



**REGULATORY AS A
REVENUE-DRIVING
COMPETITIVE
WEAPON AND FUTURE
PROOFING QUALITY,
REGULATORY, AND
CLINICAL (QRC)**

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Agenda

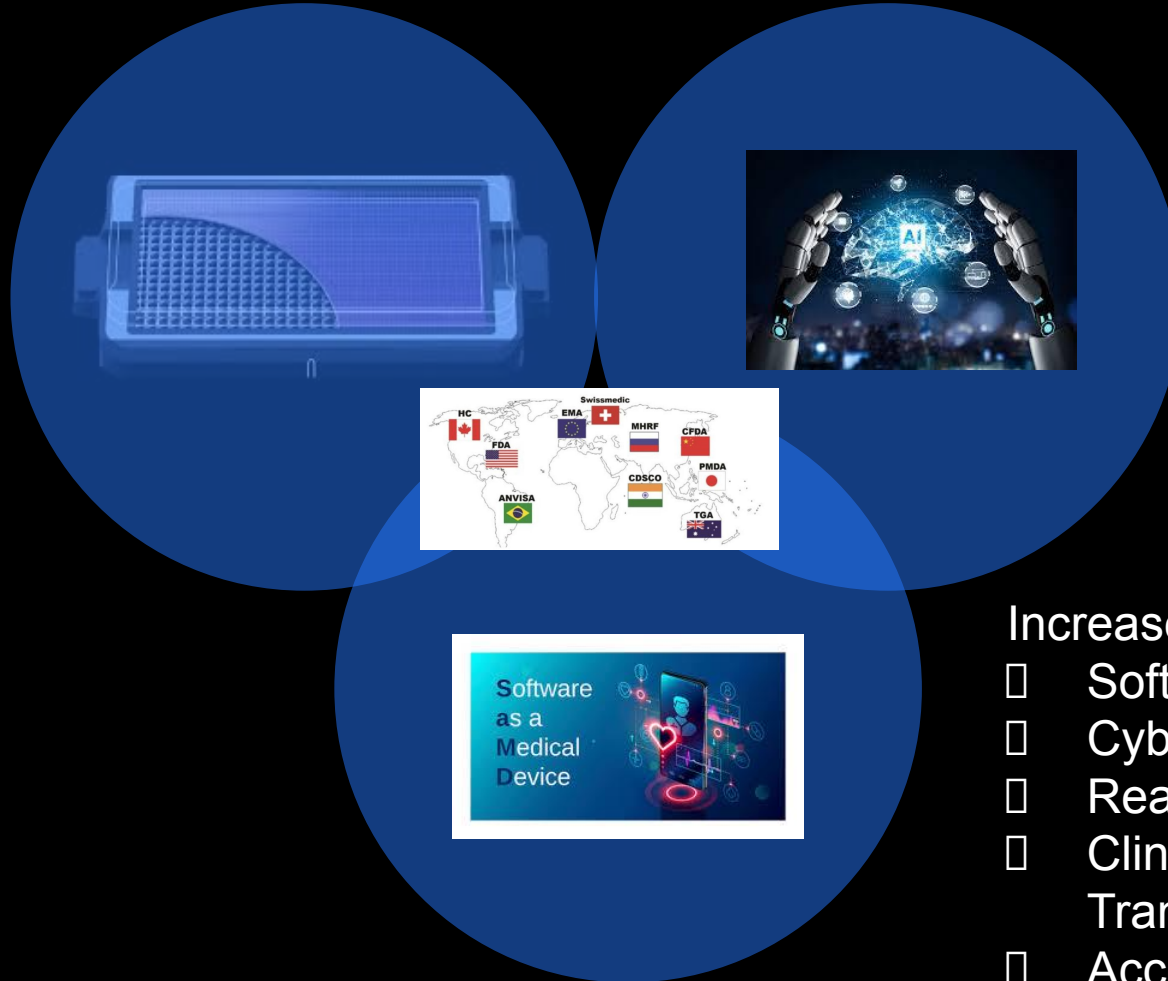
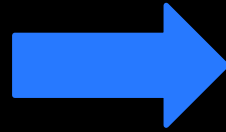
1. Business Context
2. What's at Stake?
3. Role and Importance of Quality, Regulatory, and Clinical Affairs (QRC)
4. Regulatory TPLC Framework
5. Proposed Framework for Mitigating Risks Through Design Thinking
6. Holistic Regulatory Ecosystem
7. Q & A

Why, yes! I **do** have time to listen to you complain about rules I didn't make!



Business Context

Industry is at the convergence of medical hardware, AI/ML/Cloud, and Software as a Medical Device (SaMD), and we operated in a multi-jurisdictional, highly-regulated environment.



- Increased scrutiny on:
- Software
 - Cybersecurity
 - Real World Evidence
 - Clinical Validation & Transparency
 - Accelerated innovation timelines



What's at Stake?

Regulatory Landscape Shifts

- Constantly changing regulatory frameworks/regulations (e.g. EU MDR, FDA's Digital Health policies, AI/ML expectations, regional data laws) can render current clearances/approvals invalid, require a new submission, or impose stricter post-market oversight.

Quality System Breakdown

- Breakdowns in CAPAs, complaint handling, supplier management, or device lifecycle controls can result in recalls, warning letters, product holds, etc.

Clinical Evidence (Real World Evidence) & Labeling Risk

- Claims not supported with valid scientific evidence or they fail to meet post-market surveillance expectations, can lead to market withdrawals, lawsuits, or rejection of a new indication.

Cybersecurity

- Connected devices and applications require rigorous cybersecurity and privacy controls. Inadequate controls trigger enforcement and reputational damage.

Risk Area	Potential Impact	What's at Stake?
Regulatory Delays	<ul style="list-style-type: none"> • Market access loss • Delayed revenue 	<ul style="list-style-type: none"> • Time-to-market • Global expansion
QMS Breakdown	<ul style="list-style-type: none"> • Warning Letters • Recalls 	<ul style="list-style-type: none"> • Brand trust • Cost of remediation
Unsupported Claims	<ul style="list-style-type: none"> • Regulatory denials • Lawsuits 	<ul style="list-style-type: none"> • Commercial strategy disruption
Clinical Gaps	<ul style="list-style-type: none"> • Lack of payer/provider acceptance 	<ul style="list-style-type: none"> • Hit a revenue ceiling
Cybersecurity	<ul style="list-style-type: none"> • Data breaches • Stock dips 	<ul style="list-style-type: none"> • FDA scrutiny • Investor confidence



Role & Importance of QRC to Company Success and Future Growth

Quality Affairs

- ✓ **The protectors of brand integrity and business continuity** – preventing recalls, enforcement actions, and compliance risks that can halt sales, damage reputation, and erode investor confidence.
 - **Ensure consistent delivery of safe, effective, and quality products** by building and maintaining the QMS that governs design, manufacturing, PMS, and continuous improvement.
 - **Reduces the cost of poor quality** through proactive risk management, supplier oversight, and process controls – preserving revenue and brand reputation.
 - **Enables faster, compliant scaling** by embedding quality into the lifecycle, making new product launches, market expansions, and audits efficient and reliable.

Regulatory Affairs

- ✓ **The gatekeepers of market access and revenue** – Many products cannot be sold, reimbursed, or trusted without regulatory clearance/approval, ensuring safety and compliance.
 - **Unlock and sustain market access** by navigating global regulatory pathways, securing clearances/approvals, and maintaining compliance across jurisdictions.
 - **Accelerates innovation-to-market** through early strategy, regulatory intelligence, and creative pathways.
 - **Protect companies from enforcement risk** by staying ahead of evolving global regulations and enabling the business to adapt quickly.

Clinical Affairs

- ✓ **Strategic enablers of innovation and growth** – ensuring new technologies, software, and AI features are developed with foresight and evidence to scale globally, differentiate clinically, and win in competitive markets.
 - **Drives product credibility and adoption** by generating high-quality evidence that proves safety, efficacy, and clinical value.
 - **Enables differentiated claims and reimbursement** by supporting regulatory submissions and payer negotiations with RWE.

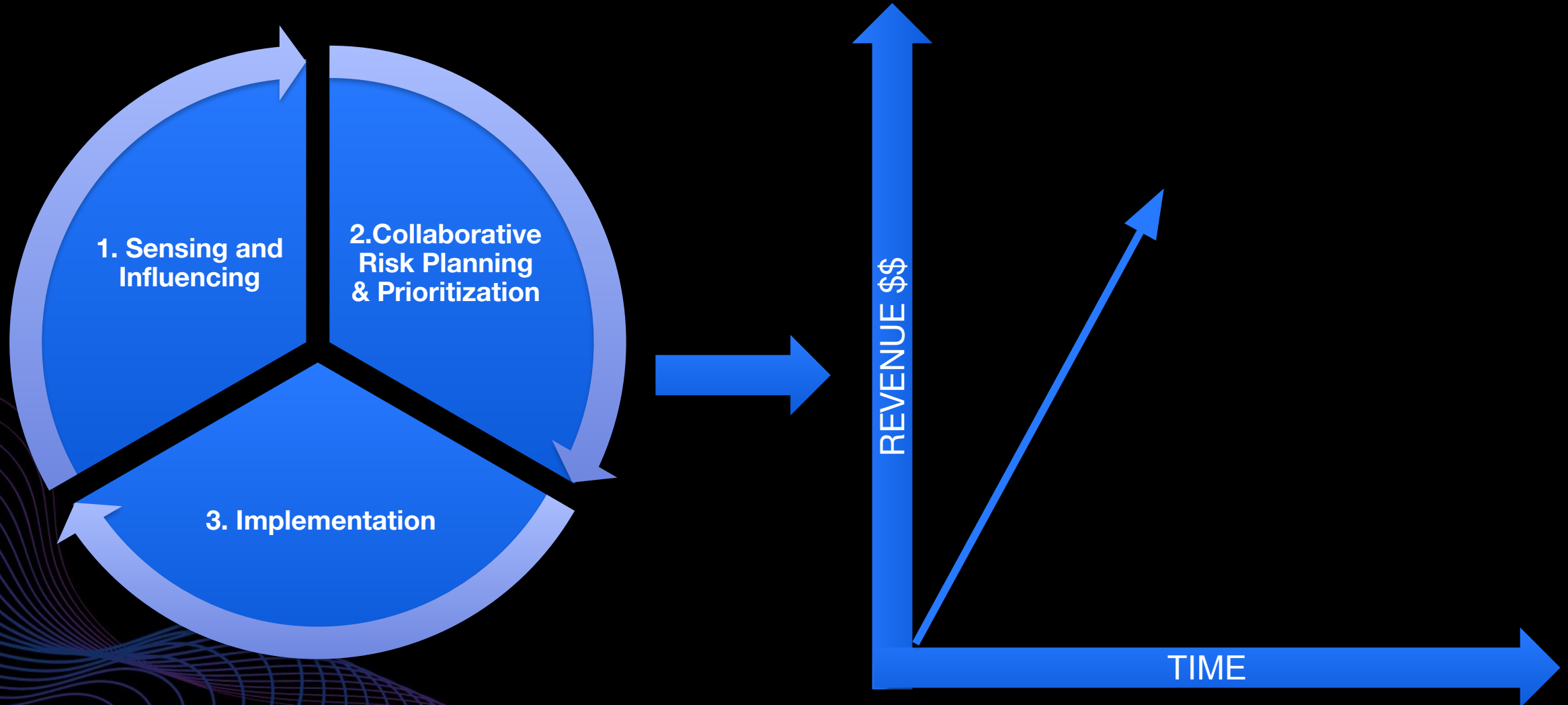




The decisions we make about our Regulatory Strategy can fuel company growth...or create unnecessary obstacles.



Regulatory TPLC Framework Stages



Sensing and Influencing



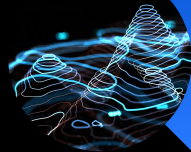
Increase Regulatory Awareness: Be proactive and participating in formulation of legislation and FDA guidance documents.



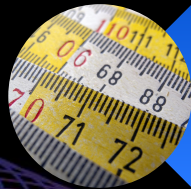
Create Global Regulatory Intelligence Team (GRIT): Leverage in-house and virtual resources.



Embrace New Technologies, Data, Analytics: Leverage RIMS and/or Regulatory data from public databases to drive action; share across the organization.



Influence for Effect: Dedicate resources to projects that impact growth & profitability; develop marketing/media content to shape public perception of company.



Measure Impact of Influence: Measure tangible/intangible outcomes, e.g. reduced cycle times, stock market increase due to new FDA clearances, cost savings or when channel-related sales rise.



Collaborative Risk Planning & Prioritization



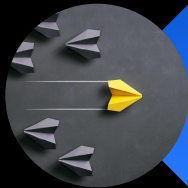
Have a single source of truth: Treat QMS as product infrastructure – architecture that enables innovation (e.g. embedded design controls, modular technical documentation).



Interpret and Prioritize: Study, learn about, and communicate shifting regulatory trends and their impact to the business and strategic plans.



Conduct Scenario Planning: Perform moderated workshops that look at “unknowns” to identify likely outcomes.



Effective Communication: To support strategic decision making.



Coordinated Implementation: Work with SMEs to develop appropriate regulatory change solutions.



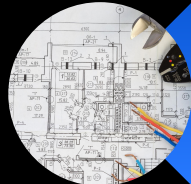
Implementation



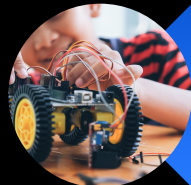
Form a Team: To understand new requirements, priorities, and timelines to effectively manage regulatory change.



Analyze: Look at the regulatory project portfolio in its entirety to drive efficiencies.



Design: A risk-based approach to regulatory compliance by mapping regulations to products and geographies, i.e. regulatory operating model.



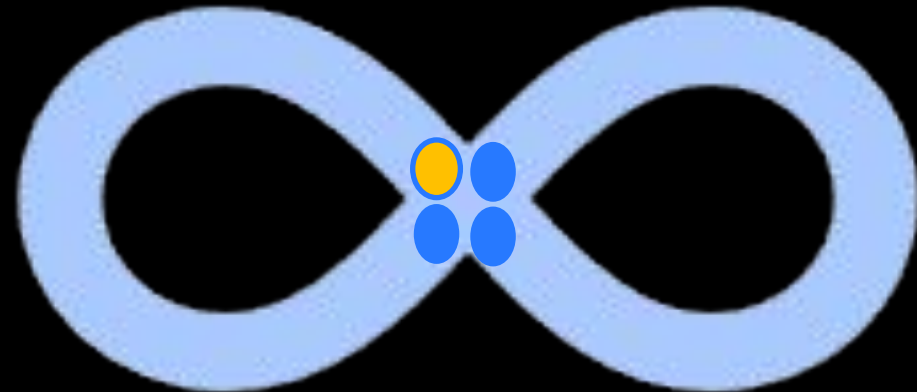
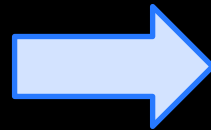
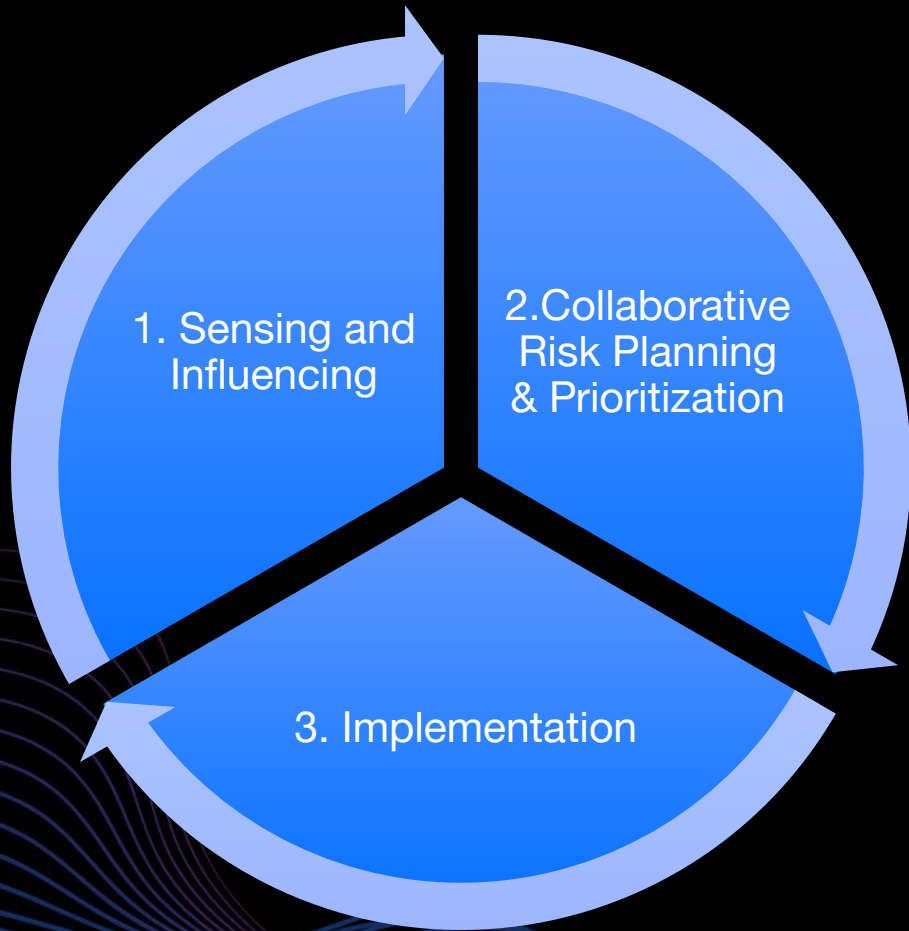
Develop: Deliver on the design.



Deploy: Go live with new capabilities and/or processes.



Regulatory TPLC Framework Stages



Observe

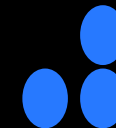
Reflect

Make



A focus on user outcomes

Put users' needs first



Multidisciplinary Teams

Collaborate across disciplines to work smarter and move faster

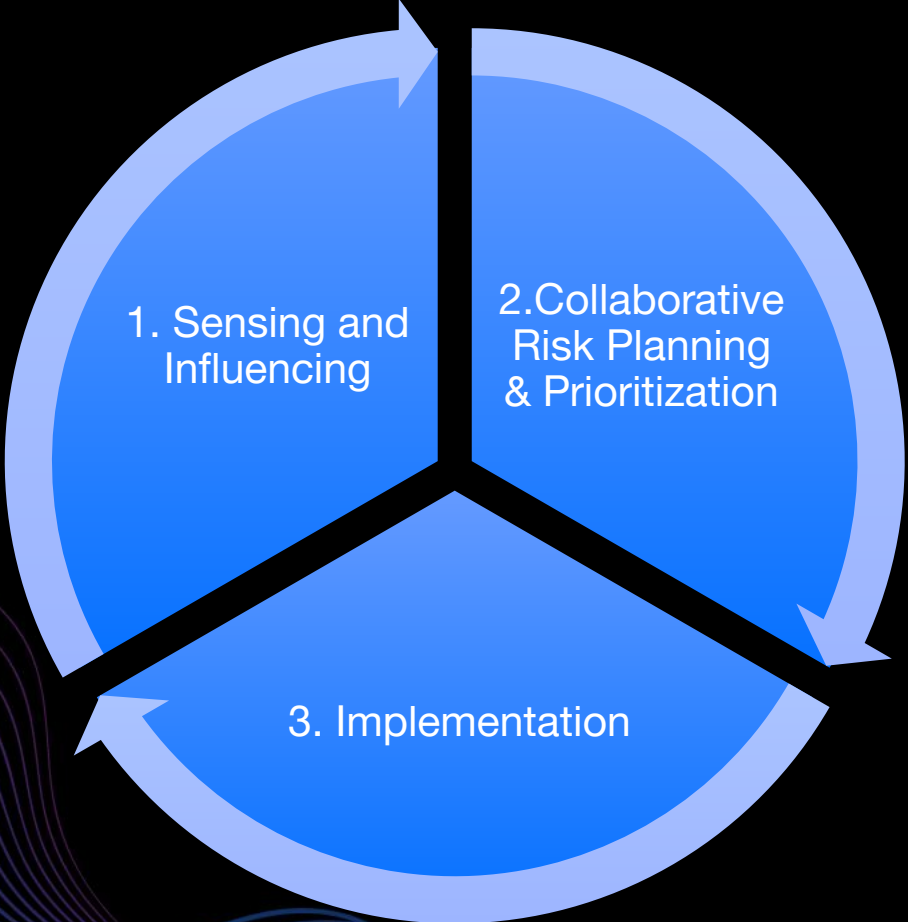


Restless Reinvention

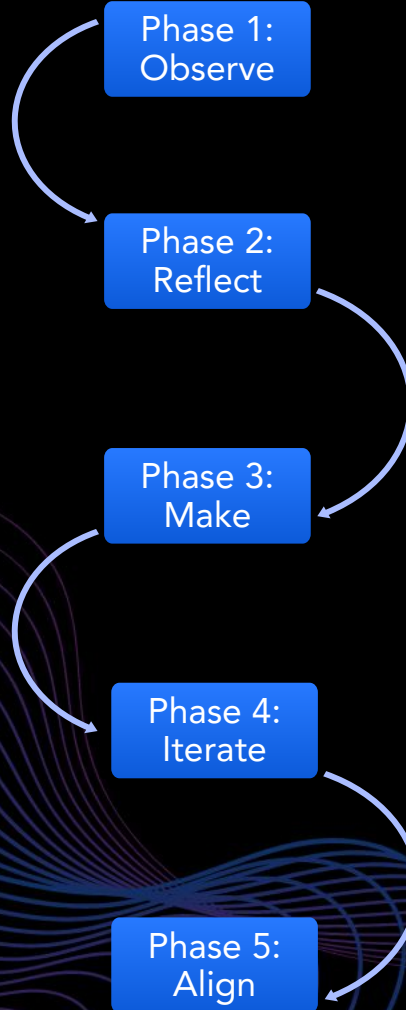
Listen, watch, learn, and correct



Regulatory TPLC Framework Stages

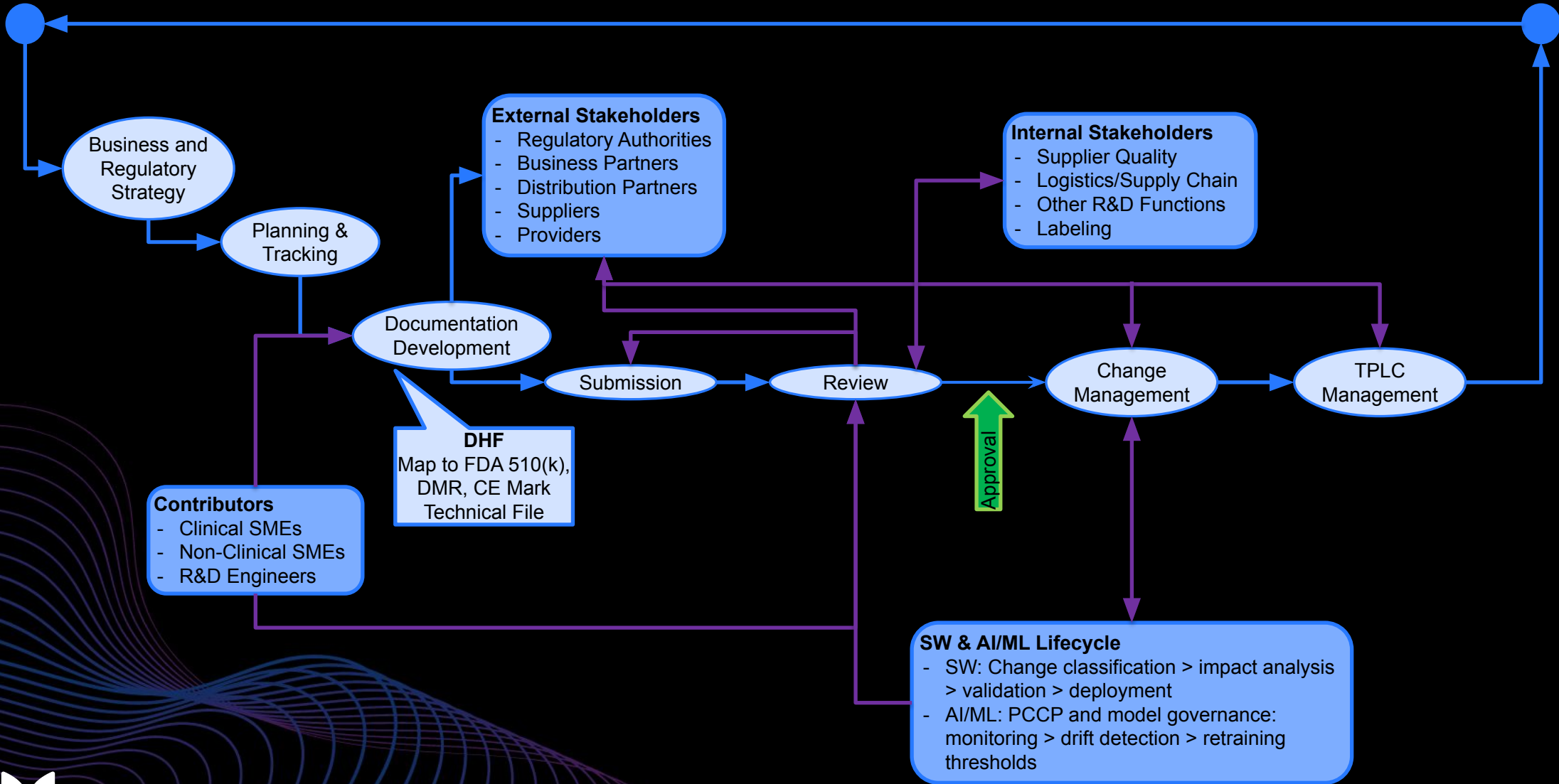


Design Thinking Framework for QRC Risk Mitigation

	Objective	Tools & Techniques	Applied to QRC
 <p>Phase 1: Observe</p>	Understand users, processes, and friction points	Empathy maps (internal and external), Root Cause Analysis	Investigate audit findings, complaint trends, regulatory delays
<p>Phase 2: Reflect</p>	Identify patterns and opportunities, what you know and what you still need to understand	“How Might We” questions, Fishbone diagrams, Assumptions & Questions, Risk Prioritization Matrices	Frame recurring risks (e.g. documentation gaps, delayed submissions, PMS inefficiencies)
<p>Phase 3: Make</p>	Co-create rapid, scalable solutions	Storyboarding, Minimum Viable Product (MVP) pilots, Risk Kanban Boards	Build tools like submission trackers, PMS Dashboards, QMS digital forms
<p>Phase 4: Iterate</p>	Test and refine improvements	Retrospectives/lessons-learned, stakeholder feedback loops	Improve CAPA processes, Design Controls, submissions SOPs, labeling workflows
<p>Phase 5: Align</p>	Ensure executive and cross-functional buy-in	Playback sessions, risk-readiness scorecards	Present impact of changes to ELT, align with business strategy



Holistic Regulatory Ecosystem



Q & A

