RegTech Forum Summary June 2022

Discussion points:

Class I approval timeframes

- TGA indicated that processing times should now be as expected
- ADIA confirmed the email for any delays experienced remains dvs@health.gov.au

Right to Repair

- ADIA and ASTA met with the TGA on 17 May
- TGA met with the Right to Repair Inquiry Manager and two Commissioners to discuss the independent public review of medical device regulation
- TGA emphasised the different legal requirements of Sponsors of medical devices and how that would be impacted by any changes resulting from the Productivity Commission report; and reinforced the point that medical devices are not ordinary products of commerce – with the focus of the Right to Repair being consumer issues

Patient Matched Medical Devices and Medical Device Production System

- ADIA proposed the need for further discussions with the European Commission to ensure alignment with the European position and definitions

Proposed Application Audit Framework

- TGA proposing a more responsive, risk-based approach that should also be more predictable and transparent
- Consultation on risk factors to be considered for selection for an audit – ADIA to provide feedback
- Additional documents to be submitted with a Class III application
    - IFU, Clinical Evaluation Report and Clinical Evaluation Assessment Report
- TGA Proposed a similar approach for Class II
    - ADIA, with MTAA and AusBiotech advocated against this approach
- Further consultation to come
- Annual reporting to be introduced

Technical Document Assessment Report requirements

- ADIA along with MTAA questioned this ongoing requirement of the TGA
- TGA position that MDR requires the Quality Management System (EMDR Certificate) and a Technical Documentation Review (Technical Document Assessment Report) therefore both documents are required to be reviewed prior to inclusion

Unique Device Identifier

- ARTG clean-up project underway ahead of the UDI implementation – to break down the models that might be covered by a single ARTG: commences July
- UDI Sandpit opens June 2022
- UDI compliance voluntary 1 January 2023; mandatory for implantable devices 1 July 2024

Digital Transformation

- New website soon to be released: web search function optimised

IMDRF

- Meeting in Sydney 12-16 September
- Two workshops for industry

FEEDBACK FROM INDUSTRY

- ADIA to present at next RegTech meeting in September
    - Members to highlight concerns and priorities for consideration
    - All feedback to be sent to national.office@adia.org.au by Friday 15 July 2022