3D Printing of Medical Devices at Point of Care

Scenario D: The Manufacturer is Co-Located at Point of Care

Highlights from the ASME March 19, 2020 Webinar

The information presented is for discussion purposes only, is not guidance, and is not intended to implement policy changes.

Working Definitions

Traditional Manufacturer: any person who designs, manufactures, fabricates, assembles, or processes a finished device. The full definition of a manufacturer is in 21 CFR 820.3(o).

Contract Manufacturer: Manufactures a device to another manufacturer's specifications. Contract manufacturers are typically a third party. Traditional Manufacturers use their own purchasing controls to evaluate suppliers and establish and maintain data to show how purchased product meets the Traditional Manufacturer's specified requirements.

Panel Questions

How close to the patient bedside would you want co-located 3D printing to take place?
Panelists agreed that the 3D printing facility should ideally be as close as possible to the patient for expediency while maintaining the safety of all parties involved. Other factors to be considered are:

- Patient-specific devices vs. off-the-shelf devices
- Requirements for the clinical and engineering team to work closely
- Cost-benefit analysis
- Access to materials, equipment

What do you see the benefits of co-location to be?

- **For clinicians**
- **For device manufacturers**

- Some clinicians have expressed the need to have direct interaction with designer and manufacturer to understand the product development product and to achieve the correct product.
- For surgeons in particular, co-location is equated with speed and the ability to provide greater service to trauma patients.
- One participant noted an analysis of production of a mandible implant. The time that elapsed between the device manufacturer's in-house production to the hospital was 43 hours for a patient-specific solution. If in house production more used a more streamlined system, the time elapsed fell by 16%. And for a device manufactured at the POC with the streamlined system, the elapsed time fell by a total of 41%. More patients could be served faster based on this hypothetical example.

How feasible is co-located 3D printing given:

- **Space/infrastructure considerations**
- **Quality control**
- **Risk assessment**

- Respondents noted that feasibility may depend on the types of devices to be produced. Materials also play a significant role, with production of additive metal-based devices requiring more training, quality management systems considerations, safety, risk assessment, and environmental controls than polymers.
- For large urban areas with several hospitals, it may be advantageous to build one co-located manufacturing facility that serves multiple hospitals.
- Points of care may want to consider hybrid models, with locating an engineer and designer onsite but housing the manufacturer offsite at a traditional manufacturing facility.

What do you think is still needed to make this a feasible business model for clinicians and device industry?

- All stakeholders, including hospitals, clinicians, patients, and manufacturers, must consider what demonstrates value (e.g., producing a device of higher quality that is better tailored to patient needs). Also, trauma needs may be able to be addressed more fully by onsite manufacturers.
- Hospitals also must consider the requirements for creating an infrastructure to have backup capacity and extra staff. Certain equipment may be designed for a factory setting but not necessarily for point of care.