TRAINING TOPICS FORM

Our training courses are based on learning by doing. This entails that the training courses are interactive and contain workshops, games, quizzes and practical modules.

Please click the appropriate boxes to indicate in which subjects you are interested.

GMP - General		
Topics	**Content**	**Add**
GMP general	• GMP introduction (+ workshop)	☐
	• Regulations and guidelines (+ Quiz)	☐
Quality Systems	• Deviations & CAPAs	☐
	• Risk Management ICHQ9 (+ workshop)	☐
	• Change control (only with risk management) (+ workshop)	☐
	• Training system	☐
	• Root cause investigations (+ workshop)	☐
GMP Documentation	• Pharmaceutical documentation (general)	☐
	• Data Integrity	☐
	• Analytical documentation (+ workshop)	☐
	• Following a work instruction (+ practice)	☐
	• How to use a BR (+ practice)	☐
	• Design a BR/SOP/WI (workshop)	☐
	• Design a document flow (workshop)	☐
	• Batch Record Review and disposition (QP)	☐
Audits and Inspections	• Introduction to audits	☐
	• Internal Audits (+workshop)	☐
	• External audits	☐
	• Audit techniques	☐
	• Audit team & program	☐
	• Execution of an audit	☐
GDP	• Labelling	☐
	• Leaflet & Packaging	☐
	• Storage	☐
	• Distribution	☐
	• Warehouse	☐

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RA	• Drug Substance • Drug Product • Lot Release	☐ ☐ ☐

Quality Control Laboratory		
QC Laboratory General	• Tasks of QC department • Test methods • OOS process (+ workshop) • Stability studies • Bill of Testing • Aseptic behaviour & gowning (+ workshop)	☐ ☐ ☐ ☐ ☐ ☐
QC safety	• Chemical safety • Biosafety • Spill training (practice)	☐ ☐ ☐
QC method lifecycle	• Method development • Method verification / qualification / validation • Method Transfer • Outsourcing & Vendor management	☐ ☐ ☐ ☐
QC methods (analytical)	• pH (+ practice) • Conductivity (+ practice) • Osmolality (+ practice) • Growth promotion test • Microbiological identification techniques • Bioburden testing (+ demo) • Sterility testing (+ demo) • Endotoxin testing • Environmental monitoring (+ practice) • qPCR (+ practice) • Digital PCR (+ practice) • Flow cytometry (+ practice)	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
QC equipment	• Pipetting basic course (2 hours) (+ practice) • Pipetting advanced course (1 day) (+ practice) • How to use a balance (practice)	☐ ☐ ☐

Operations		
Validation & Qualification	• Equipment lifecycle / Equipment qualification (+ workshop) • Process validation (+ workshop) • Media simulations (+ workshop) • Computerised system (GAMP 5) (+ workshop)	☐ ☐ ☐ ☐
Contamination control	• Pharmaceutical microbiology and disinfection (+ workshop) • Cleaning & Sterilization (+ practice) • Environmental monitoring (+ workshop) • Cleaning a cleanroom (+ practice) • Annex 1; cleaning control strategy	☐ ☐ ☐ ☐ ☐
Operations / Manufacturing Theoretical	• Cleanroom principles • Cleanroom behaviour & communication (+ workshop) • Gowning class D, C, B, A (+ practice) • Working in a BSC/LAF cabinet (+ practice) • Biotech production; the basics • Basic principles manufacturing process • Basic principles ATMP manufacturing • Basic principles mRNA manufacturing • Basic principles vaccine manufacturing • Basic principles viral vector • Starting materials & raw materials • Sterilisation methods	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Manufacturing Equipment	• Biowelder (practice) • Sterile Connection Device (practice) • Automatic filling line (practice) • Manual filling pump (practice) • Autoclave (practice) • Particle counter (practice) (part of EM practice) • Microbiological Air Sampler (practice) (part of EM practice) • Filter tester (practice) • Cell counter (manual/nucleocounter/ViCell) (practice) • Bioreactor (30 L Stainless Steel) • Bioreactor Single-use (Wave-rocker or stirred tank reactor) (practice) • MVP – filtration (practice) • MVP – mediaprep (practice) • AKTA ready (practice) • Single-use mixer (practice) • Biosafety cabinet (practice) • qPCR • digital PCR • pH meter • Conductivity meter • Osmolality meter • Dyna select • Rotea • Balance • Pipettes (single -and multichannel, multipette) • Black & white panel & polarized light (visual inspection) • Isolator	☐ ☐

Manufacturing general	• Cell banks • Cell culture & counting (+ practice) • Process control (+ workshop) • Buffer & media preparation (+ practice) • Fermentation (+ practice) • Aseptic filling: manual fill (+ practice) • Aseptic filling: using an automatic filling line (+ practice) • Visual inspection (+ practice) • Chromatography (+ practice) • Clarification (+ practice) • Filtration (+ practice) • Virus inactivation (+ workshop) • Viral clearance • Ultrafiltration & diafiltration (+ practice) • Lyophilisation (+workshop) • Working with disposables (+ practice)	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Manufacturing ATMP	• Isolation (+ practice) • Concentration (+ practice) • Transfection (+ practice)	☐ ☐ ☐
Process Development	• Critical aspects during production (CQA) • Extractables & Leachables • Scale up	☐ ☐ ☐
Single-use technology	• Single use materials • Single use systems	☐ ☐
Safety	• Biosafety • Chemical safety • Chemical spill training (+ practice) • Biological spill training (+ practice)	☐ ☐ ☐ ☐
In-process control	• pH (+ practice) • Conductivity (+ practice) • Osmolality (+ practice)	☐ ☐ ☐
Facility & Utilities	• From conceptual design to a qualified facility • Facility Lay out and classifications • HVAC system (+ demo) • Pharmaceutical Water (+ demo)	☐ ☐ ☐ ☐

Research & Development		
GMP in Pharmaceutical Development	• GMP during Research & Development (+ workshop) • The life cycle of a pharmaceutical product • The development process of a pharmaceutical product • Risk assessment (+ workshop) • Identifying specifications (+ workshop) • Legislation • Test methods and test validation • Validation process (+ workshop) • Investigational Medicinal Product (IMP): production, testing, release and transportation	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Process Validation in Biopharmaceutical Production	• Basics of process validation and regulatory expectations • Validation step by step • Different types of process validation • Media simulations (+ workshop) • Validation documentation • Validation and risk assessment (+ workshop) • Control strategy • Performance monitoring, ongoing process verification • Clearance validation • Cleaning validation (+ workshop) • Validation of extractables and leachables	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
Technology Transfer	• Capabilities and culture of receiving company • Batch production records • Test procedures • Sampling plan (+ workshop) • Release specifications • Process implementation (CQAs and CPPs) • Change management • Transferring analytical method (+ workshop) • Transferring process from R&D to GMP (+ workshop) • External Tech Transfer	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Educational Games		
Games	• Pharma Mystery (QA) • Escape Room (Operations) • Escape Room (QC) • Lean Lab (Lean) • Pictionary (General GMP) • 30 seconds (General GMP)	☐ ☐ ☐ ☐ ☐ ☐

Notes

DISCLAIMER: This document is used to give you an idea of what we can do for you. If you would like to have a certain topic trained which is not mentioned on the list, please let us know so we can check if this is something what lies within our capabilities.