



## The Relevance of cGMP Training for Senior Managers

How many senior managers have up-to-date cGMP training? If they do, how relevant was it to their day-to-day work?

Regular cGMP training, a mandatory requirement of the regulatory authorities and a basic important tool for those of us working in compliance with the GMP regulations within the bio/pharmaceutical and biotechnology industries. Yet as senior managers, how often have we undergone cGMP training sessions and come away gaining only an entry in our training records and little else? Indeed, we seem to get less out of cGMP training as we climb the corporate management ladder and yet we make important decisions routinely regarding GMP issues.

So why is it that cGMP training appears to be more relevant to “hands-on operational” staff than “desk-based” senior managers? In the author’s opinion, this is due largely to the fact that cGMP training courses are designed with practical learning and the target audience are typically working at operational levels where their jobs involve performing specific practical tasks (e.g. analysis of a product, operating a blister packer, cleaning of a granulation machine, completing batch records etc) using set instructions such as SOPs and protocols. For us senior managers, there are no standard manuals or training templates when it comes to communication and making decisions. These activities take up a large percentage of our job and we all do it differently because each one of us have a different management style. It is no wonder then that we often think of the standard GMP training as a tick in the box, because we have long past the days when we carry out practical tasks. That leaves us in a bit of a dilemma when it comes to cGMP training. We attend the training because it is mandatory but resent the time spent as an opportunity cost to getting some other work done.

It is the author’s opinion that relevant cGMP training is of paramount importance to senior managers, in particular those who do not work within Quality/Production/Engineering, because we make critical decisions with potential major impact on product quality and patient safety. FDA and MHRA guidelines require personnel to be trained so the question is not whether we need cGMP training but its relevance to our jobs. Without a doubt, any training will only benefit and improve performance when it is relevant. Well designed, developed and executed cGMP training specific to the senior managers’ needs (combined with maintaining up-to-date technical knowledge) will not only help us do our jobs more effectively but also that of our staff. Critical elements of any training and education should include an understanding and appreciation of each of our roles, in terms of how they interact with each other and how our actions can impact the organisation. Everyday decisions are made by senior managers, with little communication or thought to the GMP implications. Without a doubt, some of these decisions lead directly to product issues. The following are just a few of the author’s real experiences:

- A seemingly simple decision made by Distribution to change a freight forwarder to reduce costs resulted in regulatory dossier complications.

- Change of site of manufacture (the same supplying Company) of a glass vial agreed by Purchasing to improve the lead-time led to manufacturing/packaging issues for Japanese supply.
- A computerised training management system purchased by HR for recording site-wide training gave rise to inspection observations for non-compliance to 21CFR part 11.

For senior managers, good cGMP means a thorough understanding of the different functionalities so that informed decisions can be made, which are communicated appropriately, to ensure the quality and GMP compliance status of the organisation is not compromised.

There is no question about the relevance of cGMP training for senior managers. The major stumbling block is the design and development of an appropriate training package to fulfil our needs and to make us more effective and informed managers.....

## About This Article

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