

# CERTIFICATE

**Dr. Claudio Gallottini**

has completed a three day ECA-Course on 12 to 14 November 2018 in  
Barcelona, Spain covering the following subject

## **ECA - ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis**

### **Contents of the course:**

- ICH Q7 - a regulatory introduction
- APIC's How to do-Guide and further APIC activities
- ICH Q7 – Q&A – What to do and How to do
- Major compliance issues at API manufacturers
- Roles and Responsibilities of the Quality Unit –  
How to apply ICH Q10 in API manufacturing
- Stability Testing of APIs
- Cleaning Validation
- Equipment qualification and calibration
- Engineering and Equipment Design
- Process Validation in API manufacturing
- Supply chain life cycle: Reduced testing and supplier qualification
- Internal Change Control Management
- Deviations and failure investigations
- Preparing for GMP inspections

### **Specific Training Sessions**

- Defining API Starting Materials
- Cleaning Validation
- Practical implementation of ICH Q11 –  
How to identify and control CQAs in API synthesis

Heidelberg, 14 November 2018



European Compliance Academy



CONCEPT HEIDELBERG