

## 5th Hard Reg Café

# Understanding EUDAMED

Barcelona, 7 February

The **CataloniaBio & HealthTech Regulatory Affairs Workgroup** is holding its fifth Hard Reg Café meeting on 7 February in Barcelona. The event will feature a training session to help start-ups and companies understand the new European database for medical devices (EUDAMED). The European Commission will launch EUDAMED in 2022 to monitor the safety and performance of devices under the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR).

### KEY NOTE SPEAKER



**Richard Houlihan** - CEO at EudaMed (Belgium)

He is a world renowned speaker on the European database for medical devices (EUDAMED) and CEO at EudaMed, a company that provides EUDAMED spreadsheet templates, support, consulting, and technical and non-technical training for the industry. During his time with the EC, he was responsible for Eudamed 2 and was technical manager for EUDAMED (2017-2019) when he left the EC to return to the private sector. Also, he has worked at IT-related businesses for over 25 years.



**Venue:** Barcelona Science Park (Sala Dolors Aleu) – Baldiri Reixac, 4-8

**Language:** English

**Capacity:** limited spots

**Registration:**

- **CataloniaBioHT members:** free (two from each company)
- Non-members: €50 (VAT not included). You will be invoiced €50/person.

On our website [cataloniabioht.org](https://cataloniabioht.org)

**Questions:** CataloniaBioHT (Ismael Ávila, Project Manager) – [ismael.avila@cataloniabioht.org](mailto:ismael.avila@cataloniabioht.org)

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## PROGRAMME

9:00 am

**Registration**

9:45 am

**Welcome**

**Lidia Cánovas** — General manager of Asphalion and CataloniaBioHT board member  
@canovas\_lidia @Asphalion

**Lluís Chico** — Managing partner of NEOS Surgery and CataloniaBioHT board member  
@neosurgery

10:00 am

**Introduction to EUDAMED and the Unique Device Identification (UDI)**

**Richard Houlihan** — CEO at EudaMed  
@rjhoulihan @eudamed

11:40 am

**Coffee Break**

12:00 am

**Exploring EUDAMED tools: training sessions and spreadsheets overview**

12:15 pm

**Session for Q&A with a participative methodology based on small workgroups**

13:00 pm

**Closing remarks**