CADENCE

January 13, 2017

To whom it may concern:

In response to the Request for Information on Identification of New Capabilities Needed by the Hollings Manufacturing Extension Partnership Program, I would like to provide input that I believe would aid small and medium-sized U.S. manufacturers who make up the medical device, instrument, and supply industry in the United States. I believe these recommendations would aid medical device manufacturers in the areas of critical manufacturing capabilities; supply chain requirements and optimization; potential business services; and other services that would enhance global competition.

There is a need for U.S. medical device manufacturers (to include medical instrument and supply manufacturers) and their supply chains to increase their critical process capability and maturity in order to win new business and not be shut out for years to come due to foreign competition. According to IBISWorld, the U.S. medical device, instrument, and supply industry has over 17,000 businesses and generates an annual revenue of over $130 billion. Since 2012, Medical Device exports have dropped while imports have increased, driving the trade balance negative. In Medical Instruments and Supply, exports have remained flat while imports have increased, increasing the negative trade balance. Future projections continue this trend of erosion of U.S. manufacturing market share and increasing trade deficits.

In 2010 cross industry benchmarking by Johnson & Johnson indicated possible benefits in product quality and patient safety by requiring medical device suppliers to undergo critical process accreditation similar to what is provided under the aerospace Nadcap. The medical device industry, in concert with Performance Review Institute, the not-for-profit that administers the Nadcap program, developed the MedAccred program. MedAccred is an industry driven critical process accreditation program for the medical device supply chain and awarded its first accreditation in 2015.

Several large medical device OEMs have discussed requiring MedAccred accreditation as a requirement of future business awards. Due to the rigorous FDA approval process, once business is awarded, an OEM tends to keep business with the approved supplier. Therefore, suppliers who delay pursuing and achieving MedAccred accreditation will face a disadvantage in the marketplace. Non-US suppliers are beginning to embrace MedAccred accreditation, placing U.S. suppliers at a disadvantage. It is imperative that U.S. based medical device suppliers become MedAccred accredited if their top tier customer will be requiring it in order to not be shut out of new business opportunities.

The NIST MEP system is in a unique position to be able to support the U.S. medical device supply base with preparation for MedAccred accreditation, resolution of MedAccred audit findings, and continued critical process validation and improvement, positioning the supply base to be competitive in both the U.S. and global marketplaces.

Sincerely,

Kevin Groth

Supplier Quality Engineer

Cadence, Inc.