

Outline of the draft Partial Amendment of the Ministerial Order for the Standard of Manufacturing Control and Quality Control for Drugs and Quasi-Drugs

1. The Ministerial Order for the Standard of Manufacturing Control and Quality Control for Drugs and Quasi-Drugs

A leading international standard of Good Manufacturing Practice (GMP) for pharmaceuticals has been established by the Pharmaceutical Inspection Convention/Pharmaceutical Inspection Cooperation Scheme (PIC/S).

In Japan, Ministry of Health, Labour and Welfare, according to the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, has adopted the Ministerial Order for the Standard of Manufacturing Control and Quality Control for Drugs and Quasi-Drugs (the ministerial order No.179 of MHLW, 2004, (hereinafter referred to as the "GMP Ministerial Order") in regard with GMP for pharmaceuticals.

2. The summary of this amendment

The GMP Ministerial Order will be amended to reflect the current PIC/S GMP Guide.

This amendment includes “requirement for Pharmaceutical Quality System to be established”, “requirement for Quality Risk Management to be utilized within Pharmaceutical Quality System” and so on.