

DI Dr. Guenter Waxenecker, MDRA

Head of the Department Biologicals, Preclinical & Statistical Assessment,
Austrian Federal Office for Safety in Health Care

Title

Rapid Scientific Advice and Rolling Reviews - Covid-19 Vaccine Developments challenging the European Regulatory System

Abstract

The urgent need of developing preventive and therapeutic options to save lives during COVID-19 pandemic still presents a global challenge. Significant advances were achieved by far reaching collaborations across drug developers, academia, governmental organizations and the private sector. European health agencies turned out to be valuable partners in advancing drug development by improving regulatory flexibility across the regulatory life-cycle of medicinal products. The national competent authorities within the European region provide experts to give scientific advice, assess marketing authorization applications and subsequent variations. This presentation will outline the many operational and regulatory challenges of COVID-19 drug developments from the perspective of a European assessor.