

REQUEST FOR INFORMATION

**Supply of Test Mixes for Interlaboratory Study**

24 June 2025

Extractables and Leachables Safety Information Exchange (ELSIE) Consortium

Request for Information

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# Introduction

## About the ELSIE Consortium

The Extractables and Leachables Safety Information Exchange Consortium (ELSIE) is a leading industry voice and scientific resource on extractables and leachables (E&L), comprised of pharmaceutical, biotechnology, and medical device companies. ELSIE‘s objectives are to reduce duplicative safety studies across companies, streamline development projects, and to help advance the practice and science of extractables, leachables, and materials evaluation. ELSIE members participate in collaborative Working Groups and Subteams that address key knowledge gaps, support members’ daily work, and advance the state of E&L risk management. ELSIE also has regular interactions with the regulatory agencies and industry stakeholders to discuss current and emerging E&L issues. ELSIE achieved an important milestone in 2024 by launching their next generation Knowledge Base.  The Knowledge Base is a valuable resource for members that will store toxicological safety information and extractables study results on raw materials, single-use products, drug packaging and delivery systems, and medical devices.

## Request for Information

Publication of this Request for Information (RFI) is the first step by ELSIE to identify a supplier for reference standard mixes to be used in an interlaboratory study under the Product Quality Research Institute (PQRI). ELSIE is one of the organizations providing support to PQRI as it plans this interlaboratory study looking at analytical uncertainty (variation) in extractable testing. The information collected during this RFI process will be used for evaluation purposes.

## Disclaimer

The contents and information provided in this RFI are meant to provide general information to parties interested in supplying reference standard mixes for an interlaboratory study. The selected respondent will be required to supply a Statement of Work (SOW) describing how they will supply reference standard mixes in support of the planned interlaboratory study. When responding to this RFI, please note the following:

* This RFI is not an offer or a contract
* Responses submitted in response to this RFI become the property of ELSIE
* Respondents will not be compensated or reimbursed for any costs incurred as part of the RFI process
* If ELSIE receives and responds to questions from RFI respondents, ELSIE reserves the right to anonymize the questions and make the questions and ELSIE’s responses available to all respondents via our website
* ELSIE is not obligated to contract for any of the products or services described in this RFI
* ELSIE reserves the right to:
	+ Accept or reject any or all proposals
	+ Waive any anomalies in proposals
	+ Negotiate with any or all bidders
	+ Modify or cancel this RFI at any time

## RFI Contact Information

All questions and inquiries regarding this RFI should be directed to:

Ms. Mary Kate Bielinski

ELSIE Secretariat

c/o Faegre Drinker Biddle & Reath, LLP

1500 K St NW

Washington DC, 20005-1209

414.207.4189

info@elsiedata.org

<https://www.elsiedata.org>

## Anticipated Time Frames for Evaluation and Selection Process\*

Issue RFI June 24, 2025

Responses to RFI due July 17, 2025

*\*Dates subject to change without notice*

***Please submit your response electronically to the above email address. Responses received after July 17, 2025*** ***will not benefit from full consideration and may be excluded from the selection process.***

# Project Information

## Description

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| PQRI has identified a common need to obtain a supply of reference standards mixes to support a planned inter-laboratory study. The study’s primary aim is to explore variation in analyte response and associated response factor / relative response factor for constituents within the supplied reference standard mixes to be supplied to each of the laboratories and used in a variety of deployed analytical extractable methodologies. **Test article:** Supplied Reference Standard Mixtures which have been further prepared as working standards by a common protocol and each laboratory’s written procedures.**Test protocol:** The common protocol will be finalized and supplied to each laboratory engaged in the studyThe supplier of the mixes must be able to do the following:* Advise the PQRI group and associated lab representatives on the composition of mixtures that can be developed and used in the laboratory study; and how the mixes will be supplied including the number of mixtures needed
* Aid the PQRI group and associated lab representatives on development of the test protocol. This would include discussing the requirements of the study with the group, and then based on study understanding, advise on the description/explanation of the mixtures to be included in the final protocol
* Provide enough mixtures to support the laboratory study at approximately 30 labs
* Ship the mixtures to each participating laboratory

The general outline of the study with respect to how the mixtures will be used is the following:* The supplied mixtures will be used to prepare working standards and analyzed to determine their response and calculate response factors and relative response factors using each laboratory procedure for volatile, semi-volatile and non-volatile extractable analysis.
* A relative response factor will be calculated from one or more defined internal (surrogate) standards, using one or more of the mixtures constituents.
* The final concentration of the substances within the prepared working standards is yet to be finalized but will likely be approximately 1 µg/mL for each deployed method. Therefore, stock mixtures concentrations will need to able to support this. Each laboratory may customize how mixes are used to produce a final working standard in accordance with their standard method but each laboratory will follow a standard protocol which will give details of stock mixes available.
* The composition of the supplied mixes will be finalized during the protocol development. The initial plan is that the total number of listed substances across all mixes will be approximately 100-250 organic substances. These substances will be split between different mixtures. Included with this will likely be the 106 FDA CLAP substances, together with additional substances to derive a useful diverse mixture for extractable RF/RRF determination.
* It is currently expected that separate mixes will be required for each method type utilized in the protocol / interlaboratory study. Method types are likely to be defined as:volatile, semi-volatile and non-volatile organic extractable mix. However, it is possible that the mixes may be supplied in several parts, which may include solid single components or liquid mixtures for technical reasons. The group seeks to communicate the final composition of each mix in the finalized protocol.
* In the supplied mixtures, the following are required:
* Composition of each mix must be clearly identified
* Statements of solvent used in each mix
* Purity and concentration of each constituent in each mix. The purity will be used together with concentration to derive response factors and relative response factors which are intended to be further analyzed before published by PQRI.
* It is anticipated that the number of mixes needed will be that required to support an interlaboratory study of approximately thirty laboratories. The locations of all laboratories will be provided.
* Mixes may become a future standard for extractable analysis (but this is not certain).

The PQRI group recognizes that exact costs for this service/engagement may not be known until after initial conversations with the group and associated labs. At this time, we are therefore requesting an estimate of expected costs (see Section 4), in addition to the ability of the supplier to provide the above services.  |

## Timeline

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| Requested Time Frames for Process and Study\*Select Supplier August 17, 2025 Supplier to provide Custom Order August 26, 2025ELSIE Board Decision September 2, 2025ELSIE and Supplier executes Agreement September 9, 2025Supplier initiates work to provide reference std mixes September 16, 2025Standard reference solutions mixes made availablefor distribution October 30, 2025*\*Dates subject to change without notice* |

## Additional Requirements

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| * Mix reference materials are produced and certified in accordance with ISO 17034
* Mix Certificate of Analysis and accompanying analytical data will be made available for review by ELSIE, PQRI, and testing laboratories
* Chemical list, composition of reference mixtures, and concentrations will be owned by ELSIE and considered and treated as confidential information by the Supplier
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## Criteria for Evaluation

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| ELSIE will evaluate all responses to this RFI based upon the respondent’s ability to meet the requirements outlined in this document, demonstration of domain expertise, and any additional capabilities that may differentiate their response from others received. The supplier will be selected for this project based on the following criteria:CostAvailability to supply mixes in short timeframe, to the appropriate quality Ability to advise on and provide support to creation of study protocol* Ability to provide Certificate of Analysis for the mixes
* Prior experience in creation of mixes of this kind

Please note that due to the volume of responses received, ELSIE only provides general updates related to the status of the review process and will not provide individualized feedback as to why a particular proposal was not selected by ELSIE. |

# Respondent Profile

*(To be completed by RFI respondent)*

Please provide information to the following:

## Company/Organization Information

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| --- | --- |
| Company/Organization Name |  |
| Address |  |
| City |  |
| State |  |
| Country |  |
| Zip Code |  |
| Website |  |

## Primary Contact Person

|  |  |
| --- | --- |
| Name |  |
| Title |  |
| Email address |  |
| Phone Number |  |

## Company/Organization Overview

Provide a brief overview of your company/organization including number of years in business, number of employees, nature of business, description of clients, and related products developed and commercialized to date.

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## Parent Corporation and/or Subsidiaries

Identify any parent corporation and or subsidiaries, if appropriate.

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## Summary of Expertise

Give a brief description of your company/organization’s expertise in the area/field related to this RFI. Include any experience working on projects with Consortia/Associations.

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## Standards Certifications

List any certifications currently held, including date received, duration, and renewal date.

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## Miscellaneous

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# Company/Organization Response to RFI *(to be completed by RFI respondent)*

## Description of Services

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## Estimated Timeline

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## Estimated Cost to Supply Mixes

* Costs should be provided as **fixed-costs in US Dollars;**
* Costs to complete individual tasks should be itemized.
* Any additional work and associated costs suggested by the supplier to enhance the project are welcome but should be clearly labeled as “optional” in the itemized price list.