

DRUG QUALITY SYSTEM **cGMP's FOR A NEW ERA - 2004**

An FDA/Industry Workshop

2 sessions for your convenience!

Monday, July 12, 2004 Parsippany Hilton Hotel Parsippany, NJ	Monday, August 9, 2004 Hyatt Regency Chicago Chicago, IL
--	--

An interactive workshop on today's relevant issues:

- What are FDA's current thinking and progress to date
- What is industry doing to help map the future direction
- What are the costs and compliance implications
- Industry's practical experiences to date in implementing systems
- The experience of FDA investigators and current observations.

**AN FDA CO-SPONSORED WORKSHOP ON DRUG
QUALITY ISSUES.**

**HEAR FDA AND INDUSTRY DIALOGUE ON THE ISSUES AND
TECHNIQUES INVOLVED.**

ASK QUESTIONS!

Presented by



Food and Drug Administration



*Consumer Healthcare
Products Association*



*Pharmaceutical Research and
Manufacturers of America*



*Generic Pharmaceutical
Association*



*International Pharmaceutical
Excipients Council of the Americas*

ON LINE REGISTRATION NOW AVAILABLE – <https://secure.chpa-info.org/2004chpa-fdaworkshop/>

DRUG QUALITY SYSTEM
cGMP's For a New Era - 2004
An FDA/Industry Workshop

WHO SHOULD ATTEND

Those with Responsibility for Management Controls

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

WHY YOU SHOULD ATTEND

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

The current GMP practices are under review using risk based analysis to achieve better quality using an integrated 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 WHO WROTE 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.

ON LINE REGISTRATION NOW AVAILABLE – <https://secure.chpa-info.org/2004chpa-fdaworkshop/>

DRUG QUALITY SYSTEM

cGMP's For a New Era - 2004

An FDA/Industry Workshop

8:30 – 9:30 a.m.	Drug Quality System, Current Topics and progress on the Risk based approach	David Horowitz (NJ/IL) Director of the Office of Compliance Food and Drug Administration Joseph Famulare (NJ/IL) Director, Division of Manufacturing and Product Quality Food and Drug Administration
9:30 – 10:15 a.m.	Site compliance assessment	Ed Bernasky (NJ) Director/Team Leader, Site Compliance Assessment Pfizer Inc Jeanne Warner (IL) Site Compliance Assessment Manager Pfizer Inc
10:15 – 10:30 a.m.	BREAK	
10:30 – 11:00 a.m.	Quality Systems	Claudio Pincus (NJ/IL) President Qantic Group
11:00 a.m. – 12:00 p.m.	Panel Discussion Q&A	Panel of FDA/Industry Representatives
12:00 – 1:15 p.m.	LUNCH	
1:15 – 2:00 p.m.	FDA 483/Compliance Trends and Analysis NJ and Chicago districts	Robert Maffei (NJ) Compliance Officer New Jersey District Food and Drug Administration Scott McIntyre(IL) Director, Chicago District Food and Drug Administration
1:30- 4:00 p.m.	Process risk assessment – CONCURRENT SESSION Space limited to first 50 registrants	Robert C. Menson Ph.D. Menson & Associates, Inc.
2:00 – 2:30 p.m.	Manufacturing Science and GMP decisions A Case study	Ralph Napolitano (NJ/IL) Director of QA, North America Hoffmann-LaRoche, Inc.
2:30 – 2:45 p.m.	BREAK	
2:45 – 3:30 p.m.	Part 11 - A practical look at the rule	Joseph Famulare (NJ/IL) Director, Division of Manufacturing and Product Quality Food and Drug Administration
3:30 – 4:15 p.m.	Progress and discussion of the Pharmaceutical Manufacturing Research Project (NJ workshop only)	Jeffrey Macher, Ph.D. (NJ) Professor of Strategy and Economics McDonough School of Business, Georgetown University Jackson Nickerson, Ph.D. Professor of Organization and Strategy Olin School of Business Washington University in St. Louis FDA Speaker (TBD) (IL)
3:30-4:15 pm	Process Validation (IL workshop only)	
4:15 – 5:00 p.m.	Panel Discussion Q&A	Panel of FDA/Industry Representatives
5:00 p.m.	ADJOURNMENT	

ON LINE REGISTRATION NOW AVAILABLE – <https://secure.chpa-info.org/2004chpa-fdaworkshop/>

DRUG QUALITY SYSTEM

cGMP's For a New Era - 2004

An FDA/Industry Workshop

Hotel Information

Contact the hotels directly for room reservations.

Be sure to mention CHPA 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.

July 12, 2004	August 9, 2004
Parsippany Hilton One Hilton Court Parsippany, NJ 07054 Phone 877-671-5746; FAX 973-884-2896 \$149.00 single/double <i>Cut-off date for room block: June 28</i>	Hyatt Regency Chicago 151 East Wacker Drive Chicago, IL 60601 Phone 800-233-1234; Fax: 312 565 2966 \$129.00 single/double <i>Cut-off date for room block: July 16</i>

Registrations will be accepted until the **Thursday prior** (July 8/NJ and August 5/IL) to each session.

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.

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

Registration for: FDA/Industry Workshop: cGMPs 2004 (✓ check proper session) <input type="checkbox"/> July 12 <i>New Jersey</i> (No refunds after June 25) <input type="checkbox"/> August 9 <i>Chicago</i> (No refunds after July 23) <input type="checkbox"/> ✓ for concurrent session Limit – first 50 registrants	Name..... Badge Nickname..... Title Company Address City, State, Zip Phone Fax e-mail <i>Special dietary needs (Please specify)</i>			
Registration Fee <i>(Includes meeting materials, continental breakfast, lunch, and coffee breaks)</i> Industry \$320.00 Government \$75.00 Make checks payable to: CHPA No refunds after 2 weeks prior to meeting date. Substitutions accepted at any time.	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;"><i>The registration fee will be waived for every 10th registration from one company. Registrations must be submitted as a group.</i></p>			
<table style="width: 100%; border: none;"> <tr> <td style="width: 30%;">Mail or fax this page to:</td> <td style="width: 40%;">Mary McDonald CHPA 900 19th Street, NW, #700 Washington, DC 20006</td> <td style="width: 30%; text-align: right;">Fax 202-223-6835 NEW ADDRESS Phone 202-429-9260</td> </tr> </table> <p>Or e-mail completed form to: mary.mcdonald@chpa-info.org</p>		Mail or fax this page to:	Mary McDonald CHPA 900 19 th Street, NW, #700 Washington, DC 20006	Fax 202-223-6835 NEW ADDRESS Phone 202-429-9260
Mail or fax this page to:	Mary McDonald CHPA 900 19 th Street, NW, #700 Washington, DC 20006	Fax 202-223-6835 NEW ADDRESS Phone 202-429-9260		

ON LINE REGISTRATION NOW AVAILABLE – <https://secure.chpa-info.org/2004chpa-fdaworkshop/>

cGMP's 2004

Additional Hotel Information

Contact the hotel directly for room reservations;
mention "**CHPA**" for the special room rate

July 12, 2004

**Parsippany Hilton
1 Hilton Court
Parsippany, NJ 07054**

- Suites Available
- Complimentary Parking
- Coffee Maker
- Non-Smoking Rooms Available
- Air-Conditioned Rooms
- Heated indoor/outdoor pools



Phone 877-671-5746 Fax 973-984-2896
Room rate for workshop: \$149.00 single/double
Cut-off date for room block: June 28, 2004

August 9, 2004

**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 16, 2004

ON LINE REGISTRATION NOW AVAILABLE – <https://secure.chpa-info.org/2004chpa-fdaworkshop/>