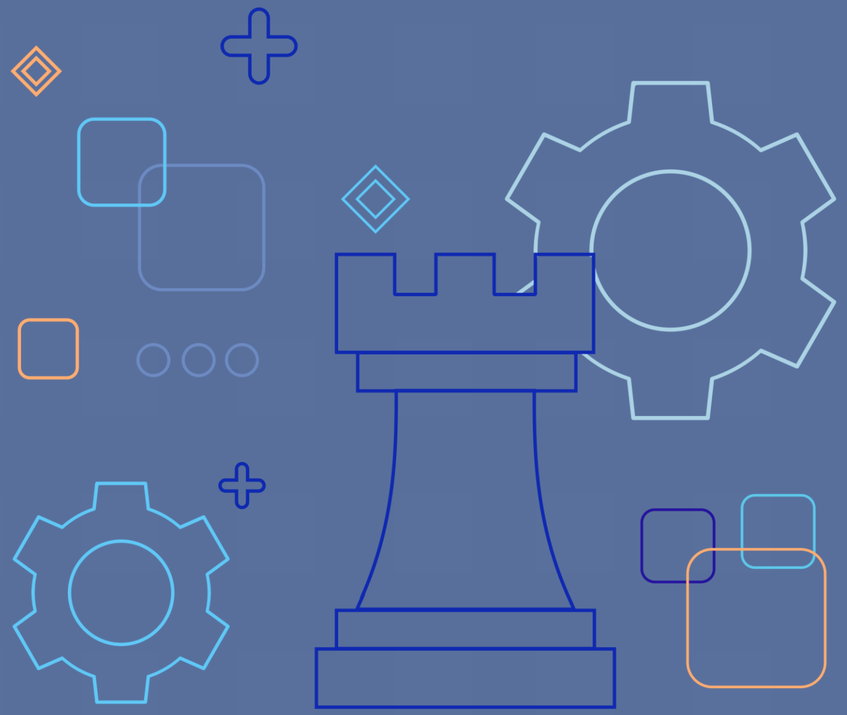
ROOK QUALITY SYSTEMS

Wearable and Home-Use Devices

Quality Management System



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Speaker Introductions

ROOK QUALITY SYSTEMS

Kyle Rose

CEO & Founder
Rook Quality Systems

- 15+ years of serving as a quality & regulatory consultant for medical device companies around the world
- NIH lead for multiple program including RADx, supporting over 100 COVID diagnostic devices
- Advisor to multiple Fortune 500 companies on all aspects of quality & regulatory for medical devices, software, and diagnostics
- Dedicated mentor to multiple medical device incubators, hospital systems, accelerators, & universities

About Rook Quality Systems

Rook Quality Systems specializes in assisting medical device companies, from startups to Fortune 500 firms, in developing and maintaining robust quality systems.

Our customized consulting services cater to all classes of medical devices, including medical software and combination devices, ensuring regulatory compliance and operational excellence.

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Our Core Values

Patient First Mentality

Our #1 priority is ensuring quality through compliance so that innovative and safe medical devices get to patients and users efficiently.

Proactive, Not Reactive

From designing long-standing quality systems to staying ahead of the ever-changing regulatory landscape, we approach each project with proactive and dynamic solutions.

High-Tech, High-Touch

Leveraging relevant technology is essential to achieving optimal results for our clients and ultimately improved outcomes for patients.

Agenda

Our Agenda For Today

1. Why wearables and home-use devices are a different QMS challenge
2. The QMS requirements you cannot skip
3. How to find and close compliance gaps
4. Building a QMS that scales with your company
5. Where design, software, risk, and testing intersect
6. Q&A

Wearables and Home-Use Devices Are a Different Animal

Why Standard QMS Playbooks Fall Short

- Devices are used outside clinical settings, by non-professional users, in unpredictable environments
- Often combine hardware, embedded software, mobile apps, cloud, and connectivity
- Continuous data collection raises cybersecurity and privacy stakes
- Iterative development cycles clash with traditional waterfall QMS templates
- Regulatory expectations have tightened: FDA cybersecurity guidance, QMSR transition, EU MDR, IEC 62304, IEC 60601-1-11 for home environments

The Real Pressure Lean Teams Face

What This Looks Like Day to Day

- Funding milestones tied directly to regulatory deliverables
- Engineering velocity that cannot slow down for documentation backlogs
- Audits scheduled with short notice, sometimes following adverse events
- Founders and small QA/RA teams stretched across QMS, submissions, and supplier oversight
- Documentation gaps that surface during a 510(k) review or first ISO 13485 audit, often too late

The QMS Foundation for Wearables and Home-Use Devices

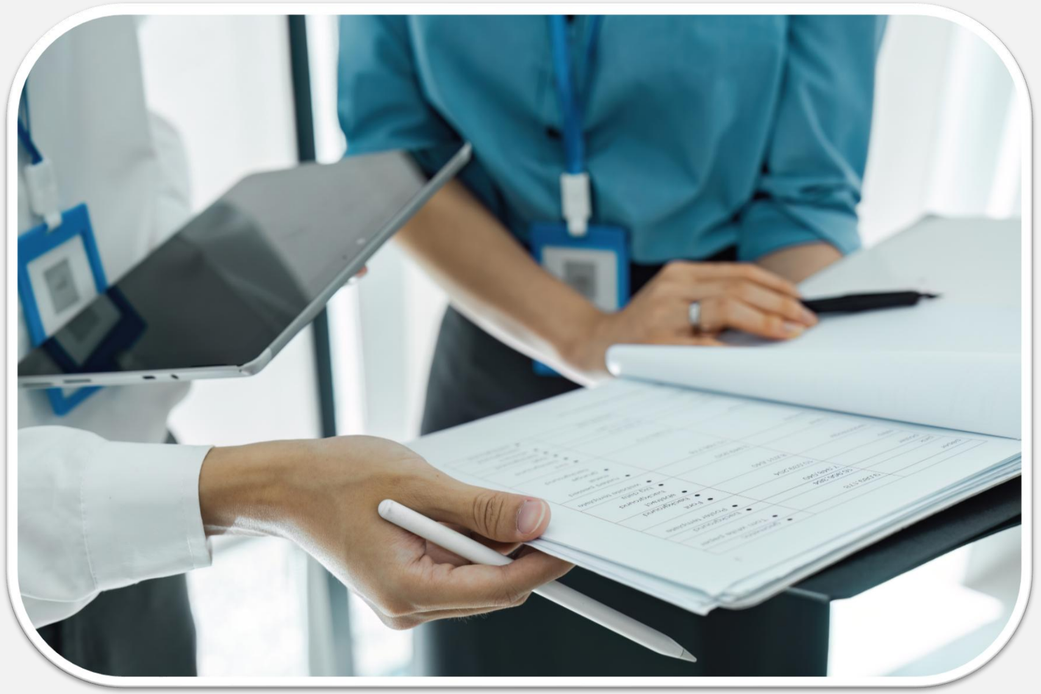
What Your QMS Must Cover

- Risk Management (ISO 14971) integrated across the product lifecycle
- Software Lifecycle Processes (IEC 62304) including SOUP and cybersecurity
- Usability Engineering (IEC 62366-1) with home-use validation
- Post-Market Surveillance, Complaint Handling, CAPA
- Supplier Controls covering contract manufacturers, cloud hosts, and component suppliers

Software, Risk, and Testing Are Not Separate Workstreams

Where Wearable and Home-Use QMS Documentation Has to Connect:

- **Design Controls** define what the product must do
- **Software Documentation** (IEC 62304) defines how software meets those requirements
- **Risk Management** (ISO 14971) drives mitigations that show up in design, software, and testing
- **Verification and Validation Testing** proves the mitigations and design outputs work in real-world use



Key Insight: *When these are documented in disconnected systems, audits and submissions get painful. When they are traceable, the whole story tells itself.*

Cybersecurity and Connectivity Cannot Be Afterthoughts

The Wearable and Home-Use Cybersecurity Reality

- FDA cybersecurity guidance and Section 524B requirements apply to most connected wearables
- Pre-market submissions need a Secure Product Development Framework (SPDF), threat modeling, and a Software Bill of Materials (SBOM)
- Post-market: monitoring, vulnerability disclosure, and patching processes
- Privacy considerations layered on top: HIPAA, GDPR, state-level health data laws

Clinical Data Is Part of Your QMS Story

Plan for Clinical Evidence Early, Not at Submission

- Wearables and monitoring devices almost always require real clinical data to support performance claims, intended use, and accuracy specifications
- Bench testing and simulated data will not carry a 510(k), De Novo, or PMA submission on their own for most monitoring indications
- Clinical strategy decisions made early shape your design inputs, risk file, usability validation, and labeling
- IEC 60601-1 and IEC 60601-1-11 (home-use environments) typically need to be submitted alongside clinical performance data for monitoring devices
- Late-stage clinical planning is one of the top causes of submission delays we see

What to Plan for Before You Run a Study

Clinical Planning Decisions That Affect Your QMS

Study design	Pivotal vs. supportive, sample size, endpoints, comparator device or method
Protocol and IRB	Documented under design controls and clinical evaluation processes
Data integrity	Source data, electronic records, and audit trails need to meet 21 CFR Part 11 expectations
Investigator and site management	Qualification, training, and monitoring documented in your QMS
Risk management linkage	Clinical findings feed back into your risk file and post-market surveillance plan
Software validation	Any data capture app, cloud platform, or analytics tool used in the study needs validation

How to Run a Real Gap Assessment

Find the Gaps Before Auditors Do

- Start with a structured assessment against your applicable standards (ISO 13485, QMSR, IEC 62304, ISO 14971, IEC 62366)
- Walk the QMS as it actually operates, not as it's written. Interview the people doing the work.
- Sample real records: design reviews, CAPAs, complaints, supplier evaluations, software releases
- Categorize findings by risk and effort: critical, major, minor
- Output: a prioritized remediation roadmap with owners and dates

Closing Gaps Without Overwhelming Your Team

Where Most Remediation Plans Fail

- Trying to fix everything at once stalls everything
- Sequence remediation around upcoming milestones (submission, audit, design freeze)
- Distinguish between "fix the system" and "fix the records." Both matter, different timelines.
- Embed quality into engineering workflows, do not add a parallel documentation process
- Use templates and tools that match your team's tech stack: Greenlight Guru, Jira, GitHub, etc.

Key Insight: *Remediation fails when it competes with the work. When quality lives inside the engineering workflow, the team can keep building while the system catches up.*

The Right-Sized QMS Principle

Scalable Doesn't Mean Bloated

- A startup QMS should fit on a few SOPs, not 60
- The system should support today's product, today's team, and the next 18 months of growth
- Documentation should reflect how decisions get made, not theoretical workflows
- Every procedure should answer: who owns it, when it's used, what it produces
- If a procedure is not being followed, the procedure is usually wrong, not the team

Scaling Without Rewriting

Build Once, Extend Many Times

Modular SOPs that can flex across product lines

A single risk framework applied consistently from device 1 to device 5

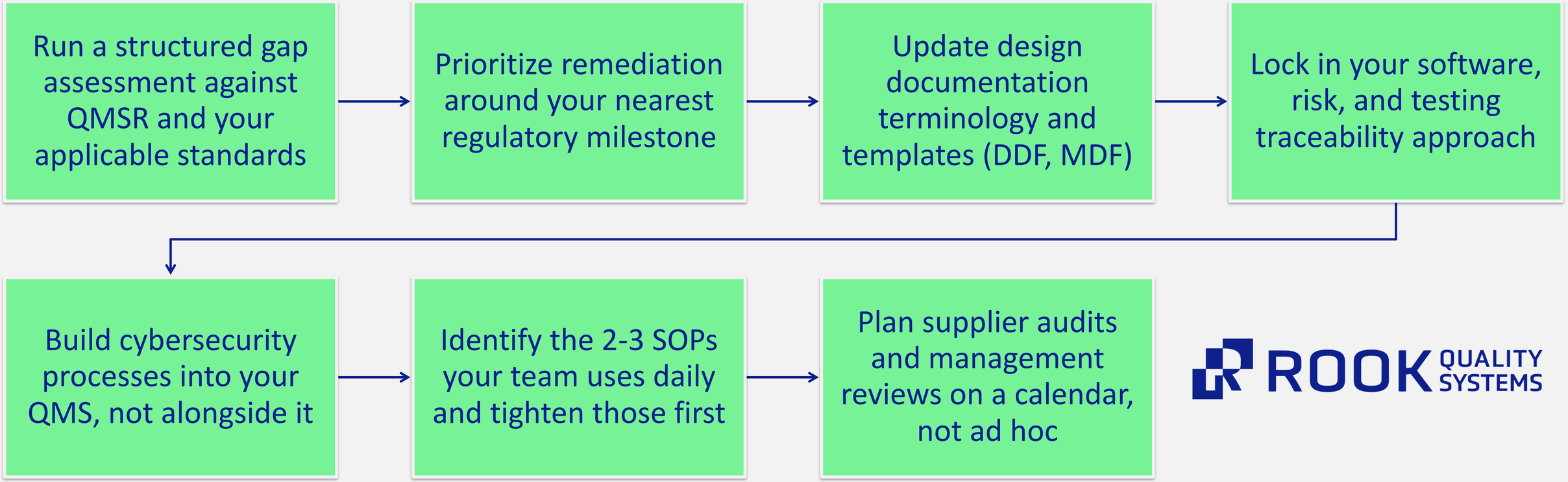
Supplier qualification process that handles your CMO and your cloud provider

Software lifecycle process that works for embedded firmware and mobile apps

Document templates with built-in traceability fields

Practical Steps to Accelerate Market Entry

What to Do in the Next 90 Days



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Key Takeaways

What to Remember

- Wearables and home-use devices need a QMS designed for their unique technical and regulatory profile
- Design, software, risk, and testing must be traceable as one connected story
- The QMSR transition is a templates-and-terminology refresh, not a teardown
- Gap assessments work when they're prioritized and sequenced, not exhaustive lists
- The right QMS scales with you. The wrong one becomes the thing slowing you down.

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