Examples of countries/regions which recognize Japan as reference country

[As of February 2025]

1. Pharmaceuticals

Country	System
EU	• Acceptance of GMP, GLP inspection results (2002)
Switzerland	• Abridged regulatory pathways (2010)
Thailand	• Abridged regulatory pathways (2015) • Japanese Pharmacopoeia (JP) as a reference pharmacopoeia (2019)
Taiwan	• Acceptance of non-clinical study review results (2016) • Abridged regulatory pathways (2016)
India	• Waiver of conducting Phase III trials in India (2019)
Indonesia	• Abridged regulatory pathways (2000)
Malaysia	• Accelerated review of additional indications (2004) • Abridged regulatory pathways (2024)
Vietnam	• Japanese Pharmacopoeia (JP) as a reference pharmacopoeia (2018)
Australia	• Abridged regulatory pathways (2019)
Ukraine	• Abridged regulatory pathways (2016)
UAE	• Abridged regulatory pathways (2018)
Philippines	• Abridged regulatory pathways (2022)
El Salvador	• Abridged regulatory pathways (2023)
Peru	• Abridged regulatory pathways (2023)
United Kingdom (UK)	**• Abridged regulatory pathways (2024)**
Egypt	**• Abridged regulatory pathways (2024)**
Uzbekistan	**• Abridged regulatory pathways (2024)**

2. Medical Devices and In-vitro Diagnostics (IVDs)

Country	System
Taiwan	• Reduction of documents on quality management systems for medical devices and IVDs (2018)
Singapore	• Abridged regulatory pathways (2010)
Malaysia	• Abridged regulatory pathways (2014)
Mexico	• Abridged regulatory pathways for medical devices (2012)
India	• Acceptance of QMS inspection results for medical devices and IVDs in Japan (2015) • Waiver of conducting clinical trials in India (2017)
Australia	• Abridged regulatory pathways (2018)
Vietnam	• Abridged regulatory pathways (2018)
Thailand	• Abridged regulatory pathways (2019)
El Salvador	• Abridged regulatory pathways (2023)
Peru	• Abridged regulatory pathways (2023)
Brazil	**• Abridged regulatory pathways (2024)**
Colombia	**• Abridged regulatory pathways (2024)**
Egypt	**• Abridged regulatory pathways (2024)**
Uzbekistan	**• Abridged regulatory pathways (2024)**

(Note)

- Those confirmed in FY2024 are shown in red. The year in which the country/region recognized Japan as a reference country or confirmed is given in parentheses.
- The framework of Japanese approval/certification system for medical devices is recommended as the “WHO Global model framework” (a regulatory system to be referred to).