

Quality Risk Management

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- 1 QRM Opportunities & Expectations
- 2 Emerging Focus Areas
- 3 Software Enablement
- 4 Assessing AI Risk
- 5 Concluding Thoughts



QRM is both an obligation and an opportunity



- Regulatory expectations
 - Annex 1, Q9 (R1)
 - Constraints on global HAs
 - Inspection trends
- Value creation
 - Anticipation and prevention
 - Risk-based approaches
 - QMM and reputational benefit



New topics are coming into focus



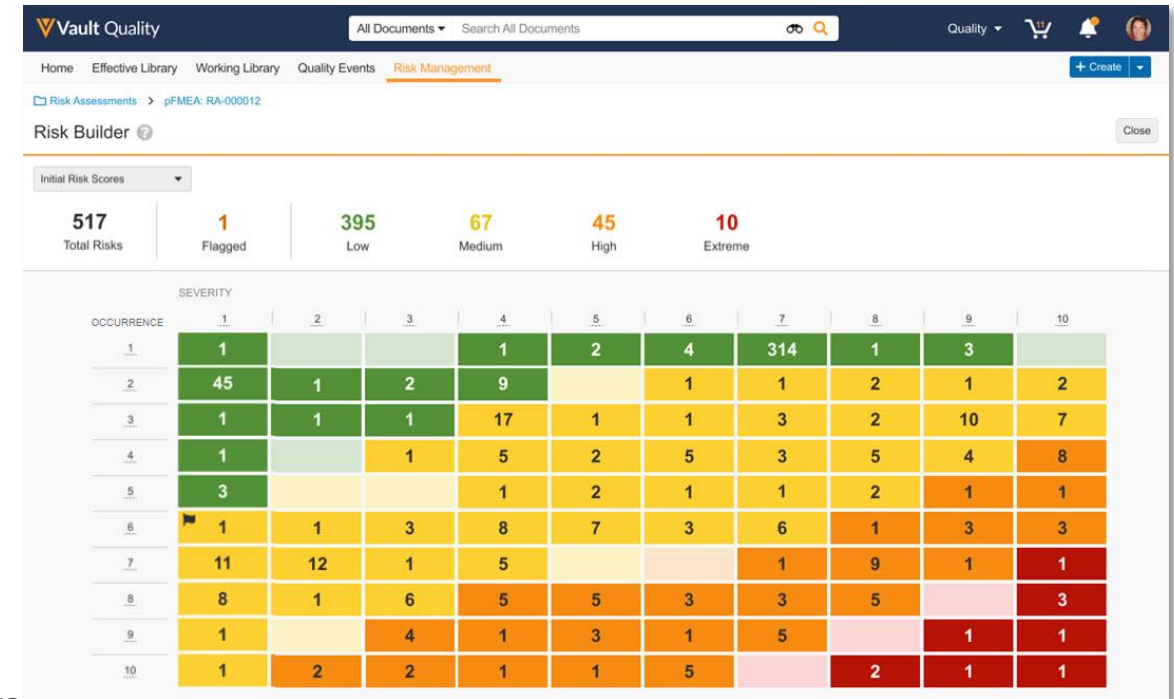
- Formality
 - Q9 (R1) spectrum of formality
 - FMEA and its discontents
- Subjectivity
 - Cognitive bias
 - Pre-determined Risk Assessment
- Validity
 - Framing
 - Future AI enablement



Companies are implanting QRM software



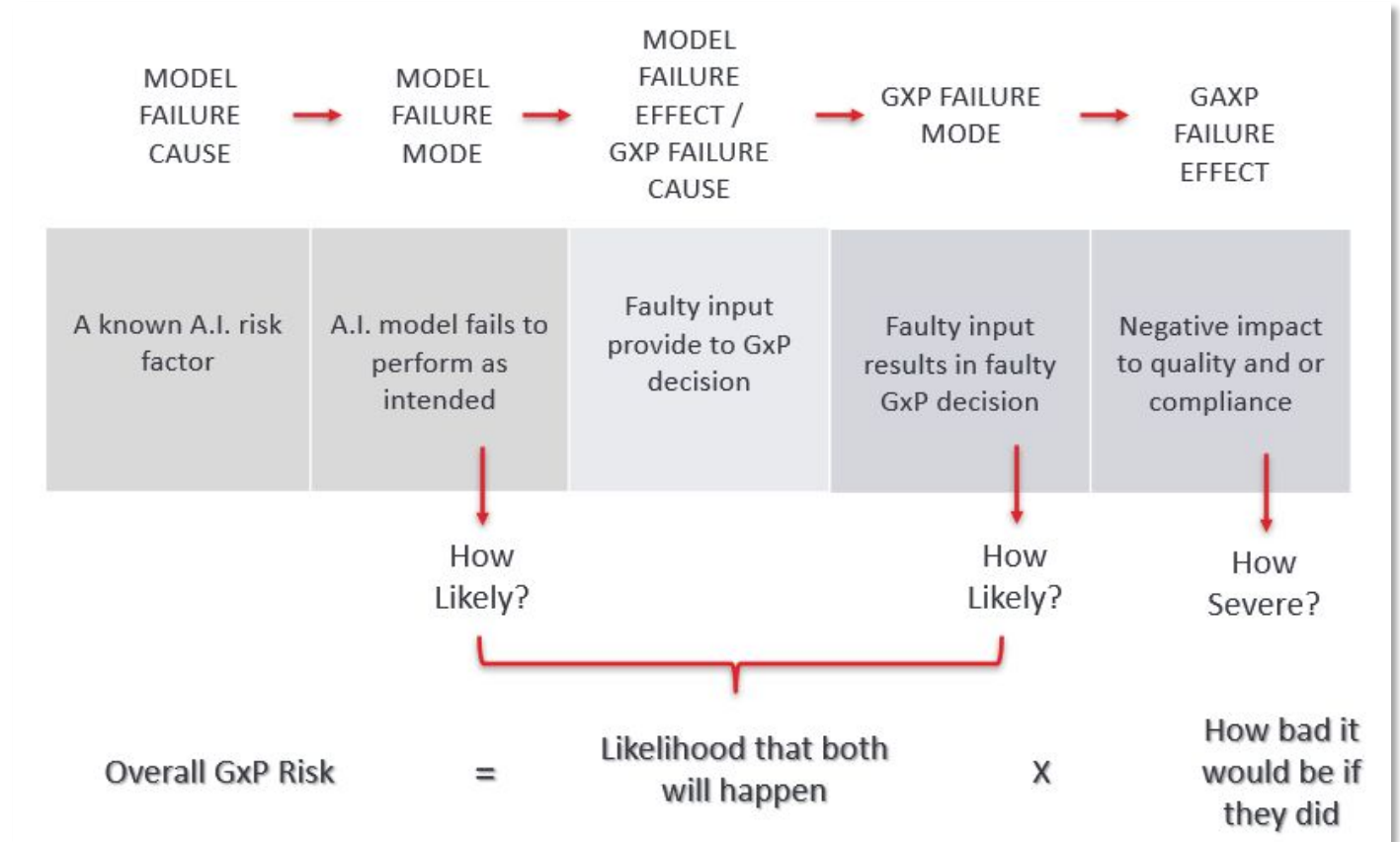
- Opportunity
 - Standardization
 - Improved LCM
 - Knowledge re-use
 - Visibility and monitoring
 - Bridging risk assessment and risk reporting/registers
- Concern
 - Efficiently performing bad risk assessments
 - Risk proliferation



AI presents unique risks in the GxP space



- Challenges
 - Lack of traceability
 - Self-modification
 - Hallucination and sycophancy
- Risk assessment
 - Framing
 - AI-specific hazards
 - Human in the loop



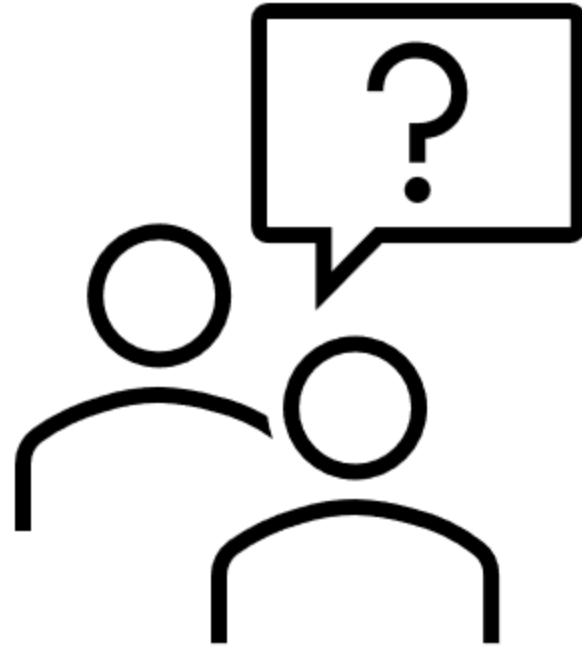
Some concluding thoughts



- QRM is both an opportunity and an expectation
- Invest in risk understanding
- Take a clear-eyed approach to AI risk so that you can leverage it aggressively and confidently



Your questions...





Thank You



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