

The Parenteral Drug Association and PIC/S Present the...



# 2016 PDA-PIC/S Training Course on **GMPs for APIs**

An Experience-Based Training Course  
for Inspectors and API Industry –  
Applying the Requirements of ICH Q7  
Accepted World-Wide

**Dates: August 8-9, 2016**

**San Juan, Puerto Rico**

Caribe Hilton

1 San Geronimo Street

San Juan, Puerto Rico 00901

Tel: 1.787.721.0303

[pda.org/2016pics](http://pda.org/2016pics)



API suppliers are subject to regulatory oversight, and you need to know what regulators are looking for. ICH Q7 is the international standard that many regulators use to define GMP requirements for APIs. Learn from regulatory and industry experts at the *2016 PDA-PIC/S ICH Q7 Training* on how these requirements are being interpreted and enforced. The *2016 PDA-PIC/S ICH Q7 Training* includes members of the original ICH Expert Work Group (EWG) and current Implementation Working Group (IWG) who are asked to develop Q&As to facilitate implementation.

**Participants will have the unique opportunity to discuss:**

- How to Implement ICH Q7 and Prepare for Inspections
- How to Receive Answers from API Manufacturing Site Inspectors
- GMP Principles
- Personnel, Facilities, Equipment, Cleaning
- Materials Management & Distribution
- Biotech API
- Manufacturing Controls
- Process Validation
- Quality System Elements
- Third Party Relationships

**Don't miss this unique chance to hear from industry and regulatory authorities.**

**Register today.**

**"What is Data Integrity?"**

An additional evening session on this important topic is included for those that register for the PDA/PIC/S Training Course. See registration form for more details.

A limited number of free registrations for regulators will be made available on a first come, first served basis.  
For inquiries, please contact Wanda Neal at [neal@pda.org](mailto:neal@pda.org).

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Pharmaceutical Industry Association of Puerto Rico

# 2016 PDA-PIC/S Training Course

August 8-9, 2016 | San Juan, Puerto Rico  
Caribe Hilton

Four easy ways to register –

Click: [www.pda.org/2016pics](http://www.pda.org/2016pics)

Fax: +1 (301) 986-1093 (USA)

Mail: PDA Global Headquarters  
4350 East West Highway, Suite 600  
Bethesda, MD 20814 USA

Call: +1 (301) 656-5900 ext 115



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[Check here to become a member and receive the member price for this event.](#) (Add \$259 to your total.)

## 2 2016 PDA-PIC/S Training Course Registration | August 8-9, 2016

Please check appropriate fee (US\$).

LIMITED TIME OFFER Expires July 25, 2016				Price After July 25, 2016			
Standard		Government/Health Authority		Standard		Government/Health Authority	
PDA Member	Nonmember	Member	Nonmember*	PDA Member	Nonmember	Member	Nonmember*
<input type="radio"/> \$ 1,295	<input type="radio"/> \$ 1,554	<input type="radio"/> \$ 500	<input type="radio"/> \$ 500	<input type="radio"/> \$ 1,395	<input type="radio"/> \$ 1,654	<input type="radio"/> \$ 500	<input type="radio"/> \$ 500
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\* For this member type or discounted rate, online registration is not available and must be faxed in.

## Have a Campaign Code? PICSPR

## 3 Additional Session | Data Integrity | August 8, 2016 Please check appropriate fee (US\$).

This additional session is already included for those who register for the 2016 PDA-PIC/S Training Course.

Data Integrity Session   Session Only	<input type="radio"/> \$ 90
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## 4 Payment Options All cards are charged in US\$.

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