

RCC Working Group Work Plan

Canada Lead(s) – Paul Glover, ADM Health Products and Food Branch, Health Canada

USA Lead(s) – US FDA – Office of Regulatory Affairs, CDER’s Office of Compliance

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.		
Task Team Members	US FDA – HC	US FDA – HC	US FDA – HC
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	1. Assessment and comparison of specific compliance processes including but not limited to: <ul style="list-style-type: none"> o site inventory o 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 process 4. Ongoing communication with stakeholders	Not Applicable
12 to 18 months	Same as above	1. Ongoing assessment of process 2. Ongoing communication with stakeholders 3. Ongoing assessment of scope	Same as above
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: <ul style="list-style-type: none"> 1. A joint GMP database used as a common

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Deliberative Materials - For Discussion Purposes Only

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Interim Deliverables:	Planning Phase	Confidence Building Phase	Mutual Reliance
			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 3 rd countries 6. Identification of any additional provisions needed for collaboration 7. Creation of a mechanism to share inspection planning information

Canadian and U.S Working Group and Task Teams Leads contacts

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