



GMP & Training needs.

For manufacturers of pharmaceutical products, herbal or traditional medicines and cosmetic products, GMP is a compulsory requirement for their manufacturing activities.

Good Manufacturing Practice (GMP) is that part of quality assurance aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use. It is thus concerned with both manufacturing and quality control procedures.

The GMP guidelines lay down concepts, principles and rules that should be followed by manufacturers. This is aim to ensure that the products manufactured are consistently safe for human consumption and meet the set quality specifications as approved by the authority.

Among GMP prime requirement is the need for a regular and continuous training for operation and quality personnel of all levels. Although most manufacturers conduct “On-the-job training”, this is insufficient to meet the demand for skill upgrades and understanding of the GMP concept and principles that lies behind those set procedures.

Chapter 2, PIC/S GMP Guideline* PE009-5, 01 Aug 2006, states that “The manufacturer should provide training for all the personnel whose duties take them into production areas or into control laboratories (including the technical, maintenance and cleaning personnel), and for other personnel whose activities could affect the quality of the product”.

There is no excuse if the appropriate training program is not regularly conducted, or worst, not conducted in any manufacturing facility that requires a GMP certification.

Training is not just GMP needs. Training is also required to serve many other purposes, such as:

- to give education and understanding of work scope
- to allow staff to start their job given correctly
- to prevent mistake and product defect
- to enhance work quality
- to maintain and improve productivity
- to refresh staff on their work scope



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The irony is, there is a prominent lack of public GMP training in Malaysia. Even when such training is organized, more often it does not meet the specific and current demand required by manufacturers. Further more, as the course fee is quite substantial, only a handful of the personnel are able to participate. It is thus necessary that experts in GMP related matters are engaged regularly to conduct in-house training.

A1 Consultancy & Integrated Services Sdn Bhd is the only GMP training provider in Malaysia who can provide GMP related training specific to the current needs of the manufacturers. We have competent trainers in their field who can make the training meaningful, knowledgeable, effective, yet interesting and 'fun'.

All our trainers have past experienced in the pharmaceutical industries. Our trainers covered a wide scope in GMP, from product development issues, to process control, quality control, qualification, validation, environmental monitoring, documentation and specific processing activities.

As A1 Consultancy & Integrated Services Sdn Bhd is approved by National productivity Corporation (NPC), all our training modules, be it standard or customized to client's need, will easily be approved and reimbursable by HRDF

As seen from the flow chart at the end of this article, we conduct extensive 'research' with client to understand their processes and problems. Appropriate training modules will be proposed and the training materials will be streamlined to meet the ultimate technical and GMP needs of the client. This is a more cost effective method of organizing and conducting training.

To further enhance the efficacy of the training, evaluations are conducted at pre-determined intervals. This serve to evaluate the trainees' understanding and their ability to absorb what has been taught during the training period.

Certificates are presented to all trainees on the condition that they must attend at least 75% of the training program, participate in all case studies and pass all the tests ($\geq 50\%$) given during the training period.

To find more about our training program, do visit our web site at www.acissb.com

* **PIC/S GMP Guideline** denotes "Pharmaceutical Inspection Convention scheme GMP guideline. Further info can be obtained from website www.picscheme.org



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TRAINING FLOW CHART

