SECTION III: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING THE PRINCIPLES OF GLP, VERIFICATION AND CONFIRMATION

THE UNITED KINGDOM	JAPAN
The Good Laboratory Practice Regulations 1999 (SI 1999/3106) and amendments thereto	1. Pharmaceuticals: (a) Law concerning Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Law No. 145 of 1960) and amendments thereto (b) Ministerial Ordinance concerning Good Laboratory Practice for Non-clinical Laboratory Studies on Safety of Drugs (Ministerial Ordinance of Ministry of Health and Welfare No. 21 of 1997) and amendments thereto (c) Regarding Treatment of Materials concerning Non-clinical Laboratory Studies on Safety of Pharmaceuticals, Medical Devices and Regenerative Medicine Products Which Should Be Attached to the Application for the Products for Manufacturing and Marketing Approval Etc. (Yakushokushinsahatsu 1121 No. 9/Yakushokukisanhatsu 1121 No. 13 of 2014) and amendments thereto

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	(d) Regarding Guidelines for the Conduct of Pharmaceutical GLP On-site Inspection Conducted by Ministry of Health, Labour and Welfare (Yakushokushinsahatsu No. 0805003 of 2005) and amendments thereto 2. Veterinary Drugs: (a) Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Law No. 145 of 1960) and amendments thereto (b) Ministerial Ordinance concerning Good Laboratory Practice for Non-clinical Laboratory Studies on Safety of Veterinary Drugs (Ministerial Ordinance of Ministry of Agriculture, Forestry and Fisheries No. 74 of 1997) and amendments thereto (c) Regarding Management of the Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (12 Chiku A No. 729 of 2000) and amendments thereto