Regulatory area to be addressed	***Pharmaceutical and Biological Products*** Health Canada and the U.S. Food and Drug Administration will continue to work closely together to harmonize and align their pre and post marketing surveillance requirements and standards (including pharmacovigilance issues) through the work of the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and the International Pharmaceutical Regulators Forum Regulators will continue to share inspection schedules through the Pharmaceutical Inspection Co-operation Scheme and to promote leveraging of inspectional resources to maximize inspection coverage. Regulators will also continue to expand the Common Electronic Submission Gateway for the biological and pharmaceutical industry, where appropriate.

Work stream A	**Consultation Meetings for Stakeholders Prior to the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Meetings**

	United States	Canada
Department/Agency	U.S. Food and Drug Administration	Health Canada

Planned initiatives and sub-deliverables	Date
Initiative A: Joint Public Consultation on ICH Guidelines There are currently approximately 20 guidelines under active development or revision at ICH. Prior to each ICH bi-annual meeting, Health Canada and FDA will hold joint U.S.-Canada public consultation meetings to seek public input on draft ICH guidelines and to identify key areas where there may currently be regulatory disharmony which potentially could benefit from harmonization in the ICH venue. Meetings will be held alternating in location, between the U.S. and Canada. Stakeholder input from the joint public consultations will be evaluated and brought to the ICH discussions for consideration. A web-based consultation will also be undertaken in parallel in order to offer an opportunity for stakeholders to submit comments in writing. The result of these joint consultations is a demonstrable commitment on the part of FDA and Health Canada to the principle of transparency and openness to the ICH process, by taking into account the views expressed by stakeholders in the U.S. and Canada. Health Canada also intends to use these opportunities to better understand areas where Canadian requirements differ from	**January 2015 – December 2017**

those in place in the U.S., with a view to minimizing these differences. FDA will continue to seek public input at Step 3 Regional Consultation in the ICH process for the development of safety, efficacy and quality guidelines, by publishing the draft guidelines in the U.S. Federal Register for public comment. Health Canada will also continue to provide stakeholders with opportunities to input into draft guidelines through ongoing engagement mechanisms such as web postings and its existing bilateral meeting program. In addition, Health Canada will continue to identify to stakeholders those guidelines that have been officially adopted for use in Canada.		
	• Joint FDA-Health Canada public consultation meeting and web posting related to upcoming ICH guidelines and topics.	**November 2016 (Canada)**
	• Joint FDA-Health Canada public consultation meeting and web posting related to upcoming ICH guidelines and topics.	**May 2017 (United States)**
	• Joint FDA-Health Canada public consultation meeting and web posting related to upcoming ICH guidelines and topics.	**November 2017 (Canada)**

Work stream B	**Good Manufacturing Practices Drug Inspection-related activities**. Key deliverables include FDA and Health Canada engaging under multilateral arrangements such as the Pharmaceutical Inspection Co-operation Scheme (PIC/S) with the objective of enhancing our bilateral collaboration with strategic direction, information sharing and standardization. PIC/S is a cooperative arrangement between pharmaceutical inspection authorities relating to the international development, implementation and maintenance of harmonized Good Manufacturing Practices (GMP) standards and quality systems of inspectorates in the field of medicinal products. This is to be achieved by developing and promoting harmonized GMP standards and guidance documents; training competent authorities in particular inspections; assessing and facilitating the co-operation and networking for competent authorities and international organizations.

	 United States	 Canada
Department/Agency	U.S. Food and Drug Administration	Health Canada

Planned initiatives and sub-deliverables	Date
Initiative A - Planning of inspections under the Pharmaceutical Inspection Cooperation/Scheme (PIC/S) - Multilateral Inspection FDA and Health Canada, as PIC/S members, will continue to actively contribute to the PIC/S master list which comprises of over 2,300 planned inspections by all members. This information allows both agencies to be informed of each other's schedule of planned foreign inspections. Furthermore, it would provide opportunities for continued collaboration including the identification of inspection sites of common interest.	**January 2015 – December 2017**
Report progress on GMP activities at annual RCC stakeholders meeting	**Annually**

Initiative B - Conduct joint inspections under the PIC/S foreign site inspection program • FDA and Health Canada continue to explore opportunities to conduct joint inspections of foreign sites of common interest including inspections with other PIC/S members. The joint inspections may also include sites located in the United States and Canada. • The goal of conducting joint inspections is to leverage bilateral cooperation by continuing to share expertise, increase awareness of each other's inspectional processes, and foster harmonisation.	**January 2015 – December 2017**
Report progress on GMP activities at annual RCC stakeholders meeting	**Annually**

Work stream C	**Common Electronic Submissions Gateway (CESG) Activities**

	United States	Canada
Department/Agency	U.S. Food and Drug Administration	Health Canada

Planned initiatives and sub-deliverables	**Date**
Initiative A - Expansion of the CESG for the biological and pharmaceutical industry, where appropriate. FDA and Health Canada will perform system checks of the Gateway quarterly to ensure the system is fully functional and industry transmissions are being delivered in an expedient manner to regulators. Health Canada's Health Product and Food Branch's (HPFB) goal is to implement a branch wide electronic-only regulatory submission intake environment across multiple product lines and regulatory activities which will provide Industry with a single service window. Expanding the use of the CESG would enable the fulfillment of this goal. Health Canada will continue to use and expand the scope of the CESG for electronic submissions in both electronic Common Technical Document (eCTD) and non eCTD format in an effort to achieve this goal.	**January 2015 – December 2017**

Expansion of the CESG across Human Pharmaceutical & Biologics submission types requires a phased approach and will be fulfilled through the following deliverables to be completed by HPFB at the end of 2016: • Support for all Human Pharmaceutical & Biologics electronic submissions in eCTD & non-eCTD format through the CESG. • Implementation of new regulatory enrollment process between Health Canada and industry to support a Common Submission intake framework. • Automate validation and uploading of Pharma and Biological submissions received through the CESG. A new HPFB project is currently underway to expand the scope of the CESG. The project will establish a new Regulatory Enrollment Process (REP) between Health Canada and industry.	**REP Pilot October 2016 - January 2017**
Health Canada will continue to engage industry stakeholders in the development of a roadmap on expanding scope of the CESG via the industry Group on Electronic Regulatory Activities (GERA) and other industry association bilateral meetings.	**May 2016**

Work stream D	Health Canada Initiatives to Improve Regulatory Convergence

	United States	Canada
Department/Agency		Health Canada

Planned initiatives and sub-deliverables	Date
Initiative D Health Canada is committed to reducing regulatory and administrative burden for stakeholders, through regulatory convergence. Health Canada is already taking steps in this area, and will continue to do so during this time period. For prescription pharmaceuticals and biologics, Health Canada will: • provide updates and obtain feedback on international activities including RCC projects at bilateral meetings with industry associations; • consider publicly available U.S. FDA product classification decisions (eg. prescription pharmaceutical, biologic, medical device) as part of product classification decision-making in Canada; • consider public U.S. FDA guidance documents during the development of any new Canadian guidance documents; • provide copies of draft guidance documents to U.S. FDA counterparts for comment, during the development phase of these documents; • notify U.S. FDA counterparts of upcoming release of final guidance documents; • finalize a framework for orphan drug authorizations which will accept US orphan drug designations for products meeting the orphan drug definition in Canada and rely on the assessment of a review already completed by the US FDA for orphan drugs for ultra-rare diseases; • prepare an updated version of its biosimilars framework which will incorporate additional harmonization provisions with the US approach and continue to participate along with the US FDA in international harmonization initiatives related to biosimilar regulation.	**January 2015 – December 2017** **Revised draft framework shared with FDA December 2016**