TÜV Rheinland Italia participates to the webinar organized by the Parenteral Drug Association (PDA) Europe

04.11.2020 | Pogliano Milanese (MI)

TÜV Rheinland Italia participates to the webinar "The Medical Device Regulation: Guidance for Pre-filled Syringes and Combination Products" organized by PDA Europe, an association of manufacturers of injectable drugs.

The webinar is dedicated to the new Medical Devices Regulation 2017/745/EU and, in particular, to article 117 which amends the European Medicinal Products Directive (2001/83/EC), with the introduction of new provisions for which manufacturers of medicines. The manufacturers will have to contact Notified Bodies, such as TÜV Rheinland Italia, to request an opinion on the conformity to the general safety and performance requirements (GSPR) of medical devices that enter as integrated components in the manufacture of drugs. The results of the evaluation should be included in the marketing authorization dossier.

During the event, there will be the participation of **Simone Antonini, Regulatory Medical Coordinator of TÜV Rheinland Italia**, with a lecture "Drug-Device Combination Products: Regulatory Framework Under MDR Article 117".

The webinar will be in English language and will take place on **November 19, 2020**, from 4.00 pm. For more information and registration, please click here.

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