Cambridge Healthtech Institute's
16th Annual
PEPTALK
THE PROTEIN SCIENCE WEEK

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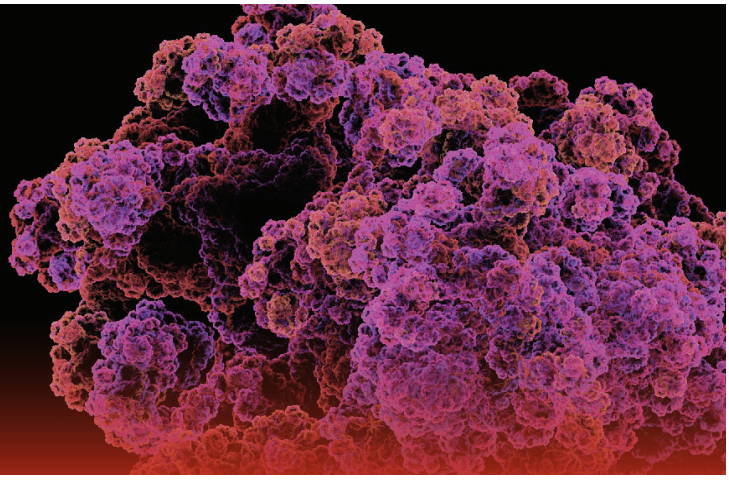
Hilton San Diego Bayfront



Extractables & Leachables Safety Information Exchange (ELSIE) Consortium – Update

Kim Li, Ph.D., DABT, MPH, Senior Manager, Environment, Health, Safety and Sustainability Product Stewardship Toxicology, Amgen

Cambridge Healthtech Institute recently spoke with Dr. Kim Li of Amgen about challenges in managing Extractables & Leachables and her upcoming keynote presentation **"Extractables & Leachables Safety Information Exchange (ELSIE) Consortium – Update"** at the **5th Annual Extractables and Leachables conference**, taking place **January 10-11, 2017** as part of the 1**6th Annual PepTalk** event which runs from **January 9- 13, 2017 in San Diego, CA.**

SPEAKER Q&A

Q Can you tell us about yourself and your work?

I am a board certified toxicologist and have broad experience in safety assessments in both R&D and Operations environment. My industry experience includes biopharmaceutical products, agrochemicals, consumer healthcare products and medical devices. In my current role at Amgen, I am the lead toxicologist on extractables and leachables (E&L) programs for container closure systems, drug delivery devices and single use technologies. I serve on the Extractables & Leachables Safety Information Exchange (ELSIE) consortium in various capacities: Vice-chair of the ELSIE Board of Directors, Chair of the Executive Committee and prior to that, as co-lead for the Safety Information Working Group. I am also active on ISO 10993 Biological Evaluation working groups to advance our knowledge base around material characterization and toxicology assessments for medical devices.

Q Why did you choose to tackle this topic?

The ELSIE consortium, consisting of members from the pharmaceutical, biotechnology and medical device companies, advances the knowledge of chemical and toxicology assessment of E&L through scientific knowledge sharing and regulatory outreach. The 2017 PepTalk conference is timely for us to share updates from our consortium activities.

Q What are the major challenges that the Extractable and Leachable field is facing?

I believe the most significant challenges that the scientists face in the E&L field are the widespread use of complex polymeric materials and the testing required for their intended applications. The testing may include material characterization (physical, chemical, functional performance) and safety evaluation (biocompatibility testing, toxicology assessments). The testing standards (e.g. ASTM, USP, ISO), developed more than a decade ago, are in need of updates to reflect the most current technologies and best practices. On the bright side, these significant challenges have created opportunities to advance the knowledge base around the chemistry and toxicology of E&L impurities as they apply to the manufacturing environment and ultimately the quality and safety of the medical devices and combination drug products.

Q Where is the Extractable and Leachable field headed in coming years and what's revolutionizing Extractable and Leachable research?

The field is rapidly changing and we need to adapt to the changes with new tools. First, the universe of extractables arising from contact materials is rapidly expanding into an unwieldly galaxy. The rapid advances in trace analysis and structural elucidation in the chemical space continue to challenge us to examine our risk assessment toolbox. Second, the study of leachables in final drug products can be hindered by assay interference. This is particularly true of biotechnology products for trace levels of leachables in a protein formulation matrix. We need new tools to examine the potential interaction of E&L with the protein formulation matrix. Third, the proliferation of single-use technologies (SUT) has raised regulatory concern and requires a systematic approach to evaluate upstream raw materials through the finished drug product under recommended storage conditions. While there are a myriad of other challenges, it is the concerted efforts by raw material suppliers, the pharmaceutical manufacturers and the regulators to share knowledge and deliver quality and safe products to patients. It is the coming together of these efforts that will revolutionize this field of research.

SPEAKER BIOGRAPHY:

Kim Li, Ph.D., *DABT, MPH, Senior Manager, Environment, Health, Safety and Sustainability Product Stewardship Toxicology, Amgen*

Kim Li is a board certified toxicologist with special interest in risk assessments. She joined Amgen in 2004 and is currently the lead toxicologist on the extractables and leachables programs on container closure systems, drug delivery devices and single-use bioprocess systems. Kim is an active member of the Extractables and Leachables Safety Information Exchange (ELSIE) consortium, serving on the Board of Directors, the Executive Committee and Safety Information Working Group.

TO LEARN MORE ABOUT HIS PRESENTATION AND PEPTALK, VISIT: **CHI-PepTalk.com/extractables-leachables/**

Q Why are you attending the 16th Annual PepTalk and what are you looking forward to at PepTalk 2017?

ELSIE was invited to the 2013 PepTalk at the inaugural E&L conference in 2013. I had the privilege to present on behalf of ELSIE on the vision/mission and more importantly on the value of the ELSIE Safety Database in sharing knowledge and in minimizing risks. I have returned to PepTalk over the years and have always been impressed with the networking opportunities, the enthusiasm and the progress in the field. 2017 should be no exception. PepTalk brings together the scientists in protein engineering and development, formulation and stability, expression and production, process technologies and analytics and impurities. This is a very unique forum unparalleled by other conferences and workshops.