Introduction to Aseptic Processing

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Background Information

- Name
- Department
- Years in the Industry
- Micro Experience/Classes
- Aseptic Gown Qualified
- Media Fill Qualified
- Specific Areas of Interest
- Expectation

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- How clean or dirty are common items you use/eat every day? Which has the most bacteria?
  - Sandwich
  - Floor
  - Fingers
  - Phone
  - Money
  - Door Handle to refrigerator

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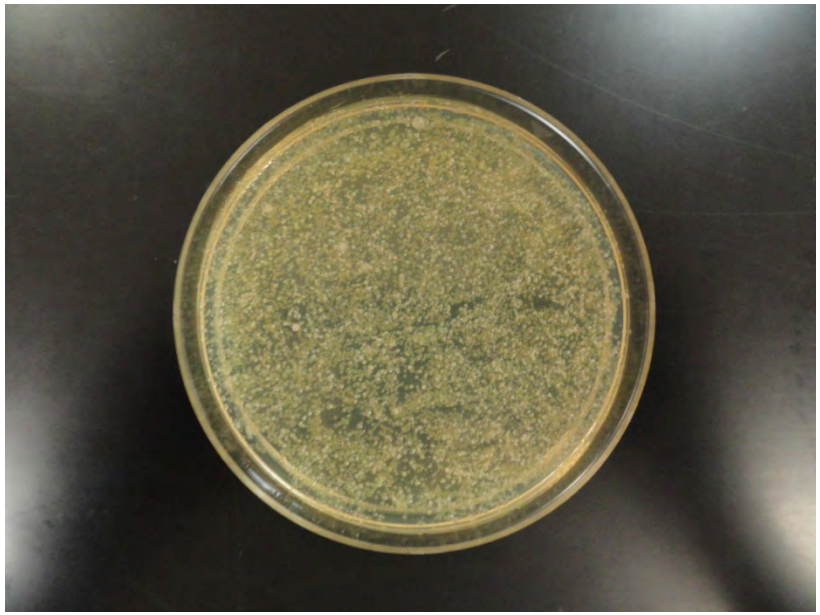
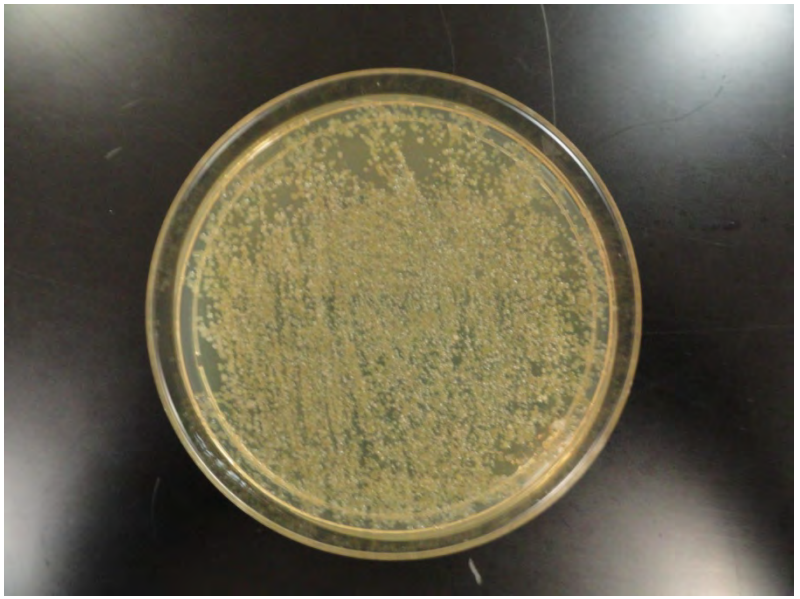
Chicken Sandwich



Lettuce



Sprouts

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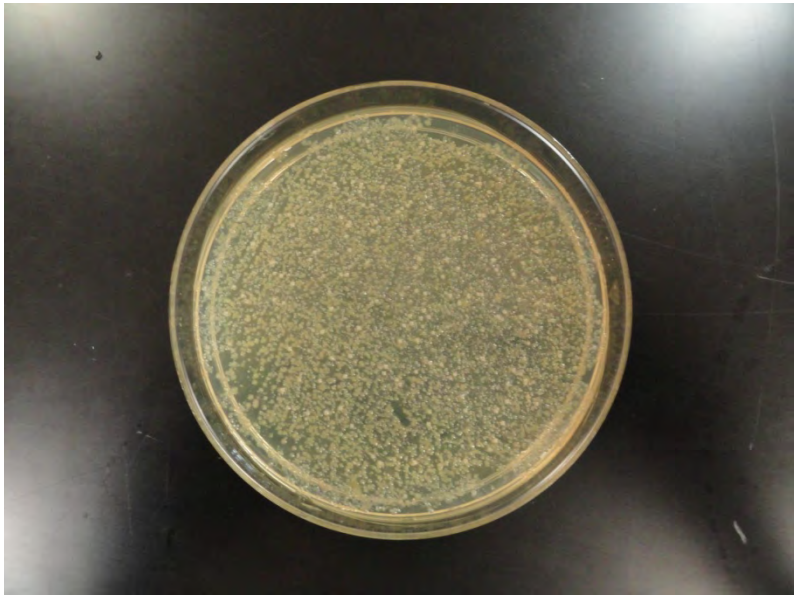
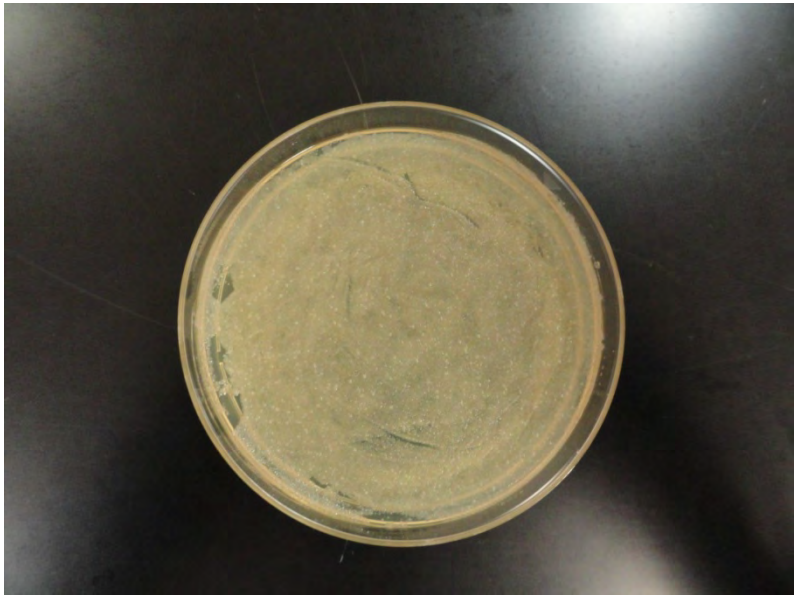
Chicken Sandwich





Tomato

Chicken

Introduction to Aseptic Processing

- **Aseptic**
  - The absence of microorganisms capable of causing infection or contamination.
- **Aseptic processing**
  - The method of manufacturing to produce sterile products that are not subjected to terminal sterilization

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- **Sterile**
  - The absence of living organisms

- **Sterility Assurance Level (SAL)**
  - The probability that a filled unit, after sterilization, might contain a viable organism that survived the sterilization process.

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- **Sterility Assurance Level (SAL)**
  - For Terminally sterilized units, the probability is 10^{-6} or 1 in 1,000,000
  - For Aseptic Processed units, the probability is 10^{-3} or 1 in 1,000 in the 1980's
  - With advances in technologies and a better understanding of the process and risk, the contamination rate is quickly approaching 10^{-6} for aseptic processing

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- **Objective of Aseptic Processing**
  - To assemble previously sterilized commodities and products, in a highly controlled environment, to produce a sterile unit
  - Examples of these environments are
    - Grade - A
    - ISO - 5
    - Class - 100

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- **Aseptic Processing Environments**
  - Bio-Safety Cabinets
  - Laminar Flow Hoods
  - Traditional Clean rooms
  - Clean Rooms with Curtains or Barriers
  - Restricted Access Barrier Systems
  - Hard or Soft Wall Isolators

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- **Process Components**
  - Basic Knowledge of Microbiology
  - Cleaning & Sanitization
  - Disinfectant Efficacy
  - Contamination Control
  - CIP/SIP of Tanks and Piping
  - Environmental Monitoring, Validation & Routine
  - Aseptic Gowning Methods & Techniques
  - Personnel Monitoring Programs

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- **Process Components**
  - Room Air Exchanges
  - Airflow Studies/Smoke Studies
  - Aseptic Techniques
  - Contamination Control
  - Facility Design & Process Flow
  - Heating, Ventilation and Air Condition (HVAC)
  - HEPA Filter Grid Pattern and Testing

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- **Process Components**
  - Fill Room Validation, IQ, OQ & PQ
  - Defining Autoclave Requirements & Validation
  - Operator Proficiency Qualification
  - Sterilization Methods and Validation
  - Lyophilization Process & Validation
  - Media Fills/Aseptic Simulation
  - Sterility Testing

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- **Process Components**
  - Understanding and Confidence in the Process
  - Change Control Systems & Requirements
  - Trending
  - Risk in the Aseptic Processing
  - New Technologies
  - Global Regulatory Requirements

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- **Develop an Understanding of the following**
  - **What** is pharmaceutical processing from a microbial standpoint
  - **How** does each unit operation work and fit into the over aseptic scheme
  - **Why** is each system important to the process

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- **Contamination Control**
  - Identify the weaknesses in the process
  - Modify the process or procedure to compensate for the weakness
  - Validate the process
  - Ensure all personnel understand the process and how it impacts process operations

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- **Contamination Control**
  - Develop strong unit operations of the process
  - Develop user friendly SOP's to eliminate errors process confusions
  - Provide useful and meaningful training
  - Develop a pro-active and not re-active approach to pharmaceutical issues

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- **What are these and how/why is it associated with processing**

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- **Rope Model**
  - Each fiber is intertwined to make a thread
  - The threads are woven together to make a line
  - Lines are put together to form a cord
  - The cords are intertwined to make a Rope
  - Each individual fiber, thread, and cord are put together to make a strong unit
  - The more fibers, threads and/or cords that break, the higher the risk of the rope failing

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- **Rope Model**
  - Each Unit operation of pharmaceutical microbiology is like a strand of a rope
  - Identify the basic strands of the ROPE
  - Understand the HOW each strand functions
  - Learn WHY each strand is important
  - The more unit operations that have issues or fail, the higher risk to the product

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- **The Biggest Issue Associated with Aseptic Processing**
  - Lack of understanding of the overall process
  - Companies have experts in the individual departments
  - Most companies do not have an expert that understands how the pieces of the puzzle fit into the overall matrix of pharmaceutical processing

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Let the Fun Begin !