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Whitepaper

Navigating ICH Q3E: Implications for Extractables and Leachables (E&L) Evaluation

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Summary

Abstract

This whitepaper provides a comprehensive overview of the ICH Q3E draft guideline (2025), which introduces a harmonised, risk-based approach to the assessment and control of extractables and leachables (E&L) across a broad range of drug products. It outlines the key components of the guideline, compares it to prior regional and industry-specific guidance, and highlights its implications for pharmaceutical development, regulatory strategy, and lifecycle management.

Introduction

What are E&Ls and why are they important for pharmaceutical manufacturers?

Extractables are chemical substances, for example additives, that are present in pharmaceutical packaging, manufacturing components, or delivery systems and can be extracted under controlled, often exaggerated, laboratory conditions. These substances represent potential impurities that might migrate into drug substances or drug products that are in contact with the material. Leachables, on the other hand, are chemical entities that actually migrate into the drug substance or drug product during its manufacturing process or throughout its shelf life under normal storage conditions. These chemical entities may pose health risks to patients if present in sufficient quantities. Therefore, extractables and leachables are assessed to ensure patient safety by demonstrating the compatibility of packaging and other product-contacting components with the product.

What is ICH doing about it?

ICH is the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, formed in 1990 with the aim of promoting public health through international harmonisation. ICH's technical guidelines are adopted by regulators globally and aim to contribute to:

- Prevention of unnecessary duplication of clinical trials and post-market clinical evaluations
- Development and manufacturing of new medicines
- Registration and supervision of new medicines
- Reduction of unnecessary animal testing without compromising safety and effectiveness

The ICH Q3E guideline sits within a suite of quality-focused guidance that is used to inform technical and regulatory expectations for medicines. This guideline complements existing ICH impurity guidelines (Q3A-Q3D, M7[1]) and aligns with ICH Q9 on risk management. It aims to ensure patient safety and product quality, especially in light of evolving materials and manufacturing technologies.

This is important because until now, no internationally harmonised guidance on E&L assessment and control has existed. Pharmaceutical companies refer instead to guidance from specific regions e.g. EU Guideline on plastic immediate packaging materials, Ph. Eur. chapter 3 (materials for containers), and US Pharmacopoeia (USP) chapters <1663>, <1664>, and <1665>. Additionally, some groups have produced recommendations for specific dosage forms [notably, Product Quality Research Institute (PQRI)] that are widely used e.g. for inhalation products. Otherwise, companies apply safety risk assessment principles from ICH M7 (although its application for leachables is not intended), ICH Q3D for elemental impurities from processing equipment and container closure systems, and ISO 10993 covering biocompatibility requirements for devices. This current gap generates uncertainty for industry and regulators, as there is a lack of clarity on the regulatory expectations for E&L.

As a result, ICH's work to develop a harmonised technical guideline is widely welcomed. The draft guideline introduces a framework for the assessment and control of extractables and leachables (E&L) in pharmaceutical products, addressing a range of product types and proposing identification, qualification, and reporting thresholds.

This article outlines the stepwise approach described in the guidance, compares it against the existing framework, and lastly discusses: Does the ICH Q3E guidance achieve what it set out to do?

The ICH Q3E guideline

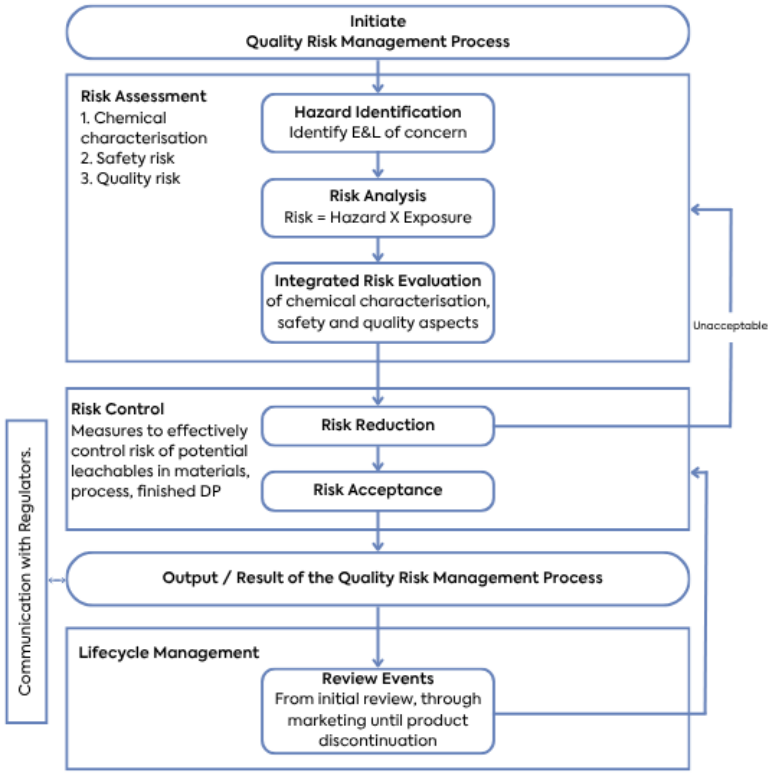
The ICH Q3E guideline applies to the following products

- New drug products, biologics (including cell and gene therapy products), and drug-device combinations.
- Excludes herbal products, radiopharmaceuticals, and investigational products unless high risk.
- Focuses on organic leachables; elemental impurities are covered under ICH Q3D.

Although the guidance drives the approach for development of new products, the risk assessment also applies to established products that are subject to change (for example changes in formulation, route of administration, manufacturing process, packaging, or patient type/exposure). Once a control system is established and the components qualified, this forms the basis for ongoing oversight as part of good manufacturing practices.

The appropriate management and control of leachable impurities is founded on a risk management framework, depicted in Figure 1. Risk assessment is based on hazard identification, risk analysis and an integrated risk evaluation that determines whether additional control measures are needed. The incorporation of risk control considerations emphasises the ICH Q3E process as a tool and echoes the approach taken in other ICH guidelines: how are impurities introduced and what is the capacity of the downstream process to remove leached impurities? The guidance integrates considerations of all product contact materials, including processing equipment composed of polymeric materials (short duration of contact, but may operate under harsh conditions), and packaging/delivery materials (for which a longer contact period is foreseen).

Figure 1: Overview of the Risk Management Process (source: ICH Q3E)

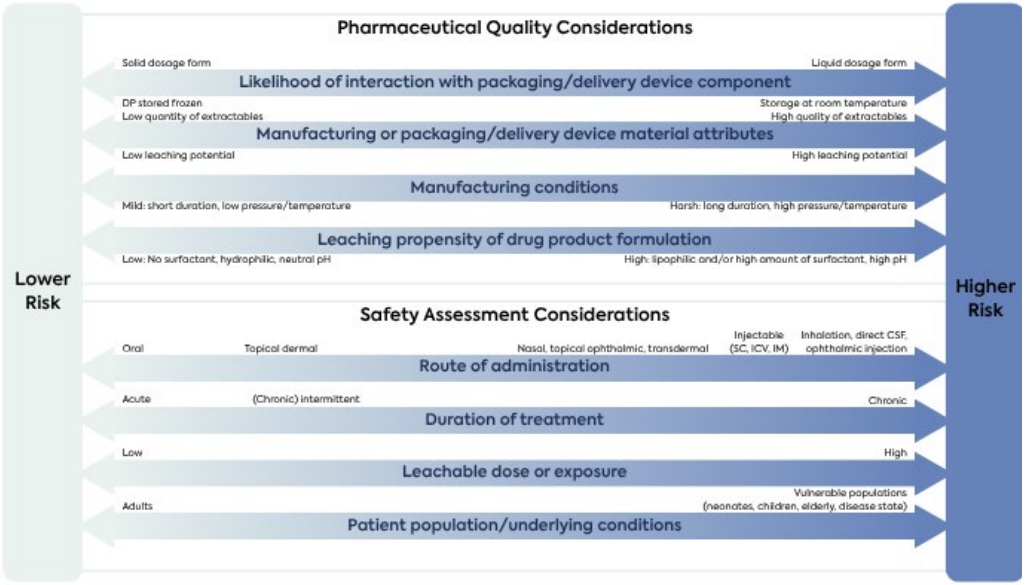


Risk Assessment

The risk assessment process considers hazards introduced when a drug substance or drug product is in contact with packaging materials or manufacturing equipment and depends on a number of factors impacting quality and safety (Figure 2). The risk of leaching may, for example, depend on whether a product is

solid or liquid, the attributes and composition of the contact material, the properties of the product such as lipophilicity, and duration and conditions of contact. The safety impact on a patient may depend on whether the medicinal product is administered orally or through a higher risk route (e.g. inhaled), the dose, frequency, duration of treatment, and the vulnerability of the patients that may use the product. The analytical evaluation threshold (AET) takes account of these dosing considerations to determine a study-specific concentration above which extractables or leachables should be identified and quantified to enable safety assessment – more on the AET later in this article.

Figure 2: Overview on Aspects to Consider for Risk Matrix (source: ICH Q3E)



In this situation it is clear that one size does not fit all and there is significant scope to tailor the risk evaluation.

Steps for risk assessment include:

Step Number	Tools	Data Sources
Step 1 Hazard Identification	Identify potential leachables that may migrate into the drug product from direct or indirect contact surfaces	• Prior knowledge: vendor data, material composition, certificates, historical data, literature, databases (e.g., ELSIE). • Experimental studies: extractables under exaggerated conditions, leachables under actual use. • Material characterisation: polymers, additives, surface treatments, processing aids. • Analytical identification: GC-MS, LC-MS, ICP-MS, FTIR. • *In-silico* screening: predictive toxicology (e.g., Derek Nexus). • Hazard classification: mutagenic, sensitising, genotoxic, irritant, systemic toxicants.
Step 2 Risk Analysis	Quantitate the potential occurrence of leachables in the drug product and assess the patient exposure to leachables	• Leachables quantitation: measure concentrations in the drug product. • Patient exposure: calculate daily intake based on dose and route. • Thresholds: set Analytical Evaluation Threshold (AET) using Safety Concern Threshold (SCT). • Comparison: identify compounds above AET for toxicological assessment.

		• Occurrence assessment: use extractables-to-leachables correlation, migration models, or empirical data. • Tools: validated analytical methods, exposure models, statistics, process knowledge.
Step 3 Integrated Risk Evaluation	Integrate findings: combine leachables, exposure, and hazard data to assess overall risk. Evaluate the potential risk to impact product quality, safety and efficacy to determine if the selected manufacturing components/systems and container/closure systems are considered qualified for the intended use	• Toxicological acceptability: compare exposure to PDE or Tolerable Intake. • Expert review: multidisciplinary evaluation (toxicology, quality, materials, regulatory). • Documentation: justify read-across, in-silico predictions, or threshold-based exclusions. • Decision: confirm qualification or define mitigation (material/process changes, additional testing). • Lifecycle management: include in Pharmaceutical Quality System for ongoing monitoring and re-assessment.

This risk-based framework allows developers to continue referring to food-contact safety standards or pharmacopeial monographs where justified e.g. for solid oral medicinal products packaged in high-density polyethylene (HDPE) bottles, but guides the approach to the more complex risks.

Chemical testing and assessment

How are the risks arising from a product contact material assessed?

1. Existing knowledge about the material is a critical starting point – consider supplier information and certifications, compliance with food contact legislation or compendial requirements, composition information, biological reactivity testing and studies performed by the material supplier. This is likely to determine whether the extractables testing is needed at all or to provide the basis for more targeted extractable tests.
2. Perform extractable studies – incorporates solvents and extraction conditions relevant to the medicinal product or manufacturing process (worst-case conditions should be used and may include a range of pH, composition, contact area and extraction conditions). Screening for volatile, semi-volatile and non-volatile organic extractables (and elemental extractables – see also ICH Q3D). Analytical procedures should be adequately qualified for this activity and may include targeted tests for leachables of highest concern, if their presence might be expected.
3. Semi-quantitative and quantitative extractables studies may be a suitable next step, to establish which extractables may be present as leachable compounds in the finished product. Quantification against reference standards is introduced here for compounds that are typically observed as E&L, allowing comparison with product-specific analytical evaluation thresholds. A semi-quantitative assessment may serve as a precursor to a planned leachables study. For manufacturing components and low-risk packaging systems, a quantitative extractables study may be sufficient – without a leachables study - to demonstrate a low risk of leachables, if all compounds in the extractable study are below their applicable safety

threshold or within permitted daily exposure limits. If some limits are exceeded or an extracted compound cannot be identified, a leachables study would then be required.

4. A leachables study builds on the understanding that has been gained in extractables testing. If extractables studies have shown there is a risk for chemical impurities to be extracted into the medicinal product, the leachables assessment is performed on the product itself under the expected manufacturing and storage conditions. Leachables studies for the container closure system are typically performed alongside the product stability tests and should cover multiple primary drug product batches manufactured with the actual packaging and delivery system intended for use with the commercial product. The extractables study may have identified certain compounds to target during leachables testing, although screening for non-targeted leachables should also be used, to detect unanticipated compounds. For this study, there are clear benefits to using the same components used in extractables assessment: establishing a correlation now between the compounds that are extracted in a model system and what finally ends up in the medicinal product may support the use of extractables testing in place of routine leachables studies for high-risk products or simplify future materials changes.

The new guideline also introduces the possibility of simulated leachables testing in cases where a full leachables study is not technically feasible or to augment the information obtained. For example, in case of large volume parenteral products where the AET is extremely low or situations where there is significant matrix interference. How is this different from the extractable study? It should be performed at conditions that much more closely match the intended drug product manufacturing and storage conditions, with the aim of mimicking the actual leachables profile generated by the drug product over its shelf life. Accelerated conditions may, however, be used, reducing the overall duration of the study.

Documentation Requirements

The ICH Q3E guideline provides unequivocal instructions on reporting in the regulatory dossier. Registration applications, such as the marketing authorisation application dossier, should include the following:

- A list of the extractables/leachables studies performed and a justification for study choice.
- The associated study reports. These should describe and justify extraction conditions, provide analytical methods, including, where used for quantification, a demonstration of their suitability (limit of detection, limit of quantification, specificity, linearity, accuracy and repeatability).
- Identification of substances above the AET (including chemical name, structure, CAS registry number and observed level) and a safety risk assessment.
- Where appropriate, a leachables to extractables correlation.
- Any risk mitigation and control measures.

Toxicological Evaluation (Section 3.3 of the guideline)

A cornerstone of the ICH Q3E guideline is the toxicological evaluation and qualification of leachables, which promotes a science- and risk-based approach to ensure patient safety while avoiding unnecessary testing. The guideline integrates established exposure thresholds, emerging toxicological tools, and lifecycle considerations to provide a harmonised framework for assessment.

Tiered Classification of Leachables

Leachables are categorised into three classes based on toxicological concern and available data:

Class 1 – Highest concern, often including compounds with unknown or potential genotoxicity, reactivity, or structural alerts. These require rigorous evaluation and may align with ICH M7 recommendations.

Class 2 – Moderate concern, generally non-mutagenic compounds with limited safety data; threshold-based qualification using approaches such as the Threshold of Toxicological Concern (TTC) is often sufficient.

Class 3– Lower concern, compounds with well-established safety profiles (e.g., pharmacopeial substances or approved food additives), which typically require minimal additional evaluation if below thresholds.

This hierarchy prioritises resources, focusing detailed testing on higher-risk compounds while allowing lower-risk leachables to be assessed via thresholds or literature-based justification.

Exposure-Based Thresholds

ICH Q3E defines key thresholds to guide decision-making:

- Safety Concern Threshold (SCT): Daily exposure level below which the probability of adverse health effects is low; for potential genotoxicants, typically aligned with the 1.5 µg/day TTC recommended in ICH M7.
- Analytical Evaluation Threshold (AET): Operational limit for identifying leachables in extractables or leachables studies. It considers factors such as maximum daily dose, route of administration, and patient population.
- Qualification Threshold (QT): Trigger for comprehensive toxicological evaluation, including systemic and, where relevant, local toxicity.

New Approach Methodologies (NAMs)

The guideline explicitly encourages NAMs to supplement or, in some cases, replace traditional toxicology testing. These include:

- *In silico* predictive models (e.g., QSAR-based tools)
- Read-across from structurally similar compounds
- Selected *in vitro* assays for relevant endpoints

NAMs enable rapid hazard screening, reduce animal use, and support evaluation of compounds with limited experimental data, providing flexibility while maintaining scientific rigor.

Lifecycle Management

Toxicological evaluation under ICH Q3E is a continuous, lifecycle activity. Any post-approval change, such as a new supplier, manufacturing process modification, or formulation adjustment, requires re-assessment of the E&L risk profile. Embedding this process into the Quality Management System and existing risk assessment framework ensures ongoing product safety and regulatory compliance.

Expert Judgment in Toxicological Evaluation

While thresholds and NAMs provide a regulatory scaffold, toxicological risk assessment is inherently expert-driven. Applying read-across, interpreting limited data, and evaluating route-specific risks require professional judgement, informed by chemical, toxicological, and product-specific context. Decisions regarding surrogate compounds, structural alerts, or threshold application must be evaluated case by case, as no single guideline can replace the nuanced interpretation of qualified toxicologists.

Breaking Down Quality and Safety Silos

One of the most impactful aspects of the ICH Q3E draft guideline is how it bridges the historical divide between quality and safety workflows. Traditionally, these functions operated in silos: quality teams focusing on analytical and manufacturing parameters, and safety teams on toxicological evaluation.

The guideline makes it clear that developers need to consider both quality and safety in tandem. For scientists involved in E&L assessments, it can be easy to think, 'my job is the safety part' or 'my job is the quality part.' This framework brings the two aspects together, recognising that both are equally important for a scientifically sound assessment. By uniting these disciplines, the ICH Q3E framework promotes a holistic, integrated approach, ensuring E&L assessments are not only compliant but also scientifically cohesive and robust.

The ICH Q3E draft guideline represents an important milestone. Like ICH Q9 on risk management, it connects safety and quality assessments. Analytical development teams are empowered to move away from trial-and-error methods towards a product-focused quality risk management process. This supports proactive decision-making throughout the product lifecycle, strengthening the link between quality and the final safety case.

3 Key Examples of Where the Guideline Is Making a Difference

Case Study 1: A new combination product with both a novel biopharmaceutical drug and a novel device

The Situation

A start-up has a combination product consisting of a novel mRNA asset delivered through a novel soft mist inhaler device. The intended market is the USA, and the team is preparing for an FDA IND submission. A determination needs to be made on the E&L requirements for submission based on the existing guidance. According to the ICH Q3E, there is no requirement to provide E&L data for clinical trials, but will this be acceptable to the regulator?

The Solution

As the ICH Q3E is a draft guidance without FDA ratification, the regulatory expectation would be to conduct, at the minimum, a toxicological risk assessment for the medical device under ISO 10993 and a risk assessment under USP <665> (or alternatively, the BPOG protocol) for the manufacturing of the mRNA drug product. Considering the high-risk nature of the product and route of administration, it is recommended that an extractable study be conducted prior to Phase 2. A leachable study tied to the stability study should then be considered for Phase 3. Notably, ICH Q3E does provide some guidance on biopharmaceuticals in Section 3.4.1 Special Considerations, which should be taken into account. The guidance raises concerns that leachables can have an impact on the efficacy or shelf life of biopharmaceutical products in particular, and recommends that additional testing

may be required to ensure product safety. This is why it is important to consider conducting E&L studies in support of Phase 2 and 3 clinical trials.

The outcome

The team conducted a toxicological risk assessment for the device and a risk assessment for the drug product to support the IND submission. In preparation for a Phase 2 clinical trial, an extractable study was performed in accordance with USP <665> and ISO 10993-18 to provide further safety information to support the trial.

Case Study 2: A change to the drug formulation of an existing combination product.

The Situation

A large pharmaceutical company has an existing pMDI device on the market that uses the propellant HFA-134A. Due to concerns regarding the environmental impact of that class of propellant, regulatory bodies such as the US FDA and EU EMA are requiring a shift towards greener propellants. A determination needs to be made on the E&L requirements for this product change.

The Solution

ICH Q3E covers product changes in Section 3.6 Risk Review / Lifecycle Management. Changes to the drug formulation require an updated risk assessment and an extractable (and likely a leachable) study to be performed. The E&L studies should be conducted in accordance with USP <661>, <663>, <1661>, <1663> and <1664> or the PQRI Guidance: Thresholds and Best Practices for Extractables and Leachables in Orally Inhaled and Nasal Drug Products.

The outcome

The team leveraged existing extractables data on the pMDI device to begin development of a leachables study on development samples. This allowed them to validate the leachables methods against the reformulation and tie the leachables study to the new product's stability studies, meeting an aggressive timeline for the launch of the new product.

Case Study 3: Maintaining and seeking new market authorisations for a legacy combination product, with no changes to the drug or device.

The Situation

A medium-sized pharmaceutical company has acquired a new asset. It is a legacy product that is currently being sold in the US and seven EU member states. The company intends to seek new market authorisations in multiple additional EU member states. As this is a legacy product, it is unclear if the regulatory dossiers have been brought in line with the current standards, and what requirements need to be met in order to maintain current and expanded market access.

The solution

For the product's existing markets, ICH Q3E does not apply as no changes are being made to the product. However, the following will need to be taken into consideration.

US Market: USP <661> goes into effect at the end of 2025, and USP <665> goes into effect in 2026. In order for the product to continue to be sold in that market, the regulatory expectation is that the product would be brought in line with these guidance documents.

EU Markets: The EU MDR came into effect in 2021 and there have been numerous changes to ISO 10993 in recent years. The expectation would be to show compliance with these standards even if the product has been on the market prior to the ratification of the legislation and standard. In addition, whilst ICH Q3E is technically not applicable in this situation, it is recommended that it is taken into account, as notified bodies may wish to see compliance in the spirit of the guidance.

For the new market introductions, ICH Q3E should be followed.

The outcome

The acquiring company reviewed the dossiers for the various countries in order to assess what was required in each country or region. In some cases, no testing was required. For the US and new EU markets, the team conducted a toxicological risk assessment for the medical device under ISO 10993 and a risk assessment under USP <661> for the drug product in accordance with ICH Q3E. An extractable study was also conducted based on the outcome of the risk assessments.

Challenges and Opportunities for Improvement

While ICH Q3E provides a robust framework for E&Ls, several practical challenges remain that require expert interpretation and offer opportunities for improvement. It introduces valuable concepts such as lifecycle risk management and toxicology integration, but falls short of delivering true harmonisation or practical technical guidance. While the intent is clear, the execution leaves critical gaps that could impact compliance and patient safety.

Scope Limitations: One major limitation is the scope. The exclusion of legacy products contradicts USP <661.1> enforcement timelines and creates uncertainty for existing packaging systems. Similarly, the lack of a defined framework for E&L expectations during clinical trials leaves sponsors without clear direction. Elemental leachables are deemed out of scope, yet Q3D does not address long-term metal leaching risks, raising questions about patient exposure over time.

Harmonisation Shortfalls: The guideline also misses its core mission of harmonisation. There is no mapping of USP and Ph.Eur chapters, nor any attempt to integrate widely accepted best practices from BPOG, ISO, or PQRI. Without these linkages, the document reads more like a risk assessment guide than a harmonisation standard.

Technical Guidance Gaps: Technical detail is another critical gap. The draft introduces concepts such as "quantitative extractables" and uncertainty factors for AET calculations but provides no methodology, validation criteria, or worked examples. Similarly, the safety assessment section offers useful toxicity thresholds but lacks guidance on surrogate data and read-across approaches—areas that remain significant challenges for toxicologists. Additional considerations highlight further weaknesses. Variability in analytical sensitivity, laboratory practices, recovery, and method validation can lead to inconsistent detection of compounds near the Analytical Evaluation Threshold (AET). Standardised calculation methods, harmonised assumptions for patient population, dose, and exposure, and clear guidance on handling analytical uncertainty would enhance consistency and regulatory confidence. While the guideline references thresholds such as SCT, AET, and Qualification Threshold, it does not prescribe practical application of read-across or surrogate data interpretation. Route-specific considerations and limited toxicological data require expert judgement, underscoring the need for qualified toxicologists. ICH Q3E also focuses primarily on systemic exposure, leaving gaps for inhalation, dermal, ocular, and other routes of administration. Additional guidance on route-specific toxicity endpoints would clarify expectations and ensure

consistent risk assessment across all pathways. Transparent documentation and justification for threshold selection, NAM application, and toxicological conclusions are essential for regulatory confidence. Strengthened documentation practices will ensure that scientific reasoning and risk-based decisions are defensible during review.

To strengthen Q3E, ICH should expand its scope to include legacy products and clinical trial expectations, clearly articulate harmonisation targets, and provide practical technical detail on testing protocols and risk assessment workflows. Enhancing standardisation of AET calculations, clarifying read-across and NAM application, and reinforcing documentation requirements could significantly improve consistency, reproducibility, and regulatory acceptance. Incorporating case examples, decision frameworks, and visual tools would transform Q3E from a conceptual document into a robust, actionable standard that supports global harmonisation and patient safety. Closing these gaps will require a coordinated effort between regulators, industry, and standards organisations. Practical steps include:

Standardising AET Calculations: Develop harmonised assumptions for patient population, dose, and exposure, and provide clear guidance on managing analytical uncertainty.

Clarifying Read-Across and NAM Application: Define when and how to apply surrogate data and new approach methodologies, supported by case examples.

Expanding Route-Specific Guidance: Include inhalation, dermal, and ocular toxicity endpoints to ensure consistent risk assessment across all administration routes.

Strengthening Documentation Practices: Require transparent rationale for threshold selection and toxicological conclusions to build regulatory confidence.

Driving True Harmonisation: Map USP and Ph.Eur chapters and incorporate non-governmental best practices to create a unified global standard.

By embedding these improvements and fostering collaboration, ICH can transform Q3E from a conceptual guideline into a robust, actionable framework that supports global consistency, reduces duplication, and safeguards patient safety.

Conclusion

The ICH Q3E draft guideline represents a landmark step toward harmonisation in E&L assessment. By integrating safety and quality, embedding risk-based principles, and emphasising lifecycle management, it provides a solid foundation for a more predictive, patient-focused regulatory model. While challenges remain, particularly in analytical consistency, scope, and the validation of new methodologies, ICH Q3E sets a clear direction for the future.

Support for Companies

EXTRACTUS

Extractus is a contract research organisation that provides high quality analytical services to the pharmaceutical and medical device industries. We specialise in delivering comprehensive Extractables and Leachables testing, risk assessments, and recommendations. We also offer a range of other analytical services including CMC investigations, biopharmaceutical characterisation, residual solvents, nitrosamines, and DMPK. We support our clients on their journey to regulatory approval from R&D through to final product testing.

Our team has extensive expertise in orally inhaled and nasal drug products, biopharma single-use systems, ophthalmic, parenteral, topical, transdermal, oral, and suppository products. We have contributed to regulatory submissions, defended agency questions and audits, and put in place mitigation strategies where needed. We have worked for big pharma, small start-ups and everything in between, so we have an intimate understanding of the customer perspective, what elements of a study are most important, and how to communicate information to customers in a timely and meaningful way. We're more than just a fee for service CRO – we're strategic partners that go the extra mile to provide high quality data and solution-focused advice to help our clients succeed.

DLRC is a dedicated consultancy team of highly qualified and experienced Regulatory Affairs professionals who have come from pharmaceutical company and regulatory agency backgrounds. We have provided our services to over 130 companies of all sizes and backgrounds, enabling them to achieve their strategic and operational development objectives. DLRC's expertise and flexible working approach ensure a highly motivated team that interacts effectively with clients and regulators globally and supports both single-issue and long-term commitment to projects.

We have significant experience in inhaled products and have helped clients develop, write, submit, and approve inhaled submissions and subsequently manage post-approval regulatory activities for the same clients. In addition, we have managed scientific advice for a number of clients for inhaled products both in Europe and the USA. DLRC also has a device team that will help clients navigate global medical device regulations and assist in the design and development process. The team helps clients meet technical and regulatory requirements while facilitating early interactions with regulatory authorities.

Meet the Authors

Catherine Flynn

Principal Regulatory Consultant, DLRC

Catherine is a longstanding consultant with DLRC having joined in October 2008, and has 25 years' experience in the pharmaceutical industry, including 20 years in regulatory affairs. Focusing primarily on regulatory CMC, she supports clients at all stages of the product lifecycle from early phase development (Scientific Advice, IMPD, INDs) to MAA and post-approval procedures. Catherine has worked on a wide variety of product types ranging from small molecule generics to herbal medicines and biologics; recent examples include a novel herbal extract, mRNA vaccine, monoclonal antibodies and inhalation products. She has a particular interest in strategy for established active substances, UK post-Brexit strategy, sterile manufacture and the GMP interface. Prior to joining DLRC, Catherine worked for Merck Generics (now Viatris) responsible for EU strategy, specialising in initial registration of in-licensed products and subsequently leading a team responsible for lifecycle management. Before that Catherine worked at GSK in radiosynthetic chemistry and in analytical development, where she gained practical experience in analytical techniques and supported drug substance scale-up to pilot plant. Catherine has a B.Sc. (Hons) in Chemistry from the University of York.

Sharon Robinson

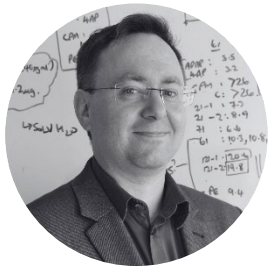
Associate Director & Principal Regulatory Consultant, DLRC

Sharon joined DLRC in January 2022 with over 20 years of experience in nonclinical development followed by 6 years in regulatory affairs. Focusing on nonclinical regulatory topics she supports clients at all stages of the product life cycle (from early phase development, Scientific Advice, PIPs, INDs, to MAA/NDA/BLA and post-approval procedures), across different research and therapy areas and has experience in the nonclinical regulatory aspects of both small molecules and biologics. Sharon has worked on a wide range of products, recent examples include scientific advice (EU and US) and authoring of the first IB for a small molecule approaching Phase 1 clinical trials, MHRA scientific advice for a small molecule approaching Phase 2b and a Phase 3 IND submission for a therapeutic protein. Prior to joining DLRC, Sharon worked as a nonclinical manager at Freeline therapeutics a clinical-stage biotechnology company focused on AAV-based gene therapy targeting the liver, where she focussed on developing and reviewing nonclinical and regulatory documents for both USA and EU submissions. Sharon also worked for GSK for 18 years, and held position in the nonclinical safety department, where she acted as Discovery Safety Leader a role in which she helped projects select molecules with the right safety profile, and the nonclinical regulatory group, where she led the nonclinical regulatory activities for multiple small molecule and biologics filings in both the EU and US. Sharon has a BSc (hons) in Biosciences and Health from the University of Leeds.

Samantha Gan

Co-Founder & CEO, Extractus

Samantha has a PhD in drug development from King's College London, and 10+ years of experience as a programme and operations management professional. She has managed the delivery of many complex, multi-million pound research programmes across organisations such as NHS England, NIHR and MRC, and is adept at influencing and working with high-level stakeholders to develop and implement effective scientific programmes at scale. Samantha has experience working in large pharmaceutical companies such as GSK, and small startups where she managed the GMP manufacture of ophthalmic and parenteral combination drug and medical device products. She also has expertise in non-combination medical devices and advising clients with MDR regulations and NHS implementation, particularly for software and AI driven devices.



Rick Reiley

Chief Scientific Officer, Extractus

Rick has over 25 years of experience working in the pharmaceutical industry, from large pharmaceutical and consumer health companies to small scale startups. He is an internationally recognised subject matter expert in extractables and leachables, and previously led the global manufacturing E&L team at GSK for the Pharma and Consumer Health divisions. In that role, he supported 26 manufacturing sites globally with their analytical challenges such as CMC investigations into unknown contaminations, and nitrosamines. He has successfully submitted and defended E&L studies to regulatory authorities for products like Otrivin, Flonase, and Ventolin, and conducted the first UK E&L studies on radiopharmaceutical (GE Healthcare) and radiolabelled biopharmaceutical products (GSK). Rick also has experience working for small scale startups where he supported key clinical assets including vaccine and ophthalmic combination drug-device products through IND and successful Phase 2 clinical trials. He has several patents for novel drug products in his name. Rick has a deep understanding of clients' requirements, from both scientific and regulatory standpoints, and is well versed in supporting clients from R&D through regulatory submission and beyond to the lifecycle management of existing products. He co-founded Extractus Ltd because he understands what the industry needs from E&L CRO providers and strives to make a difference in a field fraught with inconsistencies and conflicting information.

References

1. European Medicines Agency., ICH Q3E Extractables and Leachables – Scientific Guideline https://www.ema.europa.eu/en/ich-q3e-extractables-leachables-scientific-guideline

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