psephos BIOMEDICA

INNOVATIVE OPERATIONAL, REGULATORY, QUALITY & CLINICAL SOLUTIONS

www.psephos.com

Innovative Regulatory, Quality & Clinical Solutions through client partnerships with spin-outs, entrepreneurial corporations and venture-backed companies

Regulatory

- CE Marking
  - Technical File/Design Dossier
  - Clinical Evaluation Report
  - Notified Body Selection
- FDA
  - 510 (k)
  - PMA
  - Investigational Device Exemption

Quality

- ISO 13485
- FDA QSR

Clinical

- First in Human/Feasibility
- Pilot/Pivotal

Interim & Project Management

- Initial development team
- Function leadership
- Operational activities

Our process

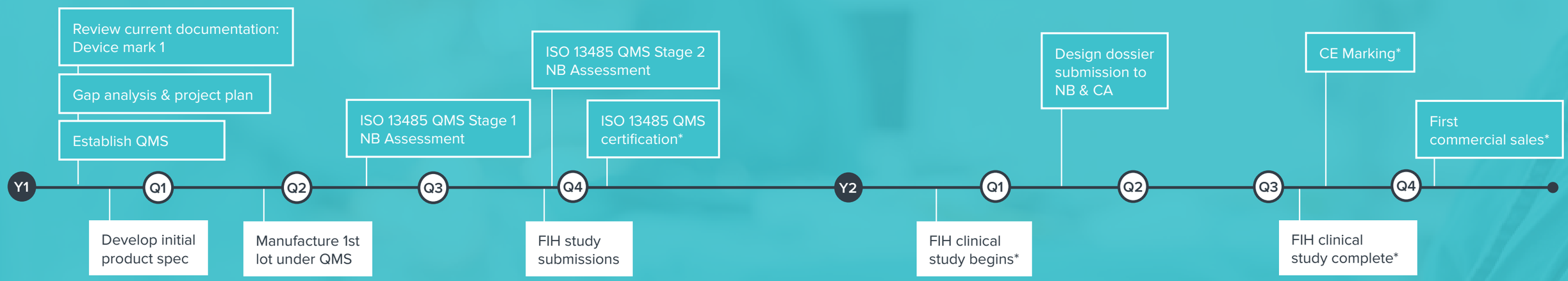
Clinical need
INVENTION
Novel solution and IP creation

Application of invention
INNOVATION
Regulatory & clinical strategy

Commercialisation
IMPLEMENTATION
Clinical Evaluation
ISO 13485
CE Mark
FDA

Illustration of regulatory & clinical milestones

* Value inflection points



Regulatory CE Marking/FDA
Initial strategy/Strategic input
Risk management system
Design and development management process
Project management/Operations management
Technical file/Design dossier management
Notified Body selection/Interaction

Quality ISO 13485/FDA QSR
Initial strategy/Strategic input
Quality Management System: Development Writing
QMS implementation
QMS assessments and certification
Document control
ISO 13485 NB Certification

Clinical (ISO 14155/CE Marking)
Initial strategy/Strategic input
Literature review plan/Execution/Report
Clinical evaluation report development/Delivery
Clinical investigation plan: Develop/implementation
Ethics committee submissions/Approvals
Competent Authority submissions/Approvals

Management & Project Management
Strategy consulting
Project management
Operations management
CEO/COO
VP/Director/Quality/Clinical/Regulatory
Director/Board member

Example: RA/QA/CA full service provision

- Provide Regulatory, Quality & Clinical strategy pre-financing
- Place Psephos RA/QA and/or CA Managers/ Specialists into early stage companies p/t & increase as the client grows
- Ensure senior management oversight of project & active involvement
- Implement Regulatory, Quality & Clinical strategy & provide effective project management
- Interact with all stakeholders in the Regulatory, Quality & Clinical processes
- Project management, production implementation, & market entry assistance

Example: Regulatory Support to CE Mark

- Type: Contracted RA Support / Technical file writing
- Term: 18 months
- Company Head Office: UK
- Activities covered:
  - Assisted in updating QMS for Medical Devices
  - Provided RA training
  - Developed & co-implemented Risk Management process
  - Interactively written client's Technical File
  - Provide ongoing RA technical support

Example: Head of Regulatory Affairs

- Type: Provision of Head of Regulatory Affairs for a cardiovascular valve company
- Term: 1 - 4 years
- Company Head Office: Switzerland
- Activities covered:
  - Oversight of international product registration activities for Class III devices
  - Developing & implementing regulatory strategy for product pipeline
  - Medical device vigilance support
  - Risk management & design validation activities

Example: QA/RA/CA Director

- Type: Full responsibility for all Regulatory, Quality & Clinical activities including development and maintenance of associated systems (ISO 13485; pipeline project management; customer service support)
- Term: 3+ years
- Company Head Office: Ireland
- Activities covered:
  - All non-clinical activities for a CE Mark clinical trial
  - Obtained CE Marking for a Class III cardiovascular long-term implant
  - Obtained ISO 13485 & CMDCAS certification
  - Supported product launch in Europe
  - One of only two directors to transition with company through M&A integration

Psephos Biomedica
Sussex Innovation Centre, Science Park Square
Brighton, BN1 9SB, United Kingdom

+44 1273 704 527
info@psephos.com
www.psephos.com