

## **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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