Virtual cGMP Training Marathon for Vaccine Manufacturing

Questions & Answers

05 OCTOBER – 11 NOVEMBER 2021

World Health Organization

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ABBREVIATIONS

AEFI adverse events following immunization
AQL acceptable quality level
ALARP as low as reasonably practicable
APS aseptic process simulation
BI biological indicator
BMS building management system
BPR batch production record
BSC biosafety cabinet
BSL biosafety level
CAPA corrective action and preventive action
CCS contamination control strategy
CE computerized equipment
CEHT clean equipment hold time
cGMP current good manufacturing practice
CIS computerized information system
CIP clean-in-place
CMO contract manufacturing organization
CMC chemistry, manufacturing and control
CNC controlled not classified
COA certificate of analysis
CTD common technical document
CV cleaning validation
CpK process capability index
CPP critical process parameter
CMA critical material attribute
CQA critical quality attribute
CTD common technical dossiers
DEHT dirty equipment hold time
DI data integrity
DNA deoxyribonucleic acid
DQ design qualification
DS drug substance
ECTC extended controlled temperature condition
EBI electronic bottle inspector
ELISA enzyme-linked immunosorbent assay
EM environmental monitoring
EMS environmental monitoring system
EUA emergency use authorization
FAT factory acceptance test
FMEA failure modes effects analysis
GC gas chromatograph
GCP good clinical practice
GDocP good documentation practice
GEP good engineering practice
GMO genetically modified organism
GMP good manufacturing practice
GPT growth promotion test
HACCP hazard analysis and critical control point
HBEL health-based exposure limit
HEPA high-efficiency particulate air
HPLC high-performance liquid chromatography
HVAC heating, ventilation, and air conditioning
IQ installation qualification
IMP investigational medicinal product
IND investigational new drug
IPC in-process control
IQ installation qualification
JIT just-in-time
KNAPP Hartung-Knapp
LAF laminar air flow
LOEL lowest-observed-effect level
LIMS laboratory information management system
LNP lipid nanoparticle
MAH marketing authorization holder
MCB master cell bank
MKT mean kinetic temperature
MSC maximum safe carryover
mRNA messenger ribonucleic acid
NCL National Control Laboratory
NDA new drug application
NMRA National Medicines Regulatory Authority
NOAEL no-observed-adverse-effect level
NRA National Regulatory Authority
OP operational qualification
PIC/S Pharmaceutical Inspection Co-operation Scheme
QA quality assurance
QbD quality by design
QC quality control
QM quality manual
QSE quality, safety and efficacy
OOS out of specification
OOT out of trend
OPV oral poliomyelitis vaccine
OQ operational qualification
PDE permitted daily exposure
PHA preliminary hazard analysis
PLC programmable logic controller
PPM parts per million
PQ pre-qualification
PQMS Pharmaceutical Quality Management System
PQR product quality review
PUPSIT pre-use post sterilization integrity testing
QP qualification plan
QA quality assurance
QbD quality by design
QRM quality risk management
Ra surface roughness
RABS restricted access barrier system
RCA root cause analysis
RPN risk priority number
RRF risk ranking and filtering
SAR sterility assurance report
SAT site acceptance test
SME subject matter expert
SMF site master file
SOP standard operating procedure
SUS single-use system
TOC total organic carbon
TOR time-out-of-refrigeration
UNICEF United Nations Children's Fund
URS user requirement specification
UV ultraviolet
VLP virus-like particle
VMP validation master plan
VVM vaccine vial monitor
WCB working cell bank
WFI water for injection

INTRODUCTION

The World Health Organization (WHO) Local Production and Assistance (LPA) Unit in the Regulation and Prequalification Department, Access to Medicines and Health Products Division, supports Member States, particularly low- and middle-income countries (LMICs), to strengthen local production toward quality assurance and sustainability to improve access to essential health products.

In response to Member States' requests for capacity building in the local production of quality-assured vaccines, the LPA Unit organized the Virtual cGMP Training Marathon for Vaccine Manufacturing (5 October to 11 November 2021) for vaccine and biopharmaceutical manufacturers, regulators, and government officials from the six WHO regions. Over 800 participants from more than 60 Member States in the six regions attended each of the 12 sessions in the training marathon to improve their knowledge, understanding and capacity to comply with WHO/international cGMP standards and requirements.

This document collates the questions raised during the 12 sessions and the answers from the good manufacturing practice (GMP) experts who delivered the training as a continuous learning resource for participants and other relevant stakeholders.

SESSION

1

Vaccine lifecycle and technology platforms

5 October 2021