

Regulators' Paradox to Bring in Novel Medicine

Date: October 22, Friday at 9:30-11:00

This seminar will be held using ZOOM Meeting



**Dr. Lu Chia-feng,
Senior Partner,
Greenberg Traurig
LLP (Washington
D.C. and Tokyo)**

The organizational reputation of the regulator in medicine has been the primary source of its power, yet also one of its ultimate constraints. Extremely diversified and inconsistent expectations from different stakeholders to the regulator further complicate the regulator's mandate in the regulation of the novel medicine development, supply, and distribution. This short course would like to take advantage of the past expedited development of COVID-19 vaccine story and current Biogen/Eisai's Aduhelm approval to examine the regulator's response to the medical needs of the society. Chia-Feng Lu has obtained his first-hand experience through the U.S.'s Operation Warp Speed for the development and partnership negotiation for the medicinal product launch. His current base in Washington D.C. also offers us a close look at ongoing PDUFA VII and 21st Century Cures Act version 2.0 negotiation on the Capitol Hill. This short course aims to inspire us to contemplate what the actual policy making know-how we should acquire, the infrastructure of the society we should invest, and how we can eventually bear the fruits of our enthusiasm to global health in the actual reality.

Schedule

9:30-10:45 Lecture
10:45-11:00 Q&A

Registration required. Please register from below:
<https://forms.gle/bVhTi47VsVJW63Gx8>

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