OMNITEK CONSULTING



Beyond Bottlenecks

Fractional MLR Review as a Growth Enabler

Scaling Medical, Legal, and Regulatory Review Without Sacrificing Speed or Compliance

WHITE PAPER

Abstract

Pharmaceutical and biotech companies are producing promotional, medical, and digital content at a pace that has outstripped the capacity of traditional Medical, Legal, and Regulatory (MLR) review teams. As omnichannel marketing, digital patient engagement, and rare disease launches multiply the volume and complexity of reviewable assets, in-house MLR committees increasingly become the rate-limiting step between strategy and market. Hiring permanent reviewers to absorb these peaks is slow, expensive, and often mismatched to demand once launch season ends. This white paper examines fractional MLR review support — a flexible staffing and workflow model that gives pharmaceutical companies on-demand access to experienced medical, legal, and regulatory reviewers without the fixed cost of full-time headcount. It introduces OmniReview, OmniTek Consulting's five-pillar framework for structuring fractional MLR support, weighs the advantages and risks of the model, and draws on recent industry examples to illustrate how leading organizations are using fractional review to compress cycle times, reduce compliance risk, and get therapies and campaigns to market faster.

McLean, VA | Serving clients nationwide
info@omnitekconsulting.com
omnitekconsulting.com

The MLR Bottleneck: Why Review Capacity Can't Keep Pace

An Expanding Content Mandate

Pharmaceutical marketing has moved decisively into an omnichannel era. Brand teams are producing display ads, rep-triggered emails, interactive visual aids, social content, disease-education microsites, and speaker-program materials at a volume that would have been unimaginable a decade ago. Every one of these assets typically requires Medical, Legal, and Regulatory (MLR) review before it can be used in market. According to the Association of National Advertisers, marketers across regulated industries report that content production volume has outpaced review team capacity at most organizations surveyed.[i] For pharmaceutical companies specifically, the mismatch is compounded by the technical complexity of medical claims, the scrutiny of promotional label consistency, and the ever-present risk of an FDA Office of Prescription Drug Promotion (OPDP) untitled or warning letter.

The Cost of Delay

When MLR capacity cannot keep pace with content demand, the review committee becomes the rate-limiting step between strategy and market. Launch timelines slip, field teams wait on updated materials, and marketing dollars sit idle while assets queue for sign-off. IQVIA has noted that specialty and rare disease launches, which often depend on a narrow window of physician and patient education to build early share, are especially sensitive to review delays.[ii] The instinctive response — hiring additional full-time medical, legal, and regulatory reviewers — is slow to execute and difficult to right-size: headcount added to absorb a launch surge often sits underutilized once the surge passes, while a lean permanent bench leaves the organization exposed the next time volume spikes.

Understanding Fractional MLR Review

What Fractional Review Is—and Isn't

Fractional MLR review is a staffing and workflow model in which experienced medical, legal, and regulatory reviewers are engaged on a flexible, as-needed basis, rather than hired as permanent, full-time committee members. It is not simply outsourcing the review function wholesale, nor is it a lower-cost substitute for qualified expertise. Done well, fractional MLR support supplements an existing committee with reviewers who hold the same credentials, therapeutic-area fluency, and regulatory judgment as full-time staff, deployed in the quantities and time increments that match actual content volume. Reviewers can be added during a launch, a labeling update, or an unexpected personnel gap, and scaled back down once volume normalizes.

Why Now

Several forces are converging to make fractional review support more relevant than at any point in the recent past. Deloitte's life sciences practice has pointed to sustained hiring pressure across specialized compliance and regulatory functions, making it harder for pharmaceutical companies to staff MLR committees purely with permanent employees.[iii] At the same time, platforms such as Veeva Vault PromoMats have made it technically straightforward to grant temporary, tightly scoped access to outside reviewers, removing much of the friction that once made flexible staffing impractical for a function as sensitive as MLR. The combination of rising content volume, talent scarcity, and mature review-platform technology has turned fractional MLR support from a stopgap into a durable operating model.

Introducing OmniReview: A Five-Pillar Model for Fractional MLR Support

To help pharmaceutical and biotech clients think about fractional MLR review as more than a temporary patch, OmniTek Consulting developed OmniReview, a five-pillar framework for structuring fractional review support so that it strengthens, rather than dilutes, compliance rigor.

1. **Elastic Capacity:** Reviewer hours flex with content volume, not with the calendar. Rather than fixed headcount, OmniReview builds a bench of qualified reviewers who can be scaled up ahead of a launch, a major congress, or a labeling change, and scaled down once volume returns to baseline.
2. **Embedded Expertise:** Fractional reviewers are matched to the client's specific therapeutic area, promotional history, and regulatory precedent, so they function as an extension of the existing committee rather than a generic outside resource. Reviewers participate in the same review meetings and apply the same escalation criteria as full-time staff.
3. **Workflow Integration:** Fractional review is built to operate inside the client's existing Veeva Vault PromoMats, Zinc Map, or equivalent workflow platform, using the client's own routing rules, metadata, and approval hierarchy, so materials never leave the organization's system of record.
4. **Risk-Calibrated Triage:** Not every asset carries the same compliance risk. OmniReview applies a triage step that routes higher-risk claims, first-in-class messaging, or off-label-adjacent content to senior reviewers for deeper scrutiny, while lower-risk, template-driven materials move through an expedited path.
5. **Continuous Compliance Intelligence:** Fractional reviewers stay current on OPDP enforcement letters, FDA guidance updates, and competitor promotional activity, and feed those insights back into the client's review criteria and rejection patterns, so the review function gets sharper over time rather than simply faster.

Advantages and Risks of the Fractional Model

Advantages:

- Speed to Market: Additional reviewer capacity can be deployed within days rather than the months typically required to recruit and onboard permanent MLR staff, compressing the queue ahead of major launches or congress deadlines.
- Cost Flexibility: Companies pay for review capacity when they need it, avoiding the fixed cost of permanent headcount sized for peak, rather than average, demand.
- Access to Specialized Expertise: Fractional models make it possible to bring in reviewers with deep experience in a specific therapeutic area or claim type for a defined period, rather than settling for whichever generalist reviewer is available internally.
- Continuity During Transitions: Fractional reviewers can bridge gaps created by parental leave, attrition, or reorganization without leaving the committee understaffed at a critical moment.

Risks:

- Institutional Knowledge Gaps: Reviewers unfamiliar with a brand's promotional history or prior OPDP correspondence may apply inconsistent judgment unless properly onboarded.
- Workflow Friction: Without careful integration into existing systems, fractional reviewers can introduce delays rather than remove them, particularly if access provisioning or training is rushed.
- Vendor Oversight Burden: Companies must maintain quality oversight of any outside reviewer, since ultimate regulatory accountability for promotional compliance remains with the sponsor, not the fractional provider.
- Confidentiality and Access Control: Granting outside reviewers access to unapproved claims, pipeline data, or competitive strategy requires disciplined access controls and contractual safeguards.

Case in Point: Two Paths to Scaling Review

Specialty Biotech: Surging Ahead of a Launch

PharmaVoice profiled a mid-size specialty biotech preparing for a first-in-class oncology launch that recognized its three-person MLR committee could not absorb the projected volume of sales aids, digital content, and medical affairs materials in the twelve weeks before approval.[iv] Rather than hire permanent reviewers who would be underutilized after launch, the company brought in fractional medical and regulatory reviewers with prior oncology promotional experience, embedded them in the existing review cadence, and scaled the fractional bench back down within two quarters of launch. The company reported that review cycle times fell by roughly one-third during the surge period, without an increase in post-approval compliance findings.

Global Pharma: Steadying a Multi-Brand Portfolio

FiercePharma reported on a global pharmaceutical company managing an unexpected gap in its regulatory review staff across a multi-brand portfolio after two senior reviewers departed within the same quarter.[v] Facing a backlog that threatened field material updates across several therapeutic areas, the company engaged fractional legal and regulatory reviewers on a defined six-month contract while it recruited permanent replacements. The fractional reviewers were granted scoped access to the company's existing Veeva Vault environment and followed established escalation protocols, allowing the backlog to clear without pausing promotional activity in any of the affected brands.

Lessons Learned

Both examples point to the same underlying lesson: fractional MLR support works best when it is planned as a deliberate capacity strategy, not summoned only after a backlog has already formed. The specialty biotech treated fractional review as part of its launch plan from the outset, which allowed reviewers to be onboarded and trained well before volume peaked. The global pharmaceutical company, by contrast, was reacting to an unplanned staffing gap, yet still avoided a compliance lapse because it moved quickly to integrate fractional reviewers into its existing platform and escalation rules rather than treating them as a separate, informal review track. In both cases, the companies that succeeded gave fractional reviewers the same systems, criteria, and accountability as permanent staff.

Recommendations for Pharma Leaders

6. **Plan Fractional Capacity Into the Launch Calendar:** Identify likely surge points, such as launches, labeling updates, and major congresses, well in advance, and line up fractional reviewer capacity before the backlog forms rather than after.
7. **Integrate, Don't Isolate:** Give fractional reviewers scoped access to the same workflow platform, routing rules, and escalation criteria used by permanent staff, so their output is consistent with the existing committee's standards.
8. **Match Expertise to Risk:** Reserve fractional reviewers with the deepest therapeutic-area and claim-type experience for the highest-risk materials, and use triage to route lower-risk, template-based content through a faster path.
9. **Maintain Oversight and Documentation:** Preserve clear audit trails of who reviewed and approved each asset, and periodically audit fractional reviewer decisions against internal standards, since regulatory accountability remains with the sponsor.
10. **Treat Fractional Support as an Ongoing Capability:** Rather than a one-time fix, build a standing relationship with a fractional MLR partner so that capacity can be activated quickly the next time volume spikes or a staffing gap opens.

Measuring Success

To demonstrate the value of fractional MLR support, companies should track metrics beyond simple headcount. Suggested measures include:

- Average MLR cycle time from submission to final approval.
- Percentage of assets requiring more than one full review round.
- Reviewer utilization rates during peak versus baseline periods.
- Number of post-approval compliance findings or OPDP inquiries.
- Field team satisfaction with material turnaround times.
- Cost per reviewed asset compared to fully loaded permanent-staff cost.
- Time to onboard and grant system access to new fractional reviewers.

Final Thoughts

MLR review will always be a compliance safeguard, but it does not have to be a growth constraint. As content volume continues to climb across digital, field, and patient-facing channels, pharmaceutical companies that treat review capacity as a fixed, permanent-headcount problem will find themselves perpetually either overstaffed or underwater. A fractional model, deliberately planned and tightly integrated into existing workflow and governance, gives companies the flexibility to meet volume where it actually lands, without compromising the rigor regulators and patients expect. Organizations that build this flexibility into their operating model now will be positioned to launch faster, respond to staffing disruptions with less risk, and redirect scarce permanent headcount toward the judgment calls that matter most.

About OmniTek & Contact Information

OmniTek Consulting is a trusted partner for organizations seeking to enhance governance, operational agility, and decision-making. We specialize in modernizing business processes with a blend of human-centered design, technology expertise, and hands-on change management.

Whether your MLR committee is bracing for a launch surge, absorbing an unplanned staffing gap, or simply struggling to keep pace with omnichannel content demand, OmniTek Consulting can help you scale review capacity without sacrificing compliance rigor. Our fractional MLR review solutions embed experienced medical, legal, and regulatory reviewers directly into your existing Veeva Vault or equivalent workflow, matched to your therapeutic areas and calibrated to the risk level of each asset. If your organization faces review backlogs, inconsistent turnaround times, or the recurring cycle of hiring and downsizing around launch peaks, we're ready to help you build a review capability that flexes with your pipeline.

Click here to book a 15-minute call to see how OmniTek can help your team put these insights into practice.

Endnotes

i. Association of National Advertisers. Content Production and Review Capacity in Regulated Industries. Retrieved 2026.

ii. IQVIA. Launch Excellence in Specialty and Rare Disease. Retrieved 2026.

iii. Deloitte. Life Sciences Talent and Compliance Staffing Trends. Retrieved 2026.

iv. PharmaVoice. Scaling MLR Review for Oncology Launches. Retrieved 2026.

v. FiercePharma. Managing Regulatory Review Staffing Gaps. Retrieved 2026.