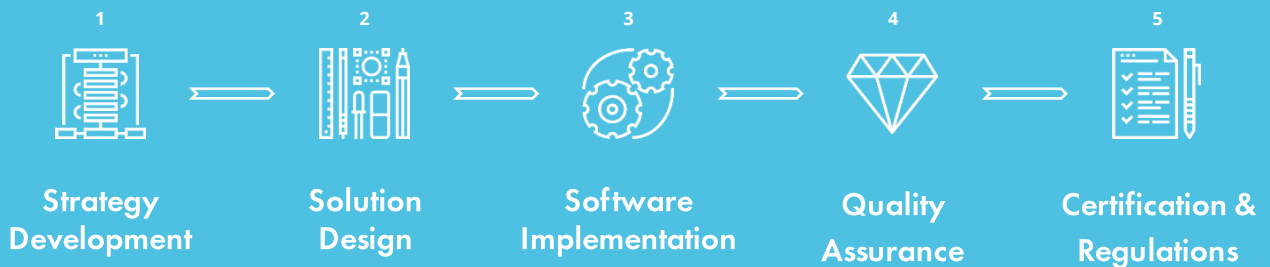


DataArt & EXCO

Custom Development of Medical Device Solutions

DataArt & EXCO offer **custom software development** services for **Medical Device Manufacturers**. Co-aligning our end-to-end **services** with 20+ years of expertise, understanding the **market** and the **industry** environment, DataArt and EXCO can help in the following areas all done from the single source:



Why Choose Us:

Industrial expertise

- Experience with medical devices of Class II
- Development in accordance with certified QMS
- Awareness of Standards & Regulations
- Security & Compliance full coverage

Technological expertise

- Full-cycle development services from idea to implementation
- Resources pool for full-stack development
- Competences in areas like IoT, AI/ML, Big Data, Data Management & Visualization, Blockchain.

Local presence

Selected Clients



Core Areas of Common Expertise

Design & Quality Controls

Requirements management, risk management, verification and validation, design transfer, employee training, tools validation

Full Cycle Development Services

Technology Consultancy, Business analysis, UI/UX Design, Solution Design, Development, Functional & Non-Functional Testing

Development in accordance to

US FDA 21 CFR Part 820.30, ISO 13485, EU MDD/IVDD, MDR/IVDR, IEC 62366, IEC 62304, IEC 60601

Post-Development Support

Infrastructure & DevOps Services, Provisioning in-house and cloud infrastructure, Deployments, Support & Maintenance

Documentation

Design inputs, design outputs, risk management plan and report, test plans and reports, post market surveillance plan, work instructions, design history file

Automated Verification

Focus on developing individual automated test strategies, and their integration in a IEC 62304 compliant software lifecycle

Validating & Qualifying

GMP-compliant validation of your production and supplier processes; qualification of your equipment and IT systems

Test Stands

Development of fully qualified test stands for your production site e.g. according to GAMP 5

DataArt & EXCO Quick Facts



20+ years

years in medical industry



2900+

full-time staff



25 locations

across the globe



Over 200

quality Specialists



95%

return clients



120+ mln

annual revenue

DataArt is a global technology consultancy that designs, develops and supports custom software systems for highly regulated industries.

EXCO is a ISO 13485 certified global technical service provider offering quality assurance measures, plans and implements test, manufacturing and production processes as well as develops software and system solutions.

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