

Regulatory area to be addressed

Medical Devices

Health Canada and the U.S. Food and Drug Administration (FDA) will continue to work closely together on pre and post market regulatory convergence topics, including in particular, through the [International Medical Devices Regulators Forum](#) (IMDRF). IMDRF aims to accelerate international medical device regulatory harmonization and convergence for regulators and stakeholders worldwide.

Work stream A

Medical Device Single Audit Program (MDSAP) – Development of Guidance Documents to Support the Program

Canada and the United States are working closely together on the MDSAP three-year pilot program which began January 2014. They are joined by Australian and Brazilian medical device regulators in an effort to provide a single efficient audit of the medical device manufacturers, reducing the number of regulatory audits for the manufacturer; as well as, defining consistent and robust regulatory authority assessments of auditing organizations performing such MDSAP audits while leveraging resources of the regulatory members. The single audit is the combination of all of the jurisdictions requirements covered in a regulatory audit including not only the quality management system requirements but also other requirements such as: post market adverse event reports, field safety corrective actions, licensing, registration, listing, etc.

The guidance documents developed as part of this work plan will support the implementation of the single audit program. Health Canada and FDA will continue to engage key stakeholders such as the Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA) and Global Medical Technology Alliance (GMTA), which includes Canada’s Medical Technology Companies (MEDEC), in the development of these guidance documents.

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| | United States | Canada |
| Department/Agency | Food and Drug Administration – Center for Devices and Radiological Health | Health Canada - Health Products Food Branch |

| Planned initiatives and sub-deliverables | Date |
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| <p>Initiative A Medical Device Single Audit Program – Auditing Report Guidance: This guidance document would describe the expectations of the regulatory authorities participating in the Medical Device Single Audit Program (MDSAP) in relation to the content of medical device regulatory audit reports prepared by recognized auditing organizations.</p> <p>Use of a set of Medical Device Single Audit Program documents would promote greater convergence of regulatory approaches and technical requirements for Auditing Organizations, such that regulators can all readily utilize the same audit report for their regulatory purposes.</p> | <p>January 2015 - December 2016</p> |

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| | <ul style="list-style-type: none"> Produce a Proposed Document for the IMDRF Management Committee (MC) meeting in March 2015 in Tokyo, Japan (collaborative work via email exchanges and face-to-face meeting in February 2015) | June 2015 |
| | <ul style="list-style-type: none"> Public Comment Period | December 2015 |
| | <ul style="list-style-type: none"> Additional Face-to-Face meeting to resolve comments | June 2016 |
| | <ul style="list-style-type: none"> Submit to IMDRF MC as Final Document for approval at the MC meeting in September in Brazil | August 2016 |
| | <ul style="list-style-type: none"> Approval of Final Document | December 2016 |
| Initiative B | | |
| <p>Medical Device Single Audit Program (MDSAP) – Regulatory Authority Assessment Method Guidance. This document provides guidance in describing the key elements of the initial and periodical assessments, and ensures consistency in the assessment program implementation, regardless of the designated assessment team and the Audit Organizations. Use of a set of MDSAP documents would promote greater convergence of regulatory approaches and technical requirements for Auditing Organizations and assessment of Auditing Organizations by the participating regulatory members.</p> | | January 2015 - December 2016 |
| | <ul style="list-style-type: none"> Produce a Proposed Document for the IMDRF Management Committee (MC) meeting March 2015 in Tokyo, Japan (work via email exchanges and face-to-face meeting in February 2015) | June 2015 |
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| Work stream B | Health Canada Initiatives to Improve Regulatory Convergence |
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| |  United States |  Canada |
| Department/Agency | | Health Canada |

| Planned initiatives and sub-deliverables | Date |
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| <p>Initiative A</p> <p>Health Canada is committed to increasing regulatory convergence with the FDA, and is already taking steps in this area. For example, in 2014, Health Canada proposed expanding the scope of medical devices that it permits to carry electronic labels in order to better align with the scope permitted by the FDA. In 2015, Health Canada notified stakeholders of its intent to regulate commercial reprocessing of devices originally authorized for single use, which aligns with the FDA. Health Canada will continue its regulatory convergence efforts by:</p> <ul style="list-style-type: none"> • providing updates to and obtaining feedback from industry on international activities, including RCC, through its bilateral association meetings • considering publicly available FDA product line classification decisions (prescription pharmaceutical, biologic, medical device) as part of product classification decision-making in Canada • considering public FDA guidance documents during the development of any new Canadian guidance documents, and • sharing with FDA copies of HC's draft guidance documents for their comment | <p>January 2015 – December 2017</p> |