

PDA EU00192  
Manage your Aseptic Filling Line  
Training Course

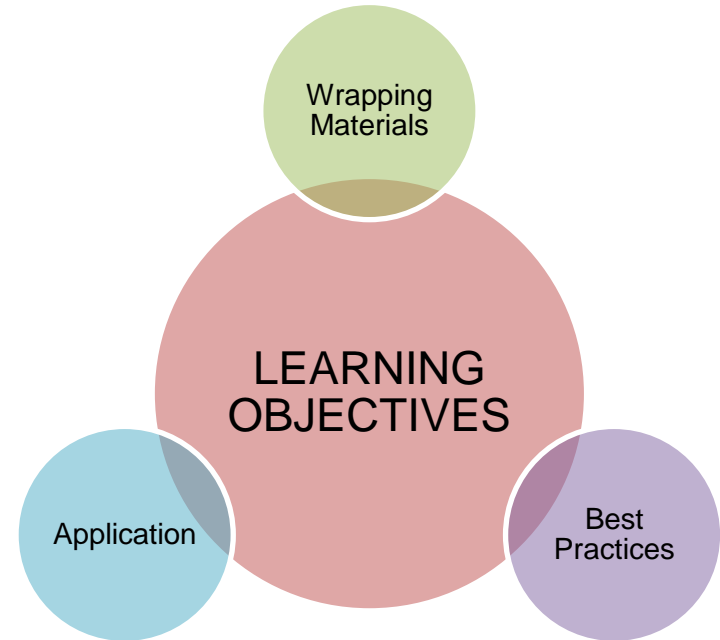
Component Preparation for  
*Sterilization*

*Bram Van Puymbroeck*



# TOPICS COVERED

- **Steam Sterilization**
- **Wrapping Materials**
- **Laboratory Session**
- **Wrapping Materials Continued**
- **Application**
- **Qualification and Validation**



# COMPONENT PREPARATION AND WRAPPING

*Wrapping Options for Preparation of  
Items for Sterilization*

# STERILIZATION METHODS

- **Gas**
  - Ethylene Oxide (EtO)
  - Chlorine Dioxide
- **Radiation**
  - Gamma
  - E-Beam
  - X-Ray
- **Cold Sterilants**
- **Dry Heat**
- **Filtration**
- **Steam (Moist Heat)**

Reference USP <1229>  
for additional information  
about these sterilization  
methods.

# HOSPITAL vs. PHARMA/BIOTECH

## HOSPITAL

- Small Autoclaves
- Short, prescribed cycles by the manufacturer
- Sterilization at “Point of Use”
- Not Validated

## PHARMA/BIOTECH

- Large Autoclaves
- Controlled Process
- Other Sterilization Methods
- Validated Cycles

## STEAM STERILIZATION

### Equipment

- Autoclave
  - Sanitary design
  - Clean utilities
  - Steam quality
  - Leak free design

### Objective

- Kill spore-forming microorganisms
  - *Geobacillus stearothermophilus*

### Parameters

- 121°C for 15 minutes (minimum)
  - Time
  - Temperature
  - Pressure

Vacuum » Steam & Pressure » Equilibrium

# STERILIZATION WRAPPING

## HISTORY

- **Originally Developed for Hospitals**
- **First Accepted Material**
  - 140 Thread-Count Muslin
- **1960's**
  - Cellulose-based Non-wovens (Blue Wrap)
- **1970's**
  - Polypropylene-based Non-wovens (SMS)
- **1980's through Current**
  - Paper/Film Pouches
  - Tyvek®
  - Tyvek/Film Pouches
    - Heat Seal
    - Self Seal

# WRAPPING MATERIALS – Types/Forms

- **Paper**
  - Wrappers
  - Pouch/Tubing (Polyethylene Film)
- **Cellulose-based Non-wovens (Blue Wrap)**
  - Wrappers
  - Covers
- **Tyvek®**
  - Wrappers
  - Pouches/Tubing (Polyethylene film, HDPE film)
  - Bags/Tubing
  - Covers
- **Others**
  - SMS (Non-woven polypropylene)
  - Sterilizable Poly (Film) Bags
  - Paper Bags
  - Foil





# STEAM STERILIZATION



## Why Wrap?



- **Protect parts after cleaning and prep – prior to sterilization**
- **Maintain sterility prior to use in aseptic area**
- **Facilitate aseptic technique during set-up and use of components**

# STEAM STERILIZATION

## What Makes a Material Suitable for Sterilization Wrapping?

- ***PENETRATION OF STEAM*** - Facilitates Sterilization
- ***TRANSMISSION OF MOISTURE*** - Permits Drying
- ***MICROBIAL BARRIER*** - Allows Storage

# WRAPPING MATERIALS - Characteristics

- **Penetrability (Steam)**
- **Aeration (Moisture)**
- **Barrier Effectiveness**
- **Cleanliness (Particulate)**
- **Temperature Tolerance**
- **Ease of Use**
  - Drapability
  - Flexibility
  - Puncture Resistance
  - Tear Strength
  - Transparency
  - Method of Closure
  - Strength of Closure
- **Post Sterilization Exposure – Disinfectants, Decontamination Methods**



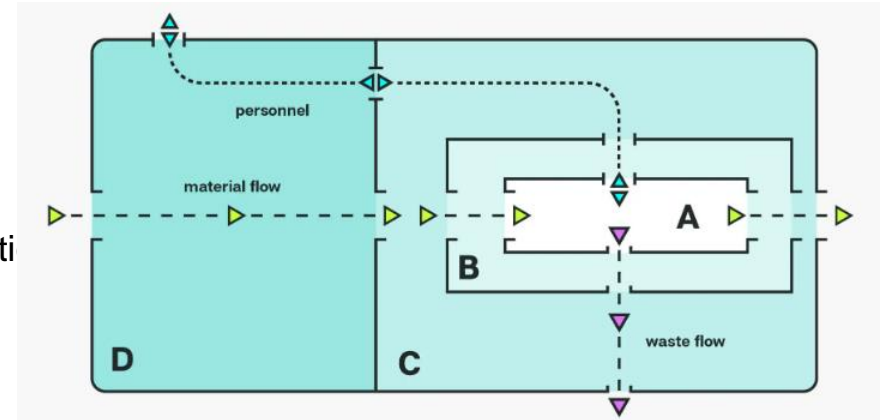


## LABORATORY SESSION

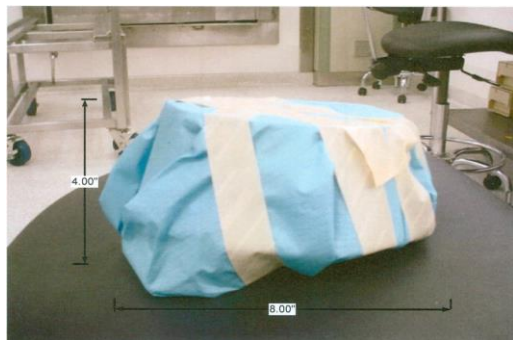
# FULL PROCESS DESIGN

## Considerations:

- **PARTS** – Component Sizes/Shapes
- **PROCESS** – Logistics/Environment/Flow
- **QUALITY ASSURANCE** – Qualification/Validati



# STOPPER BOWLS



# REPRODUCIBILITY

## STOPPER BOWL COVERS

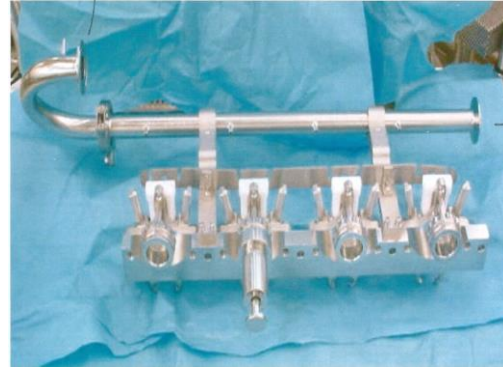


# LARGE STOPPER HOPPER AND SCROLLS

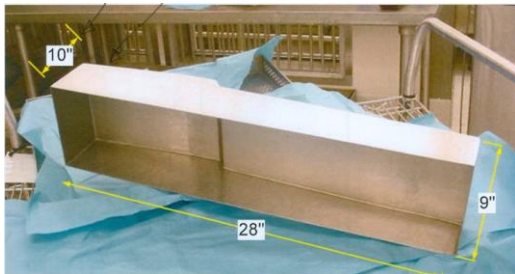




# FILTER HOUSINGS AND SANITARY FITTINGS



# VERY LARGE COMPONENTS



# SMALL COMPONENTS



# POST STERILIZATION- RABS/ISOLATORS

EU  
Annex 1

5.5 For aseptic processes, direct and indirect product contact parts should be sterilised. Direct product contact parts are those that the product passes through, such as filling needles or pumps. Indirect product contact parts are equipment parts that do not contact the product, but may come into contact with other sterilised surfaces, the sterility of which is critical to the overall product sterility (e.g. sterilised items such as stopper bowls and guides, and sterilised components).



# QUALIFICATION AND VALIDATION

- **Minimize Material Types/Forms**
  - Take Holistic Approach
  - Do not “Piecemeal” It
- **Procurement of Samples**
- **Change Documentation**
  - Change Control
- **Qualification of Supplier**
  - Manufacturer vs. Supplier
  - Ability to Audit Facility
  - Cleanliness of Manufacturing Environment
  - Robustness of Supply Chain
- **Equipment Load Validation**
  - Wrapping Material and Method
  - Orientation and Location within the autoclave
  - Maximum number of items



# SUMMARY

When addressing sterilization wrapping needs...

## CONSIDER:

- Types and Forms of Wrapping Materials
- All Component Shapes and Sizes
- Logistics/Environment/Flow of your Process
- Qualification/Validation Requirements

***TAKE A HOLISTIC APPROACH***

# Thank you for your attention



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