

2023

A year of Nitrosamine milestones

2023 marked five years since the discovery of nitrosamine impurities in pharmaceutical products spawned a series of recalls and industry-wide focus on controlling for the impurities in order to keep products safe and available to patients around the globe.

USP has led a multi-faceted response, working with stakeholders to develop solutions and to facilitate the exchange of crucial information to overcome challenges and advance the science. This year saw tremendous activity and progress – from regulatory actions taken around the world, to advancements in research – worth noting. Read on for highlights from USP’s work on the issue.





nitrosamines.usp.org



Nitrosamines Exchange

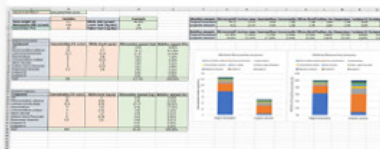
A knowledge based community for all-things Nitrosamine

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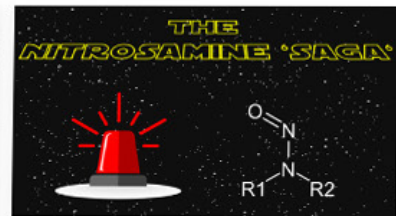
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Limits of Nitrosamine Impurities

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Drug Products



Would users of the exchange and/or their networks find it useful if USP held a joint workshop or other... with US FDA, EMA, and other Health Authorities to review the... subject region and develop risk assessment best practices... industry? Attendees could also

2023

The Nitrosamines Exchange

This year, USP's Nitrosamines Exchange – a global online learning hub where users share information, resources, and potential solutions – gained its 4,000th member.

The Exchange offers a platform for real-time exchange of information about nitrosamines and is accelerating the global effort to find solutions for mitigating the risks of nitrosamine impurities.





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Global reach

In 2023 USP hosted regulator or industry trainings, workshops, or roundtables in:

- Vietnam
- Thailand
- Indonesia
- Philippines
- Malaysia
- South Korea
- Japan
- Brazil
- Mexico
- Guatemala
- Turkey
- Jordan
- Saudi Arabia
- Egypt
- Kazakhstan
- Uzbekistan

Throughout the year, USP hosted dozens of workshops and trainings in countries around the world – from Latin America to the Middle East and South Asia – to help industry and regulators gain a deeper understanding of the challenges posed by nitrosamines and to hear from them about their experiences. Read about [**USP's work on nitrosamines in Vietnam here.**](#)





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Nitrosamines

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Naiffer Romero



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2023

Regulatory insights

Medicines // August 29, 2023

Part two: Industry examining FDA guidance

This summer, agencies from around the world recently publishing new or revised guidances on nitrosamines

Among a flurry of regulatory activity that took place around the globe in 2023, the FDA and other agencies released new and revised guidelines on nitrosamines for pharmaceutical manufacturers, providing new frameworks and acceptable intake levels. Read about the new frameworks [here](#) and additional nitrosamines-related content at Quality Matters.





2023 Original research



In what started as a discussion within the Nitrosamines Exchange, USP's Naiffer Romero, Principal Scientist, teamed up with a diverse group from industry, academia, and nonprofit entities, to conduct new research on nitrosamines impurities that was ultimately **published in the *Journal of Pharmaceutical Sciences***. The new research took a deeper dive into the implications of the new regulatory frameworks on the potential landscape of nitrosamines.





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Thought leadership



In a piece published by *European Pharmaceutical Review*, USP's Mrunal Jaywant, Vice President, R&D, USP-India, wrote about the challenges of nitrosamines facing industry, the progress we have made in the last five years, and the need for a collaborative, cross-community approach between stakeholders in order to overcome remaining challenges. Read her reflections [here](#).

USP's Jaap Venema, Chief Science Officer, was interviewed by [Bloomberg's The Big Take podcast](#) about nitrosamines – how impurities make their way into medicines, and what pharmaceutical companies and government agencies are doing to ensure the safety of the medications patients take.

Click to
watch USP's
nitrosamines
video





Looking ahead



“We expect to see significantly increased attention focused on the threat posed by nitrosamine impurities in medicines, from both a manufacturing and regulatory perspective. Drug manufacturers will need to find ways to mitigate the formation of nitrosamines in their products, including those that arise from excipients contaminated with nitrites. This will not only require drug manufacturers to perform thorough risk assessments themselves; they will also need to request the same from their ingredient manufacturers. As the industry navigates this new landscape, there will be continued opportunity for collaboration among stakeholders to share knowledge about guidance updates, discuss challenges, and provide ways to overcome barriers while tackling an issue that is critical to protecting public health.”

– *USP's Mrunal Jaywant,
Vice President, R&D, USP-India*

