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# Committee E55
## Manufacture of Pharmaceutical and Biopharmaceutical Products

NEWSLETTER



# Introduction
# Committee E55

Welcome to the latest ASTM E55 Committee Newsletter!

As was noted in the last newsletter, it is important to focus the efforts of our committee members working in Task Groups to develop Standards that meet the needs of all of our stakeholders. In this issue, Louis Traglia reports on the feedback that E55 committee members provided in the survey of possible areas for future standards development. The goal is continuing to work to strengthen our links with our stakeholders and among the new members of E55, we're delighted to welcome Dolores Hernán (European Medicines Agency) and John Logar (Chairman ASTM committee E61 on Radiation Processing) to the E55.90 Executive Subcommittee.

As always, any comments or topics for future issues of the newsletter are very welcome and you should send your ideas to Travis Murdock (ASTM Staff Manager, Technical Committee E55; tmurdock@astm.org).

This year also marks the election for the E55 Chair, Vice Chair, Recording and Membership Secretaries for 2018 onwards will take place by the end of 2017. If you are interested in standing for one of these positions, or being involved in the E55.90 Executive Subcommittee in any form, please contact Travis.

**Graham Cook PhD**
*Chairman*

**Ferdinando Aspesi PhD**
*Vice-Chairman*

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NEWSLETTER

## E55 Subcommittee Reports

# Planning for Success

Committee E55 continues to make significant strides on its existing catalog of standards activities as we progress through 2017. The following subcommittee reports highlight each group's accomplishments and ongoing efforts in standards development. We encourage members and interested industry stakeholders to join these efforts by reaching out to the subcommittee chairmen.

### E55.01 Process Understanding and PAT System Management, Implementation and Practice – *Chair: Martin Warman, Martin Warman Consultancy Ltd*

Since the winter issue of the E55 Newsletter, the main activities within E55.01 have been WK51471 (revision of E2968-14 Standard Guide for Application of Continuous Processing in the Pharmaceutical Industry) and WK41265 (New Practice for Sampling) and ballots have taken place for both. In the case of WK51471 the ballot resulted in 3 negatives and several comments, and after active discussion at the face to face meeting held at E55 Committee meetings held at ASTM International in West Conshohocken, PA on 24th and 25th of May, it was decided to find 2 of the negative votes persuasive, with draw the ballot and make the editorial changes required before re-balloting. However, one of the negative votes and one of the comments highlighted the lack of focus on large molecule/biopharmaceutical continuous manufacturing. A meeting is being arranged to discuss the need and the scope for a second standard to address BioCM and members are welcome to make contact if they want to be involved. The ballot on WK41265 also generated both negatives and useful comments which are currently being reviewed and discussed and members are recommended to check with the collaboration areas for both work items.

During the next six months two activities are planned. The first is a review of ASTM E2891-13 Standard Guide for Multivariate Data Analysis in Pharmaceutical Development and Manufacturing Applications, to assess if it is still current and should be revised or re-balloted. The next is WK57018 (revision of E2629-11 Standard Guide for Verification of Process Analytical Technology (PAT) Enabled Control Systems); this standard is being updated to align with current terminology and thinking and will be balloted before the end of the year.

Any members that wish to be part of any of these activities are welcome to make contact with either Martin or Benoit Igne (GSK) who recently joined the subcommittee as subcommittee vice chair.

### E55.03 General Pharmaceutical Standards – *Chair: Claus Weisemann, Luitpold Pharmaceuticals*

The work items of the subcommittee E55.03 have made steady progress over the last months. The following is a collection of activities underway.

E2537-16, Continuous Quality Verification, one of the early and quite successful standards developed by E55, has been reviewed and approved for republishing unchanged, a testimony to the robustness of this concept.

The team for WK15778, New Standard Guide for Science-based and Risked-based Cleaning Process Development and Validation, has spiked a lot of interest in the community. After successfully resolving set of negative votes, new discussion items have come up. This lively discussion both reflects the importance of this subject and the vitality of the ASTM process to approve new standards.

WK51651, Standard Guide for Raw Material eData Transfer from Material Suppliers to Pharmaceutical & Biopharmaceutical Manufacturers, has been approved as E3077-17 and reflects the growing importance of accurate data transmissions in today's complex supply chains.

The development of WK52609, Validation of End-user Sterilizing Filtration, has begun with upwards of 16 active team members who developed and initial draft. The group aims to have its first ballot by the end of 2017.

E2810, Standard Practice for Demonstrating Capability to comply with the Test for Uniformity of Dosage Units, is a practical guide to predict the capability of a batch to pass the United States Pharmacopeia (USP) content uniformity test. It has been recommended to ballot the existing standard as is. In parallel, revision and additions will be drafted to be inserted and balloted at a later date.

E2500-13, Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment, and E2504-13E1, Standard Practice for Qualification of Basked and Paddle Dissolution Apparatus, are in their 4th year since approval and will be coming up for review next year.

### E55.04 General Biopharmaceutical Standards – *Chair: Bob Steininger, Voyager Therapeutics*

The focus of E55.04 draft standards continues to be on standards for single use equipment and for viral removal/inactivation. The work on extractables from single use equipment now focuses on assays to determine the amount of extractables and will try to leverage existing ASTM extractable standards for plastics. A standard focused on the extraction and isolation of particulates from single use equipment is being drafted and should be available for review during summer 2017 in the ASTM Collaboration Area.

In addition, committees are working on two standards related to the characterization of particulate matter from single use equipment. The goal is to bring these draft standards to the balloting process by the end of the year.

Finally, a committee has been formed to move forward the viral filtration standard for large viruses. Should any members of E55 or interested stakeholders wish to learn more or participate in any of these efforts, they are encouraged to reach out to the subcommittee chair.

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Committee E55
Manufacture of Pharmaceutical and Biopharmaceutical Products

NEWSLETTER

## Standards Roadmapping

# Areas of Focus

### E55.95 Roadmap for Standards Development – *Chair: Louis Traglia, Commissioning Agents Inc.*

During the fall 2016 meeting, a major topic for discussion was reviving the E55 Roadmap. The first part of the discussion focused on the general intent of the Roadmap. One important element that was determined is that it needs to provide stakeholders with a simple graphic that showcases the committee's catalog of published standards in an organized manner. The second objective is to incorporate a graphical illustration of new standards under development as well as what is considered as future areas of focus for needed standards. Thus the Roadmap becomes a document by which the committee can plan for what lies ahead and convey to the membership in a simple format the future areas of focus moving forward.

The first topic discussed last fall was a general format of the Roadmap. Over the years it had many forms, ranging from a block diagram to a mind map. The format discussed at the fall 2016 meeting, and then presented in draft form at the 2017 spring meeting was a general set of swim lanes. The intent with this format is that the lanes will be used to group standards topics together, as well as be able to show a temporal aspect. A screenshot of the draft shared at the 2017 spring meeting is shown below in Figure 1. The current draft file is available for download to E55 members through your MyASTM member account.

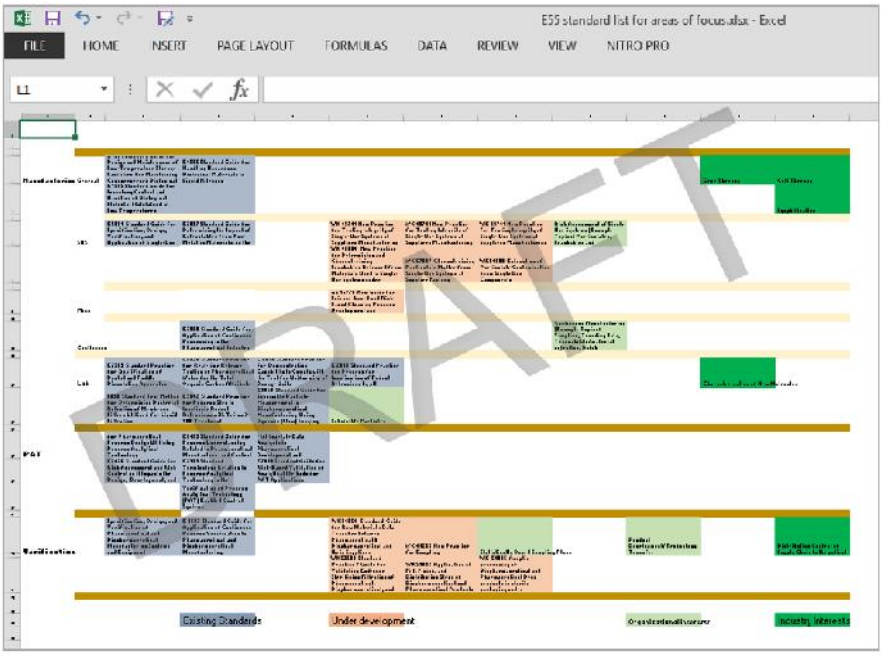


**Figure 1 – Draft View of E55 Areas of Focus Roadmap**

The second item discussed at the 2016 fall meeting was how the committee should identify potential areas for new standards. As a result of the discussion, the *E55 Standards Development Prioritization (Areas of Focus)* survey was sent out to the membership in the early part of 2017. The survey had three key questions: what standards did the respondents think their organization (company) were interested in developing; what standards did they think the Industry was interested in seeing developed; and what standards they are interested in or able to contribute to developing. The results of the survey were presented at the 2017 spring meeting.

After reviewing the data, the following analysis was performed. For each potential standard, we added up the low and the high votes for each of the three questions posed. The 2017 spring meeting subcommittee time was then used to review and discuss the results. The following initial observations were made and presented.

| **Number of responses based on a total of 72 completed surveys* | **Highest Interest Areas** | **Lowest Interest Areas** |
|---|---|---|
| **Organization Interest** (Current Company Priorities) | Continuous Manufacturing (58*) | Gene Therapy (42*) |
| | Risk Assessment of Single Use Systems (55*) | Lyophilization (41*) |
| | Product Development/Technology Transfer (51*) | 3D Printing (38*) |
| | Subvisible Particle (44*) | |
| | Statistically Based Sampling Plans (44*) | |
| **Industry Interest** (Observations) | Gene Therapy (52*) | Metrology and Qualification (23*) |
| | Cell Therapy (49*) | Continuous Manufacturing (18*) |
| | Lyophilization (48*) | Data Integrity (14*) |
| | New Molecule Characterization (44*) | |
| | Distribution of Supply Chain (43*) | |
| **Individual E55 Member Interest** (Willingness to Participate) | Metrology and Qualification (41*) | Gene Therapy (50*) |
| | Continuous Manufacturing (34*) | Lyophilization (48*) |
| | New Technologies (34*) | New Molecule Characterization (47*) |

Observations from the data show that what the membership perceives as the interest of their organization does not have good correlation to where they think the industry in general is headed. However, one conclusion was that in general this data does present guidance on a path forward for the Roadmap effort. First, what organizations are interested in is generally more near term, and these areas of interest are probable items of near term interest to E55. Second, what the membership sees as Industry trends and interest, probably represents emerging trends and topics. Finally, the lack of correlation between interests of either organizations and industry to what people feel they can contribute to means E55 will have to find subject matter expertise to help with future standards, much like during the inception of E55 and finding PAT experts.

Finally, a substantial part of the 2017 spring meeting focused on the exact nature of what types of standards and what specifically would be useful for the top areas of focus. Unfortunately, due to the high level nature of the survey, that data was not readily available. In order to gain such granularity, several small sub-teams were formed to reach out to experts in the various fields to investigate what kind of standards may be of use within those areas.

Preliminary sub-teams have been formed. If you are interested in participating, please contact the E55.95 subcommittee chair, Louis Traglia and you will be put in touch with the appropriate team. These sub teams are scheduled to report their finding at the 2017 fall meeting.

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Committee E55
Manufacture of Pharmaceutical and Biopharmaceutical Products

NEWSLETTER

## Outreach Strategies

# Reaching the Global Community

### International and Regulatory Outreach

Following the successful Workshop with the FDA on Future Standards Development last October, E55 has continued to reach out to regulatory authorities to help us understand where E55 Standards can add value. To support our European regulatory perspective we're very pleased that Dolores Hernán has agreed to become a "Member at large" in the E55 Executive committee. Dr Hernán is in the Quality Office of the Specialised Scientific Disciplines Department at the European Medicine Agency (EMA). We are also in discussion with WHO to see if there are opportunities for E55 to support WHO's important goal to build a better, healthier future for people all over the world

### ASTM Responses to New Administration

In June of 2017, ASTM International submitted comments addressing improvements to the organization and functioning of the Executive Branch in accordance with Executive Order 13781, Comprehensive Plan for Reorganizing the Executive Branch. As part the submission, ASTM Committee E55 also contributed committee specific comments concerning the Food and Drug Administration's (FDA) potential to carry out critical aspects of its mission more effectively by working in public/private collaboration with a diverse range of international stakeholders to create voluntary consensus standards that will help define and advance future innovations in pharmaceutical manufacturing.

As part of the comments, ASTM expressed the importance of the existing Federal policy found in the Office of Management and Budget (OMB) Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities, which aids in the development and use of private sector technical standards. OMB A-119 encourages Federal agencies to maintain strong preference for using voluntary consensus standards instead of government-unique standards when it comes to regulations and contracting while also providing direction to Federal agencies to consider private sector conformity assessment mechanisms.

The submission also highlighted the presence of scientists and technical experts from FDA at Committee E55 meetings, participating in standard development activities, and providing important input and insight to the committee's strategic leadership and road mapping activities. With increasing globalization of pharmaceutical and biopharmaceutical supply chains, it is vital to the continued competitiveness of these industries, and to the safety of consumers, that FDA experts engage in the voluntary consensus standards development activities as they have with Committee E55 and others. Through this engagement, ASTM believes that the FDA will find itself better equipped and more efficient in meeting the agency's strategic goals to improve product manufacturing and quality, and maintain international leadership in the development of regulatory science.

## Fall 2017 E55 Meeting in the Making

E55 will meet in Lausanne, Switzerland, during the period October 24-26, 2017. The meeting, which will be held at the Innovation Park of Ecole polytechnique fédérale de Lausanne (EPFL), will feature a Workshop—topic(s) to be determined—subcommittee deliberations on work items, subcommittee status reports and one or more tours of companies associated with EPFL. Representatives from the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) and the World Health Organization (WHO) have been invited to participate. Complete meeting and Workshop details, registration information and agenda will be provided as soon as plans have been finalized.

## Increasing Awareness - Newsletter Distribution

In the previous issue we pointed out increased efforts in the distribution of this newsletter to the greater industry beyond E55 members. By taking advantage of our network of colleagues and contacts, the newsletter was spread globally to long list of major company managers, regulators, professional associations, and social media contacts. With this latest issue, the distribution plan will continue to grow by, leveraging ASTM's Global offices in Belgium, Ottawa, Beijing, and Lima for further distribution in their country or Regions. Additional targets for outreach include contacts within academia who may be conducting research or educating the next generation in areas of study aligned with the Committee.

As stated in previous issues, all readers of this Newsletter are encouraged to help us spread the good word about Committee E55 by forwarding this on to any of your colleagues and industry networks you feel may be interested or impacted by the numerous standards development activities.

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NEWSLETTER

## 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 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 2018-2019 term, the slate will be put forward for approval by 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

### Directly Impacting the Content of your Standards

Welcome new members of the E55. Your participation in the technical committee allows you to directly impact the content of the standards. Members on the list below have joined E55 are new members in the last 6 months.

New Member Orientation

The current roster has over 170 stakeholders involved from around the world. Countries represented are as follows: Belgium; Canada, China; Denmark; France; Germany; Ireland; Japan; Mexico; Nepal; Peru; Portugal; Singapore; Sweden; Switzerland; UK; USA.

| Name | Organization |
|---|---|
| Busse, Ursula | Novartis AG |
| Callan, Melody S | Johnson Johnson |
| Degaetano, Robert | MilliporeSigma |
| Dixit, Mandar | Sartorius Stedim Biotech |
| Drummond, Scott | Johnson and Johnson |
| Duemmler, Heinz | Burkert.Contromatic |
| Hernán, Dolores | European Medicines Agency |
| Houts, Carol | |
| Johnson, Abby | Sanofi |
| Pai-Wechsung, Sheetal | AbbVie Deutschland GmbH |
| Ramon Gomez Chiarella, Carlos | Ozo6 s.A. |
| Thomas, Colleen | US Food and Drug Administration |

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Committee E55
Manufacture of Pharmaceutical and Biopharmaceutical Products

NEWSLETTER

## Effective Participation Tips

# Maximize Your Investment

### 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/. 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.

### Proactive Participation

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

### Initial 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. We recommend participation in the New Member Orientation and Balloting and Handling Negatives Votes sessions.

*View member training topics and upcoming sessions at www.astm.org/MEMBER_TRAINING*

### Who's Who?

All ASTM committees are staffed with a Committee Chairman (elected), Committee Manager and Administrative Assistant who act as resources for any questions you may have. Introduce yourself to the Chairman or Committee Manager at a meeting, by phone or email.

### Meetings

Attendance at ASTM committee meetings is not required; however, it is one of the most effective ways to engage the process and have the opportunity to network with industry colleagues. Most committees meet face-to-face twice per year, hold teleconferences and communicate via email throughout the year. These are the forums at which decisions are made. Scheduled committee meetings are listed on our website. They are free to attend and online preregistration is available.

### Website Navigational Videos

Click here: http://www.astm.org/MEMBER_TRAINING/howto.html

### Self-Manage ASTM Emails - Short Video

Click here: https://vimeo.com/155144864

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