AXENDIA™

BLOG

Digital Transformation Is a Journey to Support EU MDR and Beyond

Are You Lost?

Contact Us for Directions

7 AREAS OF INTEREST

ROAD HAZARDS

EU MDR 10 CHAPTERS 97 ARTICLES

RE-CERTIFIED
All medical devices must be re-certified to keep them on the EU market

NO GRAND-FATHERING
of products currently on the market

EFFICACY & SAFETY
Require greater traceability and data transparency

EVENT REPORTING
Adverse event reporting reduced from 30 days to 15 days

IVDR
4 out of 5 IVD medical devices are checked by a Notified Body before they are placed on the market

CLINICAL EVIDENCE
Controls will be tightened on clinical trials and evidence

EU MDR DISRUPTION

Imagine tracking down records for ALL your products going back to the 60s and 70s

RESOURCES CONSTRAINTS

Older products will present a real challenge for us

HOSPITAL

MASTER DATA MGMT

Decisions based on data sovereignty, not data alchemy

TECHNOLOGY

X-RAY

51% of industry executives believe better use of technology reduces compliance risk*

IMPACT ASSESMENT

Calculate ROI for compliance. Estimate cost per product / family

PLATFORM APPROACH

Visibility into your products' digital footprint

CULTURAL CHANGE

Data belongs to the product, not any functional group, system or location

CLOSED LOOP

Companies currently closing the loop are better positioned for EU MDR

Only 8% of companies are currently closing the loop*

DIGITAL TRANSFORMATION

FINISH

Axendia can provide with a roadmap to sustainable positive disruption

AXENDIA™

ABOUT AXENDIA: Axendia, Inc. is a leading trusted advisor to the Life-Science and Healthcare industries. • We provide trusted counsel to industry stakeholders on Business, Regulatory and Technology issues. • We are honored to be recognized by CIOReview as a one of the 20 Most Promising Life Sciences Technology and Services providers. • For more information, visit **www.axendia.com**

*Axendia MedTech Industry Survey, 2016