Consultation on Annex 21: Importation of medicinal products, of the EudraLex Volume 4

Stan O'Neill

Webinar for members of EIPG in conjunction with PIER and University College Cork

Wednesday 5th August 2020 at 17.00 CEST (16.00 BST)

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About the Speaker

Stan O'Neill, a pharmacist from Trinity College, Dublin, is the Managing Director of The Compliance Group, a specialist consultancy group consisting of ex-Regulators. After qualifying as a pharmacist, Stan spent over five years working in the pharmaceutical industry in Regulatory Affairs, Marketing and Quality Assurance (Qualified Person) and then joined the Irish Medicines Board (IMB), now the Health Products Regulatory Agency (HPRA), for a period of ten years. In his capacity as a Senior Inspector, he performed GMP inspections throughout the world, represented Ireland at European level for the negotiation of standards of inspection for medicinal products and trained Inspectors at Irish, European and International levels. He has been a consultant to the pharmaceutical industry, Regulatory Authorities, Government Bodies and NGOs since 2009.

Overview of Webinar

The European Commission has announced a targeted stakeholders' consultation on the draft Annex 21: Importation of medicinal products, of the EudraLex Volume 4. This new Annex, in which the Qualified Person (QP) has a key role, and which has been under discussion for a long time, provides guidance for the interpretation of the principles and guidelines of GMP for both human and veterinary medicinal products. The document intends to bring clarity to areas which have been unclear for some time, and the speaker will discuss the background to the Annex, the challenges which have existed within the EU Regulatory Framework, and how the proposed Annex may or may not address these challenges. The speaker will suggest potential areas of concern, and how delegates may wish to communicate these to the European Commission both via the European Commission's own communication process, and through the participation of their member organisations in the consultation process within the European Industrial Pharmacists Group.

Leaning Outcomes

By the end of this presentation, you will:

1. Understand the potential implications of the proposed Annex 21
2. Understand how delegates may communicate their concerns to the European Commission

To Join the Webinar

Please register for the event by filling out the form at https://forms.office.com/Pages/ResponsePage.aspx?id=JyXrHv_AJUeBnS4kTn1CfOCIkfr1hJNCpQuKaBczc51UNklOMUdaNlpZVTI5NkVESU4xUVFZS1kzViQlQCN0PWcu. Further instructions will then be sent in the form of a Calendar Invitation.

Continuing Education:

A certificate of attendance will be issued after the webinar. The session will be an hour of Continuing Education.