World Compliance Seminars

GMPS FOR THE LIFE SCIENCES COURSE

COURSE DESCRIPTION

Understanding GMP requirements, refreshed on a yearly basis is critical to maintain high-GMP standards in your company. Knowledge and skill surrounding the application and practice of GMPs is fundamental to avoiding regulatory issues. It's simple – you have to do it and you and your team must comply. You cannot assume that once taught, the content associated with GMPs will be retained from year to year. As human beings, we tend to forget over time and as we forget, we also get careless. In the health sciences there is no margin for error or tolerance for carelessness. This training will provide foundation to your GMP training.

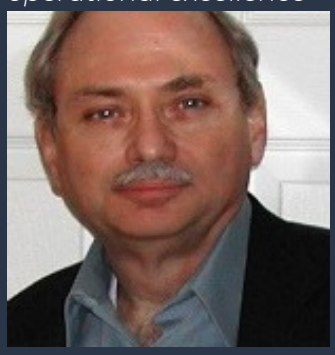
WHO WILL BENEFIT

- *Virtually everyone in the health sciences, everyone within the organisation, can benefit and in most cases, is required to attend periodic GMP training.*
- *Compliance*
- *Quality*
- *Marketing*
- *Engineering*
- *Operations*

SPEAKER

PRESIDENT AT C. H. PAUL CONSULTING LLC

Charles H. Paul is the President of C. H. Paul Consulting, Inc. – a regulatory, training, and technical documentation consulting firm. Charles is a management consultant, instructional designer and regulatory consultant and has led C. H. Paul Consulting, Inc. since its inception over 25 years ago. He regularly consults with Fortune 500 pharmaceutical, medical device, and biotechnology firms assisting them in achieving human resource, regulatory, and operational excellence



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COURSE BACKGROUND

CGMPs or Current Good Manufacturing Practices is a general encompassing term for the regulations that the control of all facets of life sciences manufacturing processes and facilities particularly pharmaceutical products. It is crucial, for any entity to be compliant, that every individual within the organization fully understand and adhere to these regulations in the course of Adherence to those regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug and medical device products meet their quality standards.

TRAINING AGENDA 2 DAYS

GMPs – Government Regulations

- *What are the regulations governing Good Manufacturing Practices?*
- *Your responsibilities*
- *Pertinent GMP topics as per the code of Federal Regulations*
- *Quality Management*
- *Personnel*
- *Premises and equipment*
- *Documentation*
- *Production*
- *Quality Assurance*
- *Materials management*
- *Production and in-process controls*
- *Packaging and labeling*
- *Storage and distribution*
- *Laboratory controls*
- *Validation*
- *Change control*
- *Rejection and re-use of material*
- *Complaints and recalls*
- *Supplier controls*

GMP Inspections

- *Preparing for a GMP Inspection*
- *The consequences of not being ready*
- *The specific areas that are inspected during a GMP inspection*

FDA Inspection Tips and Recommendations

- *The FDA Inspection – how is it structured and conducted*
- *Responding and organizing for the FDA Inspection*
- *Importance of truthfulness*
- *knowledgeability and confidence*
- *FDA Tricks to elicit information*
- *Arguing and challenging*
- *Behavior during the inspection*
- *Importance and role of documentation*
- *Effective communication skills*
- *Being deceptive*
- *Opinion versus fact*
- *Phrases never to say*
- *Handling adverse findings during the inspection*

Summarise

- *Questions & Answers with Faculty*
- *New GMP Topics*
- *Many Case Studies*
- *Certificate Awarded to all the attendees*

Each Day Session End Time 04:00 PM EDT

12-Hour Instructor Led Video Conference

GMPs for the Life Sciences Course

REGISTRATION FORM

Name _____ **Email** _____

Organization _____ **Department** _____ **Position** _____

Phone _____ **Mobile** _____

Register Online At www.worldcomplianceseminars.com

or by calling our offi ce : 844-267-7299

Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
- WCS reserves the right to make alterations to the conference/executive briefing content, timing, speakers without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of WCS. If such a situation arises, we will refund your registration fee or we will try to reschedule the event.