

## **Canada and the European Union's - Recognition of Good Manufacturing Practices Extra-Jurisdictional Inspection Outcomes**

On April 22, 2021, Health Canada communicated in DEL Bulletin No. 111 that Canada and the European Union (EU) would officially recognize Good Manufacturing Practices (GMP) inspections conducted outside of their respective jurisdictions (i.e. extra-jurisdictional inspections). The scope was limited to extra-jurisdictional inspections conducted on or after April 1, 2021.

Health Canada is pleased to inform you that starting on July 12, 2021, Canada and the EU will also recognize extra-jurisdictional inspections conducted prior to April 1, 2021 as long as the Certificate of GMP Compliance (CoC) is within the period of validity issued by the EU Regulatory Authority. If the CoC is still valid, you may submit a Drug Establishment Licence Application (FRM-0033) and a cover letter to Health Canada at [hc.el.applications-le.sc@canada.ca](mailto:hc.el.applications-le.sc@canada.ca). Health Canada will obtain the CoC from the EU on your behalf to support adding, amending or renewing the foreign building on your Drug Establishment Licence.

For more information on this extra-jurisdictional initiative, please visit the [Mutual Recognition Agreement website](#). Alternatively, you may contact us at [hc.foreign.site-etranger.sc@canada.ca](mailto:hc.foreign.site-etranger.sc@canada.ca).