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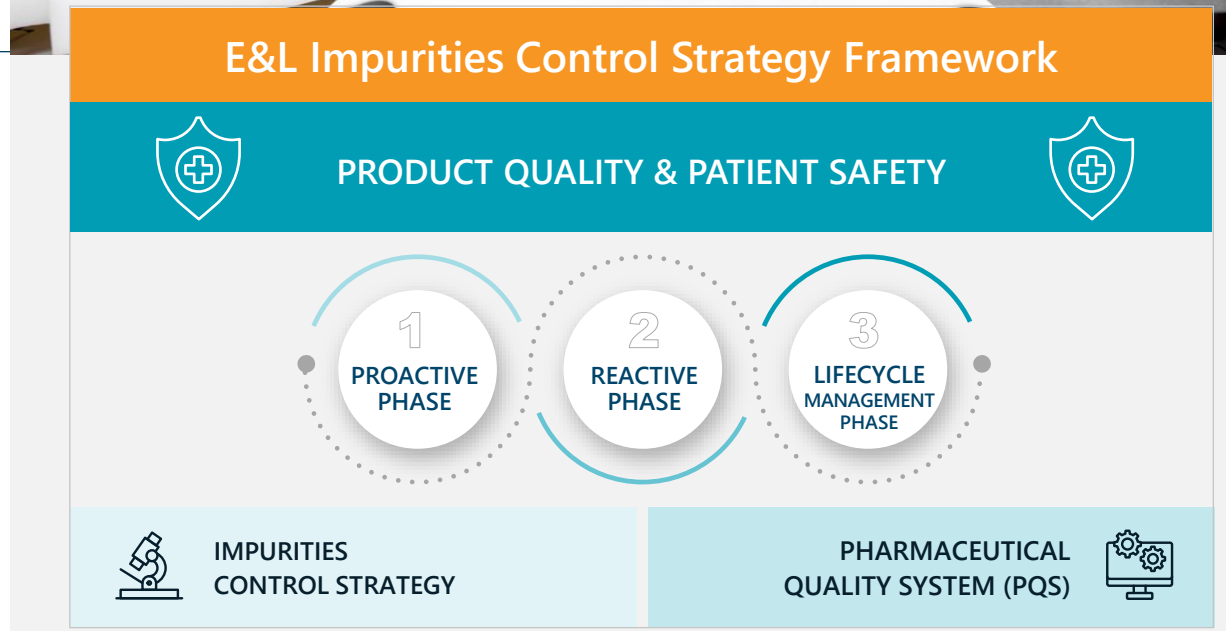
Why you need to build your ICH Q3E compliance now!

A risk-based control strategy for Extractables & Leachables management.

The upcoming adoption of the ICH Q3E guideline on Extractables and Leachables (E&L) will require a robust impurity control strategy for pharmaceutical product manufacturers.

To maintain regulatory alignment and ensure inspection readiness ahead of the anticipated 2027 implementation, Productlife-group (PLG) provides a range of proactive technical evaluation and data integration services.



This structure is designed to bridge the gap between current regulations and the final ICH Q3E requirements, ensuring that your company is fully compliant and audit/inspection ready.

ICH Q3E Guideline implementation
The current situation

The public consultation of the ICH Q3E draft guideline was completed at the end of January 2026.

Comments arising from the public consultation are being addressed by the ICH Expert Working Group (EWG), and according to the ICH Q3E EWG Work Plan, the date for final adoption of the guideline will be July 2027.

KEY MILESTONES in the ICH Expert Working Group (EWG) work plan

Expected future completion date	MILESTONE
Jan. 2026	Begin addressing public consultation comments (4 months public Consultation; 1 month constituent administration; 1 month consolidating comments)
Mar. 2026	Interim F2F Meeting - Safety Team Focus
Sep. 2026	Develop Q3E Training Materials
Jul. 2027	Step 3 sign-off and Step 4 adoption of final guidance

The value of early adoption

Engaging with our ICH Q3E support framework during the draft and transition phases offers significant operational advantages.

By acting now, companies can:

- Identify Gaps Early: Detect potential vulnerabilities in early development and lifecycle management stages, allowing for technical adjustments before they impact timelines.
- Align Internal Stakeholders: build awareness concerning the guideline across R&D, Quality, and Regulatory departments, ensuring a cohesive compliance culture.
- Build a Science-Based Roadmap: Develop a science and risk-based roadmap consistent with ICH principles, on which a robust, risk-based impurity control strategy will be built.

Which Products fall under the scope of ICH Q3E?

Understanding the specific applicability of the ICH Q3E guideline is fundamental to developing a proportionate compliance strategy.

Although the exact final scope has not been approved yet, PLG can still assist you with the mapping of your portfolio to identify the extent of the impact that the new ICH Q3E may have on your company activities.

ICH Q3E Guideline

Products within Scope

Currently, the ICH Q3E principles apply to the following Drug Product categories, where the potential for extractables/leachables to impact patient safety or product quality must be assessed:

- **New Chemical Drug Products**
- **New Biological Drug Products:** Including advanced therapeutics such as cell and gene therapy (CGT) products.
- **New Drug-Device Combination Products:** Specifically, those requiring marketing authorization that meet the definition of a pharmaceutical or biological product.
- **Approved products** (belonging to the category above reported) Specifically, those impacted by post-approval changes relating to formulation, manufacturing processes, dosing, and/or container closure systems (CCS).

Special considerations regarding packaging components **for liquid or semiliquid active pharmaceutical ingredients (APIs) storage** are required.

Products excluded from Scope

Currently, the guideline does not apply to the following Drug Product categories:

- **Approved products** not impacted by post-approval changes relating to formulation, manufacturing processes, dosing, and/or container closure systems (CCS).
- **Herbal and Crude Products:** Herbal medicinal products and non-processed products of animal or plant origin.
- **Clinical Development Products**
- **Excipients**
- **Radiopharmaceuticals:** These are generally excluded unless a specific cause for concern is identified.

Which Products fall under the scope of ICH Q3E?

PLG offers a specific set of 'readiness roadmap' services focused on data collection, impact assessment, and regulatory intelligence.

1 Data Mapping and Architecture

a. **Data Collection/Mapping:** Systematic identification and collection of all the relevant information for E&L across your company's product portfolio.

b. **Database/Dashboard Development:** Creation of digital repositories/database and an interactive dashboard to centralize and integrate all collected information into a single, coherent system. The dashboard enables real-time data visualization and provides an interface for analysis by system, country, category, or any relevant parameter, ensuring quick access to critical insights.

2 ICH Q3E Impact and Readiness Assessment*

Gap analysis between the existing E&L situation within your Pharmaceutical Quality System and the Q3E draft guideline requirements.

*Only if we or the client have completed step 1.

3 ICH Q3E Awareness Training and Workshops

SME-led sessions focused on building a shared understanding of ICH Q3E principles across key functions and supporting aligned risk-based decision making.

4 Regulatory Intelligence

Continuous monitoring of the regulatory landscape to provide timely and actionable insights on regulatory developments, enabling your organization to proactively manage compliance, reduce regulatory risks, and align strategies with evolving legal and regulatory frameworks.

Complementary Risk Assessment services

To provide a holistic impurity control strategy, PLG offers integrated assessments that overlap with ICH Q3E requirements:

- E&L Risk Assessment for Single-Use Systems (SUS): Targeted evaluation of leachable profiles specifically for polymer-based manufacturing components. This requirement is already in force to ensure compliance with cGMP Annex 1, “Manufacture of Sterile Medicinal Products” (ref. to point 8.136 of the Annex 1)
- Inorganic Risk Assessments (ICH Q3D): Risk assessments for potential Elemental Impurities (EIs) contamination in finished products due to Extractables and Leachables, ensuring simultaneous compliance with established ICH Q3D requirements.

With a presence in 150+ countries, own resources in 50+ countries, and a team of over 2,000 professionals, **ProductLife Group** acts as an end-to-end partner for the pharmaceutical, biotechnology, medical device, nutrition, and cosmetics sectors.

Our mission is to support clients in accelerating innovation, ensuring compliance, and ultimately improving human health.

From Product Development to Market & Patient Access, from Regulatory Affairs and Safety & Vigilance to Consulting & Digital, our global experts join forces to shape the future of PLG’s client offering across multiple domains, including Biopharma industries, Consumer Healthcare, and Medical Devices.

With a goal of continuously improving the value delivered to people and customers, PLG is committed to long-term partnership, innovation, flexibility, and cost efficiency.

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