

Quantitative Risk and Compliance Maturity Index

The life sciences industry is among the most heavily regulated in the world with companies today facing an increasing number of disputes and regulatory, compliance and investigation issues. The risks of non-compliance include severe financial penalties, delayed product launches and reputational risks that can cause damage to the organization. Organizational silos and interdependencies with third party partners make understanding vulnerabilities even more daunting.

Compliance officers have the onerous task of implementing safeguards, monitoring compliance, and predicting and reporting on business risks. But understanding where an organization's highest exposure area is can be difficult without the right tools in place to quantify the likelihood of being cited and the financial impact the exposure has on the organization. All too often compliance scores are qualitative rather than data driven.

Do you know your quality score?

CQRM XD Compliance Risk Predictor helps life sciences companies conduct quantitative assessments of business risks. The patented solution improves a company's ability to understand current compliance status, know business risks and prioritize actions. Understanding higher visibility and prioritized actions make teams more productive and reduce costs.

Only CQRM XD Compliance Risk Predictor provides a quantitative score for a company's Risk and Compliance Maturity Index (RCMI) at the company level, country level and functional area level and turns it in to actionable information that empowers you prioritize actions based on findings. The tool can be used internally as well as with your third party vendors.

How it works

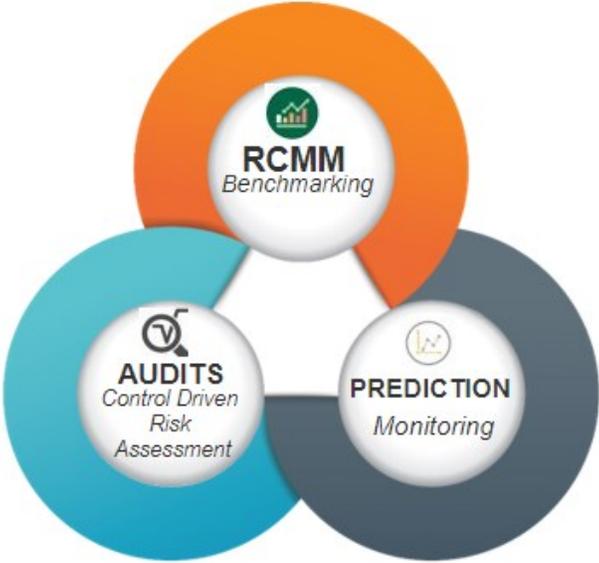
At the core of the CQRM XD Compliance Risk Predictor solution is a proprietary industry index that compiles 483 citation documents, internal audit databases, Department of Justice fines and settlements and a country business risk database. The data lake includes more than 35,000 records from the past ten years and continuously pulls in the latest information to make real-time reporting and trend analyses possible.



Predictable Compliance
Reduce number of non-compliances



Lower Cost
Reduce compliance cost per capita

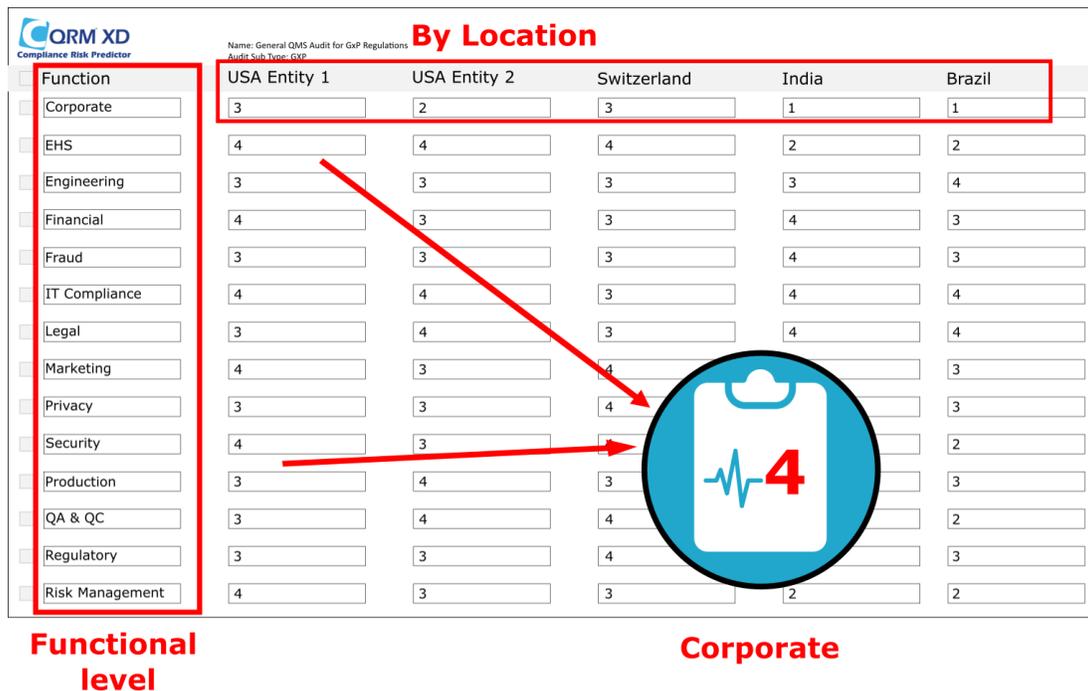


- 1** Benchmark using standard questionnaire to understand the current state of maturity
- 2** Setup execute and analyze audits, XybionEye to automatically find non-conformances in documents.
- 3** Compliance Risk Predictor to assess non-conformance driven business risks using Xybion proprietary database.

To determine your company's RCMI, the system guides users through a questionnaire that assesses your current state of maturity. Follow-up audits are conducted based on identified areas of risk. During the audit stage, the system automatically finds non-conformances in documents. Compliance Risk Predictor classifies all non-conformances based on a proprietary database and prioritizes actions based on likelihood of citation and the financial impact.

Know your Score

The RCMI score uses a 5-point scale to scorecard results by functional area and location so that you can easily identify aggregate and function or location specific results. The ability to drill down into the report allows you to prioritize areas of focus.



You can further drill into functional reports. The system provides color-coded reports of risk areas based on function vs. control types. The Predictive Risk Algorithm assesses audit results against risk based on external and internal data sources.

Predictive Compliance Sample Report

| Function/Control Types | Process | People | Quality | Technology | Governance | Investigation | Improvement | Third Party |
|------------------------|------------------|-------------------|-------------------|-------------------|-------------------|------------------|-------------------|-------------------|
| QA | 0.27 Low | 0.95 Very High | 0.43 Medium | 0.81 Very High | 0.95 Very High | 0.31 Low | 0.79 High | 0.63 High |
| Document Control | 0.18 Very Low | 0.70 High | 0.95 Very High | 0.13 Very Low | | 0.18 Very Low | 0.33 Low | 0.95 Very High |
| Facility | 0.51 Medium | 0.51 Medium | 0.57 Medium | 0.51 Medium | 0.95 Very High | | 0.95 Very High | |
| Materials | 0.43 Medium | 0.95 Very High | 0.33 Low | 0.95 Very High | | | 0.83 Very High | |

Actionable information = reduced costs

The ability to reduce risks and noncompliance costs is at your fingertips. CQRM XD Compliance Risk Predictor helps you to prioritize your actions, create remediation plans and automate monitoring. Let Xybion help you stay in compliance with the industry's only quantitative tool for measuring and reporting on risk and compliance.

