TMQA Regulatory News Update September 2017

MHRA Launches Introductory Guide to Medical Device Regulations

The Medicines and Healthcare products Regulatory Agency (MHRA) launched an interactive introductory guide last month to help manufacturers understand their obligations under the new EU Regulation on Medical Devices (2017/745) and the EU Regulation on In-vitro Diagnostic Medical Devices (2017/746). The new regulations entered into force on 25 May 2017, which is when the three and five-year transition periods began. Hence, the new regulations will come into force across EU Member States from May 2020 and May 2022 respectively. During the transition period, devices can be placed on the market under the current EU Directives or the new Regulations. However, devices placed on the market after the transition period will need to fully comply with the new regulations, unless they wish to make use of the extended period of CE certificate validity. The new regulations include clearer obligations for those involved in manufacturing and supplying devices, greater emphasis on traceability throughout the whole supply chain with the introduction of a unique device identification (UDI) system and new standards for clinical evidence. They also set out more rigorous vigilance reporting requirements, including new reporting timescales, as well as clearer requirements on what a manufacturer's post-market surveillance system should comprise of.

https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr

BIA and MHRA Publish Report "Innovation in Life Sciences in a Changing and Dynamic Environment"

Following their seventh annual joint conference, the UK BioIndustry Association (BIA) and the MHRA have published a report titled "Innovation in Life Sciences in a Changing and Dynamic Environment". The BIA and MHRA brought together experts from across the sector to discuss some hot topics and important developments that are having an impact on the changing and dynamic UK life sciences ecosystem. Key topics that were debated and analysed through a series of presentations, panel discussions and Q&A included: the Accelerated Access Review and the Life Sciences Industrial Strategy, personalised medicines and companion diagnostics, the Priority Medicines (PRIME) scheme, and the challenges posed to medicines regulations by Brexit. Key note speakers included the Parliamentary Under Secretary of State for Health and the Chief Executive of NHS England. The report summarises the presentations and perspectives from senior experts and leading speakers from MHRA, government, NHS England, the National Institute for Health and Care Excellence (NICE), the life science industry, academia, research charities and patient organisations.

https://www.gov.uk/government/news/bia-mhra-publish-report-innovation-in-life-sciences-in-a-changing-and-dynamic-environment

EMA Launches Survey on Reporting Side Effects of Medicines

The European Medicines Agency (EMA) has launched a survey to assess whether patients and doctors are aware of the arrangements for reporting side effects. The main aim of the survey is to evaluate the awareness, attitudes and reporting behaviours of patients and healthcare professionals to report side effects. The survey has been translated into all official European Union languages, is open for responses until 09 October 2017, and the results will be analysed by the EMA and the European Commission and conclusions published in 2018. Regulatory authorities continuously look at reports of side effects alongside all the information they already have to make sure that the benefits of medicines remain greater than their risk and to take any necessary action. Medicines under additional monitoring are monitored particularly closely by regulatory authorities. They can be easily identified by a black inverted triangle that is displayed in their package leaflet and in the information for health professionals called the Summary of Product Characteristics (SmPC). Healthcare professionals and patients are encouraged to report any suspected adverse reactions.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/09/news_detail_002807.jsp&mid=WC0b01ac058004d5c1

Update on EMA Relocation Preparedness

The EMA will shortly publish its assessment of all bids submitted by EU Member States for the relocation of the EMA, following the withdrawal of the UK from the EU. To complement this, the EMA has made available the results of its most recent staff retention survey, which has raised serious concerns. The survey was launched on 4 Sep 2017 in the context of the EU's business continuity planning, after all candidate host cities were known and EMA staff had the opportunity to study in detail the 19 Member States' bids. The results of the survey emphasize the importance of the upcoming decision on the EMA's future seat, as the retention of skilled and experienced staff is crucial for the EMA's continuity of operations. The results of the survey reveal that the best case scenario would result in a retention of 81% of employees following relocation but for certain locations staff retention rates could be as low as 30%, meaning that the EMA would no longer be able to function and this would have important consequences for public health in the EU. In accordance with the current business continuity planning, four clusters of candidate cities have emerged. The first cluster includes those cities where more than 65% of EMA staff indicated that would be likely to move. The second cluster includes cities where staff retention rates are likely to be between 50% and 64%. The third cluster includes those to which between 30% and 49% of staff are likely to relocate, and the fourth cluster includes those where staff retention is likely to be less than 30%. The EMA has carried out several surveys since Nov 2016 to help the EMA prepare for staff losses and to improve planning for succession and knowledge transfer. While some staff losses can be absorbed with the EMA's business continuity plan, beyond a critical threshold the EMA will no longer be able to fulfil its mandate to protect the health of EU citizens.

Although the results of the survey do not name the cities, reports indicate that Amsterdam came out on top and would result in the greatest staff retention.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/09/news_detail_002814.jsp&mid=WC0b01ac058004d5c1

EMA Publishes Draft ICH E9 (R1) Addendum for Consultation

ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials was published by the EMA on 31 Aug 2017 for consultation; the consultation periods ends on 28 Feb 2018. The E9 (R1) addendum aims to clarify and extend ICH E9 by elaborating on the choice of estimand and sensitivity analysis in clinical trials, providing a framework to align its planning, design, conduct, analysis and interpretation. This addendum presents a structured framework to link trial objectives to a suitable trial design and tools for estimation and hypothesis testing. The framework introduces the concept of an estimand, translating the trial objective into a precise definition of the treatment effect that is to be estimated. It aims to facilitate the dialogue between disciplines involved in clinical trial planning, conduct, analysis and interpretation, as well as between sponsor and regulator, regarding the treatment effects of interest that a clinical trial should address. The statistical analysis, aligned to the estimand, will be associated with assumptions and data limitations, the impact of which can be investigated through sensitivity analysis. The definition and the role of sensitivity analysis is clarified in the addendum.

http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500233916&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc