



**IMDRF**

International Medical  
Device Regulators Forum

# IMDRF Regulated Products Submission (RPS) WG Update

Nancy Shadeed  
Health Canada



# IMDRF

International Medical  
Device Regulators Forum

## Updates

- First Working Group Meeting
- electronic Submission Template And Resource (eSTAR) Updates, Demo, and FAQ
- Updates for Harmonized ToC



# IMDRF

International Medical  
Device Regulators Forum

## First Working Group Meeting

- Co-Chaired by US Food and Drug Administration (FDA) and Health Canada.
- Overview of eSTAR, FDA utilization of eSTAR, and detailed feature demo of eSTAR harmonization.
- Upcoming work for eSTAR and working group



## eSTAR Update, Demo, and FAQ

- FDA received 100 eSTARs by Aug 23
  - 33 are cleared for marketing
  - Applicant feedback is very positive
- eSTAR and conversion tool demo showing promising harmonization and regional difference handling
- Questions from members were answered and progress plans are being formed.



## Updates for Harmonized ToC

- Aligning requirements of all members to harmonize ToC to current requirements.
- With better harmonized ToC, eSTAR will be better adapted for other jurisdiction requirements.
- eSTAR performance and user experience would also be improved for easier submission creation.



## Upcoming work

- Establishing monthly WG meeting for work item actions and updates.
- Further aligning requirements in ToC to improve eSTAR harmonization
- eSTAR updates based on US and CA Medtronic feedback, and improved FDA and HC harmonization in eSTAR, followed by a cross jurisdiction pilot



# **IMDRF**

International Medical  
Device Regulators Forum

## **Questions/comments**

Thank you!