

Bern - Thursday 4th May 2017



ICHQ3D Elemental Impurities
8 months before the go live.
Are you ready for the implementation?



Plant visit

CSL Behring

All the information :

www.a3p.org

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THURSDAY 4th MAY 2017

08:30 Welcome of the participants

09:00

Introduction

Vincent GRIFFOUL - A3P Switzerland President

09:10

Operational Implementation of ICH Q3D - Proposed Analytical Methods

Elise GALLAIS - SGS

09:50

Implementation Strategy of ICH Q3D guideline for a parenteral long term sustained release formulation

Marco SALVAGNI - DEBIOPHARM

10:30 Coffee Break at the Exhibition Area

11:00

Feedback from a Biotech industry on ICH Q3D Implementation

Aurélie DUCLOS - VIFOR PHARMA

11:40

How to implement ICH Q3D - Defining a Risk-Assessment Strategy for Elemental Impurities

Elisabeth MOREAU - LABORATOIRES BOUCHARA-RECORDATI

12:30 Lunch

14:00

ICH Q3D - Implementation, a control strategy in Biotech - Feedback of the "drug product" solution used to monitor Elemental Impurities based of the Risk Assessment approach

Sylvain PLAGELLAT - MERCK

14:40

Elemental Impurities testimony of implementation by a contract manufacturing organization

Jean-Marc LIBERSA - FAREVA

15:20

Round Table

All speakers and participants

16:00 Departure for the plant visit of CSL Behring

19:30 Dinner at the Novotel