# Extractables and Leachables Safety Information Exchange

## Strategic Plan 2025 - 2027

### ELSIE's Founding Principle

Sharing data and collaborative, open dialogue are essential.

### Vision

ELSIE seeks to be the leading industry voice and scientific resource on extractables and leachables (E&L).

### In the next three years, ELSIE would like to see:

- Increased alignment and understanding among and within regulatory agencies and standards bodies regarding E&L safety and risk management across products and processes
- Impactful improvement in efficient, meaningful and clinically relevant testing across products

# The Current Context

ELSIE's strategic goals are based on the current state and trends within the scientific, industrial and regulatory environment.

## Regulatory Pressures

- Lack of alignment among and within Agencies and standards bodies
- The ongoing ICH Q3E expert working group is striving to enhance harmonisation.The outputs are expected within the time frame of this plan
- Increasing scrutiny
- Requirements based on weak science, e.g., safety assessments and thresholds; simulating solvents and simulation studies; requests for tox studies in lieu of published data

## Varied and Growing Footprint of Products and Processes

Large and varied pool of products and processes where E&L is an important quality and safety consideration, requiring varied approaches, knowledge, flexibility, risk-based approaches, e.g.,

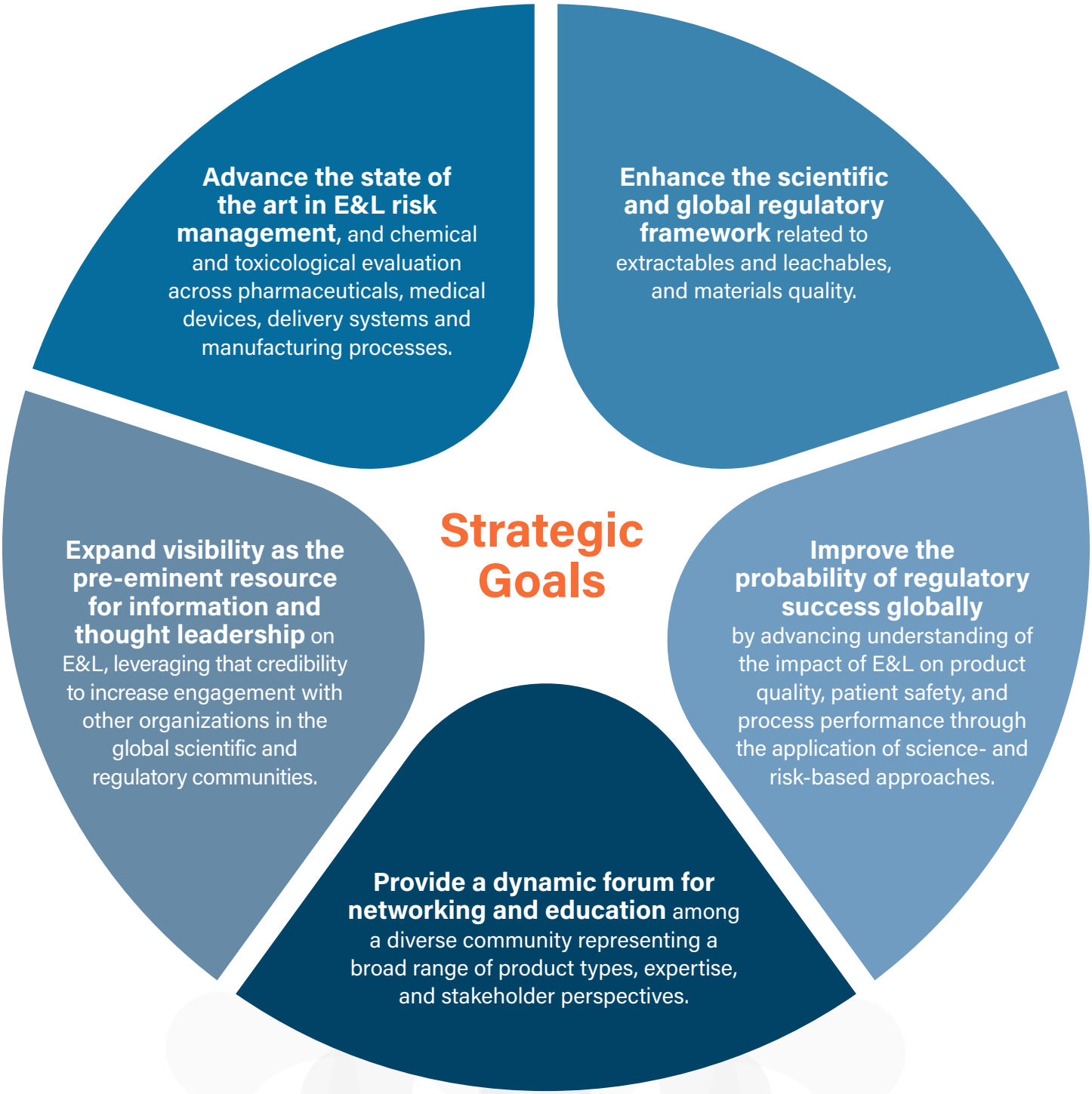
- Bioprocessing systems
- New modalities & processes
- Pharmaceuticals
- Medical devices
- Drug device combination products
- Administration sets

## Knowledge Gaps Negatively Impact E&L Management

There exist many gaps in the scientific knowledge that hinder efficient, meaningful E&L management and regulatory requirements

## Innovation Will Drive Changes to E&L Management

- Modeling and simulation tools are being developed and used in all aspects of product development including to support leachables risk evaluation
- Patient, regulatory and industry mandates to meet 3R goals and sustainability targets impacting drug products and medical devices




***These strategic goals support ELSIE members' ability to efficiently and effectively develop safe and efficacious pharmaceutical products that sustain and save lives around the world.***

# Priorities to Achieve Strategic Goals

Provide specific scientific input to support development and aligned implementation of ICH Q3E.

Establish regular lines of communication with regional regulatory agencies and standards bodies; liaise with and leverage complementary organizations and stakeholder companies.

Develop assessments, publications and presentations, addressing key knowledge gaps that support and advance members' daily work and the state of extractables and leachables risk management.

Actively share pre-competitive safety and materials information on extractables and leachables among the industry and stakeholders, through establishment and growth of the ELSIE Knowledge Base.

***ELSIE will advance these priorities to meet its goals by initiating and leveraging specific activities through its workstreams.***

## Implementing ELSIE's Strategic Plan

The ELSIE Board of Directors adopted this Strategic Plan at its November 2024 meeting. The ELSIE Board provides guidance and oversight to all of the ELSIE workstreams. ELSIE fosters development of new ideas and proposals among its members, which are discussed and established as working projects under the Strategic Plan. Each ELSIE Working Group and Subteam aligns their activities and deliverables with ELSIE's Strategic Plan and the priorities set forth above. The consortium is intentional about measuring its output and impacts against these strategic priorities.

ELSIE seeks opportunities to present and publish on the consortium's work. We hope to contribute to the science of E&Ls and promote transparent dialogue and knowledge sharing.