

# APV exchange of experience online workshop on nitrosamine impurities

- Practical strategy approaches of Marketing Authorization Holders (MAH)
- Nitrosamine impurities in biological medicinal products



06 May 2021  
Online Seminar

Course no. 6866

## ONLINE SEMINAR

### Quality control/analytics

#### Target group

Employees from development, production, quality control, quality assurance and drug regulatory affairs in the pharmaceutical and biopharmaceutical industry.



## Objectives

The first part of the workshop will present different strategy approaches to comply with the regulations for MAHs in regards of nitrosamine impurities in human drugs. The second part is focused on the upcoming challenging topic of nitrosamine impurities in biological medicinal products. The third part is designed as panel discussion for an extensive experience exchange on all aspects of nitrosamine impurities between speakers and participants.

## Moderator



**Dr. Horst Dieter Friedel**  
former Lead External Affairs at Bayer AG

Dr. Friedel has about 30 years experience in Pharmaceutical Industry and has lead the department External Affairs in Corporate Quality, Process & Knowledge Management at Bayer AG in Berlin until his retirement in 2020. He has been a member of various industrial associations, such as the EFPIA and the vfa Committee on Production, Quality and Environment and has been co-chair of the F.I.P (International Pharmaceutical Association) focus group Dissolution / Drug Release since 2005. Since 2002 he is member of the APV focus group analytics and quality assurance.

## Programme

Thursday, 06 May 2021, 13:00 - 17:00 h CEST

### Welcome address

#### Horst-Dieter Friedel

APV focus group analytics and quality assurance and former Lead External Affairs at Bayer AG, Germany

### Part I

**Nitrosamine impurities in metformin – testing strategy, experiments with isotope labeling and manual granulation**  
Brunhilde Güssregen, Head of Laboratory Analytics Healthcare, Merck KGaA, Darmstadt, Germany

#### Testing strategy for marketed products

Andreas Henkel, Global Head of Quality, NextPharma Germany Bidco GmbH, Waltrop, Germany

### Part II

#### Nitrosamines in Biologics and ADCs

Karoline Bechtold Peters, Senior Strategy & Technology Leader - Pharmaceutical Development, Novartis, Basel, Switzerland

### Part III

Panel discussion for experience exchange and Q&A session

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### Registration fee

Industry	300,00 EUR
Authority/University	150,00 EUR
Students*	50,00 EUR

(free of VAT according to § 4,22 UStG)

\* Limited places for full time students available; written evidence must be submitted.

### Registration

If you have decided on the APV seminar, you can easily register online. We will process your registration immediately and will be happy to help you if you have any questions.

Directly to the online form:  
<https://www.apv-mainz.de/en/seminare/events/>

An invoice/registration confirmation will be sent to you by email after you have successfully registered online.

**Registration: [www.apv-mainz.de/seminare](http://www.apv-mainz.de/seminare)**

