

International Conference on Advanced Manufacturing

Research to Application through Standardization

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Industrial Sector: Medical Manufacturing and Biofabrication

Additive Manufacturing (AM) capability to fabricate complex geometries on demand, paired with advances in inert materials, digital workflows, and process control, has driven broad adoption in medical devices, anatomic models, implants, and surgical planning. In parallel, innovations in biofabrication technologies show promise in the use of novel methods for the production of new tissue. Biofabrication, the Additive Manufacturing of living materials, shows great promise for healthcare and the life sciences by enabling new ways to design, produce, and deliver regenerative medicine therapies.

Despite strong progress, significant technical, translational, and industrialization gaps remain. Key challenges include robust personalized device design methodologies, in-process monitoring and materials state awareness, post-processing, and validation of performance to meet verified needs. End-user adoption barriers, clinical workflow integration, economic feasibility and reimbursement, often determine whether AM solutions scale, and is a place where standards can reduce stakeholder uncertainty.

For biofabrication, additional focus is needed on material property authentication, construct shelf life and functional lifetime, and reliable scale-up from lab demonstrations (TRL 1-6) to clinically and commercially viable manufacturing (TRL >7).

As these technologies evolve from prototyping to routine deployment, there is a growing need for fit-for-purpose standards, terminology, test methods, qualification, validation, and regulatory frameworks. This includes data integrity and traceability, inspection and metrology, imaging-to-design workflows,

process controls, quality systems, and the development of consensus methods to support safe, effective, and reproducible products across medical and biofabrication applications.

Topics of interest include but are not limited to:

- Functional Performance, Reliability, and Long-Term Behavior of Medical AM and Biofabrication
- Novel Materials for AM Biomedical Applications and Biofabrication
- Materials State Awareness in Medical AM
- Hybrid Manufacturing: "AM + X"
- Post-processing, Surface Modification, Coatings, Cleaning, and Sterilization of AM Medical Devices
- Design & Performance of Functionally Porous Structures and Biointerfaces
- Design & Manufacture of Personalized Medical Models, Surgical Guides, Jigs, External Prosthetics, Dental Products, Medical Implants, and Other Patient-Specific Medical Devices
- AM at the Point-of-Care and Distributed Manufacturing Models
- Clinical Implementation of Point-of-Care Manufacturing: IQ, OQ, and PQ (Installation Qualification, Operational Qualification, Performance Qualification) and QMS (Quality Management System)
- Point of Care Manufacturing Reimbursement Models
- Role of AM in Medical Education & Surgical Planning
- Clinical and Translational Case Studies of AM Applications
- Integration of AR/VR/MR in the Surgical Planning and Intra-Operative Deployment of AM-Enabled Solutions
- Digital Thread: Imaging-to-Design, Data Integrity, Traceability (e.g. MES), and Cybersecurity Considerations
- Qualification, Validation, Certification, and Quality Assurance Challenges
- Standards and Regulatory Developments for AM and Biofabrication
- Biofabrication Modalities: Freeform bioprinting, embedded bioprinting, chaotic printing and co-axial micro-channeling, melt electrowriting, and on-chip applications.
- Biofabrication Workflows: Scale-Up, Automation, and Manufacturing Readiness
- Novel Materials for AM Biomedical Applications and Biofabrication



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