HORIBA Medical

HORIBA Group

When regulatory constraints become an opportunity

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EPRISE
EMPOWERING PHOTONICS

Horiba Group

Automotive Test Systems

Process & Environmental

Medical

Semiconductor

Scientific

The HORIBA Group An Expert in Analysis and Measurement Technologies

Founded in Kyoto in 1945, HORIBA is an international Group specialized in the design and production of analysis and measurement systems for liquids, gases and solids

CA: 170 BJPY (1 460 MUSD)
Worldwide Employees: 7149
R&D Expenditure: 7,8% of net sales

Quality Management System Certification

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

International Organization for Standardization
ISO
9001:2015 & 13485:2016

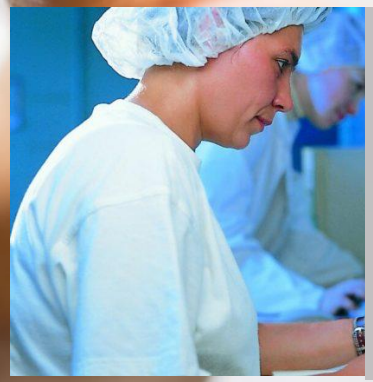
US FDA CFR

BRAZIL ANVISA RDC

AUSTRALIA TG

CANADA SOR

JAPAN PMDL



International Organization for Standardization
ISO
ISO 15189:2012
Medical laboratories

EUROPEAN IVD 98/79

EUROPEAN IVD 2017/745

New

Main critical countries for registrations and regulations

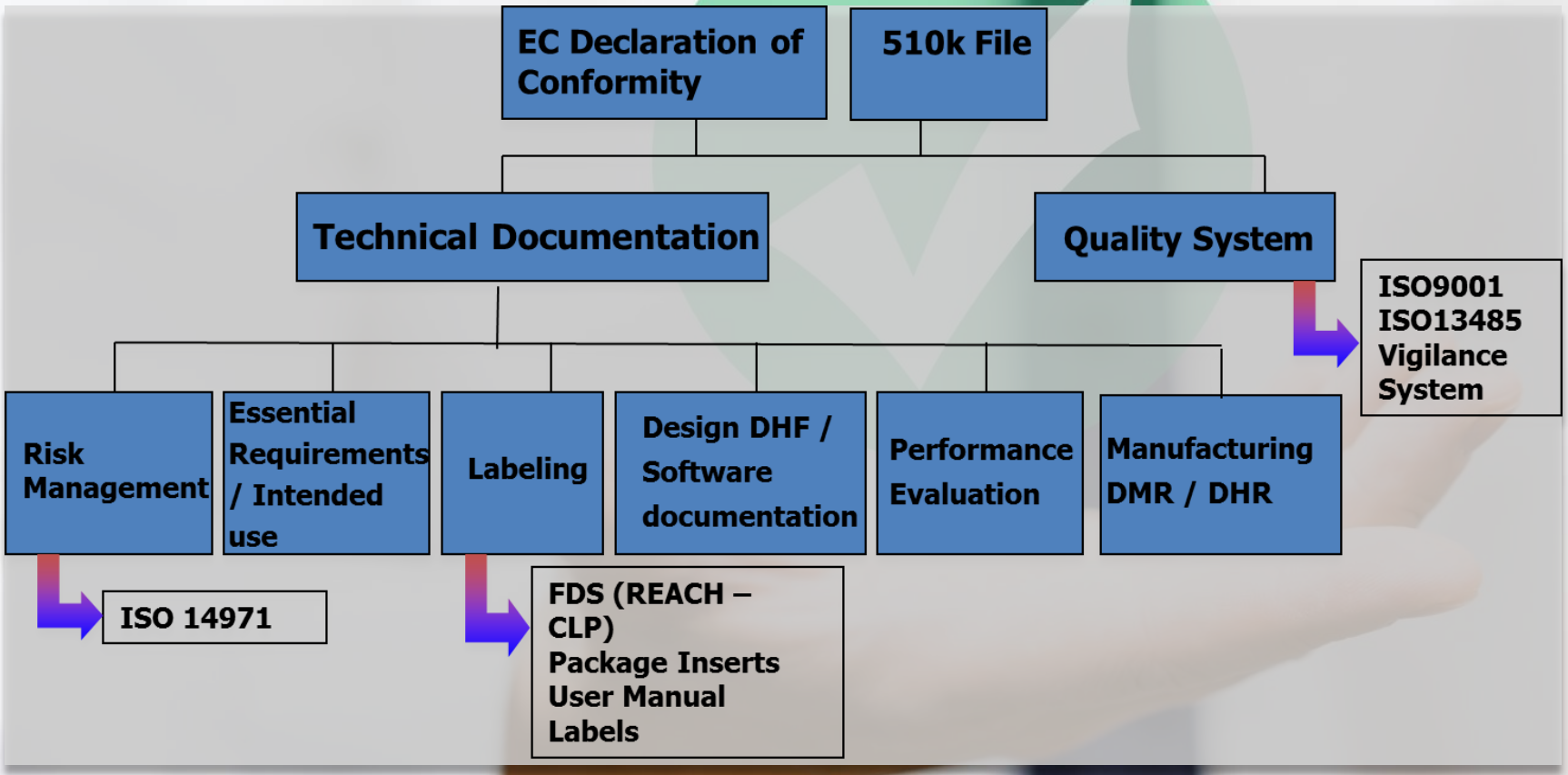
Country	Regulation	Registration
USA 	• Code of Federal Regulation (CFR) • Authority: FDA	• 510(k) file to be sent with performance data obtained at 3 clinical sites, including 2 in the United States • FDA Review: 90 days • Average total registration time: 2 years
CHINA 	• Chinese Regulation • Authority - CFDA	• Registration file to be sent to the CFDA with detailed internal documents. • Evaluation of the file and the product by the CFDA • Average total registration time: 3 years
BRAZIL 	• Medical Device Regulations • Authority: ANVISA	• Registration file to be transmitted with detailed internal documents. • Site of the " legal manufacturer " or even production site must be certified by ANVISA • Evaluation of the dossier and the product by the Brazilian authority • Average total recording time: 3-6 months

Main critical countries for registrations and regulations

Country	Regulation	Registration
INDIA 	• India Medical Device Regulations • Authority - Ministry of Health and Family Welfare (MHFW)	• Registration file to be transmitted only for reagents with detailed information on the production site • Evaluation of the file and the product by the Indian authority • Average total registration time: 9 months
RUSSIA 	• Resolution 1416 • Authority - Roszdravnadzor (RZN) through Russia Authorized Representative (RAR)	• Registration file to be transmitted with detailed internal documents and specific documents in response to specific Russian requirements: Sealed, notarized and apostilled paper file • Evaluation of the dossier and the product by the Russian authority • Average total recording time: 2 years

Today, there are more than 80 countries in which regulations and registration procedures are required to market our products.

From Technical file to best practices



From technical file to best practices

Keys topics to early anticipate

- Project plan & risk plan
- Intended of use, essential requirements
- Clinical performance evaluation protocol
- Design & manufacturing files
- If needed plan software and required documentation

From technical file to best practices

- While **regulatory rules** are often experienced by R & D teams as a constraint, they must be **known, anticipated and controlled: use regulatory input as the best known practices in the world**
- **Regulatory practices**, if controlled and anticipated, **improve the quality** of the medical devices design: **best practices will allow you to better meet customer needs**
- **Use the regulatory framework as an opportunity**, guiding the strategic decisions needed to develop a medical device: **Authorities represent the Voice of customers**