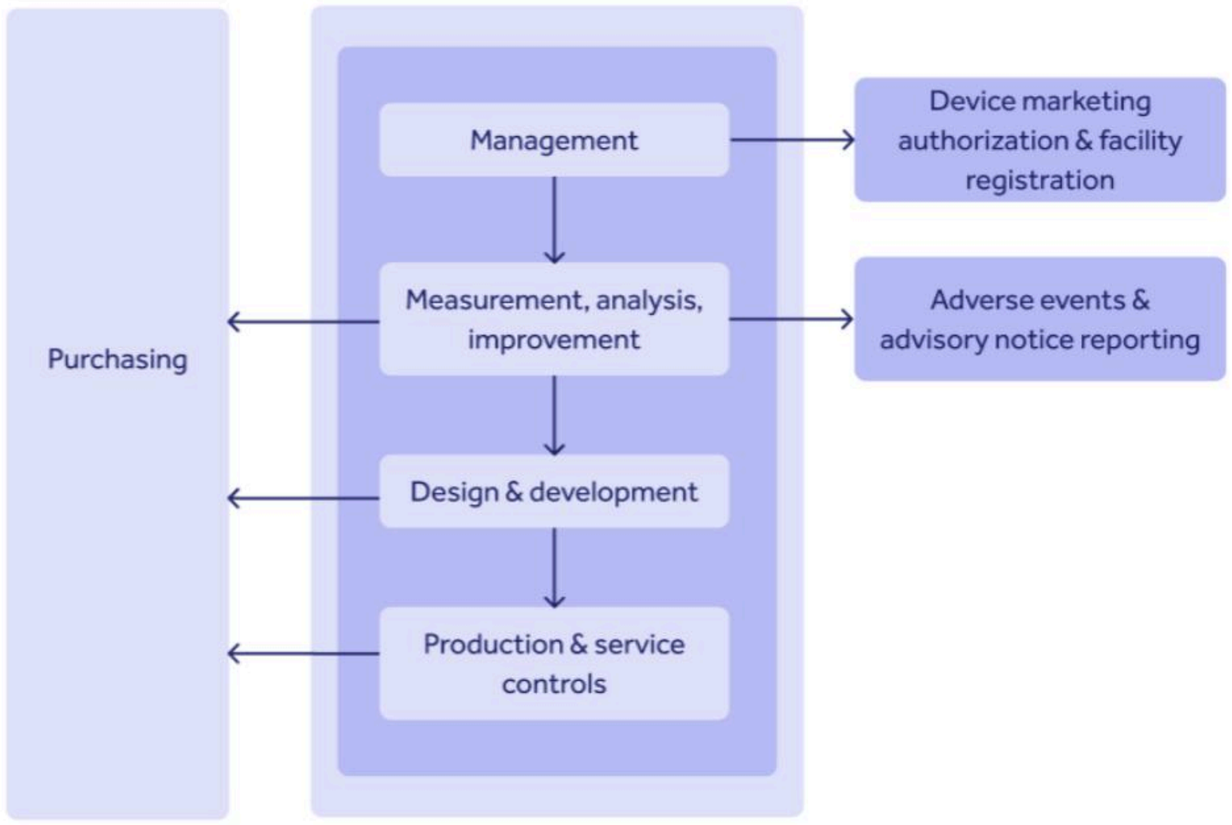
MDSAP audit checklist

Aiming to unlock 5 major global markets at once for your medical device with the Medical Device Single Audit Program (MDSAP)?

You'll need a complete, well-organized medical device quality management system, with defined processes for the 4 primary and 1 supporting areas of focus in an MDSAP audit.

Follow this MDSAP audit checklist to get everything in place.



Management	
☐	Quality manual
☐	Quality policy
☐	Management review
☐	Holistic medical device QMS
☐	Evidence of senior management commitment/input/support
☐	Document control
☐	Marketing/registration/clearances/approval processes for all relevant MDSAP territories
☐	Review of existing marketing clearances/approvals

Measurement, analysis & improvement

☐	Internal auditing
☐	QMS data analysis
☐	CAPA
☐	Non-conforming material
☐	Complaints
☐	Adverse events (detection/reporting)
☐	Post-market surveillance
☐	CAPA records

Design & development

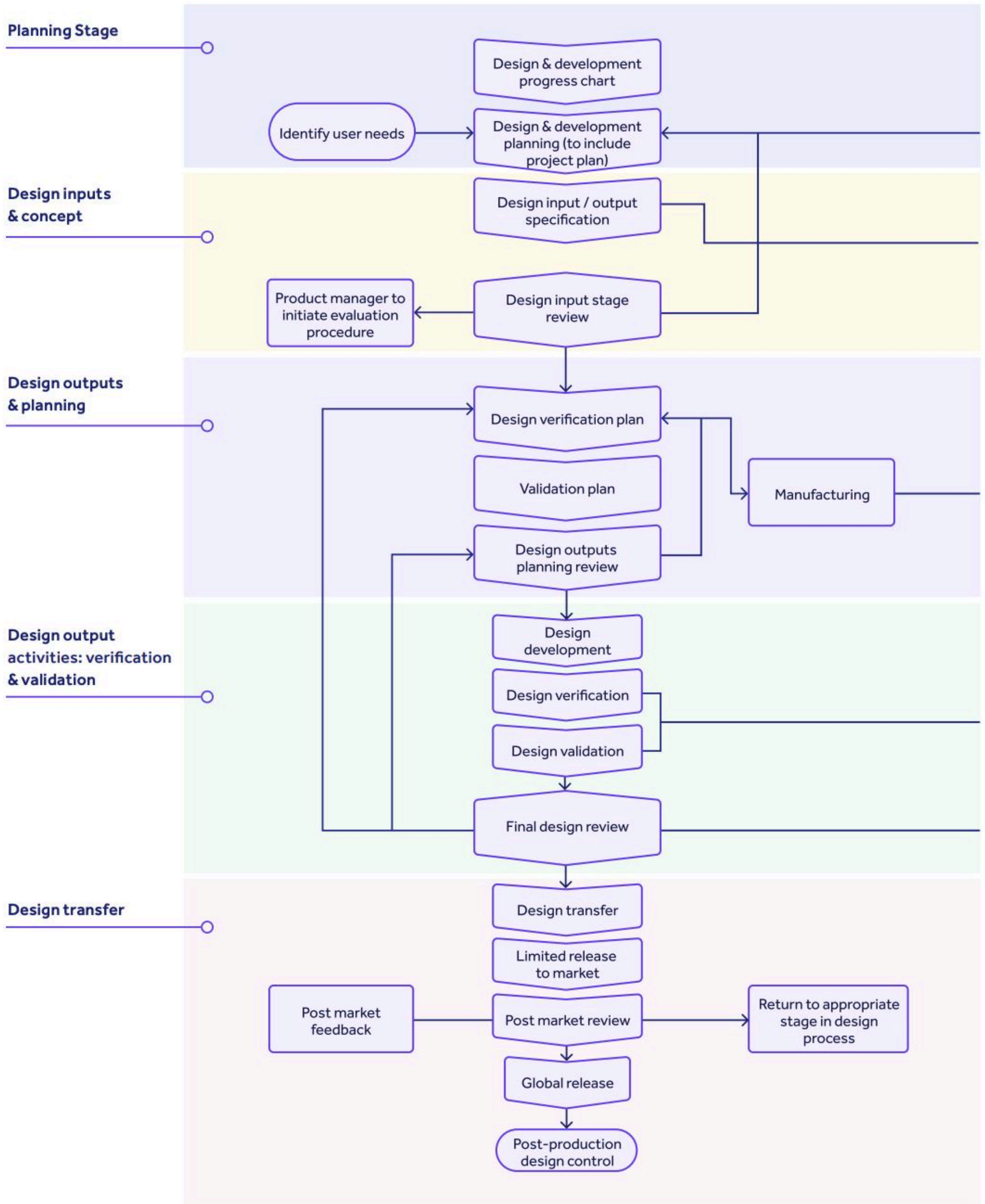
☐	End-to-end design process with defined inputs and outputs
☐	Verification & validation
☐	Change control
☐	Design review
☐	Design transfer
☐	Software design & development (if applicable)
☐	Validation/clinical data
☐	Documented risk management processes (connected to V&V activity)
☐	Defined design & development scope

Production & service controls

☐	Medical Device File (MDF)
☐	Process validations/change control
☐	Product realization
☐	Risk management
☐	Control of defects & rework
☐	Identification & traceability
☐	Installation & servicing (with risk management throughout)
☐	Sterilization
☐	Incoming inspection/verification
☐	Batch records & control
☐	Control/rework of non-conforming product
☐	Use of customer property
☐	Preservation of product

Purchasing	
☐	Purchasing/outsourcing processes
☐	Supplier selection/evaluation
☐	Supplier monitoring/auditing
☐	Supplier data evaluation
☐	Risk evaluation
☐	Verification/traceability of purchased product (with records)
☐	Potential auditing of your critical suppliers as part of your own audit

Medical device design and development pathway

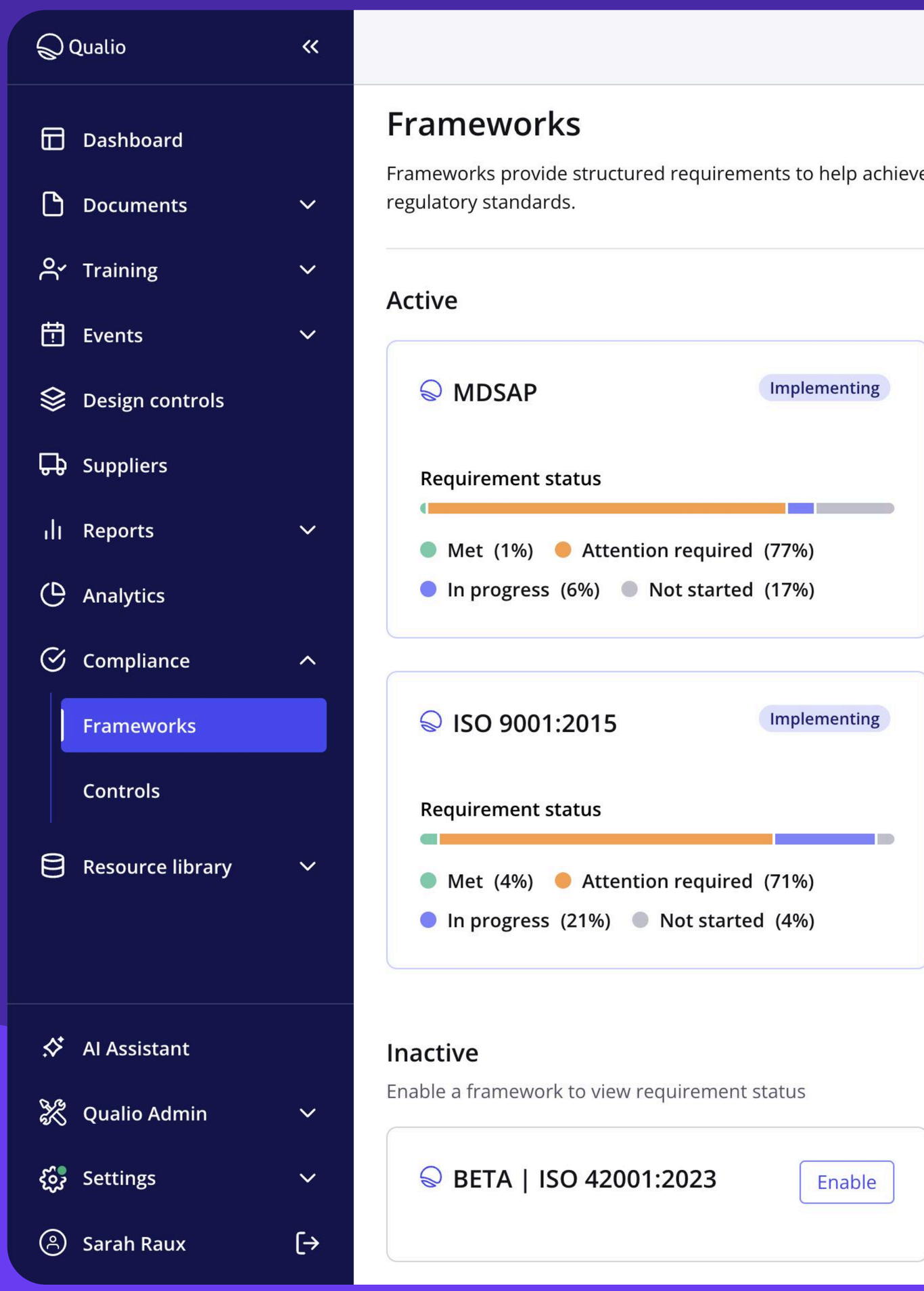


Qualio

Master the MDSAP

Our quality and compliance management software gives you everything you need for MDSAP success — from document control and training, to AI-powered gap analysis for 100% audit readiness.

Book your demo



Call us today
1.855.203.2010 • +353 1 697 1522