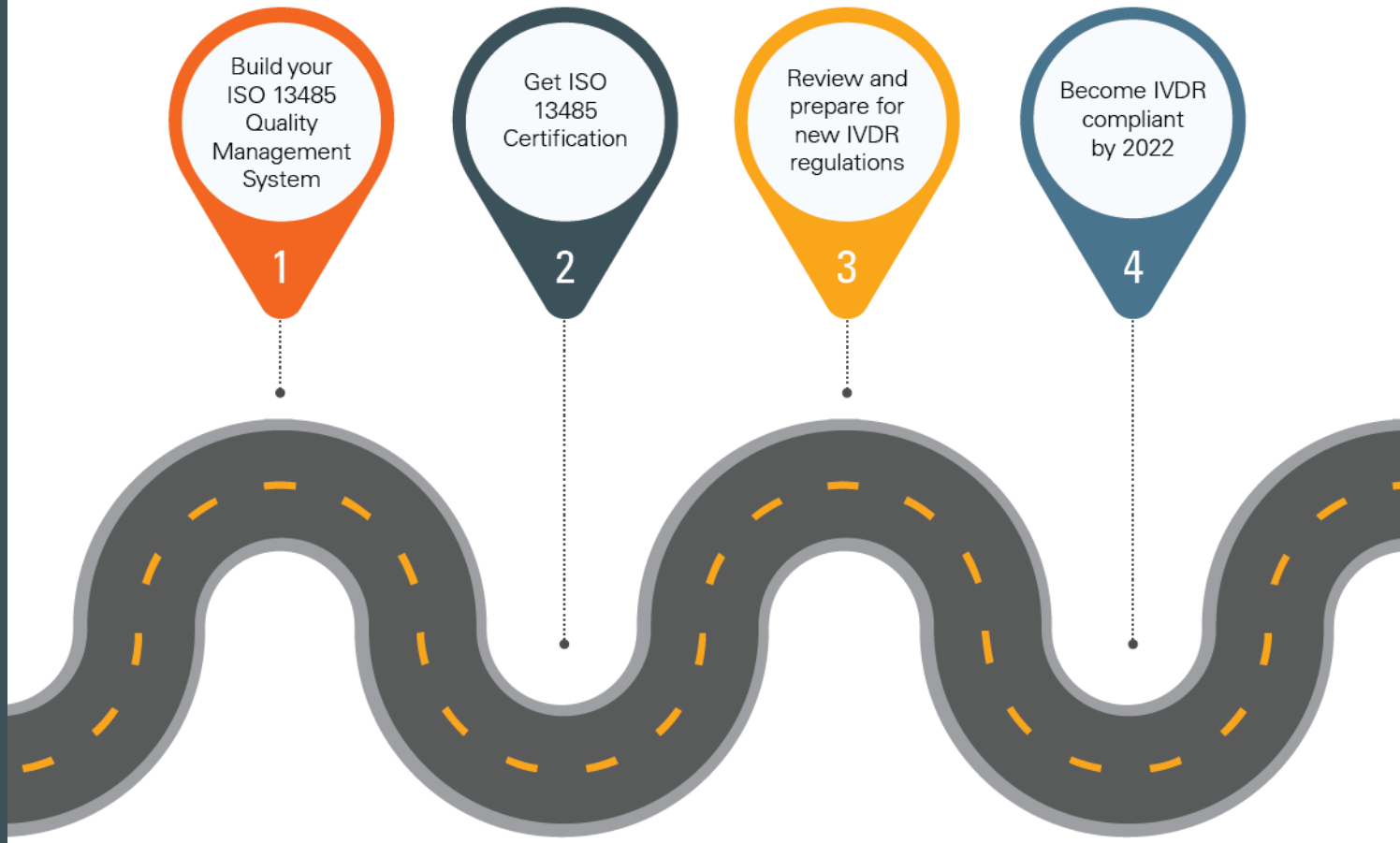
Journey to Regulatory Compliance for IVDR

Compliance with the new EU IVD regulation (IVDR) becomes mandatory in 2022. IVDR (EU) 2017/746, the new IVD medical device regulation, is a regulatory framework that replaces the current IVD Directive 98/79/EC. Legal manufacturers of IVD medical devices will need to comply with IVDR in order to use CE marking and gain access to the EU market.

BENEFITS

- Builds a strong Quality Management System (QMS) which enables companies to manufacture consistent quality products and control their activities
- Demonstrates that IVD manufacturers are addressing and meeting their mandatory regulatory obligations, with certification by an accredited 3rd Party certification body such as SGS
- Attractive for IVD MD manufacturers
- Reduce safety and legal risks while creating more effective work environments through a managed quality system
- Provides IVD manufacturers with recognized sector certification to identify them as reputable, trustworthy providers in the Healthcare market



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