PART B

SECTION I: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING MEDICINAL PRODUCTS, GMP REQUIREMENTS FOR MEDICINAL PRODUCTS, VERIFICATION AND CONFIRMATION

EUROPEAN UNION	JAPAN
1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311 of 28.11.2001, p. 67) and amendments thereto 2. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34) and amendments thereto 3. Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13) and amendments thereto	1. The Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Law No. 145, 1960) and amendments thereto 2. Cabinet Order of the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Cabinet Order No. 11, 1961) and amendments thereto 3. Ordinance of the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Ordinance of the Ministry of Health and Welfare No. 1, 1961) and amendments thereto

4. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1) and amendments thereto	4. Pharmaceuticals Designated by the Minister for Health, Labour and Welfare under the provisions of subparagraphs 6 and 7 of Article 20(1) of the Cabinet Order of the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, and under the provisions of subparagraphs 6 and 7 of Article 96 of Ordinance of the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Notice of Ministry of Health, Labour and Welfare No. 431, 2004) and amendments thereto
5. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22) and amendments thereto	5. Ordinance for Facilities and Equipments for Pharmacies etc. (Ordinance of the Ministry of Health and Welfare No. 2, 1961) and amendments thereto
6. Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use (OJ L 337, 25.11.2014, p. 1) and amendments thereto	6. Ministerial Ordinance for the Standard of Manufacturing Control and Quality Control for Drugs and Quasi Drugs (Ordinance of the Ministry of Health, Labour and Welfare No. 179, 2004) and amendments thereto
7. Current versions of the Guide to good manufacturing practices contained in volume IV of Rules governing medicinal products in the European Union and the Compilation of the European Union Procedures on Inspections and Exchange of Information	

SECTION II: COMPETENT AUTHORITIES

EUROPEAN UNION	JAPAN
Competent Authorities of the European Union are the following authorities of the Member States of the European Union or authorities succeeding them: Austria Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH Belgium Federaal Agentschap voor geneesmiddelen en gezondheidsproducten / Agence fédérale des médicaments et produits de santé Bulgaria ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА Croatia Agencija za lijekove i medicinske proizvode (HALMED) Cyprus Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας Czech Republic Státní Ústav pro Kontrolu Léciv (SÚKL) Denmark Lægemiddelstyrelsen Estonia Ravimiamet Finland Lääkealan turvallisuus- ja kehittämiskeskus France Agence nationale de sécurité du médicament et des produits de santé (ANSM)	Ministry of Health, Labour and Welfare or an authority succeeding this ministry

Germany Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Paul-Ehrlich-Institut (PEI) Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel (biologicals only) Greece Ethnikos Organismos Farmakon (EOF) (ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ) Hungary Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet (OGYÉI) Ireland Health Products Regulatory Authority (HPRA) Italy Agenzia Italiana del Farmaco Latvia Zāļu valsts aģentūra Lithuania Valstybinė vaistų kontrolės tarnyba Luxembourg Ministère de la Santé, Division de la Pharmacie et des Médicaments Malta Medicines Authority Netherlands Inspectie voor de Gezondheidszorg (IGZ) Poland Główny Inspektorat Farmaceutyczny (GIF) Portugal INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P	

Romania Agenţia Naţională a Medicamentului şi a Dispozitivelor Medicale Slovakia Štátny ústav pre kontrolu liečiv (SUKL) Slovenia Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP) Spain Agencia Española de Medicamentos y Productos Sanitários Sweden Läkemedelsverket United Kingdom Medicines and Healthcare Products Regulatory Agency European Union European Medicines Agency	