



B u s i n e s s C o n s u l t a n t s

Global Competitiveness Strategies through Regulatory Compliance & Best Practices in GMP			
Day 1			
From ... To		Total	Course Content
8:30	8:45	0:15	Introduction
8:45	10:30	1:45	<ul style="list-style-type: none"> • The Global Regulatory GMP-scene • Changes in the PIC/S Code of GMP PE009-09 May 2009, Reorganisation of the Code of GMP Guide in Part I, Part II and Annexes, Revision of Annexes • Revision of PE009-09 Annex 1 for Sterile manufacturing, environmental monitoring, room classification, hygiene zones, particle counting, • Revision of PE009-09 Chapter 1, Revision of Chapter 6 and Deletion of footnotes in Chapter 6, Corrections to revision of Chapter 6, Revision of Chapter 8, Incorporation of PE 007 (API guide) as Part II, Revision of PE009-09 Annex 3 for radiopharmaceuticals, new Annex 19 and Annex 13, New Annex 20 and their applicability to Thai manufacturers • Changes to Eudralex Vol 4 during 2009-09-12 • The US regulatory scene – 21 CFR 210, 211, and 11 • WHO New revised GMP guidelines
10:30	11:00	0:30	Coffee Break
11:00	12:00	1:00	Review of cleaning validation requirements, calculation of MACO, residues testing, use of rinse water and swab, comparison of specific and non-specific analytical methods, use of surrogate products, use of riboflavin for demonstration of residues, finding MSDS and LD50s
12:00	13:30	1:30	Practical – setting up matrixes of products, calculation of cleaning validation results. (Laptop with Excel or calculator is necessary)
13:30	14:30	1:00	Lunch Break
14:30	15:30	1:00	The GMP of powders and tablets, Tablet development in practice Principles of formulation development, Material and product characterisation Developing stable processes, Mixing and blending Dry granulation, Blend uniformity assessment Sampling for accurate results, FDA Guidance on Blend Uniformity Testing
15:30	15:45	0:15	Coffee Break
15:45	17:00	1:15	Beyond GMP, ICH Q10 – complying with the requirement for Quality System: Setting up a three level quality system, Policies, Technical Guides, Manufacturer's manuals, Training requirements,
17:00	17:30	0:30	Discussions, questions and answers



B u s i n e s s C o n s u l t a n t s

Global Competitiveness Strategies through Regulatory Compliance & Best Practices in GMP			
Day 2			
From... To		Total	Course Content
9:00	10:30	1:30	<p>GMP Audit Process review</p> <ul style="list-style-type: none"> ○ Six steps to successfully surviving GMP audits ○ Current global audit and enforcement practices ○ Writing an SOP for inspections ○ Preparing your staff for Regulatory Audit ○ Conducting internal audits in preparation for GMP audits ○ Required documents and the right format ○ How to treat the auditor ○ Understand what the Auditor is most interested to look at and why ○ What to say and what not say during audits ○ Responding to GMP deficiency reports ○ Current most common US FDA inspection findings
10:30	11:00	0:30	Coffee Break
11:00	12:00	1:00	<p>Process validation review and Matrix validation - Design of experiment (DOE) Fractional Factorial Designs Screening experiments, Resolution of a design, Building an appropriate model</p>
12:00	13:30	1:30	<p>Practical – Process validation studies using Matrix validation and Design of experiment (DOE) – how to actually calculate and set up partial factorial experimental designs to minimise validation work and maximise data. Requirements – Minitab14 and laptops, Determine the most robust settings in your process to minimize the different sources of variability.</p>
13:30	14:30	1:00	Lunch Break
14:30	15:30	1:00	<p>How to Audit Active Pharmaceutical Ingredient Manufacturers. Why audit API Manufacturers? EU Directive 2004/27/EC (Regulator's view) What are the requirements? What role should secondary manufacturers play? Techniques and tips, checking you are at the right address. Process mapping and selection of critical steps for review Solvents and solvent recovery. Re-recrystallisation and reprocessing Sharing information, Using 3rd party audits</p>
15:30	15:45	0:15	Coffee Break
15:45	17:00	1:15	<ul style="list-style-type: none"> ▪ Technology transfer, setting up a GMP contract ▪ Why Transfer Technology? Pharmaceutical Product Life Cycle, Development, Innovative, Mature/Generic ▪ Product Transfers and Technology Transfers ▪ Intellectual Property, Technology, Techniques. ▪ Regulatory Considerations, ▪ Variation Procedures, Types of Variations ▪ Human Challenges
17:00	17:30	0:30	Discussions, questions and answers