



WHO DOES THIS APPLY TO:

- For pharmaceutical, radiopharmaceutical, biological, veterinary and disinfectant drugs:
 - Fabricators
 - Packagers/labellers
 - Distributors
 - Importers
 - Wholesalers
 - Testers

KEY POINTS:

- The GMPs state, “The effectiveness of continuing training is periodically assessed.” We do not yet know how HPFBI will audit this requirement, but it is a broad statement that can be interpreted on four levels:
 - Training reaction: This measures the satisfaction the trainees have with the learning experience. It is normally measured through course evaluations.
 - Training learning: Selecting the most appropriate tools for evaluating learning depends on the type of information and the objective of the training. Typically tests, simulations or on-the-job demonstrations are used.
 - Trainee performance: Here we are trying to determine if the learning has been transferred back to the job. This needs to be evaluated three to six months after the formal training has occurred.
 - Business results: At this level, we are looking at what is ultimately important to the business (for example, quality measures, efficiency, return on investment, etc.). This type of evaluation is conducted months or even years after the training has been initiated and it is vital that the original objectives of the training were clearly defined.
- The following flowchart (page 3) describes the general process we recommend in deciding how to respond to potential issues raised by the GMP evaluation. We recommend if an individual has failed at least one quiz they must move through this follow-up process.

9-6975 Meadowvale Town
Centre Circle, Suite 410,
Mississauga, Ontario,
L5N 2V7, Canada
TOLL FREE: 1-877-877-5152
PHONE: 905-363-1182
FAX: 905-542-7981
www.qualityandcompliance.com
www.validapharm.com
www.nhpcompliance.com





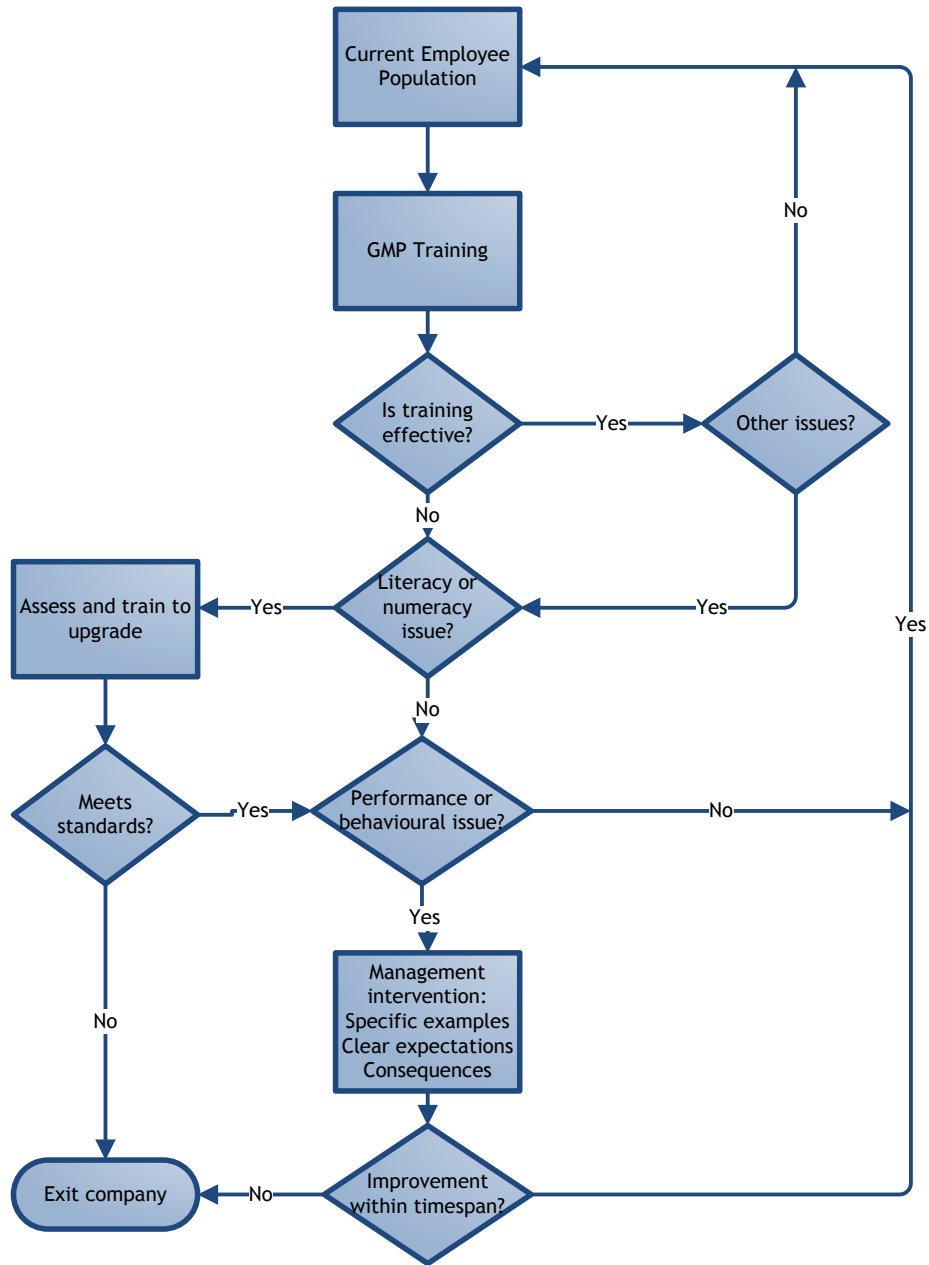
- Addressing this issue may require a further evaluation of the standards for each job function, as well. For example, an operator may not need to demonstrate the same level of GMP understanding as a Quality Management associate.
 - Is there a larger issue such as English language skills, numeracy skills or literacy that is preventing the individual from succeeding?
 - If this is the case, we must deal with this issue with further assessment and training before continuing.
 - Is there a performance or behavioural issue?
 - If so, there needs to be formal management intervention from management using clear and specific examples. This would involve coaching and feedback including a discussion about management's expectations and potential consequences.
- Is this an ability issue?
 - If so, how can we assist the individual?
 - Repeat the course
 - Provide remedial teaching
 - Provide individual coaching

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GMP TRAINING FOLLOW-UP PROCESS:



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Quick NOTES

Evaluation of GMP Training

JULY 2010
GMP Training



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Author: Deborah Campbell

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