



The Alliance for Quality Medical Device Servicing (Alliance) on November 29, 2018, hosted the “Summit on Safety, Quality and Effectiveness of Servicing Medical Devices” in Chicago as part of its objective to advance safety, quality and effectiveness for medical device servicing. The meeting was an industry first, convening a broad group of stakeholders to discuss four actions identified in the May 2018 “FDA Report on the Quality, Safety and Effectiveness of Servicing Medical Devices” and determine if there are common interests and opportunities, as well as the desire to pursue the formation of a Collaborative Community. Over sixty participants representing medical equipment manufacturers, independent service providers, in-house service organizations, health care providers, remanufacturers, FDA, Joint Commission, AAMI and ECRI Institute were in attendance. It was an energetic day filled with robust and engaging discussions on each of the topics with many areas of common opportunity identified and a consensus that there is interest in creating and participating in a Collaborative Community.

The medical device servicing topics discussed were (i) clarifying the difference between servicing and remanufacturing, (ii) quality management principles, (iii) strengthening cybersecurity practices, and (iv) evidence development. Regarding the differences between service and remanufacturing, there was common agreement that clarification is needed in defining these activities, including what constitutes “significantly change” and how OEMs can work with third parties to provide access to Service Materials (i.e., tools, parts, training, software keys etc.). On the topic of quality management principles, the group discussed differences between principles and systems and agreed that this area would benefit from more definition. For cybersecurity, there was both deep and broad discussion that this is an area of significant challenge for providers. Some of the key opportunities identified for collaboration included patch management, risk profiling devices, and education. The final topic of evidence development yielded significant interest and discussion, with the general conclusion that there is a need to establish quantifiable and repeatable measurements for safety and quality of servicing medical devices to establish a baseline, identify trends and determine the impact of change.

Based on feedback received, the Alliance believes the Summit was successful in achieving its goal of determining interest in forming Collaborative Communities related to the topics in the FDA report. As next steps, the Alliance has been actively participating in related activities, including attending the FDA “Public Workshop - Medical Device Servicing and Remanufacturing Activities” in December and participating in the panel discussions. The Alliance plans to maintain an active leadership role on these issues and seek to encourage and lead the development and formation of a broader Collaborative Community. The Alliance also plans to continue its active participation and leadership in FDA-sponsored activities, standards development, and other related activities.