

Contents of **New** QMS Ordinance

Chapter 1.	General Provisions (Article 1~3)
Chapter 2.	<u>Medical Devices Manufacturing</u> (Article 4~64) Harmonized to ISO13485:2003
Chapter 3.	<u>Additional Requirements</u> (Article 65~72-3)
Chapter 4.	<u>Biological-origin Medical Device, etc. Manufacturers (Domestic, Foreign)</u> (Article 73~79) Additional requirements according to the characteristics of the products
Chapter 5.	<u>In-Vitro Diagnostic Radioactive Reagents Manufacturers (Domestic, Foreign)</u> (Article 80~81) Additional requirements according to the characteristics of the products
Chapter 6.	Provisions Applied Mutatis Mutandis of Medical Device, etc. Manufacturing Sites, etc.(Article 82~84)