Solutions for

Medical Devices

DIGITAL TECHNICAL PUBLICATIONS

The implementation of the new Medical Device Regulation (MDR), the In-Vitro Diagnostic Regulation (IVDR) and the Unique Device Identification (UDI) is the key challenge for medical device manufacturers along with the growing pressure of cost reduction and high demand for innovation.

Development and production of documentation as per the latest FDA/MDR requirements and the certification as per 21 CFR part 801, 809, 830, 820 and MDR 2017/745 is a critical function for medical devices companies.

Capgemini has profound sector expertise with 18+ years of experience in various clinical specialities to assist the technical publications, lifecycle management and regulatory reviews, ensuring the traceability and compliance.

Our state-of-the-art, ready-to-use infrastructure and dedicated Center of Excellence (CoE) with 1000+ engineers support the technical publications delivery with operational cost savings and improved customer services for our clients.

WHAT WE OFFER

Technical Publications Core
- Authoring
- Illustration
- Animations

EU-MDR Documentation Support
- Gap Assessment
- Labels , IFU & Marketing Content Update
- Translation Services

Technical Publications Platform
- Configuration & Customization
- Maintenance
- Migration

Technical Publications User Experience (UX)
- Publishing
- Packaging (3D/ Augmented /Virtual Reality (AR/VR))

Technical Publications Consulting
- Flash Diagnostic Consulting
- Benchmarking Study
- Transformation Consulting

Training Module Development Services
- WBT/CBT Modules Development

OUR EXPERTISE

- **PUBLICATIONS**
  - User manuals
  - Instructions For Use (IFU)
  - Operator manuals
  - Service manuals
  - Quick setup guides
  - Installation manuals
  - WBT training modules
  - Periodic maintenance guides
- **LABELS**
  - Device labels
  - Accessory labels
  - Package labels
  - Warnings and cautions
- **MARKETING DOCUMENTS**
  - Marketing materials
  - Brochures
  - Technical specifications
  - Performance highlights
- **TOOLS**
  - Adobe FrameMaker
  - Adobe InDesign
  - XML Editor
  - Adobe Illustrator
  - Adobe Captivate
  - PTC Arbortext

DIGITAL ENABLERS
for an *Intelligent Industry*

- **Smart Product & Integrated Product Services**
  Manuals on hand-held devices, 3D service instructions, augmented manuals, service excellence and predictive maintenance
- **Intelligent Automation**
  RPA tool chain to improve the quality and productivity of the service
- **Digital Manufacturing**
  Manufacturing & process documentation, manufacturing work instructions, 3D work instructions, augmented work instructions, digital operator and virtual assistant
- **Total Process Manager (TPM)**
  A single, in-house developed tool for project lifecycle management

SUCCESS STORY

Documentation for EU-MDR gap assessment, labelling and IFU update for a leading surgical navigation devices company.

OUR ADDED VALUE

Rightshore® approach with global delivery teams

Industrialized approach to **technical publications management**

18+ years of experience, engaging with 65+ medical device companies

CoE approach to support the engagement throughout the lifecycle

Assured **cost savings**

Academy CoE for competency management and team qualification

Move up the value chain of technical content by embracing **emerging technologies** like AR, VR & interactive 3D

For more information, contact:
marketing.dems.global@capgemini.com