Literature Reviews as a Strategic Tool

Meeting Global Demands for Ingredient and Material Safety

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In today's dynamic regulatory landscape, staying on the market means more than meeting minimum requirements, it means staying ahead of evolving expectations. From Europe's Medical Device Regulation (MDR) to growing U.S. Food and Drug Administration (FDA) scrutiny around materials and ingredients, the ability to quickly generate, align, and defend evidence has become a strategic imperative.

As regulatory frameworks evolve globally, one trend is clear: maintaining market access is no longer just about initial approval - it's about continuously justifying product safety and performance. The European Union's shift from the Medical Device Directive (MDD) to the MDR is a case study in how regulatory changes reshape expectations. And the U.S. FDA is increasingly following suit, including in its intensified focus on the safety of materials and ingredients.

Literature reviews, which were once seen as a tool primarily for clinical evaluations, are now emerging as a powerful means to meet global post-market requirements. They enable companies to produce real-world evidence (RWE), support safety assessments, and reinforce product credibility with regulators.

The Regulatory Wake-Up Call – from MDD to MDR and its Implications

Under the EU MDR, most legacy devices required reevaluation, with over 500,000 previously certified devices facing new scrutiny, and many low-risk products reclassified into higher-risk categories, which significantly increased documentation and clinical evidence burdens for manufacturers.[1-3] Systematic literature reviews have become one of the primary tools for bridging this regulatory gap. These were used to support Clinical Evaluation Reports (CERs) and can also be used to justify the continued use of materials and ingredients in devices without needing new clinical trials.

The MDR experience demonstrated that comprehensive literature evaluations are not only a regulatory requirement, but a key enabler for sustained market presence.

Is the FDA next?

While the FDA operates under a different system, there are signs of regulatory convergence. Recent activity around New Dietary Ingredients (NDIs), Generally Recognized as Safe (GRAS) substances, and drug preclusion clauses show that the FDA is putting more pressure on ingredient-level evidence. Companies working with natural extracts, polymers, and novel excipients, especially in areas like

dermatology, dental materials, and dietary supplements, should anticipate requests for justification beyond historical use.

The FDA increasingly expects:

- Scientific substantiation of safety for **biocompatible materials and ingredients**
- RWE to demonstrate ongoing **clinical performance and tolerability**
- Post-market data to guide regulatory **reclassification or enforcement decisions**

Much like the MDR, literature reviews are becoming a central tool for satisfying these expectations.

Who Needs to Collect this Data?

Medical device manufacturers using polymer-based or coated products, pharmaceutical companies incorporating novel excipients or delivery matrices, and dietary supplement brands facing increased scrutiny under evolving NDI and GRAS criteria are all under growing pressure to substantiate safety claims. Likewise, material developers working in regulated fields such as dental and dermatologic products must be prepared to justify the safety and function of their components. Whether supporting submissions, responding to regulatory questions, or updating technical documentation, the need is the same: efficient, accurate synthesis of global clinical evidence.

Why Literature Reviews?

Literature reviews provide a:

- Rapid, rigorous way to justify safety and performance
- Path to evidence generation, especially when new trials aren't feasible
- Way to proactively monitor emerging signals and protect products already on the market

The effectiveness of literature reviews depends on thoughtful design, execution, and quality control - areas where specialized partners can make the difference. As Mathes et al. (2017)[4] and Wang et al. (2020)[5] highlight, human error rates in screening and data extraction can range from 10% to over 50%, potentially compromising evidence quality and slowing timelines. Inaccurate or incomplete syntheses can misinform decision-makers, trigger unnecessary follow-up studies, or leave emerging risks undetected. Recent advances in artificial intelligence (AI) offer powerful tools to mitigate these risks. AI-driven anomaly detection can further highlight extraction inconsistencies or outliers that warrant closer inspection. By integrating these AI-augmented workflows, teams can reduce manual burden, tighten quality control, and accelerate timelines, ensuring that literature reviews remain a robust, trustworthy foundation for evidence generation.

Literature Reviews are Not the Endpoint - they're the Foundation

While literature reviews are not a substitute for all forms of evidence, especially when primary data is needed, they serve as a critical foundation. Before launching new clinical investigations or toxicological studies, a well-structured literature review helps teams:

- Understand the current safety and performance landscape
- Identify known material interactions, risks, or contraindications
- Detect gaps that can guide study design, PMCF, or regulatory strategy
- Reduce duplication and focus resources where they're most impactful

This approach aligns decision-making with existing science, making downstream evidence generation more strategic, efficient, and regulator ready.

ECNE's Role

At ECNE Research, we collaborate with medical device, pharmaceutical, nutrition, cosmetic and other life science companies to deliver systematic literature surveillance tailored to global regulatory expectations. Our technology-enabled and expert-driven services help teams align with evolving regulatory expectations, close evidence gaps proactively, and accelerate readiness for audits, submissions, or market expansion.

Let us help you with your safety surveillance and clinical evidence needs.

Book a free consultation

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