American Association of Pharmaceutical Scientists

Advancing Pharmaceutical Sciences, Careers, and Community

Ask Me Anything About Nitrosamine Risk Assessments

The pharmaceutical industry has faced significant challenges in recent years related to the discovery of potentially cancer-causing N-nitrosamine impurities in some pharmaceutical products, leading to several drug recalls and increased regulatory scrutiny. Setting up a nitrosamine risk assessment is a key element of the overall control strategy set forth by regulatory agencies to control for these impurities; however, how to go about doing this is not 100% clear. We have gathered experts from industry to answer your pressing questions regarding how to set up and execute a robust nitrosamine risk assessment from how to identify sources of potential risk, what to look for in a structure of an API or excipient, what tools are available to help with this process, etc. No question is off limits. Please join us on September 12 as we open the discussion. This is your chance to **ask anything!**

Hosted by the AAPS Pharmaceutical Impurities Community

Live, 1-hour discussion thread in the AAPS Community
Date: September 12, 2022, from 10:00 am–11:00 am ET
Email your questions before the event to axlers@aaps.org.

Meet the expert panelists:

Leo Allain, Ph.D.
Leo Allain, PhD, is a Distinguished Scientist with Merck & Co., and has over 20 years of experience in pharmaceutical product development, where he has led CMC teams responsible for several approvals in multiple countries. He has authored guidances on the development of sterile products, ophthalmic and topical creams, photostability, nitrosamine formation in solids, and has expertise in the development of chemically unstable APIs in lyophilized products, injectables, and amorphous dosage forms.

Leo has authored over 40 publications and patents, and is a guest lecturer for the USP, Sindusfarma, ANVISA and AAPS on pharmaceutical impurities, degradation mechanisms, photodegradation, including mutagenicity and nitrosamine assessment and derisking strategies. He is a member of the IQ working group on nitrosamines and the Lhasa Industry consortium on nitrite in excipients.

Dr. Ron C. Kelly, Pharm.D., Ph.D.
Dr. Ron C. Kelly is a Principal Product Quality Leader at Amgen, Inc. He earned his PharmD degree from Xavier University of Louisiana and Ph.D. from The University of Michigan, Ann Arbor in Pharmaceutical Sciences. Prior to joining Amgen, Ron was a Research Investigator at SSCI, Inc. where his responsibilities included crystal form screening and characterization, small scale crystallization development, and stabilization of amorphous systems. Ron joined Amgen's Pharmaceutical Research & Development (PR&D) – Preformulation organization in 2006 where his responsibilities included molecule assessments, preclinical formulation development, and identifying crystal forms for clinical development. He has taken on roles of increasing responsibility during his tenure at Amgen. From 2011 to 2015, he led the Amgen San Francisco Preformulation group supporting early discovery programs from discovery through candidate selection.In 2015, Ron transitioned to Amgen Thousand Oaks where he established and led the Materials Chemistry and Characterization group that was fluent in synthetic, biologic, and raw material solid state characterization enabling innovative approaches to deliver pipeline molecules to support Amgen's multi-modality portfolio. Ron also led teams within Materials Science where he provided leadership for technical raw material initiatives including support for the expansion into the China market, readiness for addressing global raw material trends including nitrosamines, and engaging with key cross functional partners to advance and apply materials expertise, tools, and data trending in support of commercialization and patient supply. In his current role as a Principal Product Quality Leader, Ron is responsible for developing strategies for product specifications, stability monitoring, and expiration justifications in support of patient oriented solutions that account for business needs. Ron is an active member with IPEC-Americas where he serves on the IPEC-Americas Executive Committee and leads the IPEC-Americas Nitrosamine Cross Functional Team.

Andrew Teasdale, Ph.D.
Andrew Teasdale, PhD, has 30 years' experience in the pharmaceutical industry as an analytical chemist and within quality assurance and regulatory roles. In his current role he chairs AstraZeneca's Impurity Advisory Group.

Dr Teasdale has published a number of papers relating to mutagenic impurities, N Nitrosamines, extractables and leachables, and other impurity related matters. He is currently the chair of the Extractables and Leachables safety Information exchange (ELSIE) and also led a number of industry expert groups; these include both safety and quality groups within Pharmaceutical Research and Manufacturers of America (PhRMA), European Federation of Pharmaceutical Industries and Associations (EFPIA), and Product Quality Research Institute (PQRI). Andrew has also represented EFPIA in ICH Q3C, Q3D and Q3E Expert working groups. He has advanced a number of key scientific advancements in the control of impurities as the inventor of the purge factor concept and the instigator of the development of Elemental Impurities database for excipients.

With over 50 scientific papers, he has also written 3 books.