RQM+
Evolving MedTech

Is Your E&L Testing Strategy Future-Ready?

A Quick-Check Extractables and Leachables Diagnostic for MedTech Teams

Regulatory expectations for extractables and leachables (E&L) have shifted. Today's ISO 10993-18 compliance demands more than standard testing; it requires a scientifically defensible strategy that anticipates material risks, identifies every compound, and withstands regulator scrutiny on the first submission.

Use this diagnostic to assess whether your current approach is positioned for success or vulnerable to costly rework.

1. Material & Chemistry Readiness

The #1 cause of late-stage E&L rework: discovering a material won't pass risk assessment after testing is complete.

- ☐ We understand the fundamental chemistry of every patient-contact material — not just what suppliers tell us, but how those materials behave under extraction conditions.
- ☐ We've screened materials early in design to identify potential extractables concerns before committing to final specifications.
- ☐ We know what manufacturing aids (slip agents, mold release, cleaning residues) our suppliers and their suppliers use and whether they persist at detectable levels.

2. Analytical Sensitivity & Identification

Regulators now expect every compound detected through E&L testing to be identified to some degree. "Unknown peaks" are no longer acceptable.

- ☐ Our analytical methods are sensitive enough for our device's specific use condition and patient contact duration, not just "standard" sensitivity.
- ☐ Our lab partner identifies all detected compounds (including partial structural identification for difficult chemicals) — no "unknowns" left in the report.
- ☐ Our extraction protocols meet the "exhaustive" requirement for all patient-contact materials, not just components we think are highest risk.

3. Quantification & Risk Assessment

Traditional estimation methods can introduce large errors. Predictive modeling reduces uncertainty and supports more accurate toxicological assessment.

- ☐ Our lab uses predictive response factors (not just surrogate-based estimation) to quantify compounds with higher accuracy.
- ☐ Our E&L testing data are structured to directly support toxicological risk assessment, so there are no gaps between lab report and safety case.

4. Supply Chain & Change Control

A "minor" supplier change can invalidate your entire E&L package if you can't assess impact quickly.

- ☐ We have a protocol to assess E&L impact when suppliers make material or process changes without triggering a full retest.
- ☐ Our lab partner can perform material deformulation to verify what's actually in our raw materials.

5. Timeline & Operational Readiness

E&L timelines have compressed dramatically. Make sure your lab partner's quoted timeline is the real timeline, not just lab time with a hidden queue.

- ☐ Our lab partner quotes timelines from sample receipt to report delivery, with no separate queue or wait time before work begins.
- ☐ Our current E&L timelines are in the 4-12-week range (not 12-22+ weeks), with rush capability when needed.
- ☐ We're testing on final, finished devices, not prototypes that may still change.
- ☐ Our lab partner's scoping process accounts for potential unknowns upfront, minimizing mid-project scope increases and timeline extensions.

How Did You Score?

- **13-14 checks:** Future-Ready. Your E&L testing strategy is built on solid scientific foundations that should withstand evolving regulatory expectations.
- **8-12 checks:** Compliance Gaps. You have a foundation, but gaps in material understanding, identification capability, or timeline predictability could expose you to rework.
- **0-7 checks:** Strategic Intervention Needed. Your current approach likely carries significant risk of late-stage material changes, submission delays, or regulatory pushback. A strategy review is recommended.

The Jordi Labs Approach

An RQM+ Company

Some teams see our rigorous approach as overkill. We see it as doing the best science possible so your submission is defensible no matter how regulatory expectations evolve.

- **The science:** We use FDA-recognized methods, high-resolution mass spectrometry (MS), and Lumo predictive response factors for highly accurate quantification; there are no "unknowns" in your report
- **The speed:** Timelines have been reduced from 12 to 22 weeks down to 4 to 12 weeks, with industry-leading speed and on-time delivery. Rush projects can be completed in 3 to 4 weeks. Our quoted timeline is the real timeline, with no hidden queue
- **The scoping:** We build complexity into initial estimates; additional compound IDs and unknown identifications are incorporated upfront, so you get fewer mid-project surprises and scope changes
- **The integration:** As part of RQM+, we connect lab science to regulatory strategy and clinical evidence; evidence gathered for one purpose creates value across your entire submission

Ready to Strengthen Your E&L Testing Strategy?

Talk to an expert about your material questions, supplier changes, or upcoming submission.

Secure Your Strategy

RQM+ Evolving MedTech

RQM+ is *The* MedTech CRO, accelerating innovation to patient impact. Our tailored solutions deliver regulatory and quality expertise, FDA-recognized laboratory services, clinical trials, and reimbursement strategies across device types and therapeutic areas to bring life-changing technologies to patients — faster, safer, better.

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