

3. Parties shall ensure that GMP Inspection reports are forwarded within 30 calendar days. Should a new inspection be carried out, this period may be extended to 60 calendar days.

## **ARTICLE XII**

### **GMP Inspections**

1. In accordance with this Agreement, and by mutual agreement between the Inspection Services, joint GMP Inspections may be conducted. These inspections are intended to develop common understandings and interpretations of practice and requirements.
2. The fee for a joint GMP Inspection shall be charged only by the Regulatory Authority of the Party in whose territory the inspection is carried out if the Inspection Service of the other Party participates in the joint GMP Inspection.
3. The Regulatory Authority of a Party may, subject to the laws and regulations of the other Party, conduct its own GMP Inspection of manufacturers in the other Party's territory for reasons identified to the other Party. Such GMP Inspections shall be notified in advance to the other Party, which has the option of joining the GMP Inspection. Recourse to this safeguard clause shall only be exercised in exceptional circumstances for the purpose of health and safety and shall only occur with the consent of the manufacturer.

## **ARTICLE XIII**

### **Inspection Services and Contact Points**

1. For the purposes of this Agreement, the Inspection Service of each Party is identified in Appendix 2 – Inspection Services. The contact points for each Party's Inspection Service shall be specified in the Joint Sectoral Group's Maintenance Program.