

# BASIC CONCEPT OF STERILE PRODUCTION, QUALITY ASSURANCE, TRAINING AND QUALIFICATION IN PHARMACEUTICAL INDUSTRIES



# STERILE PRODUCTION

- OPERATION OF STEAM STERILIZER
- OPERATION OF DRY HEAT STERILIZER
- OPERATION OF IN-SITU STEAM STERILIZER
- OPERATION OF PACKING MACHINE
- OPERATION OF TUNNEL
- OPERATION OF CONTAINER WASHING SYSTEM
- OPERATION OF VIAL FILLING MACHINE
- OPERATION OF WATER FOR INJECTION
- OPERATION OF STEAM STERILIZER

# STERILE PRODUCTION

- PROCEDURE FOR GENERATION OF WATER SYSTEM
- PROCEDURE FOR KSM ISSUANCE AND DISPATCH
- DISCUSSED TO STERILIZATION AND TYPES OF STERILIZATION
- DISCUSSED TO METHOD OF STERILIZATION
- ROLL OF HEPA FILTER IN STERILE AREA
- ASEPTIC PRACTICES IN STERILE AREA
- IMPORTANCE OF CGMP
- IMPORTANCE OF GDP

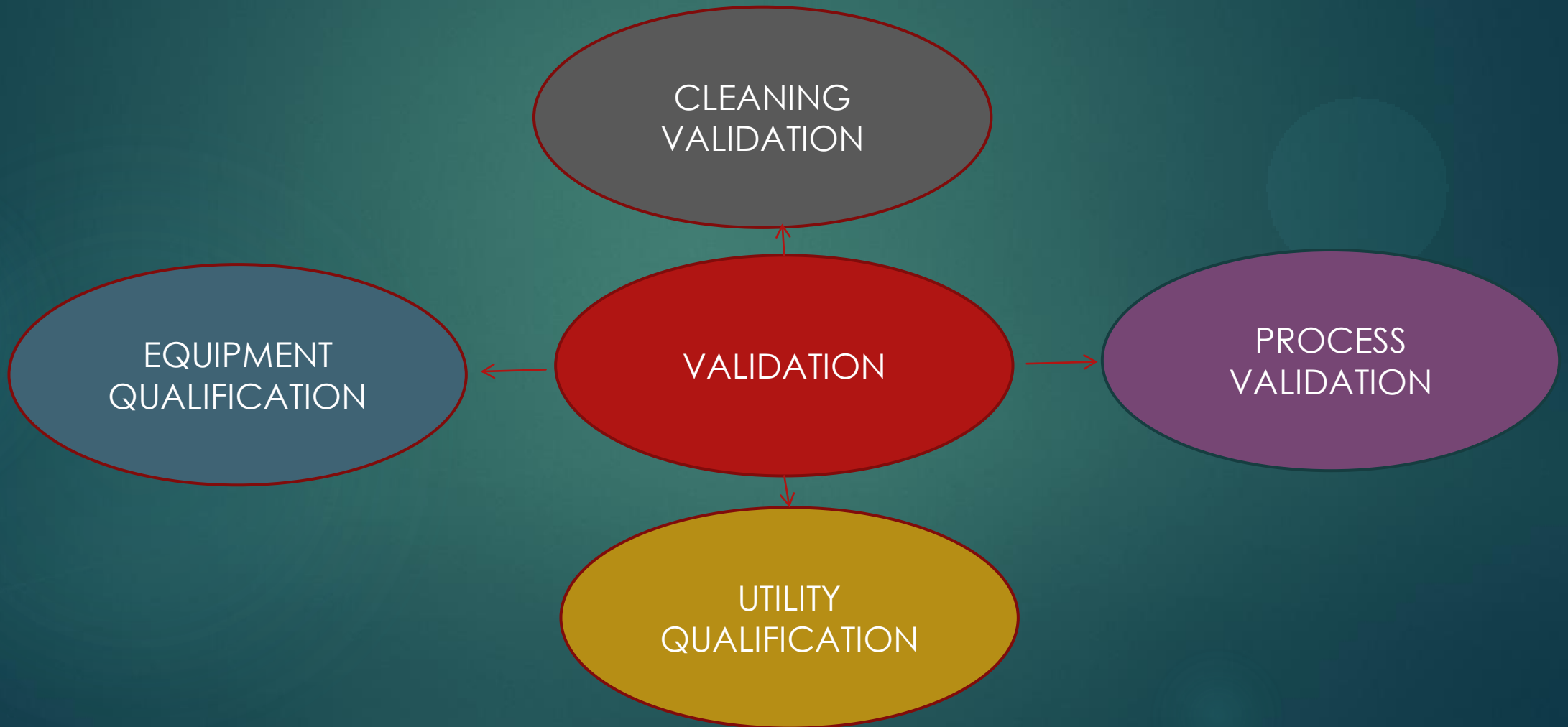
# QUALITY ASSURANCE

- PREPARATION AND APPROVAL OF PROTOCOLS, SOP & MASTER DOCUMENTS
- HOW TO REVIEW THE MASTER DOCUMENT I.E. BATCH PRODUCTION RECORD, BATCH CLEANING RECORD, EQUIPMENTS LOG BOOK.
- LINE CLEARANCE BEFORE BATCH PRODUCTION
- ROLL OF DOC CELL
- TYPES OF DOCUMENT I.E. PERPETUAL AND NON PERPETUAL
- DISCUSSED TO CHANGE CONTROL, DEVIATION, CAPA, MARKET COMPLAINT

# TRAINING

- OBJECTIVES OF TRAINING
- WHY NEED EDUCATED, TRAINED AND QUALIFIED PERSONNEL IN PHARMACEUTICAL INDUSTRIES.
- TYPES OF TRAINING
- METHOD OF TRAINING (BLENDED TYPE, WBT TYPE, ILT TYPE)
- WHAT IS THE COURSE HOW TO CREATED IT
- WHAT IS THE SESSION AND WHO IS CONDUCT THE SESSION
- DISCUSSED TO FUNCTIONAL TRAINING, CGMP TRAINING AND REMEDIAL TRAINING.

# QUALIFICATION



# CLEANING VALIDATION

- CLEANING VALIDATION SHALL BE PERFORMED MALTY PRODUCT FACILITY
- CLEANING VERIFICATION SHALL BE PERFORMED ONLY SINGLE PRODUCT FACILITY
- CAMPAIGN LENGTH VERIFICATION SHALL BE PERFORMED
- DIRTY EQUIPMENT HOLD TIME STUDY SHALL BE PERFORMED
- CLEANED EQUIPMENT HOLD TIME STUDY SHALL BE PERFORMED

# PROCESS VALIDATION

- DISCUSSED TO PROSPECTIVE VALIDATION
- DISCUSSED TO RETROSPECTIVE VALIDATION
- DISCUSSED TO CONCURRENT VALIDATION
- DISCUSSED TO REVALIDATION



# EQUIPMENT QUALIFICATION

- PREPARATION OF URS
- PREPARATION OF DESIGN QUALIFICATION
- FAT & SAT
- INSTALLATION QUALIFICATION
- OPERATIONAL QUALIFICATION
- PERFORMANCE QUALIFICATION

# UTILITY QUALIFICATION

- COMPRESSED AIR QUALIFICATION
- AHU QUALIFICATION
- TEMPERATURE MAPPING QUALIFICATION
- FACILITY QUALIFICATION



THANKS