

Effective exchange during operational use

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Effective Information Exchange in Operations

Format

- Introductory Remarks
- Panel Discussion of Relevant Topics
- Audience Participation

Introducing the Information Exchange Panel



**Lance Bospflug,
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Canada**



**Duncan Trapp,
CHC Helicopter**



**Steve Hawkes,
BP**



Effective Information Exchange in Operations

Why Information Exchange?

- For Safety Stupid!
- Improve collaboration between Operators
- Improve collaboration with OEMs
- To build trust
- How widespread is the practice?
 - IVLL, IATA, ICAO, Pharmaceutical Industry
- Provide a one stop shop for information?



The screenshot shows the homepage of the ELSIE (Extractables and Leachables Safety Information Exchange) website. The header features the ELSIE logo and tagline. A navigation menu includes links for Home, ELSIE Database, Current Program and Organization, LAE Events, ELSIE Publications, and Contact. The main content area is divided into two columns. The left column, titled 'ELSIE MEMBERS', lists various pharmaceutical and biotechnology companies. The right column, titled 'WELCOME TO ELSIE', provides an overview of the consortium's mission and core objectives. A footer banner invites all pharmaceutical, biotechnology, and medical device companies to join ELSIE.

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ELSIE

Extractables and Leachables
Safety Information Exchange

Home | ELSIE Database | Current Program and Organization | LAE Events | ELSIE Publications | Contact

ELSIE MEMBERS

AbbVie
Amgen
Aquestant
Alta Zentca
Baxter
Biogen Idec
Boehringer Ingelheim
Eli Lilly
Ferring
GlaxoSmithKline
LFB
Merck
EMD Serono
Novartis
Pfizer
sanofi
Teva

WELCOME TO ELSIE

The Extractables and Leachables Safety Information Exchange (ELSIE) Consortium is comprised of pharmaceutical, biotechnology, and medical device companies. The ELSIE Consortium

- Collects, reviews, and compiles toxicological data on leachables and extractables in an information-rich, database, enabling rigorous assessments.
- Advances understanding of the impact of extractables and leachables on product quality and process performance.
- Provides opportunities to share and leverage experiences, insights, and practices with respect to the potential safety impact of drug product packaging, delivery and manufacturing systems.
- Advances the state of the art in chemical/box assessment of leachables and extractables by supporting and publishing research and participating in the global scientific and regulatory communities.

CORE OBJECTIVES OF ELSIE

- Advances principles of Quality by Design by enhancing the prospects for identifying potential safety issues at the initial stages of the development process, when container closure materials are being screened and selected.
- Supports member companies' regulatory filings.
- Reduces duplication of effort and minimize testing.
- Decreases the risk of substantial, unanticipated delays and associated costs.

All pharmaceutical, biotechnology and medical device companies are invited to join ELSIE

Effective Information Exchange in Operations

A Few Key Questions/Challenges

- Do we need more?
- Who should be involved?
- What should we share?
- How do we do it?
- What is the way forward?
- What is missing with existing systems?
- HeliOffshore InfoSpace currently limited to Operators
- What would make the biggest difference?
- Options go from simple communications to BIG DATA
- Step by Step or Big Bang Theory?

Effective Information Exchange in Operations

Conclusions

- Information Exchange is and will increasingly become a force for safety improvement
- Commitment required from all stakeholders
- Protocols need to be agreed to define 'rules of engagement'
- Significant data analysis by technology and humans needed to extract best value and target results in a meaningful way



THANK YOU FOR YOUR ATTENTION



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