearance/inactivation standards to cover topics such as, but not limited to, using anion exchange chromatography. Should the subcommittee decide to proceed, more information will be presented during the October 2021 meeting.

### **E55.05 Lyophilization**

Chair: Arnab Ganguly, Amgen

We are delighted to announce the completion of the first E55.05 standard, **E3250-21 Standard Practice for Product Temperature and Equipment Pressure Instrumentation in Pharmaceutical Freeze Drying**. Congratulations to Arnab Ganguly and his team for all their hard work to develop, disseminate and educate standard practices and guides relevant to lyophilization of parenterals and other pharmaceutical and biological products. This standard is the result of construction input from E55 members at NIST and FDA throughout the development and balloting process.

In addition to this work item, the subcommittee is also focused in parallel to establish best practice guidance on equipment performance validation, scale-up, and validation strategy applied to lyophilization. The group will soon be looking to convert these Best Practice documents into Standards. Interested members are invited to contribute to the working group.

### **E55.06 Microbial/Sterility Assurance for Pharmaceutical and Biopharmaceutical Products**

Chair: Scott Drummond, Johnson & Johnson

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.

Recently the subcommittee announced the appointment of Dr. Martin Muellner as sub vice-chair for E55.06. Dr. Muellner comes from Boehringer Ingelheim in Germany and strengthens the international scope of ASTM. Membership of E55.06 currently is 42 members. During the October meeting the subcommittee approved **WK69826 New Practice for Standard Template for Environmental Monitoring Trend Analysis** for ballot where it received negatives that remain unresolved. The subcommittee also agreed to continue on standards development around a guide for Microbiological Quality and Contamination Prevention Strategy.

A collaboration space for **WK74412 Proposed Standard Guide for Critical Airflow Visualization** was also started and regular meetings have been ongoing still being established back in November 2021. The subcommittee also approved the start of work to develop a standard on Selection and Management of Aseptic Gowning, work toward the creation of this standard will commence soon.

For any questions or to participate in standards development please reach out to either Scott Drummond, Johnson and Johnson organization or Martin Muellner at Boehringer Ingelheim.

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## Committee Outreach

# Reaching the Global Community

### **E55 Leaders to Present at ISPE 2021**

The ISPE Biopharmaceutical Conference Organizing Committee has accepted abstract submitted by ASTM E55 members for the 2021 ISPE Biotechnology Virtual Conference, on 22-24 September 2021.



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Led by E55 Officers, Duncan Low, Louis Traglia, and Jeff Carter, the paper titled “Standards for Emerging Technologies Facilitate Regulatory Acceptance” will look at how standards are being developed at ASTM International to support and facilitate acceptance of improvements in productivity and investments in new capacity, specifically in continuous biomanufacture, continuous process verification and single-use technologies.

### E55 Executive Committee Approved New Subcommittee for SDO Liaisons

Earlier this year, the E55.90 Executive Subcommittee approved the establishment of the new subcommittee, E55.96 Standards Developing Organization Liaisons. The scope of this new administrative subcommittee is to track all current relationships between ASTM E55 and other standards developing organizations as well as to help support the formation of any new collaborative efforts with other SDOs.

The 2021 ASTM Chair of the Board, John Logar (Johnson & Johnson), will serve as the sub-chair, and plans to formally introduce the new group to the rest of E55 during the E55 October 2021 virtual meeting.

## Upcoming Events

### Future Meetings

#### Next E55 Meeting: Q4 2021

E55 Committee leadership is currently working closely with ASTM staff to plan for the next semi-annual full committee meetings for 4<sup>th</sup> quarter 2021. Based on the current status of the COVID-19 pandemic and related travel restrictions, the committee has decided to continue meeting virtually for the remainder of 2021.

Stay tuned for additional information regarding the 2021 meeting which will be distributed to all members in the coming months.

## Membership Updates

### Colleagues in Industry

#### Call for E55 Committee Officer Nominations

As defined in the *ASTM International Regulations Governing Technical Committees*, as well as the *By-Laws for Committee E55*, the Executive Subcommittee is seeking nominations for main committee officers to fill a selection of officer roles. Terms for committee officers last two years with a limit of three consecutive terms. The E55 Executive Subcommittee has established a nominating committee to solicit and review nominations. Any E55 members with interest in an officer role on the main committee are encouraged to notify ASTM staff for consideration. Once the nominating committee formulates a slate of officers for the 2022-2023 term, the slate will be put forward for approval by E55 committee membership.

If you have any questions or would like to nominate yourself or a fellow E55 member, let us know via email to Travis Murdock at [tmurdock@astm.org](mailto:tmurdock@astm.org).

#### Welcome New E55 Members

For those just joining the Committee – Welcome! Your participation in the technical committee allows you to directly impact the content of the standards. The following list of new members includes those who joined E55 since the previous issue of the E55 Newsletter.

New Member	Organization
Stauffer, Oliver	
Rivera, Ernesto	
Hoshi, Ryan	AbbVie
Patel, Khevna	Astrazeneca
Ambrosini, Serena	AstraZeneca UK Ltd.
Yarlott, Linda K	HORIBA
Polen, Morgan	Microrite, inc.
Bramhall, Alison	Standards Coordinating Body
Lordo, Gina	Tolmar
Davis, Richard	Tolmar
Chancey, Jason F	US Food and Drug Administration

The current E55 membership consists of over 200 subject matter experts from around the world. Countries represented include Belgium, Canada, Chile, China, Denmark, France, Germany, Ireland, Japan, Luxembourg,

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Malta, Mexico, New Zealand, Peru, Singapore, Spain, Switzerland, United Kingdom, and the United States.

### 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 [www.astm.org/MEMBERSHIP/](http://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](mailto:tmurdock@astm.org).

## Effective Participation Tips

# Maximize Your Investment

### Proactive Participation

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](http://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](#)