



COMPREHENSIVE ECONOMIC AND TRADE AGREEMENT (CETA)

MEETING OF THE JOINT SECTORAL GROUP (JSG)

OF THE

PROTOCOL TO THE COMPREHENSIVE ECONOMIC AND TRADE AGREEMENT
(CETA) BETWEEN THE EUROPEAN UNION AND CANADA ON THE MUTUAL
RECOGNITION OF THE COMPLIANCE AND ENFORCEMENT PROGRAMS
REGARDING GOOD MANUFACTURING PRACTICES (GMP) FOR
PHARMACEUTICAL PRODUCTS

NOVEMBER 16, 2018 BY VIDEOCONFERENCE

PROPOSED AGENDA

1. Welcome remarks and Introduction
2. Adoption of Rules of Procedures (RoP) and Governance
3. Implementation of the Protocol to the CETA between the European Union and Canada on the Mutual Recognition of the Compliance and Enforcement Programs regarding GMP for Pharmaceutical Products
4. Discussion / Approval of the CETA Protocol related Administrative Arrangements
 - i. Components of the Information Sharing Process
 - ii. Two-way Alert Program
 - iii. Procedure for Evaluating New Regulatory Authorities
 - iv. Equivalence Maintenance Program
 - v. Components of a GMP Compliance Program
 - vi. Contact Points
5. Recognition of the Active Pharmaceutical Ingredients Program under the CETA Protocol on Pharmaceuticals

6. Canada's Proposal on MRA for Drug Facility Inspections in third countries (re: CETA Regulatory Cooperation Forum (RCF))
7. Updates from EMA, EC and HC
8. Follow-up actions
 - i. Approval process for the brief summary of the meeting (web posted)
9. RoundTable
10. Next meeting