A Whitepaper from DDi

eIFU Regulations for EU MDR and other Countries

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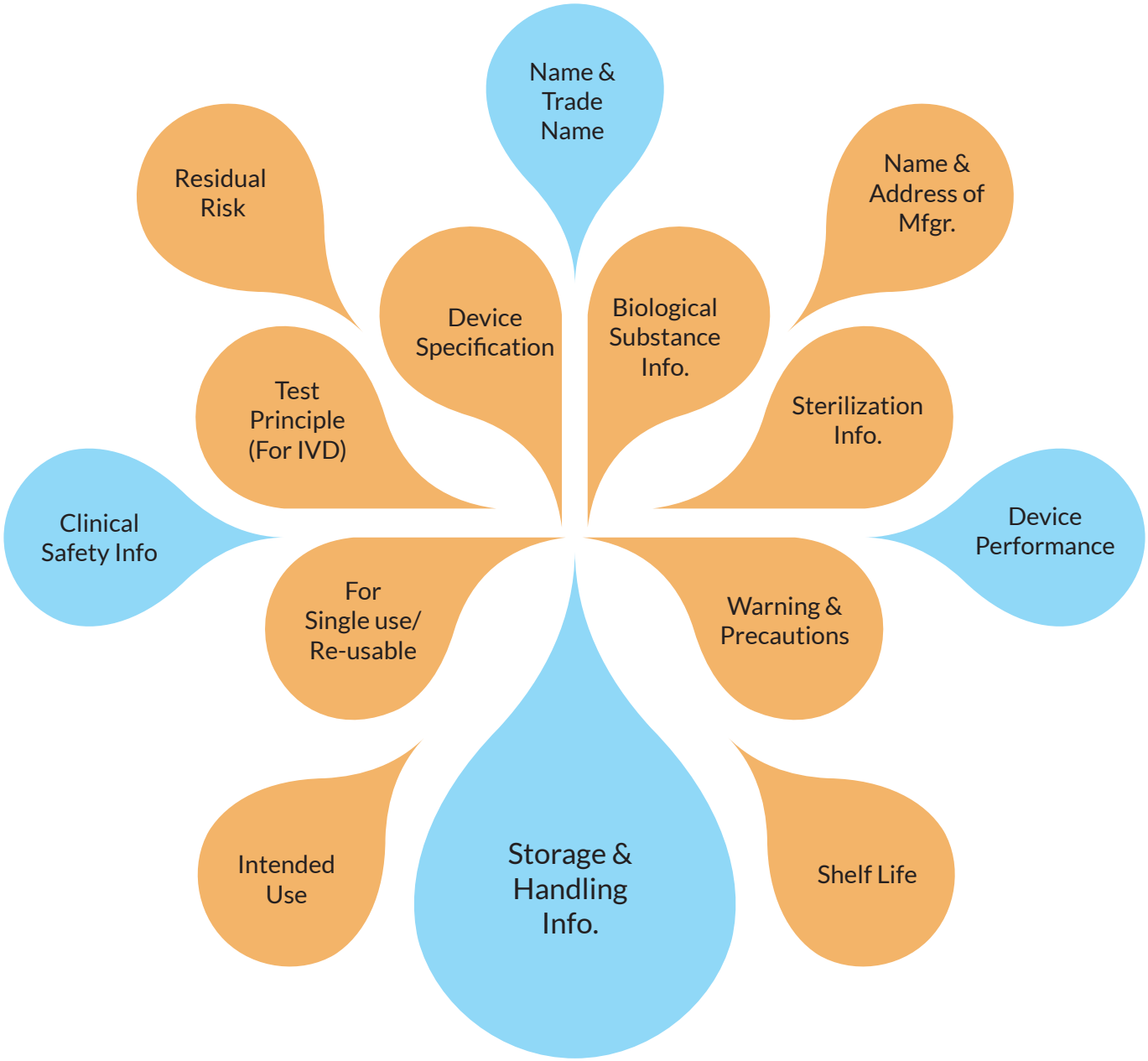
VISU™

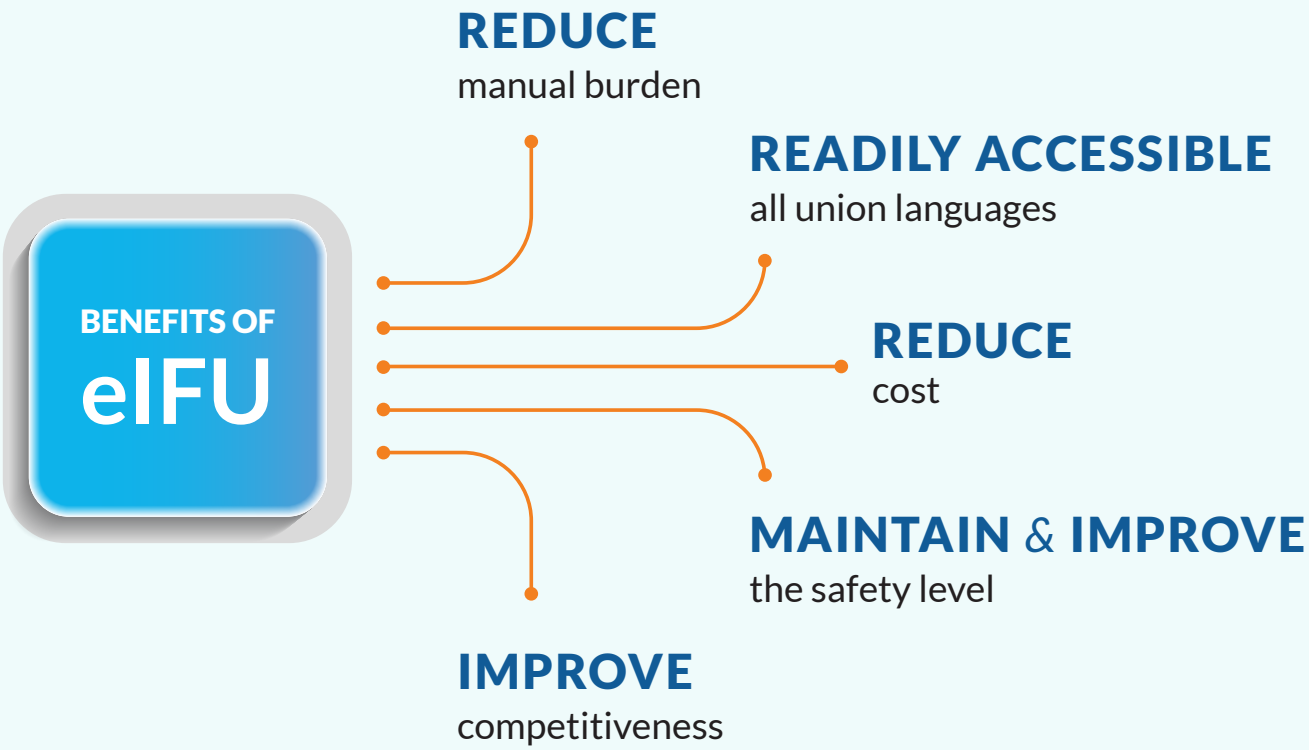
eIFU Regulations for EU MDR and other Countries

Information provided by the manufacturer to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken.

Instructions for use in electronic form means instructions for use displayed in electronic form by the device, contained in portable electronic storage media supplied by the manufacturer together with the device, or instructions for use available through a website.

Content of IFU





Few Country Regulations

eIFU is currently applicable for Europe, USA, Brazil, Australia, India & Saudi Arabia. Canada & Japan are under process of implementing eIFU. Below references suggest the use of eIFU for Europe, USA, Brazil, Australia, India & Saudi Arabia.

USA

Submission of Electronic Labeling for Home-Use Devices 24 Oct. 2016

EU

COMMISSION REGULATION (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices

Brazil

NORMATIVE INSTRUCTION - IN No. 4, OF JUNE 15th, 2012 Establishes rules for providing instructions for use of healthcare products in non-printed formats

Australia

Electronic Instructions for Use - eIFU For professional users of medical devices (including IVDs) Version 1.0 August 2018

India

Gazette notification on acceptance of eIFU published on January 15, 2019 by Ministry of Health & Family Welfare

Saudi Arabia

Guidance document dedicated to the requirements for electronic instructions for use (eIFU) of medical devices published on August 22, 2019 by SFDA

European Regulations for eIFU

eIFU supplied along with paper IFU

- Content of eIFU consistent with P-IFU
- If the eIFU is provided through a website, the website shall:
  - Be protected against hardware and software intrusion
  - Protection of individuals with regard to the processing of personal data and on the free movement of such data
  - Maintain the version history of eIFUs

eIFU supplied instead of paper IFU

- Risk assessment should demonstrate that eIFUs maintain or improve the level of safety obtained by providing paper eIFUs
- Verifications and validations of the design and functioning of eIFUs
- Provide information on how to access the eIFU either on packaging or a separate leaflet

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DDi is a prominent Technology partner to the Life Sciences industry. DDi has built its solution competency with a unique blend of functional and domain expertise to serve the technology needs of global clients. We provide smarter technology for Clinical Development, Regulatory and Safety domains by providing innovative technology products and solutions for organizations of various sizes. Our customer base includes organizations from global Top 100 life science companies to small & mid-size manufacturers.