INTERNATIONALLY RECOGNIZED PHARMA EXPERTISE, NOW AT YOUR FINGERTIPS!

Visit Merck's all-new 3D virtual booth to explore the latest in drug formulation, starting with our first e-Seminar on 30th June, 2021

Time: 02:00 pm to 04:30 pm IST

register now !

Emprove® Program

Your fast track through regulatory challenges

Date: 30th June, 2021
Timing: 02:00 pm to 04:30 pm IST

Agenda

Timing	Topic	Speaker
02:00 pm - 02:05 pm	Welcome & Introduction	
02:05 pm - 02:55 pm	Nitrosamines: New Requirements Risk Assessments and Perspective of an API & Excipient Manufacturer	**Dr. Ulrich Reichert** M.D.R.A.Head of Pharma and Food Materials, Regulatory Management, Merck KGaA, Darmstadt, Germany
02:55 pm - 03:40 pm	Emprove® Program for chemicals: Your fast track through regulatory challenges	**Dr. Torsten Schadendorf** Senior Marketing Manager for the Emprove® Program Merck KGaA, Darmstadt, Germany
03:40 pm - 03:55 pm	Q&A Session	
03:55 pm - 04:25 pm	Breakaway Session	**Sonali Zende** Associate Manager - Regulatory Management & Trade Compliance **Sharvari Pande** Associate Manager - Regulatory Management & Trade Compliance **Dr. Smita Rajput** Field Marketing Manager - Liquid Formulation **Manisha Chaudhari** Field Marketing Manager - Small Molecule Solid & Liquid Formulation
04:25 pm - 04:30 pm	Thank you Note	

Abstract & Speakers

Topic 1 - Emprove® Program for chemicals: Your fast track through regulatory challenges

Raw Material Risk Assessment has come more and more in focus of both industry and regulatory. One major challenge is the collection of required information from manufacturers and suppliers to conduct risk assessments efficiently and appropriately. Within this presentation, scope and risk criteria of the BioPhorum Raw Material Risk Assessment are shown. Furthermore, it will be demonstrated the Emprove® Program and information within can support and facilitate Raw Material Risk Assessment.

In this e-Seminar, you will learn:

- Risk assessment for raw materials
- Risk criteria of the BioPhorum Raw Material Risk Assessment
- Advantages of Emprove® Program in risk assessment to fast track your development

Dr. Torsten Schadendorf

Dr. Torsten Schadendorf is Senior Marketing Manager for the Emprove® Program. He has been working within Merck KGaA for 13 years in various marketing functions, focusing on raw and starting materials for (bio-)pharma applications. Since 2016, he has been responsible for the Emprove® Program for our cell culture media, APIs, excipients and process chemicals for (bio-)pharmaceutical production. He holds a PhD in Organic Chemistry obtained from TU Berlin.

Topic 2 - Nitrosamines: New Requirements Risk Assessments and Perspective of an API & Excipient Manufacturer

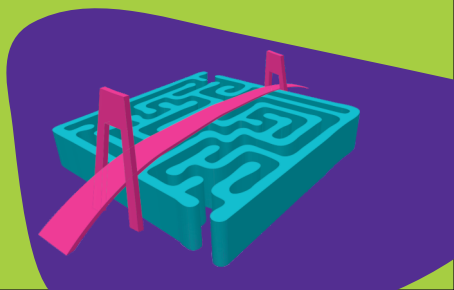
Nitrosamines are a hot topic among regulatory agencies across the world. This has become a global issue since several Health Authorities wordlwide, such as EMA, US FDA, Health Canada, ANVISA, and many others, expect the Marketing Authorization Holders to identify products at risk of N-nitrosamine formation or contamination and to report the outcome. This e-Seminar will review the current requirements for nitrosamine risk assessment and focus on contribution of APIs and excipients to the risk evaluation.

In this e-Seminar, you will learn:

- Overview about the root causes that led to Nitrosamine contaminations in APIs
- Awareness of the various potential sources for nitrosamine formation and/or introduction
- Approach for nitrosamine risk assessment for pharmaceutical starting materials
- Latest developments in the Pharmacopoeias Ph. Eur. and USP

Dr. Ulrich Reichert

Dr. Ulrich Reichert, M.D.R.A. is a Head of Pharma and Food Materials, Regulatory Management, Life Science, Merck KGaA, Darmstadt, Germany. He has more than 20 years of regulatory and quality experience for materials for the pharma and food industry. He is also a member of the Nitrosamine task forces of IPEC Europe (Leading Position), APIC, Life Science business sector of Merck KGaA, Darmstadt, Germany (Leading Position).



Emprove® Program

Your fast track through regulatory challenges

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Please register me for this event

First Name : .....

Last Name : .....

Company : .....

Department : .....

Position : .....

Company Address : .....

Country : .....

City:..... Telephone No. : .....

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