Symposium

[S03]Harmonization of pharmaceutical regulation and innovation

Organizers: Tetsuya Kusakabe (Grad Sch Med, Osaka City Univ), Masuo Kondoh (Grad Sch Pharm Sci, Osaka Univ)

Thu. Mar 26, 2020 9:00 AM - 11:00 AM [Room C] Room B-2 (2F)

In his *Dialectics of Nature*, the German philosopher Friedrich Engels described the transformation of quality and quantity as the "mutual penetration of polar opposites and transformation into each other when carried to extremes." This raises the question of whether regulations are a roadblock for innovation. Medical products must be developed in accordance with regulatory frameworks to ensure their quality, effectiveness, and safety. After approval, medical devices are subject to a regulatory framework for post-marketing surveillance. A regulatory framework is needed to ensure that patients have access to safe medical products. However, sometimes, a series of regulatory frameworks ends up acting as a roadblock for, and thereby preventing, medical innovation, leading to delayed patient access to innovative products. By contrast, when regulation is optimal, it is not roadblock; rather, it is the actual pathway to achieving real and lasting innovation (Margaret Hamburg, Feb 2012). In this symposium, symposiasts from regulatory authorities, academia, and industry will speak about recent topics in regard to the development and/or regulation of medical products. Subsequently, we will discuss the current status of harmonization between regulation and innovation with pharmacists and pharmaceutical scientists. We hope that this symposium will serve to promote interpenetration between the regulation and innovation of medical products, leading to initiatives for medical innovation in Japan.

[S03-Opening]はじめに

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