



Master Biennale di II livello in  
Discipline Regolatorie "G. Benzi"



Master in Tecnologie Farmaceutiche e Attività Regolatorie  
Università di Pavia



FEDERCHIMICA  
ASCHIMFARMA

## **WORKSHOP**

### **Regulatory Expectations on impurities in Drug Substances: Authority and Industry perspective**

**Pavia, 2<sup>nd</sup> October 2015 (ore 9.00)**

**Aula Jucci, Dipartimento di Biologia e Biotecnologie "Lazzaro Spallanzani"  
Via Ferrata, 9 - Palazzo Botta 2 -Pavia**

The University of Pavia (Master on Regulatory Sciences) with the support of Italian Biocatalysis Center and Aschimfarma, organises a Workshop focused on the quality and regulatory aspects for API production.

#### **Scientific Program**

##### ***Morning***

**9.00-9.30: Registration**

**9.30-10.00: Welcome and introduction**

**10.00-10.25:** Luisa Torchio (*Euticals*)  
*Reference guidances on Impurities in drug substances: the status of the art.*

**10.25-10.50:** Andrea Ruggiero (*MHRA*)  
*Expected approach in Developing Control Strategies for Impurities in Drug Substances*

**10.50-11.15 Coffee break**

**11.15-11.40:** Luca Ginnari Satriani (*AIFA*)  
*Carry-over of impurities from materials for API Synthesis*

**11.40-12.05:** Pascale Poukens-Renwart (*EDQM*)  
*Impurities in Drug Substances prepared via fermentation and other bio-processes*

**12.05-12.30:** Sergio Gonella (*Consultant*)  
*Impurities in Biological Drug Substances*

**12.30-12.55:** Marco Ernesto Martinelli (*Indena*)  
*Impurities in Drug Substances of vegetable origin*

**13.00-14:30 Lunch**

***Afternoon***

**14.30-14.55:** Antonio Conto (*ChemSafe*)  
*Genotoxicity, mutagenic and carcinogenic risk related to impurities*

**14.55-15.20:** Damiana Gentili (*Procos*)  
*Strategies to minimize the impact of presence of residual solvents in APIs*

**15.20-15.45:** Annalisa Scali (*Euticals*)  
*Elemental impurities impact on APIs*

**15.45-16.10:** Anna Fumagalli (*Labochim*)  
*Impurities from degradation of Drug Substances*

**16.10-17.00 Closure and remarks**