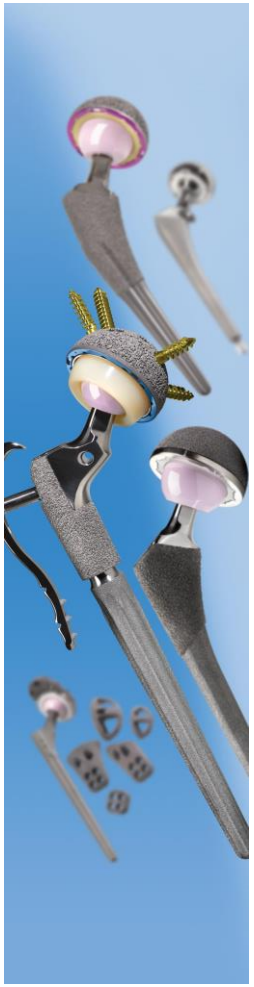
Association of British Healthcare Industries

ABHI's Contribution to the Life Sciences Industry

Developing Evidence to Ensure Regulatory Compliance

Phil Brown, Director, Technical and Regulatory

Clinical Evidence



Clinical Evidence

- **Directive (and Regulation) based on 'Risk Classifications' for Products – higher the risk, the more comprehensive the data requirements**
  - Clinical Evaluation
  - Clinical Investigation
  - Combination of Both
- **Satisfaction of Chapter VI and VII of Regulation 2017/745; Satisfaction of Art.15 and Annex I provisions of 93/42/EEC et al.**
- **Extensive Post-Marketing Requirements**
  - Vigilance
  - Surveillance

Clinical Evidence

- **Regulation 2017/745 Additionally Requires;**
  - Product Safety Update Reports
  - Clinical Evaluation Reports
  - EUDAMED Entries
  - Clinical Investigation Transparency
  - Less Reliance on ‘Equivalence’, Meaning Class III/IIb Products Require Clinical Investigation
  - Greater Notified Body Review of Post-Marketing Surveillance Activities
  - Changes to Vigilance Reporting Times

Clinical Evidence

- **ABHI Role;**
  - Establishing Regulation Content
  - National Interpretation of Regulation
  - Collective MHRA Communication
  - ‘Education’
  - Integration With Industrial and International Strategies
  - European Input Through MedTech Europe
  - Notified Body Liaison
  - Implications of BREXIT

Clinical Evidence

Thank You!!

Phil Brown

phil.brown@abhi.org.uk

Telephone: 020 7960 4390
Mobile: 07889 536323