Extractables and Leachables Safety Information Exchange

Strategic Plan 2022 - 2024

ELSIE's Founding Principle

We should not compete on safety; 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 November 2021, the ELSIE Board of Directors engaged in an in-depth, interactive strategic planning session to assess. The current context is outlined on page 2.

In the next 2-5 years, ELSIE would like to see:

- Increased alignment and understanding among and within regulatory agencies and standards bodies regarding E&L safety and chemical risk control 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 in the scientific, industrial and regulatory environment.

Regulatory Pressures

- Lack of alignment among and within Agencies and standards bodies
- 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, 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 Impacting E&L Management

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

Growing Recognition and Standing

- ELSIE is increasingly seen as a credible and respected collaborative resource and leader in E&L in US and Europe; in bio/pharmaceuticals; manufacturing process
- Has room to grow in influence and recognition internationally and in the medical device space

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

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 Knowledge Base.

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

Each color corresponds to a priority area. The priority area is expressed in that color, in the table.

- Support and Impact ICH Q3E
- Address Key Knowledge Gaps
- Impact Regulatory Requirements
- Knowledge and Data Sharing

ELSIE Workstreams

Initiatives	Executive Committee	Overview Team	Visibility & Engagement	Materials Information	Process Paradigms	Predictive Modeling	Medical Devices	Safety Information	TTC	Sensitization	Knowledge Management
Promote and communicate on TTC and sensitization work through webinars, presentations – invite ICH participants			● ● ●					● ● ●	● ● ●	● ● ●	
Respond to specific questions and needs from ICH Q3E EWG through data collections, publications, benchmarking surveys, etc	● ● ●	● ● ●		● ● ●	● ● ●	● ● ●	● ● ●	● ● ●			
Provide guidance and examples to link risk management concepts to development of testing strategies		● ●		● ●	● ●	● ●		● ●			

Table continued on next page...

ELSIE Workstreams

Initiatives	Executive Committee	Overview Team	Visibility & Engagement	Materials Information	Process Paradigms	Predictive Modeling	Medical Devices	Safety Information	TTC	Sensitization	Knowledge Management
Support data sharing to Knowledge Base; grow and continually enhance the Knowledge Base	●			●		●		●			●
Establish relationships with materials supply chain entities to collaborate on specific projects; support data-sharing				●	●	●					●
Utilize ELSIE Knowledge Base for joint ELSIE knowledge sharing, research projects, information to support daily workflows		● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	● ●	
Publish and promote guidance on read-across and class-based thresholds								● ●	● ●		
Identify priority questions, conduct research, surveys, data sharing, and other benchmarking to address these				●			●	●			
Advance development of predictive modeling use cases						●					
Publish and promote output from process paradigms efforts					● ●						
Establish communications with FDA CDER and CDRH to discuss current thinking on thresholds, predictive modeling, methods	● ●	● ●		● ●		● ●	● ●	● ●	● ●	● ●	
Build liaisons / collaborations with stakeholder groups, e.g., EFPIA, PhRMA, AdvaMed, other	● ●			● ●	● ●		● ●	● ●			
Provide input to and communications with USP, ISO, ChP	● ●			● ●			● ●	● ●			
Establish regulatory roundtable discussions in Medical Device Discussion Group							●				
Provide input to and communications with USP, ISO, ChP				● ●				● ●			