# WEATHERING THE STORM
## OF TECHNOLOGY ADVANCEMENT *IN MEDICAL DEVICE DESIGN*

**IT'S GETTING PRETTY COMPLEX IN HERE!**

Timeline: 1980 — 1990 — 2000 — 2010 — 2020

**MANUAL DATA** | **eQMS** | **CLOUD** | **QUALITY 4.0**

**PROCESS**

| MANUAL DATA | eQMS | CLOUD | QUALITY 4.0 |
|---|---|---|---|
| Manual data scribing and early computers. Walk files through the process. Filing cabinets store docs. | Electronic docs shared via email, fax, and directories. Physical reviews and signatures required. Product development isolated in multiple design tools. | Electronic docs in early cloud solutions. Majority of quality systems are doc-centric and disconnected from complete product design stored in relational databases. | Cloud-native solutions. Connected, digital quality and product processes. Closed-loop design control. |

**MED DEV EVOLUTION**

| MANUAL DATA | eQMS | CLOUD | QUALITY 4.0 |
|---|---|---|---|
| Separate, distinct products: mechanical, drug, electromechanical. | Electromechanical devices with simple software. Manual monitoring and calibration. | Sophisticated, complex products with onboard technology and data-share interfaces. | Connected, complex products. Crowd-sourcing data. Artificial intelligence, augmented and virtual reality. Digital therapeutics. |

## THE SOLUTION:
## A PRODUCT-CENTRIC QMS
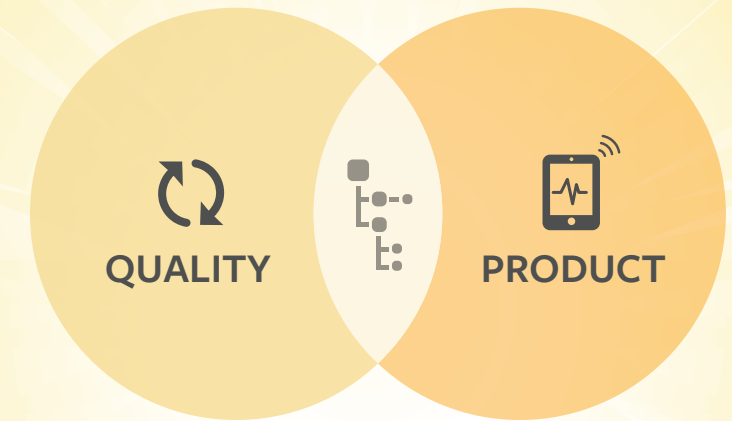
QUALITY — PRODUCT

A product-centric QMS solution enables complete control and traceability throughout the new product development and introduction (NPDI) process with unified quality and product record management.

**Get our free eBook** to see how Arena's unique product-centric QMS solution drives compliant quality management in context to the complete product record.

**arena**