Programma GMP Mid-Level
Day 1 - Theory and Workshops

Time (Hr)	duration (Hr)	Title	Content
08:30-08:45	0,25	**Welcome with coffee and tea**	
08:45-09:00	0,25	**Introduction**	Welcome to BTF
			Health and Safety
			Eating and drinking policy
09:00-09:45	0,75	**introduction into GMP - the regulations**	guidelines EU, ICH
		Theory	background on GMP, why GMP?
			the product life cycle
			History and how GMP evolved
09:45-10:45	1,00	**Quality systems**	Deviations
		Theory	CAPA
			Change Control
10:45-11:00	0,25	***Coffee / tea***	
11:00-11:45	0,75	**Training**	How to develop a training system
		Theory	How to follow up on training requirements?
			Developing a company-training matrix
			On the Job Training (OJT.)
			Documenting a training training
			How to test the effectivity of training?
11:45-12:30	0,75	**Deviations and OOS**	What is a deviation?
		Theory	What is an OOS?
			What are the critical aspects?
			How to perform an investgation?
			Corrective actions versus preventative actions
			Design a Deviation and OOS system
12:30-13:15	0,75	***Lunch***	
13:15-13:45	0,50	Tour	
13:45-14:15	0,50	**Documentation**	Document types
		Theory	Why do we need documentation
			procedures (SOPs)
			batch records
			document life cycle
			issuance of documents
14:15-14:45	0,50	**Facility and equipment**	Equipment qualification
		Theory	What are the requirements for a facility and equipment
			How to qualify the production area's and equipment
			What are manufacturing requirements
			What are the product requirements
14:45-15:30	0,75	**Data Integrity**	data recording rules
		Theory	data integrity
			lab notebooks
			archiving
			Computerized systems
15:30-15:45	0,25	***Coffee / tea***	
15:45-17:30	1,75	**Filling in a batch record**	Fill in workshop, Fill in a batch record
		practice	What can be improved?

Day 2 - Theory and Workshops

Time (Hr)	duration (Hr)	Title	Content
08:30-09:30	1,00	**Tasks of the QC department** *Theory*	incoming goods
			In process controls
			Release
			Environmental Monitoring
09:30-10:15	0,75	**Outsourcing and Vendor Management** *Theory*	Different vendor types (manufacturing, raw materials, services)
			What are the critical aspects per vendor type
			Audits (initial qualification and re-qualification)
			Technical Agreements / QA agreements
			Raw material receipt and testing
			How to manage your suppliers?
10:15-10:45	0,50	**Change Control** *Theory*	What is change control?
			When do we follow the change control procedure?
			Why is change control relevant?
			Design a change control system?
			What are key aspects of change control?
10:45-11:00	0,25	***Coffee / tea***	
11:00-12:00	1,00	**Risk Management** *Theory*	ICH Q9
			How to make use of ICH Q9 in the different phases of the product life cycle?
			How to report risk assessments?
			FMEA
			Examples
12:00-13:00	1,00	**Risk Management** *Workshop*	Introduction of a new stopper type. Lyo product, nitrogen blanketing. Make a risk assessment
13:00-13:45	0,75	***Lunch***	
13:45-14:30	0,75	**Process Validation** *Theory*	Validation of the manufacturing process
			Media simulations
			life cycle process of validation
			Virus removal steps
14:30-15:30	1,00	**Contamination Control** *Theory*	microbiology
			bacteria, molds and viruses
			basic hygiene
			intoduction cleanrooms
			Environmental monitoring
10:45-11:00	0,25	***Coffee / tea***	
	0,75	**Environmental Monitoring** *Practice*	Perform some tests
	0,25	Wrap up course	

Trainers

Jolanda Muurman	Biotech Training Facility
Wilma Meijs	Wilma Meijs Farmaceutisch Advies