Dear SOT Program Manager;

I am writing a letter of support for the IAT designation, for the proposed 2018 SOT workshop (Session ID 128), "Drug-Device Combination Products and Their Components." Historically, medical device and combination product evaluation involved conducting a battery of standard *in vitro* and animal tests as outlined in the medical device and container closure standards (ISO 10993; USP 87 and 88). Medical device sessions, posters, and toxicologists involved with medical devices were in short supply at SOT meetings. With the changing medical device standards (many of these coming changes announced in October 2016), US FDA Guidelines (published 2016), and EU expectations (per the new medical device regulations published in 2017), we are seeing a shift toward chemical characterization of devices, and use of toxicological risk assessments to address certain biological endpoints and to support the overall safety of medical devices.

Due to the availability of sophisticated analytical instruments that allow for thorough chemical characterization of these products, and innovative tools for in *silico* modeling of chemicals and toxicological prediction software, the overall approach to safety evaluation has changed significantly. This change supports the use of a risk management process, resulting in overall reduction of animal testing, and improvements in predicting the safety of medical devices and combination products. These techniques are important for screening the ever-increasing number of novel materials and chemicals in these products, to keep up with the need for new and innovative technologies for treating and curing disease. Ultimately this will reduce the time it takes for patients to have access to these products. Unfortunately, while regulatory bodies are now requesting chemical characterization and risk assessments, the current standards and guidance are outdated (more than 10 years), and upcoming standards and guidance that incorporate these new methodologies are not yet available. The communication of best practices and innovative techniques across the industry is through webinars, and scientific programs at meetings like SOT. This proposed workshop will provide a forum to share current and innovative practices for chemical characterization and risk assessment of these products, and allow the attendees access to key subject matter experts across the industry.

The topics of interest were determined through a poll taken at the MDCPSS reception at the SOT 2017 annual meeting; and speakers were found through networking (current and former EC members, and MDCPSS members). Speakers were selected to represent a range of subject matter experts in this field. For an international perspective, [speaker 1], a consultant from Germany, was selected to give an overview of the state of the industry and current and upcoming standards and techniques. He is an internationally recognized expert in cytotoxicity and biological evaluation of medical devices and is heavily involved in international standards development. [Speaker 2] is a toxicologist from industry with a great deal of experience in evaluation of many complex combination products in higher risk categories (e.g. cardiovascular products). [Speaker 3] is from industry and will share her experience utilizing different laboratories and techniques for chemical characterization of devices, and is involved in the technical committee for ISO 10993. Finally, [speaker 4], on the federal agency side, is the study matter expert in chemical characterization of medical devices and assists in the review of medical device and combination product regulatory submissions. She will provide the agency's current thinking and regulatory expectations for chemical characterization of medical devices to support toxicological risk assessments.

Thank you for considering this letter of support. If there is any other information that you would like me to provide, please let me know.

Best regards,