Welcome to the webinar

Everything you need to know about the FDA QMSR

With Sumatha Kondabolu & Yuan Li

dqs Qualio

Today’s hosts

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Today’s agenda

01 What the QMSR means for your business

02 Using ISO 13485 to bridge the gap

03 A new way to meet QMSR requirements

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What the QMSR means for your business

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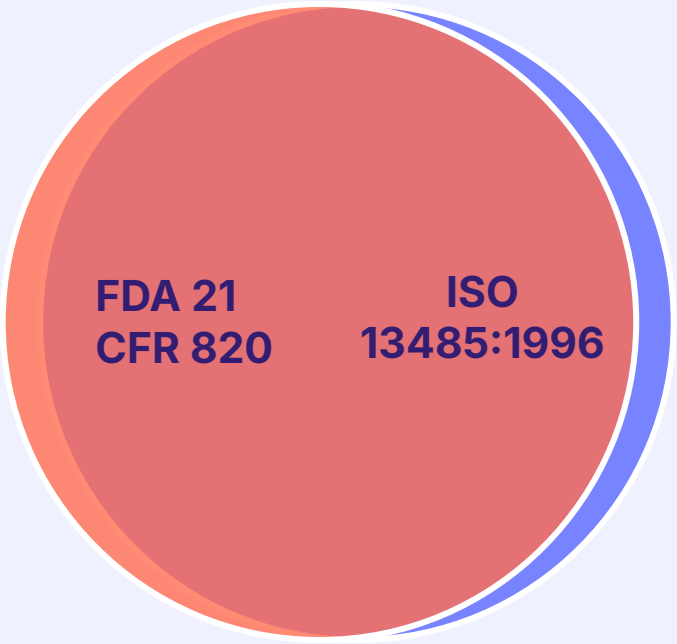
Why is the QMSR coming into being?



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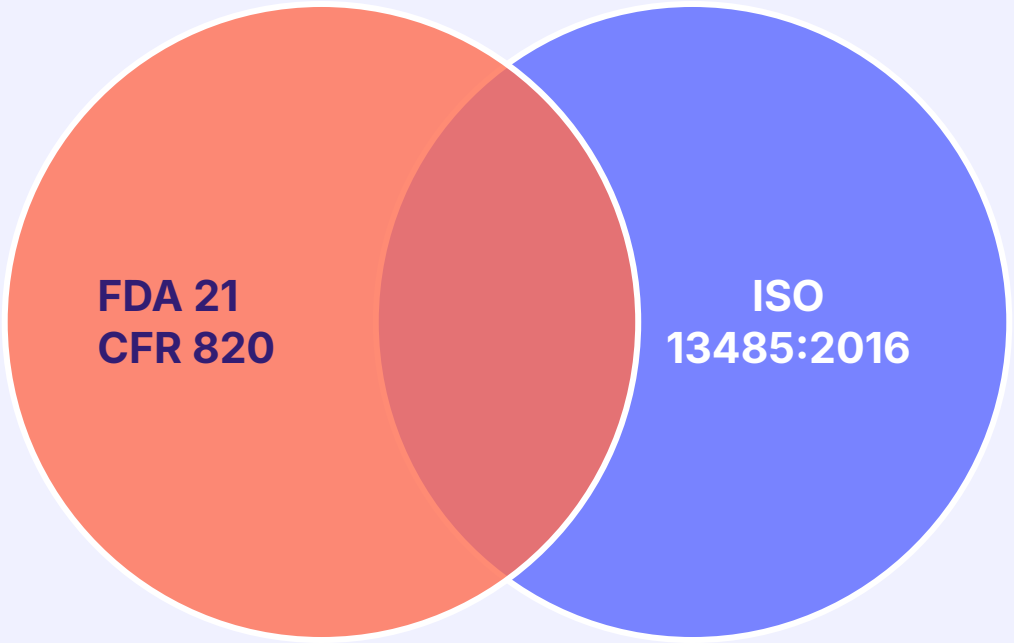

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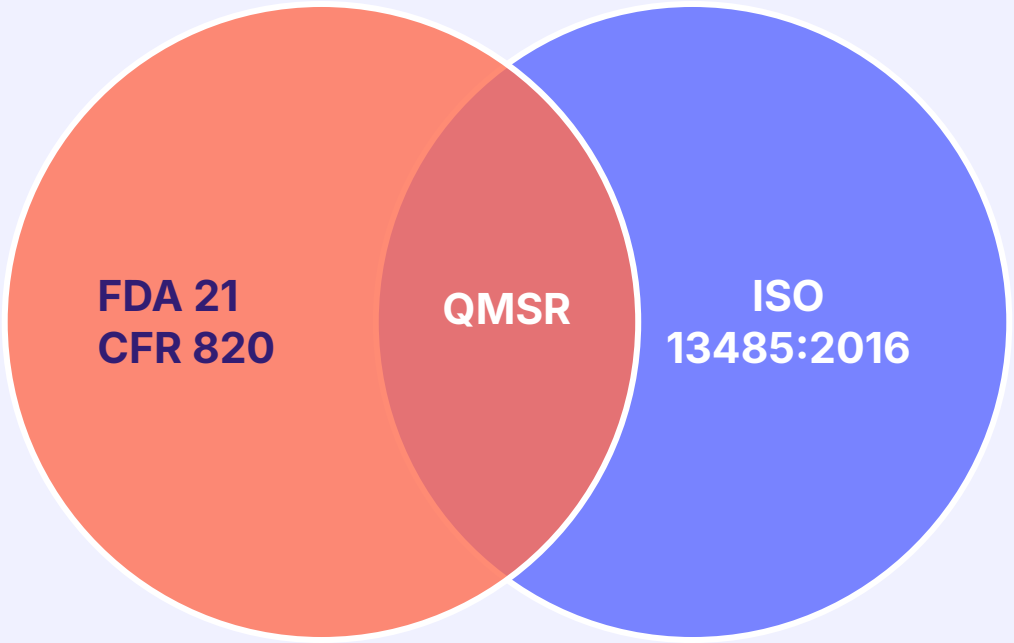

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The benefits

- US device expectations aligned with latest best practice
- Simplify international expansion of US medical device companies by aligning them with ISO
- Simplify expansion into US of foreign medical device companies by closing the gap between FDA & foreign standards
- A standardized, more global device regulatory model

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What’s changing?

✅ Mainly terminology (phew!): the FDA has been keen to point out that Part 820 and ISO 13485 are still ‘substantially similar’.

The QMSR is about bridging multiple small gaps and simplifying international regulatory compliance activity!

✅ Some process and documentation expectations

✅ FDA QSIT inspection process (specific changes TBC, but management review and internal/supplier audits no longer exempt from inspection)

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The contents

Subpart A: General Provisions

820.1	Scope
820.3	Definitions
820.5	*Reserved from QSR*
820.7	Incorporation by reference
820.10	Requirements for a QMS ***Links additional FDA requirements such as MDR, UDI, Corrections & Removals, and Tracking; applicability of Design and Development activities***

Subpart B: Supplement Provisions

820.20-30	*Reserved from QSR*
820.35	Control of records ***Supplements record keeping activities, complaint/servicing records, UDI, and confidentiality***
820.40	*Reserved from QSR*
820.45	Device labeling & packaging

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Your QMSR cheat sheet

QS Regulation	ISO 13485:2016	QMSR Final Rule
Subpart A- General Provisions	Clause 1. Scope Clause 4. Quality Management System	Requirements substantively similar
Subpart B- QS Requirements	Clause 4. Quality Management System Clause 5. Management Responsibility Clause 6. Resource Management Clause 8. Measurement, Analysis, & Improvement	
Subpart C- Design Controls	Clause 7. Product Realization	
Subpart D- Document Controls	**Clause 4. Quality Management System**	**Differences addressed in 820.35**
Subpart E- Purchasing Controls	Clause 7. Product Realization	Requirements substantively similar
Subpart F- Identification and Traceability	Clause 7. Product Realization	
Subpart G- PP&C	Clause 4. Quality Management System Clause 6. Resource Management Clause 7. Product Realization	
Subpart H- Acceptance Activities	Clause 7. Product Realization Clause 8. Measurement, Analysis, & Improvement	
Subpart I- Nonconforming Product	Clause 8. Measurement, Analysis, & Improvement	
Subpart J- CAPA	Clause 8. Measurement, Analysis, & Improvement	
Subpart K- Labeling and Packaging Control	**Clause 7. Product Realization**	**Differences addressed in 820.45**
Subpart L- Handling, Storage, Distribution, and Installation	Clause 7. Product Realization	Requirements substantively similar
Subpart M- Records	**Clause 4. Quality Management System**	**Differences addressed in 820.35**
Subpart N- Servicing	**Clause 7. Product Realization**	
Subpart O- Statistical Techniques	Clause 7. Product Realization Clause 8. Measurement, Analysis, & Improvement	Requirements substantively similar

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New sections

- Section 820.7 - Incorporation by reference
- Section 820.10 - QMS requirements
- Section 820.35 - Control of records
- Section 820.45 - Device labeling & packaging controls

Scope

- Largely identical to current Part 820, but with some additions
- Components and parts of finished devices/blood components not included: actors for all other types of device, from manufacturers to sterilizers and repackers, now need to meet QMSR requirements
- Asserts that FDA regulations have priority in case of conflict with ISO 13485 (more on next slide!)

Incorporation ‘by reference’

- The QMSR will incorporate ISO 13485:2016 into the current QSR ‘by reference’: new requirements integrated by referencing their location within the ISO 13485 standard
- Some ISO terminology adopted, some superseded by existing FDA terminology
- New requirements added in key areas where ISO 13485 doesn’t go far enough for the FDA

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Definitions

- Harmonizes with ISO 9000's Clause 3 definitions in most cases
- **KEY CHANGE** 🔑 Device Master Record (DMR), Design History File (DHF), Device History Record (DHR) ➡️ Medical Device File (MDF)
    - Old DMR requirements replaced with ISO 13485 Clause 4.2.3
    - Old DHF requirements replaced with ISO 13485 Clause 7.3
    - Old DHR requirements replaced with ISO 13485 Clause 7.5.1
- Broader definition of risk, which incorporates regulatory compliance risk, borrowed from ISO 14971
- FDA definitions of 'device', 'labeling' and 'manufacturing' remain and override ISO definitions

QMS requirements

- Blends ISO 13485 references with additional, pre-existing FDA requirements as follows:
- **ISO 13485 Clause 7.5.8 ➕ 21 CFR Part 830 🟰identification & UDI requirements**
- **ISO 13485 Clause 7.5.9 ➕ 21 CFR Part 821 🟰traceability & tracking requirements**
- **ISO 13485 Clause 8.2.3 ➕ 21 CFR Part 803 🟰reporting requirements**
- **ISO 13485 Clauses 7.2.3 / 8.2.3 / 8.3.3 ➕ 21 CFR Part 806 🟰advisory notice requirements**

- Replaces Part 820.30 design control requirements with ISO 13485 Clause 7.3 design & development requirements
- Quality manual now required

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Control of records

- Record approval processes replaced by ISO 13485 requirements, but the QMSR also goes further to mandate date/signature on approvals (Part 11 remains applicable if you do this digitally)
- CAPA requirements replaced by ISO 13485 requirements
- Specific focus on complaint records:
    - Need to include associated CAPA records
    - Mandates investigation of complaints involving device/packaging/labeling failure
    - Mandates centralized complaint procedures and coordinating unit to ensure complaint handling is standardized across your organization
- Outlines previous slide's additional UDI requirements that go beyond ISO
- ***You must meet 820.35 requirements as well as Clause 4.2.5 requirements***

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Device labeling & packaging controls

- Goes beyond ISO 13485 with extra requirements for packaging, labeling and labeling inspection
- Mandates manual label checks of label samples before release: pure automation not accepted
- ***You must meet 820.45 requirements as well as Clause 7.5.1(e) requirements***

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Using ISO 13485 to bridge the gap

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Alignment with the FDA’s revised QMSR

- Per the Final Rule, ISO 13485:2016 will essentially become the backbone of the FDA’s quality system expectations
- Much stronger position to comply with the FDA’s updated requirements when the QMSR takes effect ***if*** you’re already certified for ISO 13485

ISO 13485-certified

Low impact

✅ Document updates

✅ Process tweaks

✅ Some additional FDA-specific requirements & definitions

Not certified

Higher impact

✅ Considerable document & process revamp

✅ Stronger emphasis on risk management needs to be embedded

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But...

❌ *ISO 13485 certification ≠ FDA compliance*

Risk-based approach

- FDA will embrace the same philosophy of the ‘risk-based approach’ as ISO 13485 and ISO 14971
- This should lead to better design controls, documentation and post-market surveillance activities

Streamlined compliance

ISO 13485 certification demonstrates a proven, third-party-audited QMS, which can:

- **Build credibility with FDA inspectors**
- **Help reduce inspection frequency under the FDA's Inspectional Authority discretion**
- **Ease submission of your regulatory filings (510(k), PMA) by showing robust design and manufacturing controls already in place**

Cutting costs

One of the goals of the Final Rule? Cost saving! 💰

- **Elimination of redundant quality systems: less duplication, internal auditing cost and training**
- **Streamlined audits & regulatory inspections**
- **Potential savings through fewer late-stage design changes, production NCs, field corrections or recalls, with risk-based thinking and design controls**
- **Efficient supplier and purchasing controls**

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Global readiness

- ISO 13485 acts as a common quality language across jurisdictions (EU MDR, MDSAP, etc.)
- It bridges FDA and international requirements, reducing redundant work and enabling smoother audits
- ISO 13485 is a key entry point into MDSAP; QMSR alignment should make your MDSAP work simpler

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Other benefits

- Stronger credibility with regulators, partners and investors
- Easier due diligence in partnerships
- Faster onboarding by OEMs
- More favorable regulatory perception (even if not a formal substitute for FDA inspections!)

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ibr.ansi.org/
standards/iso2.aspx

A new way to meet QMSR requirements

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The rising complexity of life science compliance

53% of life sciences leaders cite regulation as their #1 external risk

Over 45,000 life sciences firms in the U.S. — expertise is limited

Compliance programs are expensive, audit prep takes months; findings are expected

66% exploring generative AI, but adoption is early and unstructured

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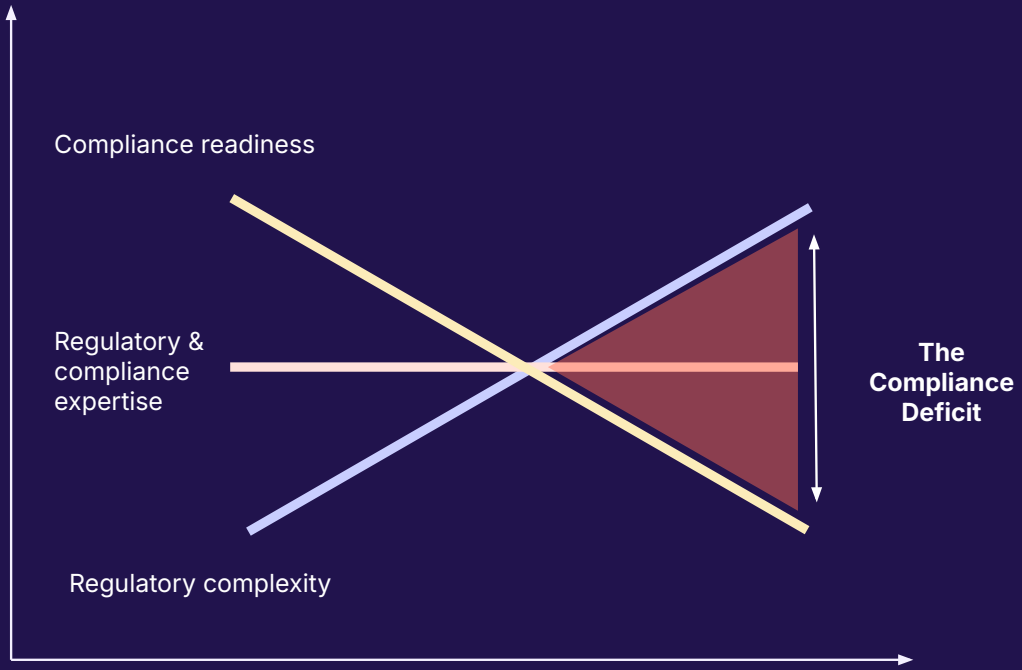
Current approaches: fragmented and reactive

Approach	Strengths	Limitations
Manual (spreadsheets, shared drive)	Flexible, low-cost	Labor-intensive, error-prone, hard to scale
eQMS	Familiar systems	Not built with compliance frameworks or for audit readiness
Public AI tools	Fast, accessible	Lacks security, traceability, consistency, compliance
InfoSec tools (e.g. Drata)	Specialized for cybersecurity	Not designed for life sciences, limited coverage

The rising complexity of life science compliance



And that gap brings real risk

- Regulatory findings
- Market delays
- Increased cost of compliance

Compliance Readiness: The ability of teams to identify, interpret, and act on regulatory requirements.

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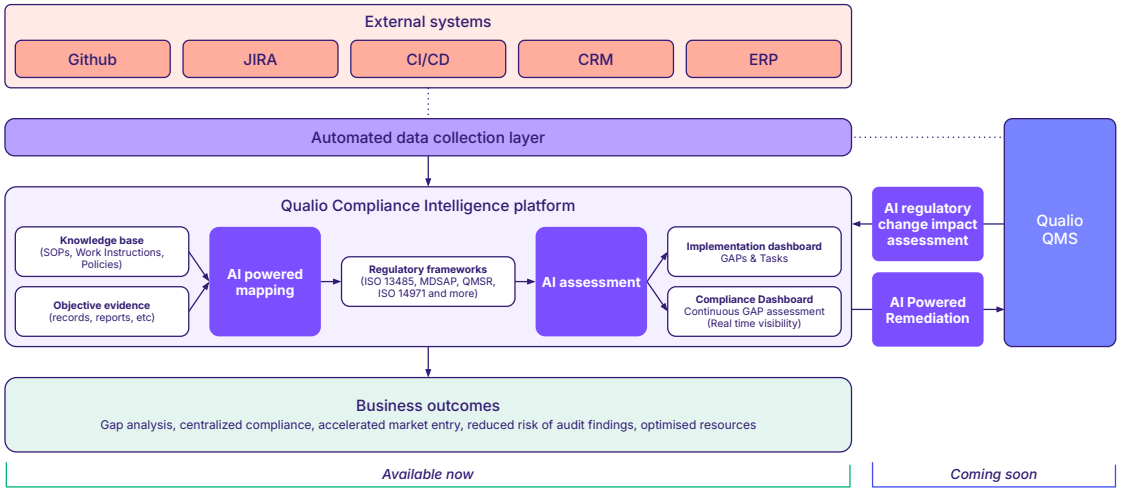
Bringing the power of AI to life sciences—securely

- Scale regulatory expertise across your organization — not just within your SMEs
- Unlock deep regulatory knowledge already present in AI
- Automate compliance with the QMSR, ISO 13485 and more — without sacrificing control or trust
- Replace siloed tools and point-in-time audits with real-time visibility
- Build confidence across teams, regulators and leadership



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Quality Management

Compliance Intelligence

- *User management*
- *Analytics*
- *Auto validation*
- *Audit trails*
- *Integrations*
- *Dashboards*

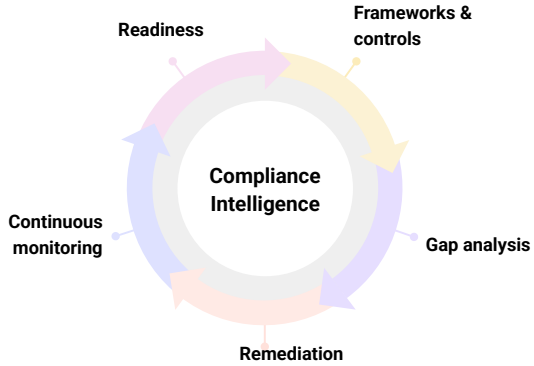
A new approach: built for life science compliance

🏥 **Pre-built, validated frameworks and controls**
Tailored for life science companies

↔️ **One-click AI-powered gap analysis**
With secure, traceable, and human-in-the-loop AI

🔄 **Closed-loop remediation**
To track and resolve gaps efficiently

🕐 **Real-time, continuous compliance**
That's integrated, visible, and always audit-ready



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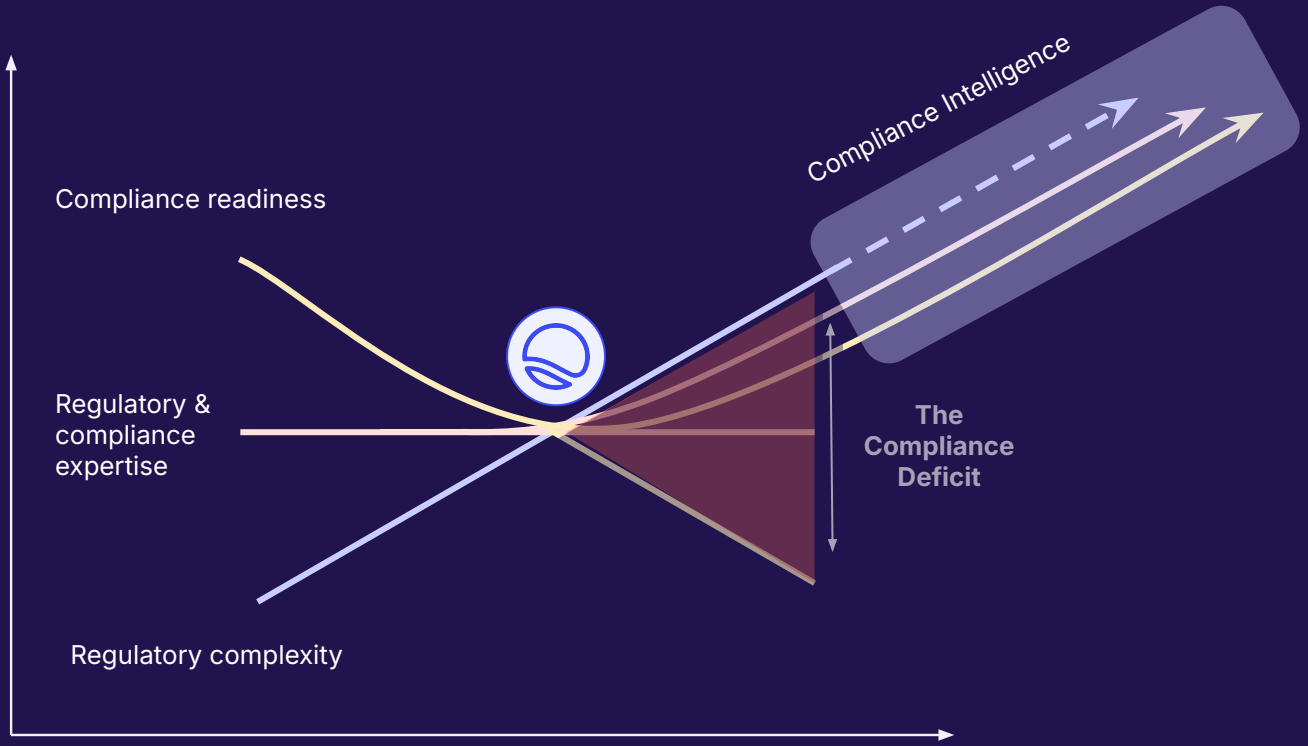
Demo...

Closing the compliance deficit



Compliance readiness: The ability of teams to identify, interpret, and act on regulatory requirements

Compliance Intelligence

Closing the gap!

- Reduced risk of compliance issues
- Increased speed to market
- Reduced cost of compliance

*"It takes a quality person weeks to perform an analysis on our compliance gaps & evaluate work and feasibility to enter a new market. With Compliance Intelligence **I can do it in hours**. That impacts productivity & speed to decision."*

— Quality & regulatory leader, SaMD company

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Thank you!