MDUFA V: How is it impacting FDA staff, industry, and patients? *International Harmonization*

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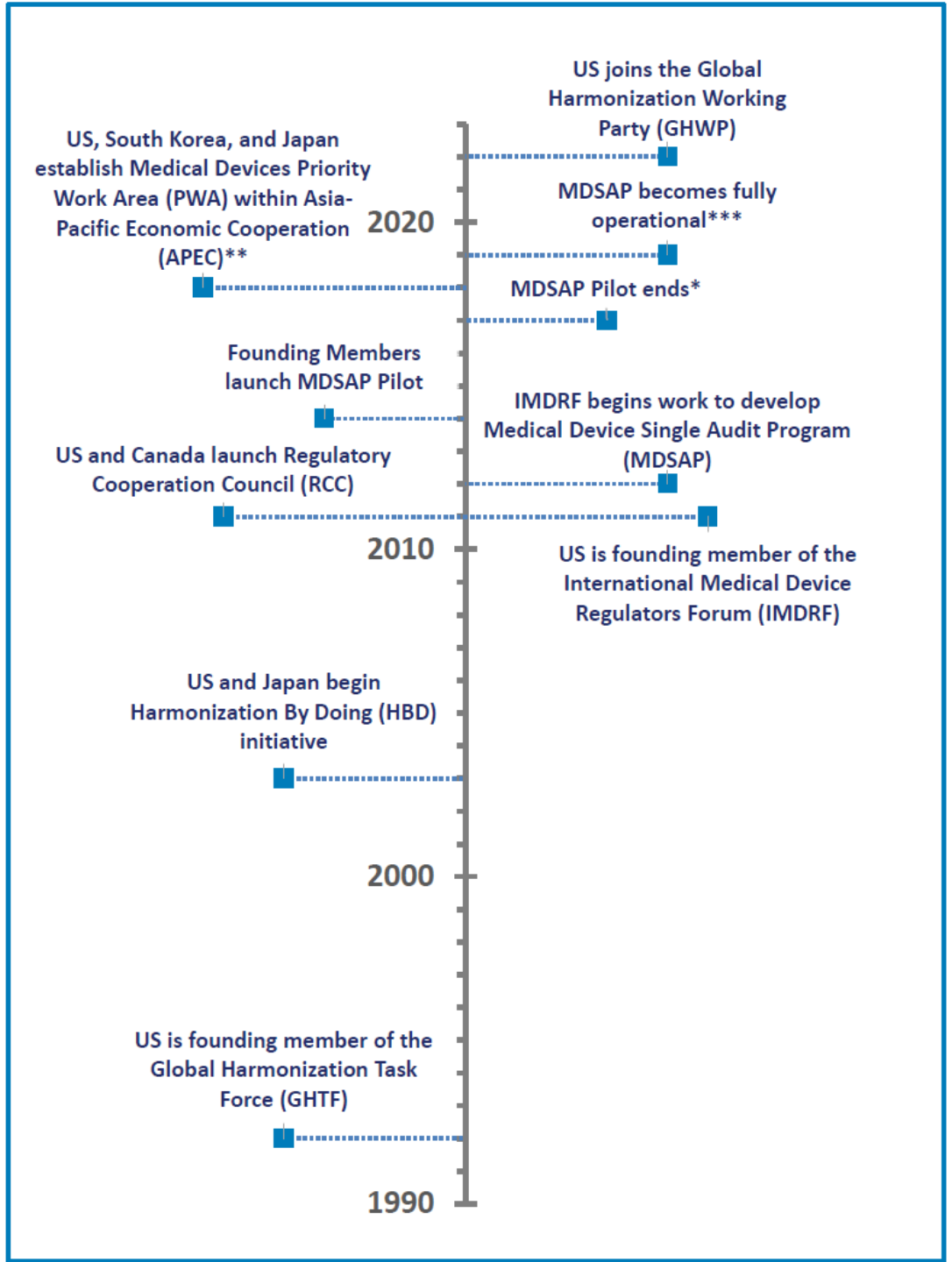
Why a global approach?

- The medical device sector has become increasingly globalized and complex.
- Each economy may develop and implement its own regulatory requirements and its own path to market products, especially as emerging and innovative technologies are considered.
- This means regulatory authorities must administer, and industry must navigate adherence to, numerous and sometimes redundant regulatory requirements.
- Reducing these inefficiencies through harmonization, convergence, and reliance on the work of others promotes a more effective regulatory model for medical devices.
- Ultimately, a more efficient and effective model means patients (in the US and globally) have better access to safe, effective, and high-quality medical devices.

CDRH has been working on global convergence for 30+ years.



Staff dedicated to International Affairs are located in the Office of the Center Director.

CDRH International Affairs

- Participate in global harmonization initiatives:
  - International Medical Device Regulators Forum (IMDRF)
  - Global Harmonization Working Party (GHWP)
  - Asia Pacific Economic Cooperation (APEC)
  - Pan American Health Organization(PAHO)
  - World Health Organization (WHO) Activities
- Participate and lead medical device harmonization programs including:
  - Medical Device Single Audit Program (MDSAP)
  - Harmonization by Doing (HBD)
- Bilateral/multilateral engagements
  - Digital Health Think Tank Meetings
  - International Medical Device Safety Meetings
  - Regulatory Cooperation Council with Canada

MDUFA International Harmonization Commitments

1. **Expand engagement in international harmonization and convergence efforts** through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees to promote alignment with international best practices and internationally developed policies, including exploring the development of harmonized premarket review processes.
2. **Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners** with whom we have appropriate confidentiality commitments to inform and align international regulatory strategy. This may include, for example, sharing of scientific, clinical, or other technical information, or policies and practices, as needed and consistent with applicable disclosure law and policy.
3. Commencing in FY 2023, **assess the extent of CDRH implementation of International Medical Device Regulators Forum (IMDRF) technical documents** and make this information publicly available to enhance clarity and transparency.
4. **Support the creation of a forum to engage with relevant stakeholders**, including industry representatives and other regulators, to identify opportunities for regulators to leverage one another's approach to decision making.
5. **Participate in outreach activities to other regulatory authorities** that encourage harmonization and may also encourage such authorities to rely in whole or in part on FDA marketing authorizations.
6. By the end of FY 2023, **issue for public comment a draft strategic plan** with additional details and timelines associated with achieving the international harmonization objectives described above.
7. Commencing with FY 2024, **publish an annual assessment of the international harmonization activities** described the strategic plan above, including the progress assessment described in subparagraph 3 above.

What these commitments mean for FDA Staff…

U.S. FOOD & DRUG ADMINISTRATION | Health Canada Santé Canada | Medicines & Healthcare products Regulatory Agency

Good Machine Learning Practice for Medical Device Development: Guiding Principles

October 2021

The U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have jointly identified 10 guiding principles that can inform the development of Good Machine Learning effective, and high-quality medical devic

Artificial intelligence and machine learni new and important insights from the vas They use software algorithms to learn fr improve the product's performance. But iterative and data-driven nature of their

These 10 guiding principles are intended foundation for developing Good Machin Practice that addresses the unique natur products. They will also help cultivate fut this rapidly progressing field.

The 10 guiding principles identify areas w International Medical Device Regulators collaborative bodies could work to advar tools and resources, international harmo policies and regulatory guidelines.

We envision these guiding principles ma

- Adopt good practices that have t
- Tailor practices from other secto sector
- Create new practices specific for

As the AI/ML medical device field evolve partnerships with our international publi advance responsible innovations in this a broader international engagements, incl

We welcome your continued feedback th look forward to engaging with you on th

Health Canada and FDA eSTAR Pilot

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UPDATE – January 27, 2023: Health Canada and the FDA launch eSTAR pilot

Health Canada and U.S. Food and Drug Administration's joint eSTAR pilot has reached its total of 9 participants. Requests to participate in the pilot are no longer being accepted.

On This Page

- About eSTAR
- Joint pilot between Health Canada and the FDA
- Eligibility factors for the eSTAR pilot program
- Requesting participation in the eSTAR pilot program
- Preparing a submission using eSTAR
- Submitting responses to requests for additional information
- User fees for eSTAR pilot
- Review timeline for eSTAR

A global perspective that continues to grow.

- Increased engagement in international harmonization and convergence efforts means more FDA staff becomes aware of activities and connect with counterparts in other countries
- Additional outreach to understand International Affairs, our role, and when/how to engage with other regulators

What these commitments mean for industry…

A call to action as we work towards a more efficient regulatory model.

- In navigating global device marketing, industry has a direct view of regulatory requirements in different jurisdictions.
- FDA benefits from hearing industry's perspective, including pain points and identification of opportunities for harmonization.
- We ask that you think globally when you're working within your region. Help us identify opportunities for harmonization and, when pilots or programs to further international harmonization are offered, please participate and provide feedback.
- FDA support of creating a forum to engage with relevant stakeholders speaks to the important role of industry

What these commitments mean for patients…

Better access to safe, effective, high-quality medical devices

- Reducing redundant regulatory requirements leads to a more efficient and effective regulatory model.
- Ultimately, a more efficient and effective model means patients (in the US and globally) have better access to safe, effective, and high-quality medical devices.

Thank you!

- CDRHInternational@fda.hhs.gov
- CDRH International Programs | FDA
- Office of Global Policy and Strategy | FDA


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