



# **DRUG QUALITY SYSTEM**

## **cGMP's For a New Era - 2003**

### **An FDA/Industry Workshop**

## **WHO SHOULD ATTEND**

### **Those with Management Controls Responsibilities**

Quality Management, Operations, Regulatory and Compliance professionals

### **Food and Drug Administration**

Investigators and Compliance professionals

### **Facilities and Equipment**

Engineering and Plant Systems professionals

### **Operations Managers**

Manufacturing Operations professionals  
Technical Operations professionals  
Packaging Operations professionals

### **Laboratory Controls Managers**

Testing, Release and Stability professionals

### **Quality Assurance Management**

Change Control professionals  
CAPA professionals, and Document control professionals

### **Those with Regulatory Responsibilities**

Regulatory Affairs Managers

## **WHY YOU SHOULD ATTEND**

**This is an FDA co-sponsored workshop on Drug Quality system.**

The current GMP practices are under review using risk based analysis to achieve better quality using a systems approach. This approach is intended by the Food and Drug Administration to make its current investigator force more productive.

The new cGMP's will have potential program management and logistical benefits for both FDA and the pharmaceutical industry. But the industry and the agency need to fully understand the process, and work together toward their common goal of safe and effective drug products of consistently high quality.

This workshop will help both industry and FDA in understanding the process.

**FDA OFFICIALS PARTICIPATING IN THE PROGRAM WILL EXPLAIN THE PROCESS IN DETAIL. GET YOUR QUESTIONS ANSWERED BY THE EXPERTS!**

## **WHAT IS AN FDA/INDUSTRY WORKSHOP?**

The drug industry and its regulator, the Food and Drug Administration, are both interested in maintaining a consistent, high quality of safe and effective drug products for use by health professionals and consumers. Both are under pressure to make more efficient use of resources. Since the resources of both the industry and the regulators are stressed by non-compliance with regulations, both have an interest in increasing the level of compliance. To this end, the Food and Drug Administration, the research-based prescription drug industry (PhRMA), the generic drug industry (GPhA), the nonprescription drug industry (CHPA), and the excipient industry (International Pharmaceutical Excipients Council of the Americas) have come together to prepare and present educational workshops directed toward increased compliance. The result is better utilization of resources by all, and a further assurance of the objective of consistent, high quality, safe and effective drug products.

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#### **PROGRAM**

8:30 – 9:30 a.m.	Drug Quality System, Current Topics and Issues	<p><b>Joseph Famulare (NJ/PR)</b> Director, Division of Manufacturing and Product Quality Food and Drug Administration</p> <p><b>Douglas I. Ellsworth (IL)</b> New Jersey District Director Food and Drug Administration</p>
9:30 – 10:15 a.m.	Global Change Management	<p><b>Richard C. Norgard (NJ/PR/IL)</b> Director/Team Leader Global Manufacturing Compliance Pfizer Inc</p>
	Management of Quality Systems	<p><b>Jeffrey T. Gelwicks, Ph.D. (NJ/PR/IL)</b> Director, Corporate Quality Assurance Eli Lilly and Co.</p>
	Industry Perspective of Drug Quality Systems	<p><b>C. Greg Guyer, Ph.D. (NJ/PR - tentative)</b> Vice President, MMD of Quality Assurance Merck</p>
10:15 – 10:30 a.m.	BREAK	
10:30 – 11:15 a.m.	Contract Manufacturing Quality	<p><b>Randy Steinbrink (NJ/PR/IL)</b> Associate Director, Contract Manufacturing Amgen, Inc.</p>
11:15 a.m. – 12:00 p.m.	Panel Discussion Q&A	<b>Panel of FDA/Industry Representatives</b>
12:00 – 1:15 p.m.	LUNCH	
1:15 – 2:00 p.m.	FDA 483/Compliance Trends and Analysis	<p><b>Joseph McGinnis (NJ)</b> Compliance Officer Food and Drug Administration</p> <p><b>Edwin Rivera (PR)</b> Branch Chief Food and Drug Administration</p> <p><b>Don Voeller or Designee (PR)</b> Puerto Rico District Director Food and Drug Administration</p> <p><b>Arlyn Baumgarten or Designee (IL)</b> Chicago District Director Food and Drug Administration</p>
2:00 – 2:30 p.m.	Applying the Quality System Approach to cGMPs	<p><b>Ralph Napolitano (NJ/PR/IL)</b> Director of QA, North America Hoffmann-LaRoche, Inc.</p>
2:30 – 2:45 p.m.	BREAK	
2:45 – 4:00 p.m.	Part 11/New Guidance	<p><b>Joseph Famulare (NJ/PR)</b> Food and Drug Administration Director, Division of Manufacturing and Product Quality</p> <p><b>Sion Wyn (IL)</b> Special Government Employee, Part 11</p>
4:00 – 5:00 p.m.	Panel Discussion Q&A	<b>Panel of FDA/Industry Representatives</b>
5:00 p.m.	ADJOURNMENT	

# DRUG QUALITY SYSTEM

## cGMP's For a New Era - 2003

### An FDA/Industry Workshop

#### Hotel Information

Contact the hotels directly for room reservations.

**Be sure to mention cGMPs 2003 to get the special room rate.**

**Reservations made after the cut-off date may not be available, or may be charged at hotel's rack rate.**

June 16, 2003	July 14, 2003	August 12, 2003
<b>Sheraton Meadowlands Hotel</b> 2 Meadowlands Plaza East Rutherford, NJ 07073 <b>Phone 201-896-0500</b> ; Fax 201-896-9696 \$159.00 single/double <b>Cut-off date for room block: May 26</b>	<b>San Juan Marriott &amp; Stellaris Casino</b> 1309 Ashford Avenue San Juan, Puerto Rico 00907 <b>Phone 800-464-5005</b> ; Fax 809-722-6800 \$140.00 single/double <b>Cut-off date for room block: June 27</b>	<b>Hyatt Regency Chicago</b> 151 East Wacker Drive Chicago, IL 60601 <b>Phone 800-233-1234</b> ; Fax: 312 565 2966 \$129.00 single/double <b>Cut-off date for room block: July 20</b>

#### Registration Form

Workshop registrations/payments are being processed by Consumer Healthcare Products Association (CHPA.)

**No phone registrations will be accepted.** Payment must accompany registration.  
 Only one registration per form, please. The form may be copied for additional registrations.

**Please attach business card or type/print (ink please) legibly.**

**NOTE: Credit card billing statement will say "CHPA"**

**Confirmations will be sent via e-mail; please print or type e-mail address where indicated.**

Registration for: <b>FDA/Industry Workshop: cGMPs 2003</b> (✓ check proper session)  <input type="checkbox"/> June 16 <i>New Jersey</i> (No refunds after May 30) <input type="checkbox"/> July 14 <i>Puerto Rico</i> (No refunds after June 27) <input type="checkbox"/> August 12 <i>Chicago</i> (No refunds after July 28)	Name..... Badge.Nickname..... Title ..... Company ..... Address ..... City, State, Zip ..... Phone ..... Fax ..... e-mail ..... <b>Special dietary needs (Please specify)</b> .....
<b>Registration Fee</b> <i>(Includes meeting materials, continental breakfast, lunch, and coffee breaks)</i> Industry \$320.00 Government \$75.00  Make checks payable to: <b>CHPA</b>  <b>No refunds after 2 weeks prior to meeting date. Substitutions accepted at any time.</b>	Method of Payment <input type="checkbox"/> Check # ..... <input type="checkbox"/> MC <input type="checkbox"/> VISA <input type="checkbox"/> AmEx Card # ..... Exp ..... Name as it appears on card (print or type) ..... Amount \$ ..... Signature .....  <p style="text-align: center; font-size: small;"><i>The registration fee will be waived for every 10<sup>th</sup> registration from one company. Registrations must be submitted as a group.</i></p>
<p><b>Mail or fax this page to:</b> <b>Mary McDonald</b> <span style="float: right;"><b>Fax 202-223-6835</b></span>  <b>CHPA</b>  <b>1150 Connecticut Ave., N.W. #1200</b>  <b>Washington, DC 20036</b> <span style="float: right;"><b>Phone 202-429-9260</b></span></p> <p><b>Or e-mail completed form to:</b> <a href="mailto:mary.mcdonald@chpa-info.org">mary.mcdonald@chpa-info.org</a></p>	

## **cGMP's 2003**

### **Additional Hotel Information**

Contact the hotel directly for room reservations; mention "**cGMP's for a New Era - 2003**"

**June 16, 2003**

**Sheraton Meadowlands Hotel**  
**2 Meadowlands Plaza**  
**East Rutherford, NJ 07073**

- Just west of Exit 16 West of the New Jersey Turnpike
- Adjacent to the Meadowlands Sports Complex
- Suites Available
- Telephone
- Coffee Maker
- Non-Smoking Rooms Available
- Air-Conditioned Rooms

**Check-in 3:00 p.m.    Checkout 1:00 p.m.**

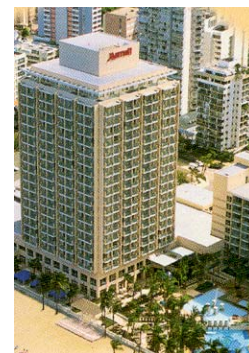


**Phone 201-896-0500    Fax 201-896-9696    Room rate for workshop: \$159.00 single/double**  
**Cut-off date for room block: May 26, 2003**

**July 14, 2003**

**San Juan Marriott Resort & Stellaris Casino**  
**1309 Ashford Avenue**  
**San Juan, PR 00907**

- Five minutes from Luis Muñoz Marín International Airport
- In the prestigious Condado area
- Close to the business district and historic Old San Juan
- Superb recreational facilities including elaborate pools, a spa and casino
- Beautiful beach



**Phone 800-464-5005    Fax 809-722-6800    Room rate for workshop: \$140.00 single/double**  
**Cut-off date for room block: June 27, 2003**

**August 12, 2003**

**Hyatt Regency Chicago**  
**151 East Wacker Drive**  
**Chicago, IL 60601**

- On the Magnificent Mile – Acclaimed Shopping
- Only blocks from the famous State & Rush Streets
- Close to Navy Pier
- Free high-speed DSL internet access in all guest rooms and suites



**Phone 800-233-1234    Fax 312-565-2966    Room rate for workshop: \$129.00 single/double**  
**Cut-off date for room block: July 20, 2003**