Programma GMP Mid Level

Day 1 - Theory and Workshops		
Time (Hr)	**Title**	**Content**
08:30-08:45	**Welcome with coffee and tea**	
08:45-09:00	**Introduction**	Welcome to BTF
		Health and Safety
		Initiate agar plates
09:00-10:00	**1. Introduction into GMP - the regulations**	Guidelines EU, ICH
	Theory & interactive session using mentimeter	Background on GMP, why GMP?
		The product life cycle
		History and how GMP evolved
	Quality systems-> dit onderdeel verwerken in part 1, 4 en 11	
	Theory	Deviations
		CAPA
		Change Control
10:00-10:30	**2. Documentation**	Document types
	Theory	Why do we need documentation
		Procedures (SOPs)
		Batch records
		Document life cycle
		Issuance of documents
10:30-10:45	***Coffee / tea***	
10:45-11:30	**3. Data Integrity**	Data recording rules
	Theory & Workshop	Data integrity
		Lab notebooks
		Archiving
		Computerized systems
		Workshop: identify mistakes in document
11:30-12:15	**4. 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
		How to test the effectivity of training?
12:15-13:00	***Lunch***	
13:00-13:30	Tour	
13:30-14:30	**5. Deviations and OOS**	What is a deviation?
	Theory & workshop	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
		Workshop: Solve a deviation using Fishbone
14:30-15:00	**6. 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
15:00-15:15	***Coffee / tea***	
15:15-17:00	**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)	**Title**	**Content**
08:30-09:30	**7. Tasks of the QC department** *Theory*	incoming goods In process controls Release Environmental Monitoring
09:30-10:15	**8. 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?
10:15-10:30	***Coffee / tea***	
10:30-11:00	**9. 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?
11:00-12:00	**10. Contamination Control** *Theory*	microbiology bacteria, molds and viruses basic hygiene intoduction cleanrooms Environmental monitoring
12:00-12:45	***Lunch***	
12:45-13:30	**11. Environmental Monitoring** *Workshop*	Moulds in the cleanroom
13:30-14:30	**12. Risk Management** *Theory*	ICH Q9 cycle? How to report risk assessments? FMEA Examples
14:30-15:30	***Coffee / tea***	
15:30-15:45	**Risk Management** *Workshop*	Introduction of a new stopper type. Lyo product, nitrogen blanketing. Make a risk assessment, FMEA and ranking
15:45-16:30	**13. Process Validation** *Theory*	Validation of the manufacturing process Media simulations life cycle process of validation Virus removal steps
16:30-16:45	**Wrap up course**	