

Brief Overview of the Draft Amendment of the Standard for Biological Ingredients

1. The Standard for Biological Ingredients

According to The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, the Standard for Biological Ingredients (the notification No.210 of MHLW, 2003) has been notified in order to provide guidance for necessary measures to be taken when a biological ingredient is used in manufacturing pharmaceutical, quasi-drug, cosmetic, medical device and regenerative medicine products (hereinafter referred to as “pharmaceuticals, etc.”).

2. The summary of this amendment

The Standard for Ruminant-Derived Ingredients in the Standard for Biological Ingredients shall be partially amended as follows;

To delete bovine-derived “placenta” and “spleen” from the list of the parts which must not be used as source materials for manufacturing pharmaceuticals, etc., in accordance with the revision of the Standard for Ruminant-Derived Ingredients.