

## **Agenda eCTD & DMS Workshop - 24 March (Basel) and 25 March (Lausanne)**

12:30 - 13:00 **Registration**

13:00 - 13:15 **Opening and introduction (All)**

13:15 - 14:00 **Information Management processes integration for Life Sciences – from a consultant’s perspective (Dr. Erick Gaussens, ProductLife)**

- Document and Content Management
- Regulatory submissions and tracking
- Quality Systems
- Insourcing and outsourcing/ offshoring scenarios

14:00 - 14:15 **EXTEDO - Your partner for all electronic Regulatory Affairs issues (Günter Rodenkirchen, EXTEDO)**

- Short company presentation
- Overview about the product and service portfolio

14:15 - 14:45 **How to work with eCTD - eCTDmanager presentation (Prof. Dr. Thomas Städter, EXTEDO)**

- Setup eCTD dossier - overview
- eCTD and paper publishing

14:45 - 15:30 **Why eCTD and Document Management System (DMS) belong together (Prof. Dr. Thomas Städter, EXTEDO)**

- Document lifecycle
- Working with templates
- Versioning of documents
- Collaborative work on dossiers
- Higher quality and more secure
- To be compliant

15:30 - 16:00 **Coffee Break**

16:00 - 17:00 **Compliance without Complexity - 21CFR11 Compliant Document and Quality Management for Life Sciences (Rainer Schwarz / Orang Gholikhani, NextDocs)**

- Company and Strategy Overview
- Document Management System: Regulatory Submission, SOP, Clinical Trial
- Interoperability & Integration
- Quality Management System : CAPA, Deviation, Audit

17:00 - 17:30 **Q&A**

## Event Information

### Date, Languages & Location

#### Wednesday, 24 March – Basel

Presentations will be in **German and English**

**Hilton Basel Hotel**  
Aeschengraben 31  
CH-4051 Basel  
Tel. +41 61 275 6600  
[www.hilton.de/basel](http://www.hilton.de/basel)

#### Thursday, 25 March – Lausanne

Presentations will be in **French and English**

**Hotel Alpha-Palmiers Lausanne**  
Rue du Petit-Chêne 34  
CH-1003 Lausanne  
Tel. +41 21 555 5999  
[www.fhotels.ch](http://www.fhotels.ch)

### Registration

The registration is **free of charge**.

#### Wednesday, 24 March – Basel

Please register online at:

[www.amiando.com/extedo01](http://www.amiando.com/extedo01)

#### Thursday, 25 March – Lausanne

Please register online at:

[www.amiando.com/extedo02](http://www.amiando.com/extedo02)

### Contact

If you have any questions regarding this event, please contact:

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