psephos BIOMEDICA

CLINICAL SERVICES

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No matter what classification of device, digital solution or IVD that you have, clinical strategy, clinical evidence and clinical evaluation are central to ensuring your product is safe and suitable for human use, for approval and access to global markets.

In order to effectively market your device and generate sales, you need to consider early in the development process the clinical elements and to efficiently implement the right integrated regulatory and clinical strategy, potential clinical investigations required and timelines.

To assist our clients Psephos provides the following clinical services:

- Integrated clinical and regulatory approach from first-in-human / early-stage feasibility studies through to pivotal trials
- Clinical trial strategy, design and management of clinical investigations (ISO 14155 / MDR / FDA)
- UK Legal Representative, UK Responsible Person
- Competent Authority, Ethics Committee and related clinical study submissions and approvals
- Clinical Evaluation Plans and Reports
- Clinical Literature Search and Reviews
- Post Market Clinical Follow-Up (PMCF), including registries
- FDA Q-Sub and related activities

If you are thinking of launching a clinical investigation in the UK, or if you have any clinical enquiries, we would be very happy to talk to you.

Please contact us via our website www.psephos.com to book a call with our Senior Clinical Associate, Clare Barclay.

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Psephos Biomedica is a medical device regulatory, clinical and quality consultancy. Founded in 2001, we have worked for over 20 years with clients from around the world to bring medical technologies to market. We provide bespoke regulatory and clinical support to access the UK, EU, Swiss and US markets.

We are a highly focused, experienced team that work with all classes of devices, covering areas such as Digital Health and AI, Cardiovascular, Neurovascular, Surgical and IVDs.

Contact us today to find out how we can support you in bringing your medical technology to market and maintain regulatory compliance.

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Qualitas Veritas
ISO13485:2016