INVITATION

Afternoon SEMINAR

Regulatory Challenges of Drug/Device Combination Products

NETWORKING OPPORTUNITY - 24th January 2018 at COBIS

Often, **medicinal products** are marketed in combination with a **medical device**, serving as tool for accurate and easy delivery of the medicine.

The drug and the device may be commercialized as separate entities, but more and more often, the drug is incorporated into the device, making it the primary packaging material as well as a tool for delivery.

In Europe, medicinal products and medical devices are regulated by different regulation and regulatory systems. There is no legal definition of drug/device combinations, and regulatory guidelines are insufficient.

Determining the appropriate level of documentation for the safe and effective use of the medical device together with the medicinal product can therefore be a major challenge.

During this seminar, ***Margrethe Erbou Andersen*** and ***Camilla Wamberg Munkesø*** from **IWA Consulting ApS** will outline the regulatory challenges for drug/device combination products in Europe.

They will give examples of marketed combination products, and discuss how these are regulated in the EU, with a view on the regulatory environment for combination products in the US.

During the seminar, there will be plenty of opportunity to ask questions and to network with peers from the Danish pharmaceutical and medico industry.

The seminar will be held in an informal atmosphere. Coffee, tea and cookies will be served.

Location: COBIS, Ole Maaløes vej 3, 2200 Copenhagen N on 24th January 2018 at 14:00 – 16:00.

Registration to Lone Buchholz (lb@cobis.dk) no later than 19th January 2018.

IWA Consulting ApS is a regulatory consulting company, which was founded in 1997.

The company consists of 21 experts, who are specialists in Regulatory & Medical Affairs and in Medical Devices.

IWA Consulting is located in Køge, and has an office at COBIS.

Margrethe Erbou Andersen is head of the RA Quality team, and leads a team of regulatory experts, who specializes in Quality/CMC documentation for medicinal products.

Camilla Wamberg Munkesø is head of the Medical Device RA & QA team consisting of specialists with profound knowledge and experience with various medical devices and combination products.