WCS
World Compliance Seminars

SPEAKER:- GINETTE M. COLLAZO

1 Day workshop GMP's in practice: quality systems, common sense compliance, and application

07 -DEC -2017
Location | Washington D.C

Single Attendee
$ 694
Contact For Group Discount

An event by:
World Compliance Seminars

COURSE SUMMARY

World Compliance Seminars WCS is known all over the world for high quality of professional training programs it offers to members of the global bio pharmaceutical community. We commit to bring you quality webinars from industry experts in a timely fashion. Ensuring your business strategy is on the right track to face the future bounties.

Topic:- 2017 workshop GMP's in practice: quality systems, common sense compliance, and application

Course"GMP's in practice: quality systems, common sense compliance, and application" has been pre-approved by RAPS as eligible for up to 6 credits towards a participant's RAC recertification upon full completion

Design: Content based, experiential (real site specific examples), 483's evaluation and Warning Letter discussions. Case studies.
Recently, the FDA has issued an increasing number of warning letters citing inadequate employee GMP training.

Meanwhile, companies consistently claim their employees are trained and they can prove it by presenting stacks of sign-in sheets from training sessions. This is the training hoax - operators are told in just a few hours about the contents of hundreds of pages of SOPs.

As a result, these reportedly trained professionals can't possibly have learned the material and have little recollection of procedures or knowledge of how to handle deviations, resulting in defects, recalls and other product problems that cost companies untold billions of dollars.

Unfortunately, GMP trainers are often expected to do just that - create a training course, get everyone's signature on the training sign-in sheet and hope that people will work differently. For training to be truly effective, organizations must move from a training environment to a learning environment.

Key Topics

This course covers all GMP 211 sub-parts including Part 11 and electronic batch records. Also, this course covers more than 30 elements of a modern quality system, it's requirements, expectations, and examples. Each element is explored with applicable regulation from US FDA, HEALTH Canada, European Union WHO and ICH (for multinationals).

Areas Covered

- Management and Supervision Responsibilities
- Quality Risk Management
- Knowledge Management and Organizational Learning
- Quality Management and Quality Systems
- Product and Process Monitoring
- Discrepancy Observation and Investigation
- Complaints
- Qualification and Validation
- Learning, Training and Performance
- Documents, Records and Recordkeeping
- Change Management

Industries who can attend

- Compliance officers
- Consultants/service providers
- Engineering and design control teams
- Executive management
- Managers
- Manufacturing directors and supervisors
- Procedure writers
- Pharmaceutical and cGMP auditors
- QA/QC personnel
- R&D staff

SPEAKER

Ginette M. Collazo
Ph.D, President, Ginette M. Collazo, Inc.

Dr. Collazo has spent more than 15 years in technical training, organizational development and human reliability.

GINETTE M. COLLAZO

She has worked with Bristol-Myers Squibb, Johnson & Johnson, Schering-Plough, Wyeth and Medtronic, many more small and mid-sized drug and device companies. An active researcher in specialized studies related to human reliability, she is the author of numerous publications on these topics.

Dr. Ginette M. Collazo obtained her PhD in Industrial/Organizational Psychology from the Interamerican University of Puerto Rico. Ginette has over 15 years of experience in the pharmaceutical industry with the Technical Training, Organizational Development and Human Reliability fields.

Currently she is the president of Ginette M. Collazo, Inc. a firm that works with organizations to improve productivity by helping them identify and implement innovative strategies that will warrant that business objectives and results are met and exceeded. GMC, Inc. specializes, also, in Human Error reduction allowing organizations to achieve savings and reduce/avoid unnecessary costs associated with people's mistakes.

Ginette's clients all over the world including Germany, Argentina, USA, Trinidad Tobago, Dominican Republic, Singapore, Europe, and more. She has been a guest speaker about these topics in several professional conferences including American Institute for Chemical Engineers Global conference, Center for Chemical and Process Safety, American Society for Quality, California State Lands Commission Prevention

Our Testimonials

David QU, senior Analytical Chemist Dalton Pharma Services.

"I learned a lot from the instructor and trainee good."

Nicola Mootoo, Senior Validation Engineer Shire Pharmaceuticals.

"Well placed, a lot of good information. Good interaction between participants.Held at a good location"

Evelyn Chang, Corporate manager Genzyme.

"Well delivered seminars, right place, good contents."

Mary Beird, Regulatory Compliance Manager
Charles River laboratories International, Inc.

"I thought the contents of the presentation and the discussion was very good"

Sajan B. Balabhadran, Watson Pharma Pvt Ltd.

"A Very Well organized event. The Speaker was just marvellous in driving to a depth of my understanding of Data Integrity and 21 CFR Part 11 aspects."

Course Outline:

8:30 AM - 4:30 PM

- Registration Process - (8:30 am till 8:45 am)
- Management and Supervision Responsibilities
- Quality Risk Management
- Knowledge Management and Organizational Learning
- Quality Management and Quality Systems
- Product and Process Monitoring
- Discrepancy Observation and Investigation
- Complaints
- Qualification and Validation
- Learning, Training and Performance
- Documents, Records and Recordkeeping
- Change Management
- Corrective Action and Preventive Action (CAPA)
- Materials and Packaging Components
- Vendors, Third Parties, and Outsourcing
- Sampling
- Equipment Cleaning
- Sanitation
- Facilities and Utility Systems
- Warehousing and Storage
- Distribution Practices
- Maintenance, Repair, and Calibration
- Materials Receiving
- Equipment
- Manufacturing and Packaging
- Identity Control
- Label Control
- Batch Release
- In-process Controls
- Clothing and Personal Hygiene

Register Now

PACKAGE	Single Attendee	Special Group Discount
1 day Workshop 07 -DEC -2017 Location | Washington D.C	$ 694	$ 2099

Special Group Discount Register for 3 and the 4th person gets a FREE pass
For more than 1 registration from same Company Contact :844-267-7299

""Each attendee will receive 2-Day workshop materials by the speaker. Seminar Also Includes Certificate, Complimentary Breakfast, Lunch & High Tea/Coffee provided by WCS""

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GET IN TOUCH
3190 STIRLING ROAD
UNIT K4,HOLLYWOOD,FLORIDA-30021
support@worldcomplianceseminars.com
www.worldcomplianceseminars.com

Call us ! Toll Free
844-267-7299