



## **GMP for APIs (ICH Q7) Training Course**

**An experience-based program for inspectors and API industry – applying the requirements of ICH Q7 accepted world wide**

**A training Course for practical implementation of GMP for APIs for industry and regulators – inspectors / reviewers**

**This course in Tokyo will provide insights on current observations provided by GMP inspectors from the EU, US FDA and Japan`s PMDA. Experts from industry involved in drafting these ICH guidelines will elaborate on the intentions of the working group and why the requirements had been established in ICH Q7.**

**All ICH Q7 Q&A sessions allow for open discussions enabling you to benefit from first-hand feedback in avoiding pitfalls in implementing the guideline and regulatory expectations. Inspectional observations will allow reviewers and CMC experts to learn about the efforts of industry to establish GMP. Inspectors will discuss various aspects of the ICH Q7 and expectations.**

**The faculty of this course will be GMP inspectors and API experts from industry and regulatory authorities, many of whom have participated as ICH expert working group members..**

**The supporting documentation was developed by PIC/S and PDA.**

**The course is part of an ICH Pilot Program, the results of which will be used in developing a strategy on the future of ICH training and implementing a holistic training approach for industry and regulators.**

**Date: 10.-11. October**

**Location: Tokyo, Congress Square Nihon Bashi**

**For further information please contact:**

**PDA Japan Chapter**

**4F 2-13-10, Torigoe, Taito-ku, Tokyo**

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# Registration Form

## GMP for APIs (ICH Q7) Training Course

10.-11. October | Tokyo, Congress Square Nihon Bashi

Tokyo Bldg. 1-3-13 Nihonbashi Chuo-ku, Tokyo Building Nihonbashi Building 2F

### ① Contact Information

### PDA Membership Number

Prefix	First Name	Last Name	
Job Title	Company		
Business Address			
City	State/Province	ZIP+4/Postal Code	
Country	Email		
Business Phone	Fax		
<input type="checkbox"/> Substituting for			

### ② FORUM Registration | 10.-11. October

PDA Members	75,000Yen
Non-Members	100,000Yen
Government	5,000Yen
Academic	5,000Yen
Student	5,000Yen



Please fill in the registration form and send to PDA Japan Chapter by E-mail or Fax.

