

# ELSIE 2019 HIGHLIGHTS

Sharing progress, accomplishments and future goals



## A Message from the ELSIE Chair



Andrew Teasdale  
Astrazeneca

At the beginning of 2019, ELSIE members embarked on a bold plan to engage with the industry through its trade associations, specifically *PhRMA*, to advocate for the adoption of Extractables and Leachables (E&L) as an ICH topic. The ELSIE Board of Directors understood that this presented considerable challenges, but we also were well aware of the issues and uncertainties surrounding management of E&Ls, and felt that this was the most appropriate direction to take. ELSIE developed and shared real examples with ICH which proved to be critical to the successful ICH outcome. This is a clear example of a benefit of ELSIE membership.

ELSIE membership not only provides access to key safety and quality data it also enables access to a dynamic organization where dissemination of knowledge and discussion and debate are core to the consortium's values and ethos. 2019 also saw major progress in a number of other key areas including the progression of the long-awaited database. ELSIE invites you to please reflect on ELSIE's 2019 accomplishments and their value to you as a member organization. If your organization is not yet a member of ELSIE, please feel free to reach out to any member of the ELSIE Secretariat for additional information.

## ELSIE Objectives



## Advancing E&L Science and Regulation

- ➔ ELSIE is benchmarking leachable study practices among the industry and regulatory feedback on these practices to advance understanding of dynamic and evolving approaches to managing leachables in new bio-pharmaceutical products
- ➔ ELSIE is helping its members understand and proactively engage on current and emerging regulatory intelligence and standards information related to extractables, leachables, and materials quality. Throughout the year, ELSIE reported on FDA, Chinese Pharmacopoeia and Chinese packaging industry guidelines, and USP and ISO chapters and standards. ELSIE members engaged directly with USP to discuss its development of chapters related to bioprocessing and packaging quality. ELSIE members shared and discussed learnings from meetings and conferences, presentations from international regulators, and updates from pharmacopoeial and industry group committees.



ELSIE Board of Directors, London (November 2019)

➔ ELSIE partnered with PhRMA to develop and support a proposal for an ICH guideline on extractables and leachables, which ICH approved in 2019. In 2020, ELSIE will be creating and publishing papers on key aspects of extractables and leachables evaluation, which could be utilized as a resource by any stakeholders, including ICH.

➔ As part of ELSIE's efforts to advance understanding and knowledge sharing between its members and stakeholders important to its members, ELSIE organized and hosted a well-attended CRO roundtable.

ELSIE also continues to engage with suppliers and analytical technology providers.

➔ The ELSIE Safety Information Database continues to be an extremely valuable resource to members of the ELSIE community. ELSIE is now poised to deliver the next step in the evolution of this resource – the ELSIE Knowledge Base! Working in collaboration with ELSIE members and suppliers, ELSIE plans to deliver a database of material extractable information from raw materials, components, and full assemblies linked to chemical safety and toxicological information.

## Places to Meet ELSIE

ELSIE continues to explore ways to collaborate with members of the E&L community through workshops, conferences, and round-table discussions.

**Pittcon Conference & Expo**- March 1-5, 2020 (Chicago, Illinois)

**Society of Toxicology**- March 15-19, 2020 (Anaheim, California)

**E&L USA**- April 20-22, 2020 (Bethesda, Maryland)

**American College of Toxicology**- November 15-18, 2020 (Austin, Texas)



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- Novartis • Novo Nordisk • Pfizer • Regeneron
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