3D Printing of Medical Devices at Point of Care

Scenario E: The Healthcare Facility Becomes a Manufacturer

Highlights from the ASME April 17, 2020 Webinar

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

Panel Questions

Why would a hospital or PoC facility choose the option of Scenario E, Healthcare Facility Becomes a Manufacturer?

Panelists agreed that most hospitals and surgeons are looking to improve lead times, receive the product faster, and treat patients in acute trauma more quickly. A facility located in-house or close to a hospital would help meet these needs by offering flexibility and innovative solutions for patients.

The option also offers design and prioritization control to hospitals when existing products do not meet the needs of clinicians and patients. Front-line staff have the opportunity to conduct on-demand, face-to-face surgical planning, which participants believed results in greater innovation.

In contrast with Scenario A., where a product with minimal risk is produced, Scenario E pushes toward high risk. In this case, a hospital becomes a manufacturer and submits a device to FDA for preclearance, which is challenging and may require hiring of specialized staff with competencies in regulatory submissions. Hospitals may want to explore such alternatives as partnering with industry, which is outlined in Scenarios B&C.

From a machine manufacturer perspective, a hospital's level of involvement on a higher risk implant translates to customers' benefit through reduction in production costs and time.

Onsite manufacturing also may provide additional benefits for patients and their families. One panelist noted an example for destination hospital facility, which may be far from a patient's home. In such cases, patients' families often travel to the facility and stay in a hotel, which can be cost prohibitive. Onsite manufacturing can reduce the amount of time for a patient hospital stay, reducing the financial burden for families as well.

Additionally, this option would allow hospitals to not only treat their own patients but also sell the devices to other facilities around the US.

What are challenges to PoC becoming a device manufacturer?

Notably, status as a device manufacturer is new for most hospitals. This status requires additional staffing and expertise in regulatory affairs, engineering, quality systems, and production. Infrastructure also must be established to promote communication among these new units. For quality systems, hospitals would be required to develop competencies in ensuring quality for the entire life cycle of the product, including post-market.

Hospitals also would be required to carve out space for industrial-scale equipment and its infrastructure, including storage.

What staffing/expertise would a hospital need to add to its staff?
Panelists noted that an entire dedicated staff would be required, including principal engineers, technicians, and administration staff to ensure proper shipping/receiving, tracking, etc. of equipment and supplies.

What resources are available to a POC facility that is considering this scenario?
Panelists noted several resources that POC facilities could utilize and look to for guidance:

- The FDA Center for Devices and Radiological Health (CDRH) has a division of industry and consumer education (DICE), which specializes in providing information for new and/or small manufacturers. Also, the CDRH's additive manufacturing working group has issued a guidance document of interest: https://www.fda.gov/files/medical%20devices/published/Technical-Considerations-for-Additive-Manufactured-Medical-Devices---Guidance-for-Industry-and-Food-and-Drug-Administration-Staff.pdf.
- Public-private partnerships, such as the Advanced Regenerative Manufacturing Institute (ARMI)/BioFabUSA offers resources for its members: armiusa.org
- Institution's tech transfer office may be a valuable resource for those looking to market or license its devices.

What would the marketing aspect of this scenario look like?
Any facility that becomes a manufacturer must seek clearance from the FDA to market and/or sell a device. A hospital's unique value in providing innovative solutions may draw patients and surgeons alike to the facility.

Audience Questions

What are the challenges faced if we only focus on custom-made devices and does it make financial sense?

One panelist noted that custom-made vs patient-specific matched devices are two separate categories with differing FDA rules. Both require facilities to be registered as a manufacturer.

What is some advice to small/medium companies with limited resources?

Panelists suggested that small-to-medium organizations home in on one a specific medical application to target and develop a specific product based on the application. Often, small-to-medium organizations benefit from a narrower focus for a device.