11-2. If **AZ** receives any quality complaint from a customer and/or medical institution and such complaint may be due to **AZ** packaging or labeling, **AZ** shall lead the process and investigate the root cause.

11-3. If a relevant governmental authority requires **DS** to recall the product, or if **DS** initiates a voluntary recall, due to a defect in the **PRODUCT** resulting from the manufacture, processing, packaging or any other matters, **DS** shall notify **AZ** within 24 hours of such defect. For issues related to **AZ** packaging or labeling, **AZ** would lead the process and inform **DS** within 24 hours of such defect.

11-4. In the case that **AZ** becomes Marketing Authorization Holder, **AZ** shall be responsible for making such notifications to applicable Regulatory Authorities. If a relevant governmental authority requires **AZ** to recall the product, **AZ** shall notify **DS** within 24 hours.

11-5. Once the **PRODUCT** recall is determined, **DS** and **AZ** shall collaborate with each other to conduct the **PRODUCT** recall smoothly. A Party shall promptly provide the other Party with information on recall per the other Party's request.

ARTICLE 12. GMP INSPECTION/AUDIT

(GMP INSPECTION)

12-1. If **DS** and/or its Affiliates or **AZ** is informed that a regulatory authority wishes to inspect a **Manufacturing Site** in connection with manufacture and supply of **PRODUCT**, each party shall inform the other party within two (2) business days with details of the proposed scope and timing of the **GMP Inspection**.

12-2. **DS** and/or its **Affiliates** has all responsibility about **GMP Inspection** and does not permit any involvement of **AZ**. In the case of the **GMP Inspection** by a regulatory authority where **AZ** is or becomes the Marketing Authorization holder, **AZ** will be in the role of observer but not active part during **GMP Inspection**. If any **CAPA** would impact **AZ** supply of **Commercial Materials**, **DS** and/or its **Affiliates** shall have a consultation with **AZ**.

12-3. **DS** shall provide **AZ** with the abstract of results for the **GMP Inspection** related directly to the **PRODUCT**.