16th January 2020

APM/PIPMG Event

The outlook for the Life Sciences and Pharmaceutical sector in post Brexit Britain

Below are key discussion points from John Faulkes workshop session to discuss how Brexit is already impacting companies you work for.

QP Release

- When we will gain clarity on whether UK QPs can still release to Europe post Brexit

Supply Chain

- Shipping materials for CTs
- Shipping via Ireland to go onto Europe
- Delaying supply chains and causing issues for stability and safety
- Companies are pre-planning shipping around Brexit date to avoid issues

Clinical Trials

- Sponsors less likely to choose UK sites for their CTs due to cost, timing, regulatory uncertainty
- How Brexit impacts safety of CTs

Regulatory Alignment

- If MHRA do not remain in alignment this will cause issues for CTs and products coming onto the market

Ethics

- Pilot schemes ongoing to coordinate ethics approvals and CT approval processes, but at present these seem to be slowing down the process instead of speeding it up

Legal Entities

- Companies are moving head offices to Europe – this means job losses and fewer CTs in UK

Falsified Medicines Directive

- Will the UK have access to the EU database?

Manufacturing

- Stock piling critical reagents for manufacturing – increase their amount of cold storage

Data Privacy

- GDPR – the UK will be a ‘third country’

R&D Investments

- What will replace the EU grant funding?
- R&D funding has been pledged by the UK gov but unclear on how it will be distributed

People

- People are paid in the UK but reside in Europe and not clear how it will be managed