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JOINT EVENT

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SINGLE-USE DEVICE REPROCESSING: PAVING THE WAY FOR INCREASED PATIENT SAFETY, LOWER COSTS AND REDUCED MEDICAL WASTE

Globally, hospital reuse of "single-use" devices, or SUDs, has the potential to adversely impact patient safety. However, international regulatory authorities are coming to regulate SUD reprocessing as a manufacturing activity, which has resulted in evidence supporting patient safety, lower device costs and waste reduction creating a win-win for hospitals and health care systems. Commercial SUD reprocessing is an established best practice in the U.S., Canada and Germany, with emerging stages of regulation happening in Japan, South Africa and all of Central and Latin America. The new comprehensive European Medical Device Regulation (MDR) set to be adopted in June of 2017 is taking SUD reprocessing to a new level there. The MDR will regulate the reuse of SUDs as a manufacturing activity and thus such reuse, whether it takes place in hospitals or commercial entities, is subject to EU manufacturer requirements, including CE marking requirements. The regulation of SUD reuse is an important first step toward stopping unregulated SUD reuse in hospitals. Moreover, regulation will provide an overt, legal and safe pathway for hospitals to acquire lower-cost and environmentally preferable reprocessed devices. The result will be increased patient safety, more competition, and lower costs and reduced medical waste for hospitals. This session will provide an overview of the literature and data supporting the safety of regulated SUD reuse, but will also briefly address a 2016 study addressing device failure rates (new versus reprocessed). This session will address the differences between hospital reprocessing and commercial reprocessors meeting medical device manufacturer requirements, and provide insight into the implications of the new requirements for hospitals. This session will also provide an overview of the economic and environmental implications for healthcare markets where SUD reprocessing has been regulated, evaluating safety, cost saving and environmental factors.

Biography

Daniel J Vukelich is the President of the Association of Medical Device Reprocessors (AMDR), the global trade associating representing the legal, regulatory and other trade interests of the commercial medical device reprocessing industry. AMDR's core mission is to promote the proper reprocessing and re-manufacturing (cleaning, repair/refurbishing, testing, sterilization, among other steps) of "single use" devices (SUDs). He also represents the industry before the European Union, Canada, Japan and other international bodies.

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