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. Last year, FDA and Health Canada drafted two guidance documents in support of the Medical Device Single Audit Program (MDSAP) as stated in the original work plan: (1) Auditing Report Guidance and the MDSAP and (2) Regulatory Authority Assessment Method Guidance. Both documents were posted for stakeholders to comment for two months (April and May 2015). The documents were revised at the end of June, 2015 based on the public comments received, and final comments from the work group were incorporated in July, 2015. The documents were approved at the IMDRF Management Committee meeting in Kyoto on September 15-17, 2015 and posted on the IMDRF website as final documents.

Work stream A	**Development of a Good Regulatory Review Practices Guidance Document** Canada and the United States are working together with other IMDRF members on the development of Good Regulatory Review Practices (GRRP). This guidance will enable more consistent pre-market review/assessment processes to be performed by Regulatory Authority partners and is in alignment with the IMDRF Strategic Priority to "Improve the Effectiveness and Efficiency of Pre-Market Review." If Good Regulatory Review Practices can be defined and certain aspects of the pre-market review/assessment processes become more consistent, this could lead to future leveraging of pre-market reviews performed by other Regulatory Authority partners. Health Canada and the 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.

	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
Initiative A - Development of a Good Regulatory Review Practices Guidance Document Development of Good Regulatory Review Practices (GRRP) will enable more consistent pre-market review/assessment processes to be performed by	**May 2016 – April 2017**

Regulatory Authority partners and is in alignment with the IMDRF Strategic Priority to “Improve the Effectiveness and Efficiency of Pre-Market Review.” The initial stage is to develop a guidance document which outlines a common set of competencies, conduct, and training requirements for regulatory reviewers in order to further develop confidence in the consistency of pre-market reviews performed by Regulatory Authority partners. If Good Regulatory Review Practices can be defined and certain aspects of the pre-market review/assessment processes become more consistent, this could lead to future leveraging of pre-market reviews performed by other Regulatory Authority partners. Adherence to this guidance document will help mitigate the risk of inconsistent or ineffective evaluations of the safety and performance of medical devices by ensuring that reviewers have the necessary competencies, experience, and training before conducting such evaluations or making decisions. The opportunity to rely on consistent assessments performed by other Regulatory Authority partners will reduce regulatory redundancies which can have positive effects on bringing safe medical devices to patients around the globe in a more timely manner. 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.		
	• Produce a Proposed Document for the IMDRF Management Committee (MC) meeting in June 2016	Completed
	• Public Comment Period	August 2016- September 2016
	• Additional Face-to-Face meeting to resolve comments	October 2016
	• Submit to IMDRF MC as Final Document for approval at the MC meeting in March 2017 in Canada	January 2017
	• Approval of Final Document • Post on IMDRF website	March/April 2017

Work stream B	Health Canada Initiatives to Improve Regulatory Convergence

	United States	Canada
Department/Agency		Health Canada

Planned initiatives and sub-deliverables	Date
Initiative A 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: • 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 and leveraging FDA public technical guidance documents during the development of any new Canadian guidance documents; • exploring potential alignment with FDA on the requirements for low-risk Investigational Testing, which the FDA exempts from regulatory review (HC does not) will enable Canadian innovation for lower risk evaluations; • exploring alignment with U.S. on the classification of high level disinfectant/sterilant products and hemodialysis solutions intended for use on medical devices. These products are classified as medical devices in the U.S. (and other countries), and as drugs in Canada. HC will explore the feasibility of re-classifying these products as medical devices, which will eliminate barriers to trade (reduction of costs due to regulatory burden and delays to market) and creating a level playing field.	January 2015 – December 2017