RCC Personal Care Products and Pharmaceuticals Working Group: Good Manufacturing Practices (GMP) Work Plan

Canada Lead(s): Paul Glover, Assistant Deputy Minister, Health Products and Food Branch, Health Canada (HC)
U.S. Leads: Murray Lumpkin, Commissioner's Senior Advisor and Representative for Global Issues, U.S. Food and Drug Administration (FDA)

Proposal to explore and develop joint proposals to identify on-going systemic alignment mechanisms between the U.S. Food and Drug Administration (FDA) and Health Canada (HC)

A goal of collaboration between HC and the FDA is to better align our regulatory systems, reduce unnecessary duplications and differences, and, to the extent feasible, better leverage resources to help both agencies meet their public health missions within the parameters allowed by prevailing laws and regulations subject to available human and financial resources.

Building on the strong, extensive and long-standing bilateral regulatory cooperation between the agencies, the FDA and HC will explore and develop proposals outlining joint regulatory collaborations in areas of mutual benefit, such as personal care products and pharmaceuticals for human and animal use. These proposals will outline key elements to help facilitate on-going better systemic alignment of regulatory systems, strategies, and practices between HC and FDA. When exploring potential proposals, FDA and HC will:

- Take stock of collaboration and experience gained to date between the FDA and HC;
- Identify mechanisms for possible regulatory alignment and mutual reliance in such areas as product review and inspection of manufacturing facilities, as well as establishing requirements/standards where appropriate; and
- Examine enablers and barriers related to implementation and identify options for addressing barriers (e.g. legislative and administrative barriers).

These proposals will foster the pursuit of real opportunities to further leverage capacity and expertise, as well as the identification and implementation of effective ongoing systems strategies to help better align regulatory requirements and avoid unnecessary duplication in areas of mutual benefit.

Health Canada and FDA will up-date stakeholders, on a regular basis, on progress and developments emanating from the four current HC-FDA RCC initiatives and future developments, as appropriate.

Deliverable outcome	Enhance collaboration on enforcement and compliance by increasing mutual reliance on each other's routine surveillance good manufacturing practices (GMP) inspection reports of manufacturing facilities for drugs and personal products, rather than having to conduct unnecessarily duplicative inspections in the other country.		
Interim Deliverables:	**Planning Phase**	**Confidence Building Phase**	**Mutual Reliance**

0 to 6 months	1. Creation and final approval by HC and USFDA management of the scope and requirements of the project. 2. Implementation of reliable processes for the exchange of regulatory information between Health Canada and the US FDA 3. Establishment of a risk framework for this project based on type of product which may include the use of a pilot (e.g., OTC drugs)	1. Assessment and comparison of specific compliance processes including but not limited to: ○ site inventory ○ full surveillance list	Not Applicable
6 to 12 months	Not Applicable	1. Routine exchange of inspection reports to assess inspectional depth and coverage for common sites of interest 2. Initiation of observational inspections (selected sites) 3. Ongoing assessment of progress of project based on the outcome of the work completed in the first 6 months and adjust work plan as needed. 4. Ongoing communication with stakeholders via the use of web postings and/or quarterly stakeholder meetings, as needed	Not Applicable
12 to 18 months	Same as above	1. Ongoing assessment of progress of project based on the outcome of the work completed in the first 12months and adjust work plan as needed. 2. Ongoing communication with stakeholders via the use of web postings and/or quarterly stakeholder meetings, as needed	Same as above

		3. Ongoing assessment of scope	
Beyond 18 months	Not Applicable	Not Applicable	Based on the results of the project and on feedback from stakeholders, adopt an on-going framework that assures reliance is continuously improved into the future which may include: 1. A joint GMP database used as a common repository to foster standardized sharing of GMP inspection reports 2. Routine exchange of inspection reports/data in order to reduce duplicate inspections based on risk analysis and product coverage. 3. Routine exchange of major regulatory actions. 4. Initiation of joint inspections of selected establishments 5. Extension of joint inspection site candidates to include 3rd countries 6. Identification of any additional provisions needed for collaboration 7. Creation of a mechanism to share inspection planning information Establishment of a new forum or use of an existing forum (e.g., PIC/S) for continuous reassessment in order to make adjustments based on changes by either regulator (e.g., APIs)

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