Boudicca Dx

NEWS RELEASE

Dr. Kelly Gordon, CEO and Founder of Boudicca DX, grew up in Northern Ireland before immigrating to the United States.

Boudicca DX Establishes First New Subsidiary in Ireland

FOR IMMEDIATE RELEASE

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[Brentwood, Tennessee] Boudicca DX, LLC a best-in-class precision medicine consulting firm headquartered in Brentwood, Tennessee is excited to announce its global expansion and establishment of its first new subsidiary, Boudicca DX Limited, which will be based in the world-renowned medical technology hub of Galway, Ireland.

With this establishment of a subsidiary in the European Union (EU), Boudicca DX will provide additional service offerings to its current and prospective clients, including acting as an EU Authorized Representative for precision medicine products, including In Vitro Diagnostics (IVDs) and medical devices.

Commenting on the announcement of this new European subsidiary, Dr. Kelly Gordon, Chief Executive Officer and Founder of Boudicca DX, stated:

> *"I was born in Belfast, Northern Ireland, and immigrated to the US when I was 15 years old. I am so excited to bring Boudicca DX to my country of birth and help more vital and innovative precision medicine products and technologies reach European patients.*
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> *As an Irish passport holder, I am proud to be the registered Company Director of this new subsidiary. I greatly look forward to building our new Quality and Regulatory team in Galway and providing insights and support for our global clients accessing the European market. Ireland is already a global leader in medical technologies and the world's third largest exporter of pharmaceuticals. There is no better place in Europe for Boudicca DX to establish a subsidiary to support our global clients."*

Boudicca DX's Ireland-based team will work in tandem with the US-based team to provide comprehensive and seamless EU and US quality and regulatory support to Boudicca DX global clients, reducing both time and financial burden for clients and facilitating access to multiple key markets through their holistic offering.

Boudicca DX is an independent consultancy with an established quality and regulatory team, technical team of PhD-trained translational scientists and analytical and clinical validation experts who review Technical Documentation to support clients' EU and US regulatory submissions. This US-based team will work closely with the Ireland-based Quality and Regulatory team to provide harmonized best-in-class consulting services to support EU clinical trials (performance study applications, notifications and qualification of health institution exemption status in accordance with Article 5(5)), and CE marking of IVDs and medical devices.

Ireland is a prime location for international business based on its comprehensive tax treaty network, attractive corporate tax rate, pro-business environment, research and development incentives, significant influence in EU pharmaceutical regulatory policy, and is one of Europe's most highly skilled and educated STEM workforces.

Medical devices and IVD manufacturers who do not have a registered place of business in a Member State of the EU/European Economic Area (EEA) are required to appoint an Authorized Representative to comply with the EU Directives and Regulations. As an independent EU Authorized Representative, Boudicca DX Limited will provide guidance to its clients on EU regulations and enable clients to maintain separation of regulatory and supply chain interests to streamline their access to the European market.

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