



Service definition document

www.psephos.com



Clients

- We've worked closely with some of the world's most innovative medical companies across Europe, North and South America, the Middle East, Africa and Asia.
- Some of our key clients and companies we've worked with include:
 - DHSC/UKHSA
 - NHSX/NHS Digital
 - Surrey & Borders Partnership NHS Foundation Trust
 - WoundMatrix
 - BeholdAI
 - Zühlke
 - NetCompany
 - Imperial College
 - BXTAccelyon
 - Fire1

Who we are

- Psephos Biomedica, founded in 2001, is a medical and healthcare technology clinical, regulatory and quality management services consultancy that bring and maintain innovative products to market. Psephos has partnered with Government, the NHS, start-up companies, entrepreneurial spin-outs and venture-backed businesses, and universities and knowledge institutes.
- With a highly focused team that brings experience from around the world to deliver solutions for all classes of devices from Class I to Class III, covering areas such as Software as a Medical Device (SaMD), Apps, Digital Health and AI, Cardiovascular, Neurovascular, Surgical and Diagnostics (IVDs).

The Senior Management Team



Robin Stephens
**CEO & Principal
Consultant**

35+ years in the industry with executive experience at all levels of management and company size/phase.



Irfan Hassan
**SaMD Regulatory &
Quality Manager**

Multiple years' experience working in the digital health space, including leadership for the regulatory & quality team for the NHS COVID-19 App.



Linnea Johnston
**Senior Regulatory &
Clinical Manager**

20+ years experience in medical device research and executive level experience in Fortune 500 companies, as well as innovative start-ups.

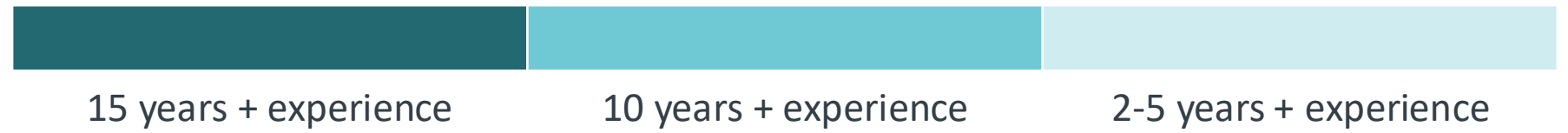


Clare Barclay
**Senior Clinical
Associate**

20+ years of experience working in clinical trials, within regulatory, biotech, electronic data capture (EDC) and clinical project management.

Skills Map

	Digital Health & AI	Clinical	Regulatory	QMS	Rep Services
Robin Stephens					
Irfan Hassan					
Linnea Johnston					
Clare Barclay					
Mark Wiesner					



What we do



UK Responsible
Person



Regulatory
Services



Quality
Management
Services



Clinical
Services



Digital Health
& AI

Services we deliver

Digital Health and AI Services:

- Regulatory and Clinical Strategy for Software and AI devices
- Categorising software based on IEC 62304 / 82304
- Software Development, Verification and Validation
- Regulatory Device Classification
- UKCA Marking, CE Marking and FDA guidance
- Technical File Preparation, Gap Analysis and Updates
- Notified and Approved Body Selection
- Executive Level Coaching

Clinical Services:

- Clinical trial strategy, design and management
- Competent Authority, Ethics Committee and related clinical study approvals
- Clinical Evaluation Plans and Reports
- Clinical Literature Search and Reviews
- Post- Market Surveillance (PMS)
- Post Market Clinical Follow-Up (PMCF), including registries

Services we deliver

Regulatory services:

- Regulatory Strategy
- Device Classification
- UKCA Marking
- UKNI Marking
- CE Marking
- Technical File Preparation, Gap Analysis and Updates
- Notified and Approved Body Selection
- Determining Device Testing Requirements
- Assistance with engaging and selecting test houses
- Executive Level Regulatory Coaching

Quality Management Services:

- Identification of appropriate QMS standards (e.g. ISO 13485) and regulations
- Tiered approach to writing, implementing and operating a QMS
- Integrated Document Control and Related QMS Activities Service
- Auditing and Corrective Action Planning and Implementation
- Training and Development

After sales support

After Sales Support Customers have access to a named Manager

SERVICE LEVELS - Support requests are prioritised as follows:

- Urgent 1 hour
- High 4 hours
- Medium 8 hours
- Low 24 hours

Response times for weekends, public and bank holidays are negotiated separately.

SUPPORT HOURS

Standard support hours are 09:00 to 17:00 (UK time), Monday to Friday. Support hours for out-of-hours, weekends, public and bank holidays are negotiated separately.



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