



1. History & Background

2 & 3. General Overview of Regulatory Strategy

36M

0M

Design & 6. Conformity Assessment Routes & Audit Development **Quality Management** 8. Vigilance Ongoing Safety Assessments Classification Clinical Evaluation 3. Classification & PMS 9. Clinical Evaluation / **Ongoing PMS** Data Investigation & Links to Acquisition 5. GSPRs Standards Risk & Marketing Product & Sales Development Overviews & 4. IVDs impacts from **5.** Digital 6. CABs Input? 10. Post Marketing 0 - 36MSurveillance 7. Risk Management (Ongoing) 11. International