



# **MxD: AMMO Update**

## **February 3, 2021**

20-17-01

# RAPID AND SECURE DEPLOYMENT OF MEDICAL DEVICES AND INSTRUMENTATION

Creating digital methodology framework to expedite the approval of medical devices by the FDA, ultimately decreasing the time to market

**Project Team:** Fast Radius, Johnson & Johnson, Siemens

**Estimated Duration:** 12 months

**Budget:** \$6.2M Total Funding

**Funding Source / Contract:** CARES Act / TIA

**PM:** Joel Sheaffer – joel.Sheaffer@mxdusa.org

**Current Status:** Ready to Kick Off

*“As a manufacturer of medical devices and medical device components I want a define digital process that will enable the FDA to quickly approve new parts.”*

## INDUSTRY CHALLENGE

The COVID-19 pandemic exposed critical vulnerabilities in the global health care supply chain. To overcome those vulnerabilities, we need to speed up the design and production of improved medical devices by leveraging the benefits of a Digital Methodology Framework combined with device manufacturing using 3D printing incorporating additive manufacturing and product simulation.

## IMPACT

The developed resources will minimize the time to market for new medical devices and medical device components. Similarly, the tools developed in this project will ultimately shorten the time it takes for “personal medical devices” to get in the hands of surgeons and end-users of the products.

## PROJECT SOLUTION & OUTCOME

- An established expanded Digital Methodology Framework to guide future project through the digital design and production process.
- Complete and properly document OQ and PQ for each component, assembly, and product
- Defined pathways for completing appropriate FDA validations
- A fully integrated Digital Methodology Framework Platform
- Multiple(4-6) Digital Methodology Framework workshops for dissemination and awareness



Where Innovative Manufacturers go to forge their future

Federico Sciammarella Ph.D.  
President/CTO  
(312) 281-6827

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

  @MxDInnovates