IMDRF International Medical Device Regulators Forum | 26th Session

Personalised Medical Devices Working Group Updates

Personalised Medical Devices Working Group

- Chair: Australia; Members: Argentina, Brazil, Canada, China, El Salvador, Europe, Japan, Saudi Arabia, Singapore, South Korea, UK, USA
- At the March 2024 IMDRF MC meeting, the MC agreed that the Working Group explore drafting of training materials for the following documents
  - N49 – Definitions for personalised medical devices
  - N58 – PMD regulatory pathways
- The MC also requested that the Working Group undertake a closed **survey** to determine the extent of implementation of the documents and challenges associated with implementation. This information would assist to focus the training materials.
- The IMDRF Training Sub-Group to be involved in the process to guide consistency across future IMDRF training materials.

PMD Survey outcomes

Document	Adoption / Implementation Status
N49 PMD definitions	4 fully adopted and 7 partially adopted across jurisdictions
	Difference between custom made and patient matched definitions not always clear
N58 PMD regulatory pathways	5 fully adopted and 6 partially adopted **custom made medical device guidance** across jurisdictions; Some have restricted supply to 5 or less devices per year
	7 fully adopted and 2 partially adopted **patient matched medical device** guidance across jurisdictions; understanding of specified design envelope not consistent
	6 fully adopted and 4 partially adopted **adaptable medical device guidance** across jurisdictions; treated the same as mass-produced devices
	0 fully adopted and 3 partially adopted **medical device production system** guidance across jurisdictions; is a novel concept and not well understood; healthcare system challenges; some exemptions for point of care manufacturing of medical devices

Considerations for training

- Training materials designed to encourage audience to read source documents. Setting pre-requisites where necessary (reading other IMDRF documents/completion of other training modules)
- Suggestions include multiple training modules (each under 15 slides/15 minutes) on specific concepts; Webinar with Q&A session; pre-recorded videos
- Developing industry-specific examples (simple and borderline cases)
- Knowledge testing to mark training completion

Personalised Medical Devices Working Group

Next steps:

- Present and discuss survey outcomes at the IMDRF MC meeting
- Proceed with preparing and delivering a general webinar about the N49 and N58 documents, including Q&A session. This will assist inform future training material options, including the target audiences (eg: regulators or industry).
- Explore case studies regarding Medical Device Production Systems

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF
International Medical Device Regulators Forum

THANK YOU