

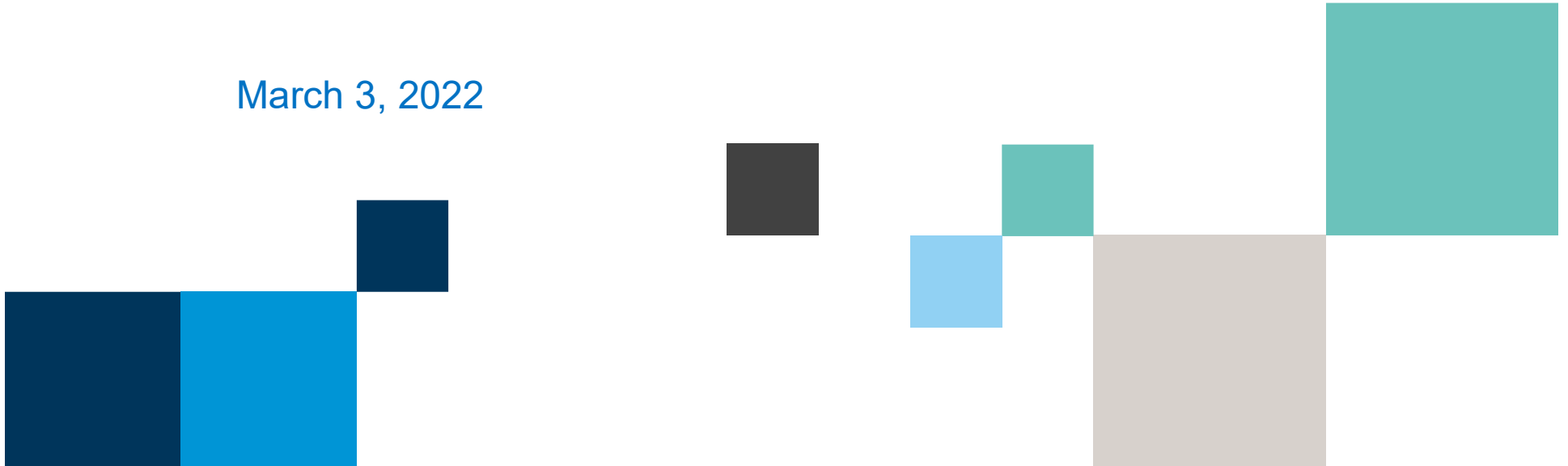


ASTM INTERNATIONAL  
Helping our world work better

# Inter-American Coalition for Regulatory Convergence – Medical Technology

Utilization of Voluntary Consensus Standards Webinar  
MedTech SDO Panel

March 3, 2022





# Topics

---

1

About ASTM International

2

Key Technical Committees, CoEs

3

ASTM Collaboration Platform on PPE  
and Related Activities

4

ASTM Supports Global Convergence

5

Conclusion/Q&A

# About ASTM International

---



## A Proven and Practical System

- Established in 1898
- 147 Committees & 13,000+ Standards (Covering 90 industry sectors)
  - Recent: Additive Manufacturing, Exo and Exoskeleton Technology, etc.
  - Older: Medical Devices, Pharmaceuticals, Plastics, etc.
- 30,000+ members
  - 8,000+ International Members from 140+ countries
  - 8,400+ ASTM standards used in 83 countries
- Headquartered in PA/USA, Offices in Washington DC, Europe (Brussels/London/Stockholm), Middle East (Dubai), China (Beijing), Canada (Ottawa), South America (Lima, Peru)
- Accreditations
  - American National Standards Institute (ANSI), Standard Council of Canada (SCC)
- ASTM Standards Globally Recognized for Quality and Relevance
  - Development and delivery of information made uncomplicated
  - A common-sense approach
  - Consensus based
  - Market relevant

# ASTM International in LATAM/Caribbean



965 Latin American members from 37 countries participating in ASTM

Dedicated Latin American Representative located in Lima, Peru

A growing number of ASTM standards and services available in Spanish

## Collaborative

New MoU agreements with Brazil and Mexico

Large number of citations of ASTM standards by MoU partners in the region

738 Student Members in LATAM/Caribbean

## Dedicated Resources

Building government and industry awareness, recognition, and support for ASTM in Latin America

Bimonthly Webinars offered in Spanish

Facilitating the work of a Student Chapter in Peru

Onsite ASTM Technical and Professional Training Programs in Spanish

## Dynamic Information

Responding to new challenges, new technology and new markets

Compilations of official ASTM translations in key market sectors

Fundamental e-learning provided with Spanish subtitles

Sector specific microsites in Spanish

# Committee F04 on Medical Devices



## Scope

- Development of standardized nomenclature and definitions of terms, test methods, recommended practices, guides, specifications and performance standards for medical and surgical materials and devices
- Encourage research in this field and sponsor symposia, workshops and publications to facilitate the development of such standards
- Promote liaison with other ASTM Committees and other organizations with mutual interests

## Subcommittees Include (34 Total)

- Orthopaedic Devices
- Medical/Surgical Devices
- Tissue Engineered Medical Products
- Cardiovascular
- Cell Signaling
- Neurosurgical
- Urological
- Etc.

# ASTM Keys for Medical Technologies



## Technical Committees

- D11 on Rubber and Rubber-like Materials
- D13 on Textiles
- D20 on Plastics
- E55 on Pharmaceutical Manufacturing
- E56 on Nanotechnology
- F04 on Medical and Surgical Devices
- F23 on Personal Protective Equipment
- F42 on Additive Manufacturing
- F48 on Exoskeletons and Exosuits

## Centers of Excellence (Research-to-Standards)

- Additive Manufacturing
- Exo and Exoskeleton Technology

147

main committees  
plus 2,030+  
subcommittees

# PPE-Related Activities

---



## ASTM Global Collaboration Forum to Advance Personal Protective Equipment (PPE) Safety, Quality and Innovation

- Identifying, discussing market, data, and standards needs
- See <https://astmppecollaboration.org>. Next meeting is March 7, 2022

## ASTM-International Finance Corp. MOU on Development and Dissemination of Knowledge on PPE Standards and Compliance Globally

- Working to provide awareness, capacity building, standards cooperation, and good international practices related to PPE

# ASTM Supports Convergence

---



- ASTM has entered into technical cooperation agreements with other international standards bodies like ISO and IEC
- ASTM maintains Memorandums of Understanding to support technical cooperation with over 115 regional and national standards bodies – including 31 in the Western Hemisphere
- Signatory of UNECE Declaration on Gender Responsive Standards (2019)
- Supporting UNECE initiative on Standards for the SDGs
- Member of the OECD Partnership of International Organizations (with ISO, WIPO, WTO, etc.)
- Advocating globally for policies that allow regulators flexibility to choose standards based on important attributes such as technical quality, relevance, and suitability to task
- Recognized by OECD as a unique contributor to international regulatory cooperation ([2021 Case Study](#))



# ASTM at Its Core

---



- Open and Transparent in deliberations, global in scope and reach
- Direct and balanced participation for all
- Keep science in and politics out
- Promote choosing standards based on merit
  - Ultimate measures of worth are technical quality and market relevance
  - Respect the choices of the market and needs of stakeholders

*The most innovative companies in the world demand flexibility and choice in standards so that they can offer exciting new products and services that meet emerging demands of the marketplace.*

*By enabling prosperity, innovation, and safety, ASTM helps our world work better!*



ASTM INTERNATIONAL  
Helping our world work better

# Thank you! Questions?

Craig Updyke  
Director, Global Policy and International Trade  
[cupdyke@astm.org](mailto:cupdyke@astm.org)

[www.astm.org](http://www.astm.org)

