Medical device submissions deficiencies from the industry Perspective

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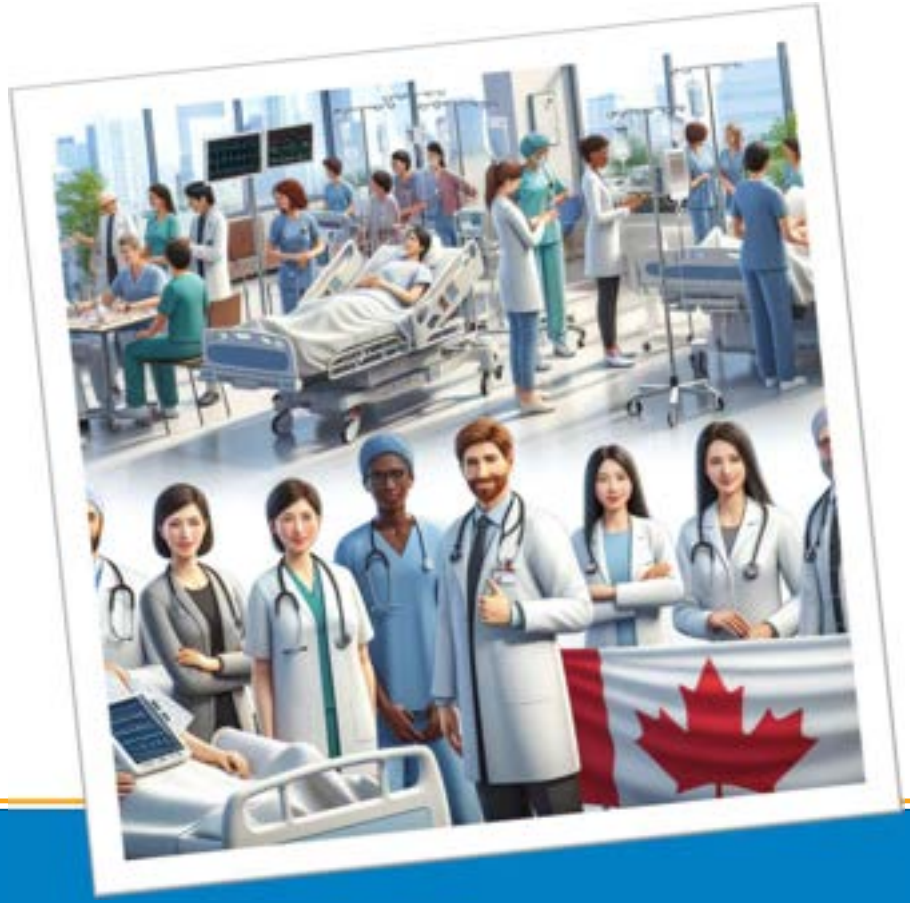
Medtech Canada - Who we are



Mission: We foster a strong, dynamic medical technology sector for better health outcomes for Canadians.

Vision: For Canada to be a world leader in realizing the benefits of medical technologies.

Advocacy: Promoting the industry and bringing forward key messages through active engagement and involvement with stakeholders.

Medtech Canada members 2022

Over 180 members and growing.
Members encompass

- Manufacturer
- Distributors
- Associations
- Consultants
- And more…..

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Why does Industry experience submission deficiencies - *an industry Perspective*

How are we tackling these challenges as an association and as an industry

- Evolving regulatory landscape
- Lack of international Harmonization
- Unclear Guidance / Regulations
- Insufficient Industry engagement and industry voice during and in between consultations

- Remain engaged – don't rely only on your current regulations saved on your drive or SOPs
  - What's New Medical Devices - What's new: Medical devices - Canada.ca
  - IMDRF Website - International Medical Device Regulators Forum (IMDRF) | International Medical Device Regulators Forum
  - MDSAP Website - Medical Device Single Audit Program | Medical Device Single Audit Program (MDSAP)
- Engage in international Harmonizations efforts
  - IMDRF Consultations Consultations | International Medical Device Regulators Forum – currently has "**Essential Principles and Content of Predetermined Change Control Plans"**
  - National Consultation with international implications (eg CUSMA)
  - Engage and share knowledge through Associations that function within international platforms (eg Medtech Canada)
- Engage with you regulators directly or through Associations in seeking clarification on Guidance / Regulations as well as provide feedback on regulatory changes coming down the pitpline
  - Medtech Work*

2023

- Agile Regulation Consultation
- Recalls and Els Consultation
- Clinical Trials
- Determining Classification of MDs
- Machine Learning MDs
- PMRA Submission*

2024

- Significant Change Consultation
- PMRA Submission*
- Recognized Standards Consultation
- N12 Companion Document (IMDRF)
- N73 Good Machine Learning (IMDRF)
- TnCs, GUI-0054/GUI-0016/FRM-0292

2025

- Servicing and installation
- MDSAP – SMEs
- MDSAP – Survey
- Sub-Committee – Clinical Trials
- Shortages – CG1, GUI-0137 & GUI-0147
- MDEL - CG1, GUI-0016, GUI-0064, GUI-0079 & FRM-0292
- SCC-NIST Workshop on Standards
- Consultation on draft guidance on co-packaged drug products
- Guidance on managing applications for medical device licences
- UDI

- ✓Evolving regulatory landscape
- ✓Lack of international Harmonization
- ✓Unclear Guidance / Regulations
- ✓Insufficient Industry engagement and industry voice during and in between consultations

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- Training Gaps
- Fear of engaging with regulators
- Overworked

- Training gaps and Overworked –a theme that is common for both parties
  - Medtech Canada strives at all time to identify way to minimize workload and improve training for both Members and Health Canada
    - Training
      - Workshops
      - Conference
      - Manufacturer / Vendor Days
  - Workload
    - Reduction in inquiries to Health Canada results in reduction of workload on both sides
    - Workload reduction (without compromising quality of work) is a constant them in all of our review and feedback to consultations
    - Coordinate feedback with other industry memebrs / associations (eg instead of 50 consultation responses how about one that summarizes all points)
    - Red Tape reduction is a perfect example of reduction of red tape on both sides
- Fear of engaging with regulators
  - Rip off that band aid and say “hello”
  - Engage through Assocaitions or anonymous feedback mechanisms
  - Provide honest and open feedback to regulators – it is the ONLY way to improve

- ✓Training Gaps
- ✓Fear of engaging with regulators
- ✓Overworked

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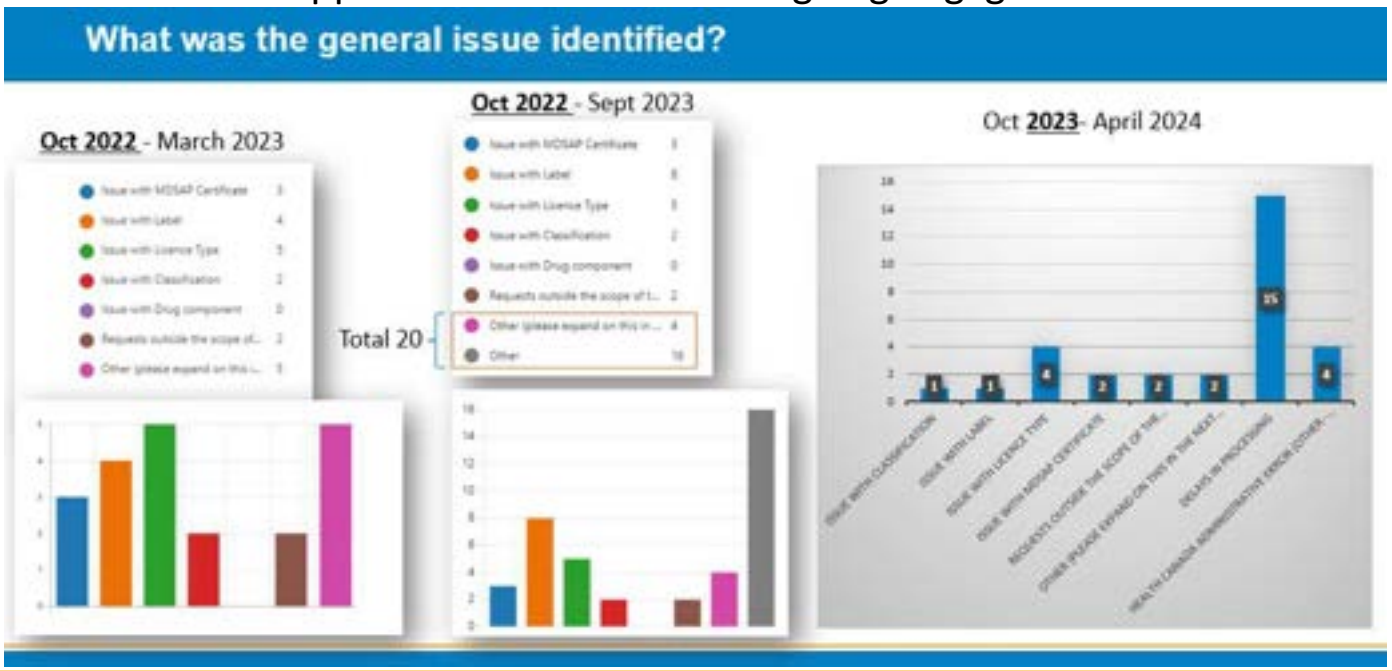
Successes

"Coming together is a beginning. Keeping together is progress. Working together is success." *- Henry Ford'*

- **Red Tape Reduction**
  - Various points noted in the recent Red-Tape reduction are areas where Medtech has been championing change or supporting change through consultation or feedback
    - Public Release of Clinical Information
    - MDEL regulatory changes
    - Ts and Cs for MDL
    - Creation of a pathway to MD Classification considerations - IBR
- **MDSAP**
  - Bringing industry's voice to the program
- **Clarification on Forms**
  - Mandatory vs optional fields for MPRs and MDEL Applications / Renewals

- **<u>Pre-market concerns – ongoing discussions to monitor Industry signals</u>**
  - Identification of Medical device application concerns and ongoing engagement with Health Canada



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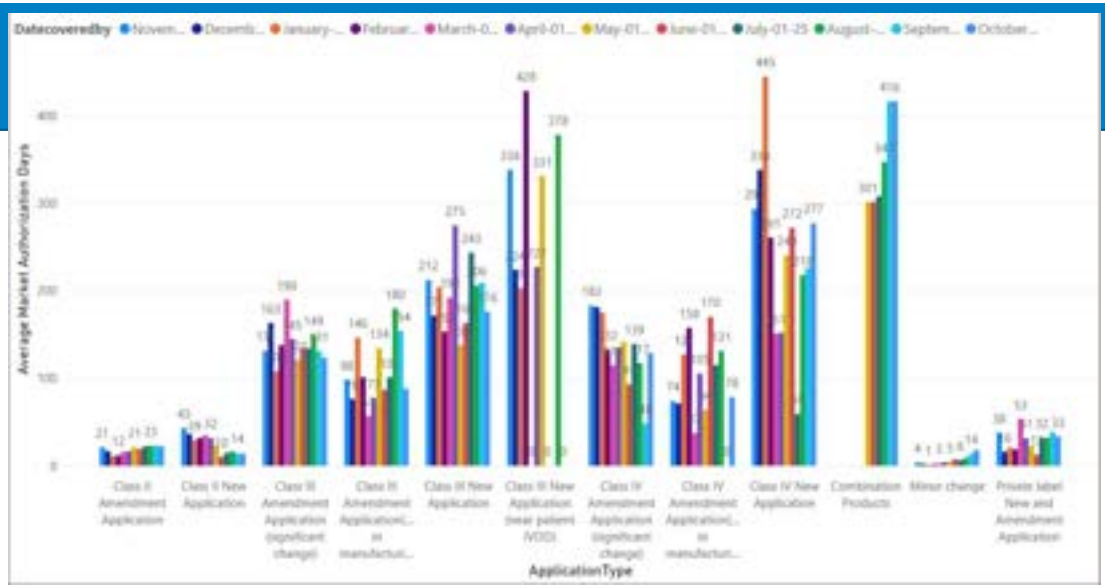
Market Authorization Time

- **MAT Table**
  - **Providing visibility to industry on Market Authorization Timelines so that industry can make informed decisions**



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A tale of two perspectives… with a common goal – to foster a strong, dynamic medical technology sector for better health outcomes for Canadians.

We welcome all to join us on a 2-day hybrid event that will focus on information exchange and enlightening conversations

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