REGLLER

Executive Briefing

What FDA's First QMM Scorecard Reveals

Nine inspection-cleared sites. Maturity scores from 2.4 to 4.6.

SOURCE	COHORT	ASSESSED
FDA / CDER QMM	**9 Sites**	**2024 – 2025**

THE ONE FACT TO CARRY INTO THE ROOM

Every site in this cohort had already cleared FDA cGMP inspection — yet two scored below 3.0 on quality maturity in a 5-point scale. The lowest practice area score was 1.8 and highest was 4.6. The gap was very wide. Compliant site does not mean high quality site.

The Headline Numbers

FDA's Center for Drug Evaluation and Research (CDER) assessed nine drug manufacturing establishments under its voluntary QMM program. Every site had recently been inspected and cleared on cGMP. These were not problem sites — they were confident enough in their own quality to invite the agency to score them. Their maturity averages ranged from **2.40 to 4.62**.

2.4–4.6	22%	9 / 9
Maturity range across the nine-site cohort	Of cleared sites scored below 3.0	Sites had already passed FDA inspection

Why a Clean Inspection Isn't Enough

Inspection and QMM answer different questions. A site can pass on the left and still fall short on the right.

FDA Inspection	QMM
Looks at artifacts	Looks at the whole system
Confirms controls ran on the day	Reveals whether the system can improve
A point-in-time snapshot	A sustained organizational property

Three findings matter for any leadership team:

- **A clean cGMP inspection does not mean a mature quality system.** Two of nine cleared sites averaged below 3. Inspection confirms documented controls were executed on the day; it is not built to detect a brittle, reactive, or culturally weak system. The gap is wider than most organizations assume.
- **Maturity behaves like a single property, not a portfolio.** Within each site, scores cluster tightly across all five practice areas; between sites, the spread is large. A site that scores high scores high across the board — and vice versa. You cannot fix maturity one module at a time.
- **The cohort's weak spot was data and risk — not culture.** The lowest sub-scores cluster in Quality Risk Management and Data Excellence. Even the strongest performers stumbled there. This is precisely the foundation AI-enabled quality systems are built to strengthen.

The program is voluntary today and now in its third year. Its lineage — drug-shortage prevention, unanimous advisory-committee support — points in one direction. Organizations that build toward measurable maturity now will be describing what they already do when expectations formalize, rather than scrambling to comply.

What the scorecard actually shows

QMM is FDA's voluntary effort to assess how mature a manufacturer's quality system is — not whether it meets cGMP, but how well it functions, learns, and improves over time. It scores establishments from 1 to 5 across five practice areas: Management Commitment to Quality, Business Continuity, Advanced Pharmaceutical Quality System, Technical Excellence, and Employee Engagement and Empowerment. It is not enforcement; it cannot find a site out of compliance.

Nine establishments volunteered for the first cohort, assessed between June and December 2024. The site-by-site averages, ordered as CDER presented them, are below.

Site	Management Commitment	Business Continuity	Advanced PQS	Technical Excellence	Employee Engagement	Average
A	2.8	2.7	2.6	2.7	3.4	**2.84**
B	4.8	4.3	4.2	3.6	4.9	**4.36**
C	4.2	4.4	3.6	3.6	4.5	**4.06**
D	4.0	3.8	3.7	4.3	4.1	**3.98**
E	4.6	4.5	4.7	4.4	4.9	**4.62**
F	4.5	4.4	4.4	4.3	4.7	**4.46**
G	2.2	2.5	2.2	2.7	2.4	**2.40**
H	3.7	3.8	3.5	3.7	4.0	**3.74**
I	3.8	3.8	3.6	3.4	3.8	**3.68**

Two patterns are worth holding onto. Between sites, the range is wide — two sites below 3, five clustered between 3.5 and 4.1, two above 4.4. But within each site, the five scores cluster tightly: Site E rated 4.4–4.9 across all five areas; Site G, 2.2–2.7. The average within-site spread is roughly two-thirds of a point, while a single practice area such as Management Commitment ranges from 2.2 to 4.8 across the cohort. Maturity rises and falls together.

Finding one: cGMP-cleared does not mean quality-mature

All nine sites had passed a recent FDA inspection. Two still averaged below 3; one scored 1.8 on a single sub-element. A clean inspection confirms that *documented controls were executed on the day*. It does not confirm that the underlying system is mature. Inspections look at artifacts; QMM looks at the system that produced them.

For an organization confident in its own quality, this is the uncomfortable takeaway: that confidence has been calibrated against an instrument that is not designed to detect what QMM detects. Most organizations that apply the QMM lens honestly find gaps they did not know they had — not because they are weak, but because nothing has ever measured them this way.

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Finding two: maturity is one property, not a portfolio

The within-site clustering is not a curiosity — it is the most actionable finding in the data. It suggests quality maturity is a single organizational property: culture, leadership, data, technical capability, and engagement rise or fall together. They share a substrate.

The strategic implication is sharp. A targeted intervention in one practice area — a new risk-management SOP, a culture campaign — tends to underperform if the substrate underneath it is weak. Organizations that treat maturity as a checklist of separable fixes spend effort without moving the number. The ones that move it work on the foundation that all five areas draw from.

> **What this means in practice:** If your self-scan (Section 6) shows you scoring evenly across the five areas, you are likely reading your true maturity level. If one area looks far stronger than the rest, treat it with suspicion — it is more often a measurement artifact than a real island of excellence.

Finding three: the weak spot is data and risk — where AI earns its place

Two sub-elements anchored the bottom of the cohort: Quality Risk Management and Data Excellence. At the practice-area level, Advanced PQS and Technical Excellence — the homes of those sub-elements — were the two lowest-scoring areas across all nine sites.

These two areas are, in effect, one weakness with two names: you cannot make risk-informed decisions without data you can trust, and you cannot govern data you have not architected. Even strong performers stumbled — one site scoring near the top on knowledge management still scored only 3.2 on Data Excellence; another with a perfect

5.0 on continual improvement landed at the same 3.2.

This is exactly where AI belongs in a quality system — and exactly where it is most often misapplied. The value is not a bolt-on dashboard on top of disconnected records. It is the layer underneath: trustworthy, connected, governed data that makes risk decisions defensible and auditable. Strong culture and engaged leadership are necessary, but on their own they cannot manufacture a data foundation that does not exist. The next decade of quality work will be measured against whether organizations build that foundation — and whether they can show their work when asked.

Beyond the pilot: the same gap, at industry scale

The pilot is pharma. Based on Regller platform intelligence data, the gap is industry-wide. Across every FDA-regulated sector over the last decade — roughly 98,500 Form 483 observations, 61,600 recalls and 112,500 enforcement actions — the same pattern repeats at scale. Supplements (5.3 obs/inspection) and Rx drugs (4.7) carry the heaviest inspection-day burden; cosmetics records 1.8 against 1,941 recalls and 668 enforcement actions — the same uncorrelated pattern the pilot showed at site level. cGMP is the floor; QMM is the ceiling. The instrument that surfaces actual maturity is a continuous signal — quality measured as a number, anchored on the data-and-risk substrate the pilot found weakest. Sectors with lighter historical footprints (biologics, HCT/P, cosmetics, supplements) are where MoCRA, the QMSR alignment with ISO 13485, and renewed Part 111 enforcement land next.

Industry	Obs / Insp.	Recalls
Processed & Packaged Foods	3.0	14,050
Medical Devices	3.8	26,351
Prescription (Rx) Drugs	4.7	11,003
Dietary Supplements	5.3	827
Animal Drugs & Feed	2.6	1,756
OTC Drugs	1.8	720
Cell & Tissue Products (HCT/P)	2.8	277
Cosmetics & Personal Care	1.8	1,941
Biologics & Vaccines	2.0	4,652

Why this is the direction of travel

QMM is voluntary today. But it is now in its third year, its advisory committee backed establishing it unanimously, and its entire reason for existing is drug-shortage prevention — a problem regulators and payers are not going to stop caring about. The shift it represents, from documented compliance toward measurable, sustainable, organization-wide maturity, is not a passing initiative.

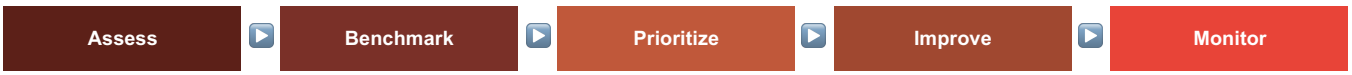
That gives early movers a quiet advantage. The organizations that begin building toward measurable maturity now will, when formalization arrives, find themselves describing what they already do — not scrambling to assemble it under deadline. The work compounds; it cannot be bought in a quarter.

How Regller helps

RegllerScore is created based on regulatory and industry standards. This sits on top of existing systems to continuously monitor and create a score that can be measured, tracked and improved.

From Assessment to Continuous Maturity

Regller turns the QMM lens into an operating capability — connecting the raw signals of your quality system through to defensible outcomes:



The Regller quality-maturity chain — fully editable; retype any label directly.

> *"The gap between a clean inspection and a mature quality system is wider than most teams assume — and it lives exactly where AI has to stand. Define quality by a number. Measure- Monitor- Mature"* **Kamal Biswas** · Co-founder & CEO, Regller

Start with a Readiness Diagnostic

An honest, structured read of where you stand against the five QMM practice areas — and where the data-and-risk substrate is thin. No obligation.

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