XCELLERATE ™

Workshop Brief

ASTM XCELLERATE HEALTHCARE

An ASTM Center of Excellence (Under Consideration)

Background

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.

ASTM International has a proven track record of developing standards in line with the needs of industry and public sectors as shown with the Additive Manufacturing Center of Excellence (AM CoE). They are clearly poised to bring together stakeholders in the healthcare industries to provide a centralized location for research and development around biopharmaceuticals and biotechnology.

In January 2023, ASTM International held an informal workshop to discuss the current challenges and needs space for biotechnology and biotechnology manufacturing. This brief covers discussion over current technology gaps, challenges to innovation, and priority areas for standards development.

Current Landscape

WORKSHOP SUMMARY

Nexight and ASTM gathered interested stakeholders for the ASTM Xcellerate Healthcare Innovation Workshop on January 27, 2023 to discuss the potential of forming a center of excellence as a potential solution. The Xcellerate Healthcare initiative would build off the structure of the current Additive Manufacturing Center of Excellence.

Two brainstorming questions were posed and explored:

01 → What challenges are slowing innovation and standards development in the biotech/biopharma manufacturing space?

02 → What manufacturing/process control topics/transformative technologies would benefit most from ASTM's Research-to-Standards approach?

CHALLENGES IN TECHNOLOGY AND PROCESS CONTROL

Process Control. Understanding and optimizing process controls necessitates extensive characterization of all parameters. As digitization of manufacturing continues (as indicated by Industry/Pharma 4.0) the need for a comprehensive database of material properties and process controls specific to Additive Manufacturing (AM) applications is evident. The data requirements for implementation of real time monitoring, the use of Artificial Intelligence (AI), and predictive process control (defect detection) will require open access to a large standard data set. At this time, the level of data analysis and integration is not fully understood.

Hardware Advancement. New technologies necessitate the need for new hardware designed specifically for AM. These new instruments must meet all current requirements for pharmaceutical devices (cleaning, sanitation, and sterilization) and be capable of equivalency testing for polymers and other new materials without the need for human intervention in order to meet the demands of Pharma

Workshop Attendees

Ferdinando Aspesi, Bridge Associates International FEA | E55, F42

Justin Barch, Standards Coordinating Body of Regenerative Medicine

Ross Brindle (Moderator/Facilitator), Nexight

Kim Brown, ASTM International

Denise Cleghorn, Boston Scientific | E61

Kate Chalfin, ASTM International

Christine Farrance, Charles River Laboratories | E55

Andrea Johnston, BioPhorum

Tessa Llewelyn, ASTM International

Kathleen May, Triskele Quality Solutions | D37, E55

Brian Meincke, ASTM International

John Logar, Johnson & Johnson | E10, E11, E55, E60, E61, F04

Len Morrissey, ASTM International

Dean Ripple, NIST | E55

Mike Sadowski, Baxter

Sebastian Scheler, Innerspace GmbH | E55

4.0. Integration of robotics, AI, continuous manufacturing, and mixed reality are essential to automation of every step of industry.

Advancements in Sensors. Sensors that are interchangeable between hardware and operating systems. Widespread adoption and integration of these technologies requires the development of a large dataset that will not be possible unless data collected from sensors is in a standard transferable format. Machine failures should be proactively addressed.

CHALLENGES TO STANDARDS DEVELOPMENT

Standardization and Certification of Hardware and Product Quality. There must be data-based quality metrics to assess instrument functionality. It should be possible to calibrate and certify instruments and products at any location – advancement of these technologies directly to health care facilities and/or point of care requires strict standards such that independent validation and verification can be performed by any trained personnel. The ability to detect and identify contaminants and defects will be essential to large scale adoption. This will also play a large role in ensuring authenticity of product. The EU has recently introduced some new regulatory standards but the data for expanding these is not standardized in a way to truly demonstrate confidence.

Workforce Development. There is an overwhelming need for a workforce with the new skillsets required for Industry/Pharma 4.0. The lack of qualified technicians and professionals has only been increasing. Standard training and personnel qualifications require sharing of data.

Standards Needs

There is a need for new and modified standards across multiple categories in healthcare. New manufacturing technologies (hardware and software) necessitate new standards for process controls and testing.

The following standards needs address the high priority gaps identified through this workshop.

CYBERSECURITY

- Ensuring confidentiality and security of systems utilizing AI

FILE FORMATTING

- Standard for file formats between software and hardware
- Standard data sets for implementation of AI and machine learning

MODELING

- Advanced modeling and simulation for hardware, robotics, and automation.
- Physical test methods
- Guidance documents for complex computation modeling
- Guidance for optimizing models

PROCESS CONTROL

- Optimization Guidelines and best practices
- Certification of systems
- Standard Coupon designs

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MATERIAL TESTING

- Biocompatibility Testing
- Testing methods for additional debris from new manufacturing technologies
- Polymer Detection (Automatic)

VERIFICATION AND VALIDATION

- Certification for authenticity of products
- Standard physical test methods
- Guidance on AI training for biopharmaceutical applications

Role of ASTM International

As a global leader in standards development, ASTM International maintains cooperation agreements with over 100 national, regional, and international standards bodies and is in a unique position to lead and champion the global collaboration platform. ASTM's role is to facilitate and maximize collaboration by acting as the coordinating organization for all global efforts. In particular, ASTM can support several key tasks.

- **Partnership Formation**. Bring together stakeholders and establish formal partnerships via memorandum of understandings to advance research on relevant topics.
- **Collaborative Engagement.** Host workshops and provide opportunities for live interaction and information exchange.
- **Communication and Outreach.** Maintain availability of standards and leverage existing network of partners (manufactures, suppliers, testing laboratories, academia, and approval bodies).
- **Standards Assessment.** Compile current standards and lead efforts to identify existing standards and gaps, and research standards needs for the future.

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