GMP BIOTECH SUMMER SCHOOL

Good Manufacturing Practice (GMP) Basic Course Biotechnology (English)

Course Program

Time:	Tuesday, 08 Oct 24 – Thursday, 17 Oct 24
Location:	Campus Berlin-Buch Gläsernes Labor, Building 13 Robert-Rössle-Str. 10 13125 Berlin-Buch Germany
Duration:	80 lessons, daily from 9:00 a.m. till 06.00 p.m. excl. Saturday 12 Oct 24 and Sunday, 13 Oct 24
Trainer:	Dr. Michael Buchholz, Internal Consultant CMC, Immutep GmbH

Course Contents:

Introduction
Welcome and introduction round
Training concept
Organizational information
History and Evolution of GMP

Regulatory
Regulatory Authorities
- EU (European Medicines Agency)
- US (Food and Drug Administration)
- Germany (Paul Ehrlich Institute, BfArM)

GMP guidance/ regulations
- Global (ICH, WHO)
- EU (EudraLex Volume 4 EU GMP Guide, EU regulations/ directives, European Pharmacopoeia)
- US (Code of Federal Regulations Title 21, United States Pharmacopoeia)
- Germany (AMG, AMWHV)

Quality Systems
Regulatory background/ requirements
Quality management systems
Quality manual
Quality Assurance / Quality Unit
Quality Risk Management
Deviation Management
Corrective and Preventive Actions (CAPAs)
Change Control
Product Quality Review
Management Review

Documentation
Regulatory background/ requirements
Documentation systems
Type of GMP documentation
Documents in production and quality control
Document Control
Data management / integrity
Electronic documentation and E-Signature
Archiving

Personnel
Regulatory background / requirements
Organizational Chart
Key personnel, qualification and responsibilities
Job descriptions
Training
Personnel Hygiene
Consultants

Premises
Regulatory background / requirements
HVAC systems
Zone concepts and classification
Isolator Technology
Clean Room monitoring
Personnel, material and waste flow
Airlocks (material, personnel)
Gowning
Room furnishing
Qualification
Cleaning
Maintenance and repair

Equipment
Regulatory background / requirements
Qualification
- User Requirement Specification
- Design Qualification
- Installation Qualification
- Operational Qualification
- Performance Qualification

Logbooks
Cleaning
Calibration
Maintenance and repair

Production: Basics
Regulatory background / requirements
Prevention of cross contamination
Change over procedures
Raw materials
Active pharmaceutical ingredients and excipients
Intermediates and bulk product
Packaging material
Final drug product
In process controls
Deviations
Logistics
Rejected and returned materials

Production Biologics: Up-stream
Regulatory background/ requirements
Products/ Market
Fermentation/ Cell Culture
Cell banks (Master Cell Bank/ Working Cell Bank)
Viral safety evaluation of Biotechnology products
Cell Culture Systems
Harvest
Testing

Production Biologics: Down-stream, Fill & Finish
Regulatory background/ requirements
Centrifugation
Filtration
Chromatography
Formulation
Filling
Labelling
Packaging
Storage and logistics
Testing

Production ATMPs: Up-stream, Down-stream, Fill & Finish
Regulatory background/ requirements
Overview ATMPs
Cell based Starting Material, procurement and logistics
Cell separation
Cell culture
Wash/ Purification
Formulation
Filling
Labelling
Packaging
Storage and logistics
Testing

Process Validation
Regulatory background/ requirements
Validation master plan
Validation plan
Validation report
Cleaning validation
Media fill
Validation of manufacturing processes
Viral clearance studies
Revalidation

Quality Control
Regulatory background/ requirements
Sampling
Reference and retention samples
Testing:
- Microbiological and toxicological safety tests (sterility, endotoxin)
- Identity and purity
- Content and biological activity
- Standards and references
Stability programs and statistics

Validation of Analytical Procedures
Regulatory background / requirements
Precision and accuracy
Detection limit / quantitation limit
Linearity,
Specificity, robustness
Compendial analytical procedure verification

Inspections and Audits
Regulatory requirements
Self inspections
Inspections by authorities
Supplier audits
Customer audits

Outsourced Activities
Regulatory background / requirements
Vendor Qualification
Contracts

Investigational Medicinal Products (IMPs), Clinical trials, License Application
Regulatory background / requirements
Specifics of manufacturing and quality control of IMPs
Stages of clinical trials
Application procedure
IMP dossier
Regulatory authorities and approval procedure
Common Technical Document
Hospital Exemption for ATMPs

Computerized Systems
Regulatory background/ requirements
Principles of validation

Job Opportunities
Regulatory Affairs
Quality Assurance
Premises/ Equipment
Production
Quality Control
Job Requirements

Final examination and course closure
Multiple choice test
Feedback
Wrap-up
Closure notes

The Trainer

Dr. Michael Buchholz studied biochemistry at the Free University in Berlin, Germany. After completion of his PhD at the University of Bath, UK, he started his career in ATMP manufacturing on the contract manufacturing organization (CMO) site at the Fraunhofer Institute for Immunology and Cell Therapy (IZI), Leipzig. 2012 he joined Prima BioMed with focus on ATMP manufacturing at CMOs in the US, Australia and Germany as well as manufacturing of a recombinant therapeutic protein at a CMO in China. In 2016, he joined Cell Medica as Site Head for Cell Medica's GMP manufacturing facility in Berlin, Germany, with focus on cell therapy manufacturing. In his role as Senior Director Manufacturing at T-knife, Berlin, Germany from 2019 Michael was responsible for development of T-knife's genetically engineered T-cell products including process development, selection of contract manufacturer, transfer of T-knifes manufacturing process to the contract manufacturer as well as regulatory filing required to start clinical development of T-knife´s TK-8001 TCR-T cell product in Europe.
In 2022 Michael joined Matterhorn Biosciences, Basel, Switzerland as Senior Vice President, in his role he was responsible for development and GMP compliant manufacturing of Matterhorn´s MR1 T cell products.
Since 2024 Michael is with Immutep GmbH focusing on the manufacturing of recombinant therapeutic proteins for Immutep`s late stage clinical development program.

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Subject to modifications
Dr. Uwe Lohmeier, Head of GLA Mgt.