

Guidance Number: 81

Appendix 1

Training System Owner

Definition	Responsibilities	Skills/Competencies
Designated individual responsible for overseeing, designing, and implementing the site GMP Training System. Must be knowledgeable of and have experience in applied GMPs, as well as training concepts and practices.	<ul style="list-style-type: none">• Develops, implements and maintains the GMP Training System• Ensures completion and maintenance of GMP Training Documents and Records• Maintains current knowledge of regulatory requirement in relation to training• Understands and works with other departments to ensure that the GMP Training System is linked properly with other quality systems (eg. Document Control, Deviations, etc.)• Maintains a list of all qualified trainers and ensures that these people are given the opportunity to stay qualified• Develops and maintains site strategy and plan for training and qualification activities• Monitor system and implement continuous improvements• Presents/explains the site GMP training system to auditors/inspectors /visitors.	<ul style="list-style-type: none">• Strategic Planning• Communication Skills• Analyzing needs• Decision making• Presentation skills• Coaching• Meeting leadership/facilitation• Process mapping• Adult learning theory

Full Time Trainer – Training is primary job function

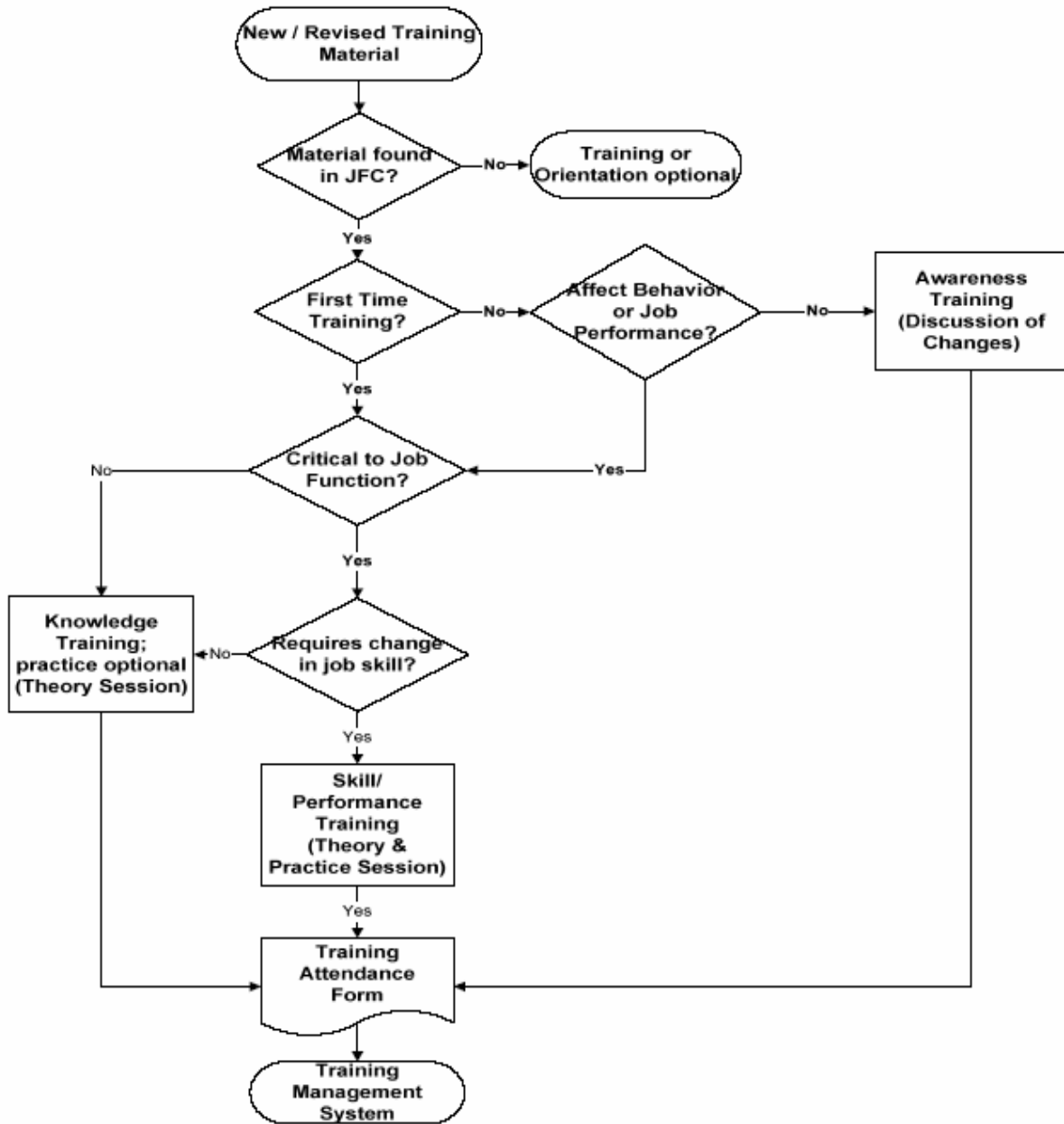
Definition	Responsibilities	Skills/Competencies
An internal site trainer who is responsible for the development, preparation and effective delivery of training activities. Typically training is their primary job function	<ul style="list-style-type: none">• Contribute to the site's strategy for training and qualification activities• Monitor training activities to ensure compliance with company, regulatory and legal requirements• Facilitates the identification, planning, actioning and evaluation of training needs for all employees• Is the reference or expert for all parts of the training process: analyzing needs, writing learning objectives,	<ul style="list-style-type: none">• Analyzing needs• Writing learning objectives• Developing training modules• Delivering training• Presentation skills• Training coordination• Developing evaluations and assessments• Facilitation skills

Part Time Trainer – Training is secondary job function

Definition	Responsibilities	Skills/Competencies
<p>A person having the education, training and experience, relative to the training topic, and demonstrated competence. These trainers may perform communication, knowledge and/or skills based training. These individuals may also be referred to as department trainers, SMEs, occasional trainers, etc. These colleagues typically perform training as one part of their overall job function.</p>	<ul style="list-style-type: none">• Maintains expertise in their field• Delivers and evaluates training in their field• Takes guidance from full time trainer• Ensures that training delivered meets the learning objectives	<ul style="list-style-type: none">• Technically proficient on topic• Experienced and knowledgeable on the GMP processes and activities related to the topic• Understands the GMP requirements in the area including requirements for the topic• Demonstrates effective communication skills• Demonstrates effective presentation skills

Appendix 2

Training Method Decision Model



Appendix 3

Model for GMP Training System

