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International Standard for Commercialization as Regulatory Science

Hajime SAKAKITA[1]
[1] Department of Electrical and Electronic Engineering, Meijo University
e-mail (speaker): sakakita@meijo-u.ac.jp

Applications of plasma-based technology to life science and medical engineering are very important for developing plasma science and for the better understanding of the interaction between plasma and biomaterials [1-9]. However, many regulations exist in the practical application of medical devices based on research results related to the life sciences.

Using present surgical hemostasis methods, the scarring that results from cauterization limits the efficacy of surgery. Consequently, a method that controls bleeding without scarring tissues is strongly required. In connection with this, low-temperature atmospheric pressure plasma (LTAPP) has been studied as a minimally invasive technology [10]. There are many reports on platelet aggregation, fibrin polymerization, hemolytic coagulation of red blood cells, and serum protein aggregation following LTAPP treatment [11-13].

The interaction between low-temperature plasma and blood components such as protein has been studied, and especially examined the charge effects supplied by the plasma on the aggregation of albumin protein [14,15]. In regarding this, potential on the substance treated by LTAPP was measured [16,17]. Then, it was found that charges were supplied on the substance [14-18]. Details of charge (ions) effects are under study.

While regulatory science has contributed to the dissemination of medical devices. Indeed, regulatory science provides scientific evidence for the standardization and justification of the use of medical devices. Therefore, based on the evidence provided by regulatory science, WTO (World Trade Organization) member countries ratify the TBT (Technical Barriers to Trade) Agreement on International Standards, and refer to international standards in their legally binding medical device review processes. Significantly, the multidiscipline collaboration between medical science and technological science provides principles and evidence for regulatory science.

Respecting the above, at the conference, I will introduce and overview our activities to establish the International Standard of IEC 60601-2-76: ed.1 document on low-energy ionized gas haemostasis equipment, which provides basic safety and essential performance specifications published in 2018.

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