

GMP, GCP & QUALITY CONTROL

PHARMACEUTICAL REGULATORY AFFAIRS AND IPR

September 25-26, 2017 Chicago, USA

Early access to unapproved medicines in EU

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Early access programs, (EAPs) are adopted by an increasing number of pharma companies due to several benefits offered by these programs. EAPs offer ethical, compliant and controlled mechanisms of access to investigational drugs outside of the clinical trial space and before the commercial launch of the drug, to patients with life-threatening diseases having no treatment options available. In addition to the development of positive relationships with key opinion leaders (KOL), patients, advocacy groups and regulators, the data captured from the implementation of EAPs supports in the formulation of global commercialization strategies. This session outlines various circumstances to be considered for the implementation of EAPs named patient programs, EU regulatory landscape, the benefits and challenges associated with implementing these programs and the key considerations for their successful implementation.

Biography

Parminder Kaur is a Regulatory Expert and a QPPV having 19 years of recognized global expertise in a broad range of therapy areas. She has also played a major role in setting the in-house RA and PV systems in compliance with the European regulations at various companies; assisted various companies during inspections and audits conducted by EU Regulatory Authorities. She was awarded Sikh Business Women of the year award in 2014. In 2011, she led an IMI Project on combination therapy at EFPIA, in close collaboration with Research & Development Group (RDG) at European Commission. In March 2007, she was selected by the European Federation of Pharmaceutical Industries and Association (EFPIA) for her global expertise and also had an honor to be the Scientific Representative from India for the year 2000-2001, duly sponsored by UNESCO. She is currently running her own regulatory affairs and pharmacovigilance consultancy, RegPak BioPharma Consulting based in Amsterdam.

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