CataloniaBio & HealthTech
Connecting companies

Regulatory Affairs Workgroup

EU-MDR

Hard Reg Café

Open talk with EU Notified Bodies about the extra transition year to implement MDR

ONLINE. 3 JUNE, 2020

The **CataloniaBio & HealthTech Regulatory Affairs Workgroup**, in collaboration with the Spanish Federation of Healthcare Technology Companies (Fenin), is holding its seventh Hard Reg Café entitled ***Open talk with EU Notified Bodies about the extra transition year to implement MDR*** on 3 June, online.

The event is an excellent opportunity **to connect with experts from the main EU Notified Bodies** on the potential effects of the one-year delay of the Medical Devices Regulation (MDR), the next steps for manufacturers and the impact it will have on the business. The EU Parliament has decided to postpone application of the MDR during the Covid-19 emergency.

For: CEOs, Chief Operating Officers, regulatory managers, compliance managers, quality managers, and consultants of start-ups and companies focusing on medical devices and in vitro diagnostics.

Language: Spanish / English

Registration fees:

- **CataloniaBioHT members**: free (first two from each company; third person on must pay full rate)
- Non-members: €50 (VAT not included). You will be invoiced €50/person.

This activity will be streamed live. You must register ahead of time. Access will be activated 5 minutes before the session on the cataloniabioht.org website (only participants who have registered before 5:00 pm on 2 June will have access trought the streaming registration form).

Questions: CataloniaBioHT · Ismael Ávila (Project Manager) · ismael.avila@cataloniabioht.org

In collaboration

federación española de empresas de tecnología sanitaria
fenin

With the support

ACCIÓ
Generalitat de Catalunya

#MDRdelay

CataloniaBio & HealthTech
Connecting companies

Regulatory Affairs Workgroup

EU-MDR

Hard Reg Café

Open talk with EU Notified Bodies about the extra transition year to implement MDR

ONLINE. 3 JUNE, 2020

PROGRAMME

3:00 pm
Welcome

Lluís Chico — Managing partner of NEOS Surgery and second vice-president of CataloniaBio & HealthTech (@neosurgery)

María Aláez — Technical director of the Spanish Federation of Healthcare Technology Companies (@fenin_es)

3:10 pm
Prospectives for the extra transiton year by notified bodies

Gloria Hernández — Head of the Certification Division of the Spanish Medicines Agency (@AEMPSGOB)

José Antonio Via — Medical Health Service Sales Partner of TÜV SÜD Italia (@TUVItalia)

Virginie Siloret — Global MDR Product Manager of SGS (@SGS_SA)

Bassil Akra — CEO of Qunique GmbH (@dr_akra @QUNIQUE_GmbH)

3:50 pm
Session for Q&A

4:20 pm
Closing remarks

Lidia Cánovas — General manager for Regulatory Affairs at Asphalion and CataloniaBio & HealthTech board member (@canovas_lidia @Asphalion)

#MDRdelay

EU-MDR

CataloniaBio & HealthTech
Connecting companies

Regulatory Affairs Workgroup

Hard Reg Café

Open talk with EU Notified Bodies about the extra transition year to implement MDR

ONLINE. 3 JUNE, 2020

SPEAKERS

aemps.gob.es

agencia española de medicamentos y productos sanitarios

Gloria Hernández – Head of the Certification Division of the AEMPS

Specialist in hospital pharmacy, degree in Food science and technology, degree in Design and statistics for health sciences and civil servant in the Spanish General State Administration in the National Healthcare Pharmacists Corps. She began her career in public and private healthcare centres. She has extensive experience in European and Spanish law regarding healthcare products, their assessment and in auditing quality systems. She has been at the AEMPS for 20 years. She has been head of the Certification Division at this notified body since 2016.

tuvsud.com

TÜV SÜD

José Antonio Via – Medical Health Service Sales Partner of TÜV SÜD Italia

Degree in Industrial engineering from the Polytechnic University of Catalonia and a Law degree from the University of Barcelona. He joined the TÜV SÜD in 2002 as director of the TÜV SÜD Iberia subsidiary and held that position until 2012. From 2012 to 2014, he was CEO of TÜV Italy and the agrifood and environment trial laboratory pH SRL. Since 2017, he has worked as an external partner to TÜV SÜD Italy for certification of medical devices.

sgs.com

SGS

Virginie Siloret — Global MDR Product Manager of SGS

Engineering degree in Food industry, Microbiology and Nutrition from ENSBANA. She has a background of over 15 years in the MedTech industry in quality and regulatory affairs. In 2017, she began in her current position as Global Medical Devices Regulation Product Manager at the Geneva headquarters of SGS, a leading inspection, verification, testing and certification company with more than 2,600 offices and laboratories around the world. She also teaches training courses on MDR for auditors, product assessors and manufacturers.

quniquegroup.com

QUNIQUE

Bassil Akra — CEO of Qunique GmbH

CEO of Qunique GmbH, a MedTech and in vitro diagnostic consultancy located in Germany and Switzerland. He spent the last 10 years of his career at TÜV SÜD Product Service GmbH, and in 2017 became Vice-president for Strategic Business Development at Global Medical Health Services. He played an essential role in implementing MDR 2017/745 in Europe and he was involved in drafting several European guidance documents.

#MDRdelay