INTERNATIONAL ASSOCIATES®

Introducing our

Post-Market Surveillance (PMS) Report Support Service

WWW.IA-UK.COM

Follow or Like us:

INTERNATIONAL ASSOCIATES®

Introducing our

Post-Market Surveillance (PMS) Report Support Service

PMS Reports: *Your at a glance guide...*

Post-Market Surveillance (PMS) Reports

Where do the requirements for PMS come from?
They come from ISO 13485: 2016 as well as regulatory requirements such as UK MDR, EU MDR and FDA QSR.

General Information

- Post-Market Surveillance (PMS) can be a complex area for a medical device manufacturer to consider. All medical devices must write a PMS plan, and with this define periodicity that a PMS report will be written.
- The PMS report must consider several areas as inputs to your PMS system. These are typically Field Safety Notices (FSNs), Field Safety Corrective Actions (FSCAs), new clinical literature, material reports, safety and news bulletins from competent authorities amongst many other things.
- In the European Union, Class IIa devices must conduct a report every two years. Class IIb and III must conduct this annually.
- Class I devices (including 1s, 1m and 1r) shall write reports at their own discretion as defined in their plan.
- With trying to get this information, comes the complexity of having to compile

How can we help you?

- Send us your PMS plan – don't have one? We can put one together for you.
- Some details of your device i.e., materials, intended use etc., this can be shared via redacted technical documentation.

Pricing

£1200 per report

The overall aim of PMS is ensure that manufacturers are able to leverage a comprehensive set of reactive and proactive data. *As well as having to compile and assess impact of information gathered.*

WWW.IA-UK.COM

Contact us today for a consultation:

+44 (0)141 3 28 29 28 enquiry@ia-uk.com