Qity

Services & Training

Lending a Hand to Life Science

About us

BIOCARTIS

nobi

orgenesis

trince
PRECISION TRANSFECTIONS

Handi move
INTERNATIONAL

Qity

Synergia
Medical

COMATE
Engineering & Design

Limitrix

ZAPARAY®

Qity

Mission

To help organizations develop medical devices and achieve the right level of regulatory compliance, at each stage of product development

RESEARCH

Meeting notes
Planning
User Needs
…

EARLY-STAGE

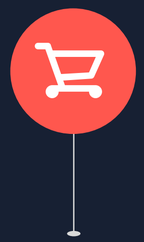
Document Control
Version Control
Requirements Mgmt
…

DEVELOPMENT

Design Control
Test Management
Risk Management
Usability Engineering
Cybersecurity
…

MANUFACTURING

Change Management
Process Control
CAPA
…



COMMERCIAL

Post-Market Surveillance
Complaint Handling
…

Services

Quality Assurance

Audits, GAP analysis, ISO-13485 QMS, SOPs and templates, Technical File reviews

Cybersecurity

Embed cybersecurity into your product development lifecycle, in compliance with MDCG 2019-16 and ISO-2700x

Regulatory Affairs

Device classification, identification of applicable standards and determination of regulatory strategy.

Data Privacy

HIPAA and GDPR compliance

Software Development

Medical-grade embedded software, mobile apps and data management solutions.

Usability Engineering

From ideation, all the way to summative evaluation, in compliance with IEC-62366

Quality Assurance
Regulatory Affairs

Quality Assurance & Regulatory Affairs

Gap Analysis and Assessment

Comprehensive review of your current Quality Management System to identify gaps and deficiencies that need to be addressed to meet the requirements of Quality standards.

Quality Management System Implementation

Development and implementation of a Quality Management System in compliance with ISO 13485 and/or ISO 9001, that grows with your organization.

Quality Assurance & Regulatory Affairs

Supplier and Internal Auditing

Internal and supplier audits to ensure that the Quality Management System operates effectively and efficiently.

Regulatory Strategy and Planning

Development of a regulatory strategy that aligns with your business objectives and goals. Identification of applicable regulatory requirements, device classification and development of a roadmap to ensure compliance.

Quality Assurance & Regulatory Affairs

Risk Management

Hazard analysis, design FMEA, process FMEA, software, cybersecurity and use-related risk analysis in compliance with ISO 14971 and applicable product standards.


Safety Testing

Compliance and Safety Testing

EMC

Radiated emissions and immunity, conducted emissions and immunity testing

ESD

Contact discharge and air discharge testing

RF

RED/FCC testing, Bluetooth qualification, coexistence and interference testing

Compliance and Safety Testing

Electrical Safety

Insulation resistance, earth continuity, leakage current, and dielectric strength testing

Mechanical Safety

Drop testing, impact testing, vibration testing, and transport testing

Laser Safety

Laser classification and laser product safety testing in compliance with IEC 60825

Compliance and Safety Testing

Environmental

Temperature and humidity testing, thermal shock testing, ingress protection (IP rating) and salt spray testing

Labeling & Marking

Design and prototyping of labels and product marking in compliance with applicable standards

Software Development

Software Development

IEC 62304 Compliant Software Development Lifecycle

State-of-the-art Continuous Integration Pipelines with automation of

- Software unit tests, integration tests, user interface tests and system tests
- Hardware tests and hardware/software integration tests
- Documentation generation
- Static code analysis
- Traceability and code coverage analysis

Software Development

System Architecture

Creation of the System Architecture Description, selection of technology, creation of context diagrams, block diagrams, and interfaces between subsystems.

Software Architecture

Creation of the Software Architecture Description(s) for embedded and PC software, mobile apps, and cloud computing and web applications. Risk reduction by segregation into software units, specification of interfaces, memory size and battery life estimation.

Software Development

Design Inputs

Identification and prioritization of stakeholder needs and design requirements in pragmatic workshops.

Software Classification and Risk Analysis

IEC 62304 and FDA classification of the software system and units. Software design FMEA.

Roadmapping

Creation of a realistic product roadmap and budget, taking into account the impact on manufacturing, logistics, clinical and regulatory.

Software Development

Firmware

Medical-grade embedded software (low-power, Bluetooth, sensors, user interfaces)

Backend

Secure and reliable data management solutions, GDPR and HIPAA compliant

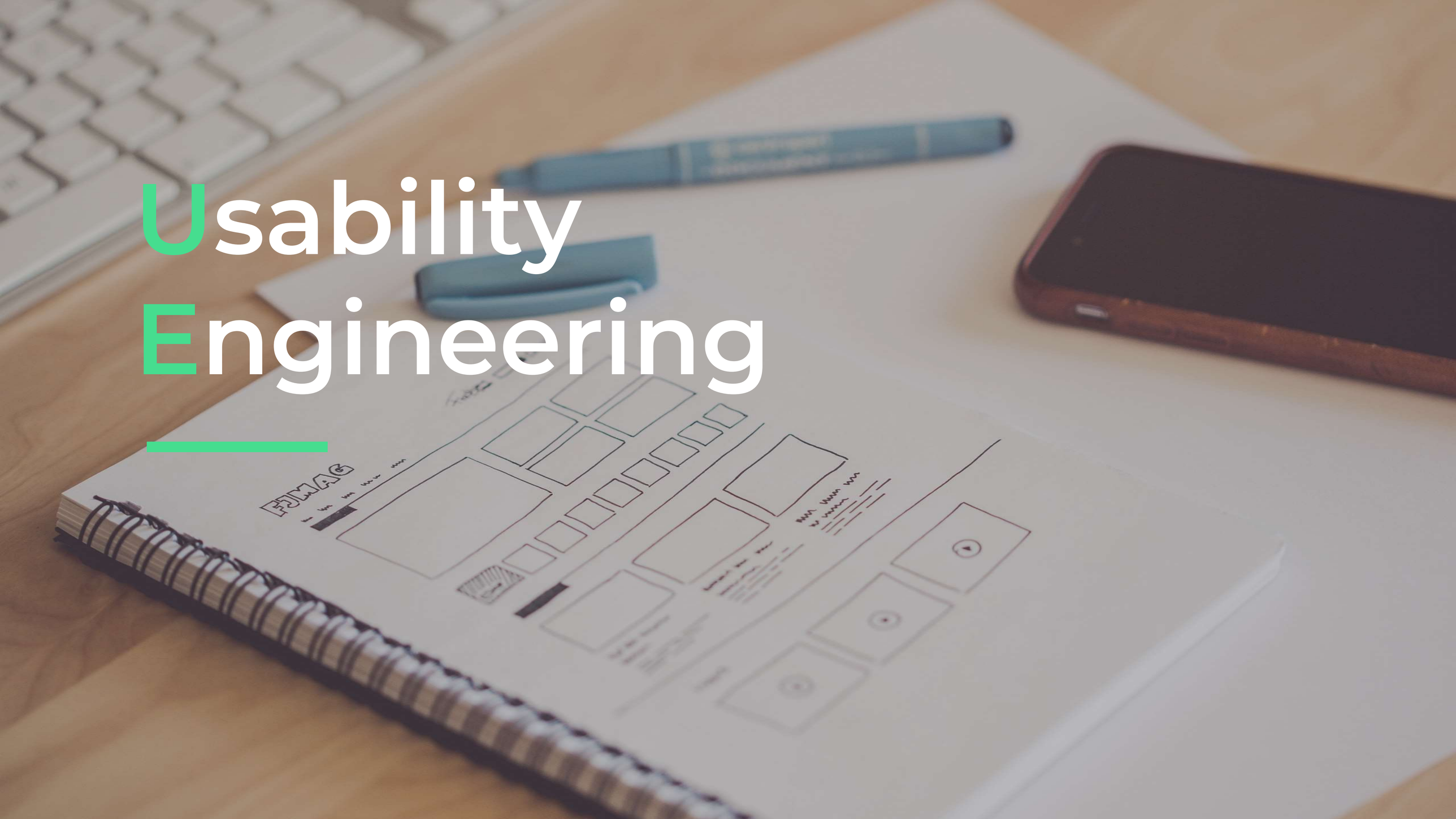
Mobile Apps

Medical iOS, iPadOS and Android mobile apps, Bluetooth connectivity

Web Portals

Healthcare portals and analytics dashboards

Usability Engineering



Usability Engineering

Compliance assessment

Compliance assessment to ensure processes, Technical File, Usability Engineering File and plans meet the requirements of IEC-62366-1, MHRA and FDA guidelines.

Usability Engineering Process

Establish a usability engineering process, workflow and tools, in compliance with IEC-62366-1, MHRA and FDA guidelines.

User Research

Identification of stakeholders, stakeholder needs, impairments, and use environment.

Usability Engineering

User Interface Design & Development

User experience design, prototyping, pixel-perfect user interface design, and software implementation.

Use-Related Risk Analysis

Identification of hazard-related use scenarios, task and function analysis, PCA-analysis (Perception, Cognition, Action) and risk mitigation strategies.

Usability Engineering

Expert Review

Expert reviews are an easy way of performing formative usability evaluation. Qity's usability experts will easily spot common user interface flaws.

User Interface Evaluation

Creation of Usability Evaluation Plan, Usability Test Protocols, and execution of Usability Tests.

CyberSecurity

Cybersecurity & Data Privacy

Security Compliance Assessment & Roadmap

Comprehensive evaluation of your organization's adherence to security regulations, best practices, and standards, accompanied by a strategic roadmap for improvement and ongoing compliance (such as ISO 27k, CFR Part 820 and 11, OWASP, NIST, CSF, and others).

Technical Security Assessment & Roadmap

Thorough review of your technical security infrastructure and product, identifying vulnerabilities and providing a detailed plan to enhance your security posture.

Cybersecurity & Data Privacy

Security Architecture & Design

Expert assistance in the design and implementation of robust security architecture, ensuring optimal protection of your product, organization's data, and IT systems.

Data Privacy Impact Assessment

Overhead analysis of your data processing activities to identify and minimize the privacy risks, helping you comply with data protection regulations such as ISO 27701, GDPR, and HIPAA.

Cybersecurity & Data Privacy

Risk Management & Threat Intelligence

Up-to-date information and insights on emerging cybersecurity threats and risks, enabling your organization to proactively defend against potential attacks and strengthening the resilience of your product to security threats.

Information Security Operations

Expert guidance to structure and operate your information security organization effectively, aligning with best practices and regulatory requirements.

Cybersecurity & Data Privacy

Agile Security

Specialized guidance to integrate cybersecurity controls seamlessly into agile development workflows, ensuring secure product delivery without compromising speed or flexibility.

CyberSecurity Awareness Sessions

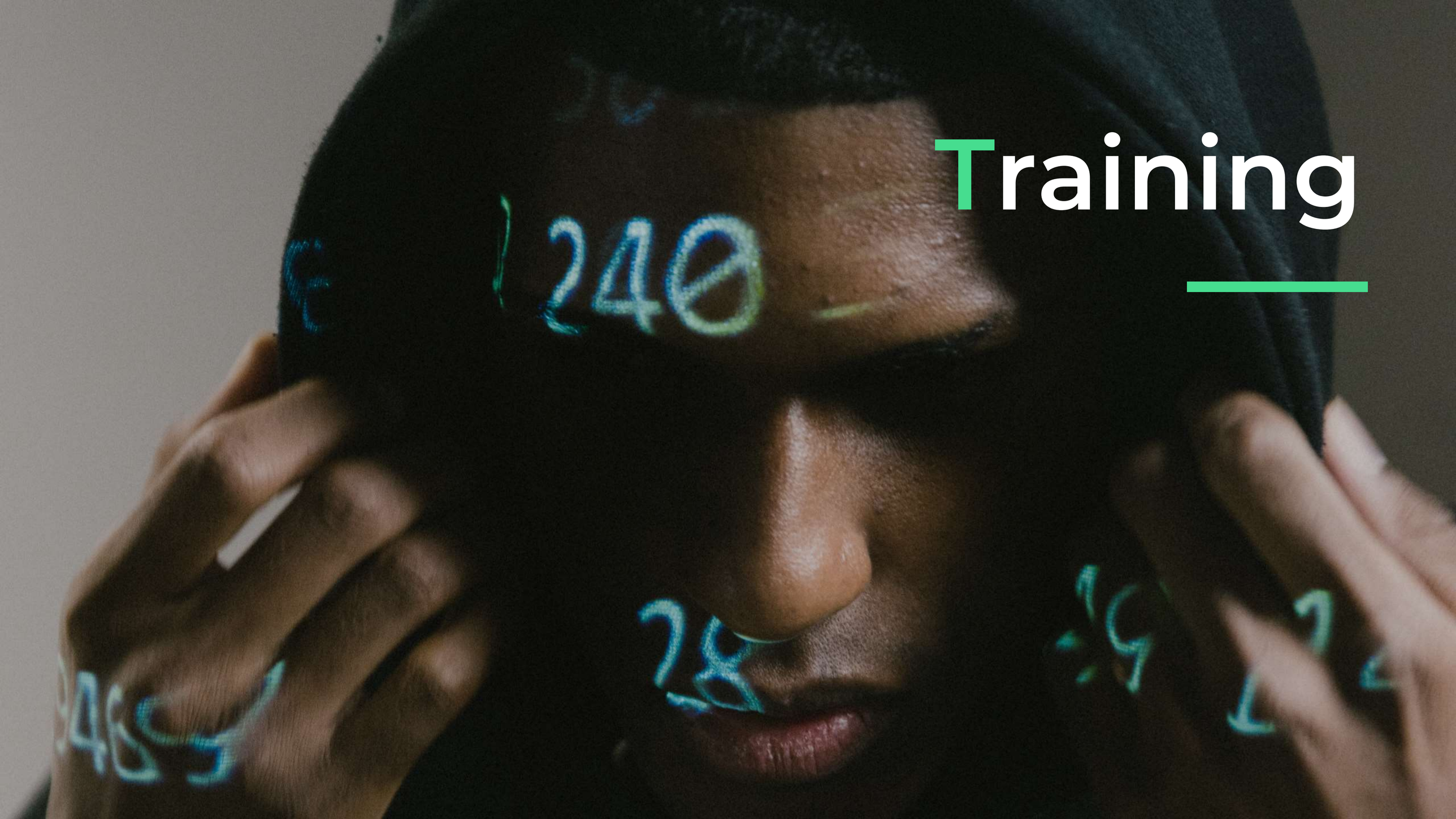
Interactive training sessions to increase your employees' awareness of cybersecurity threats and best practices, reducing the risk of human-induced security incidents, focused on the project’s specific scope. (Best when taken with the CyberSecurity & Data Privacy Training, as a package)


Digital
Transformation

Digital Transformation

Boost your efficiency using Atlassian's industry-leading collaboration platform, enriched with Qity's custom developed apps and ready-to-use templates.

Easily digitize any process in your organization, with unmatched traceability.



Training

Atlassian Software

Confluence

Learn how to organize, find and collaborate on documentation in Confluence.

Jira

Learn how to organize your work, automate processes and manage projects in Jira.

Confluence & Jira Administration

Learn how to configure, manage and maintain your Confluence and Jira instances

Medical Device Training

Introduction to Medical Device Development

Crash course in the development of medical devices

Quality Management Systems (ISO 13485)

Train your team on the fundamentals of a Quality Management System for medical and in-vitro devices.

Software Development (IEC 62304)

Learn how to establish a software development lifecycle for medical and in-vitro devices.

Medical Device Training

Introduction to Basic Safety & Essential Performance (IEC 60601/61010)

Learn how to demonstrate basic safety and essential performance for medical and laboratory equipment.

Basic Safety & Essential Performance (IEC 60601/61010) (Advanced)

Deep-dive into regulatory requirements and safety testing (Completion of Introduction to Basic Safety & Essential Performance (IEC 60601/61010) is a prerequisite)

Medical Device Training

Safety for Multimedia & IT Equipment (IEC 62368-1)

Learn how to demonstrate basic safety and essential performance for multimedia & IT equipment.

Usability Engineering (IEC 62366)

Learn how to establish a human-centric usability engineering process for the design and evaluation of medical and in-vitro device user interfaces.

Risk Management (ISO 14971)

Learn how to manage risks throughout the lifecycle of a medical or in-vitro device.

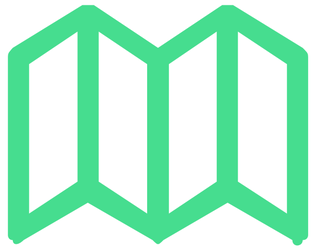
Medical Device Training

Cybersecurity & Data Privacy

Learn how to manage Cybersecurity risks for medical devices, and how to manage confidentiality, integrity and availability of your data.

Software Validation (ISO 80002)

Learn how to validate software in compliance with EU and FDA regulations and guidelines.



THANKS FOR WATCHING

See You Next Time

Qity