



IMDRF

International Medical
Device Regulators Forum

IMDRF Regulated Products Submission (RPS) WG Update

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Updates

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



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



Questions/comments

Thank you!