

Sterility Assurance & Quality Risk Management Conference





**Sterility Assurance & Quality Risk
Management Conference**

**October
8th & 9th**



Training for Competence and Not Just a Checkbox



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Oh, hey!

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- Sr. Technical Services Specialist



- From Columbus, Ohio
- Mom of 2
- Fur mom of 4
- Teacher's wife





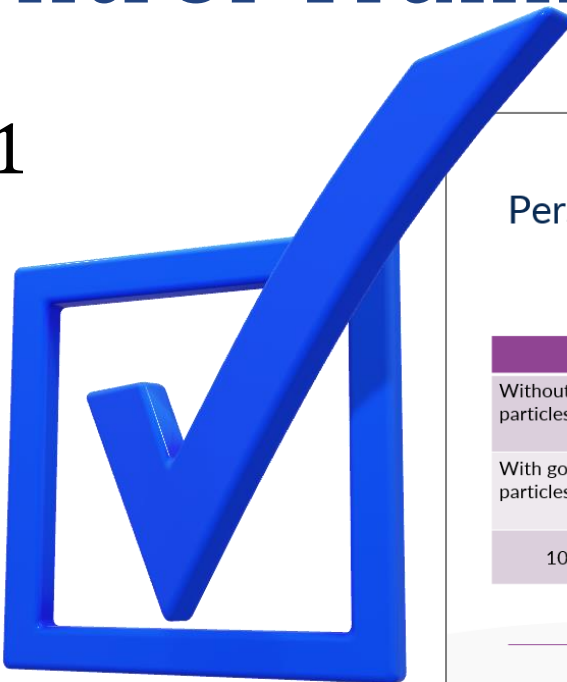
Contamination Control Training

“This training should include the basic elements of microbiology and hygiene, with a specific focus on cleanroom practices, contamination control, aseptic techniques and the protection of sterile products (for those operators entering the grade B cleanrooms and/or intervening into grade A) and the potential safety implications to the patient if the product is not sterile.”

Annex 1: Manufacture of Sterile Medicinal Products, Aug 2022



Contamination Control Training



- Contamination Control 101
 - What is contamination?
 - What are the impacts of contamination?
 - Intro to microbiology
 - Sources of contamination
 - Controlling contamination
 - Personnel behavior and hygiene

Personnel Behavior

Existing	Moving	Operating
Without gowning: 10 million particles shed per minute	Walking 2 feet/second generates 5 million particles per minute	Glove surfaces can become recontaminated within minutes
With gowning: 100,000 particles shed per minute	Moving 7 feet/second generates 10 million particles per minute	Human error and poor aseptic technique are the top root causes of microbial contamination in sterile manufacturing
10% of particles shed carry viable microorganisms		ALL personnel in the cleanroom introduce contamination risk



Contamination Control Training



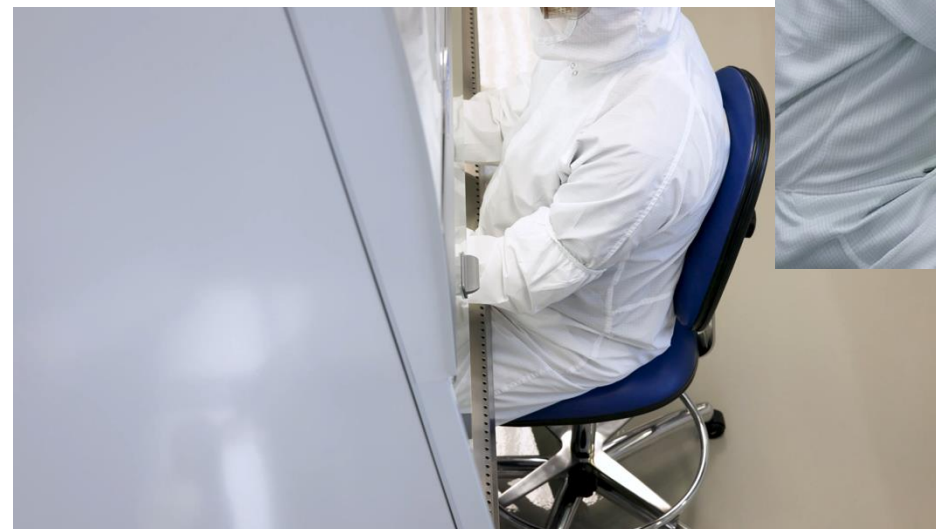
2.1 Operators will exhibit good aseptic behaviors

2.1.1 Operators will walk using slow, deliberate movements to avoid excess particle shedding

2.1.2 Operators will not hold open doors

2.1.3 Operators assisting Grade A activities will avoid direct intervention into the Grade A area

2.1.4 Operators will not rest their hands on critical surfaces





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Training

Training

- Acquisition of skills and behaviors
- Prepares individual to execute a specific task
- Short-term focus for immediate objectives



Training vs. Teaching

Training

- Acquisition of skills and behaviors
- Prepares individual to execute a specific task
- Short-term focus for immediate objectives

Teaching

- Imparting knowledge, concepts, and theories
- Fosters critical thinking
- Long-term focus for holistic development of learner



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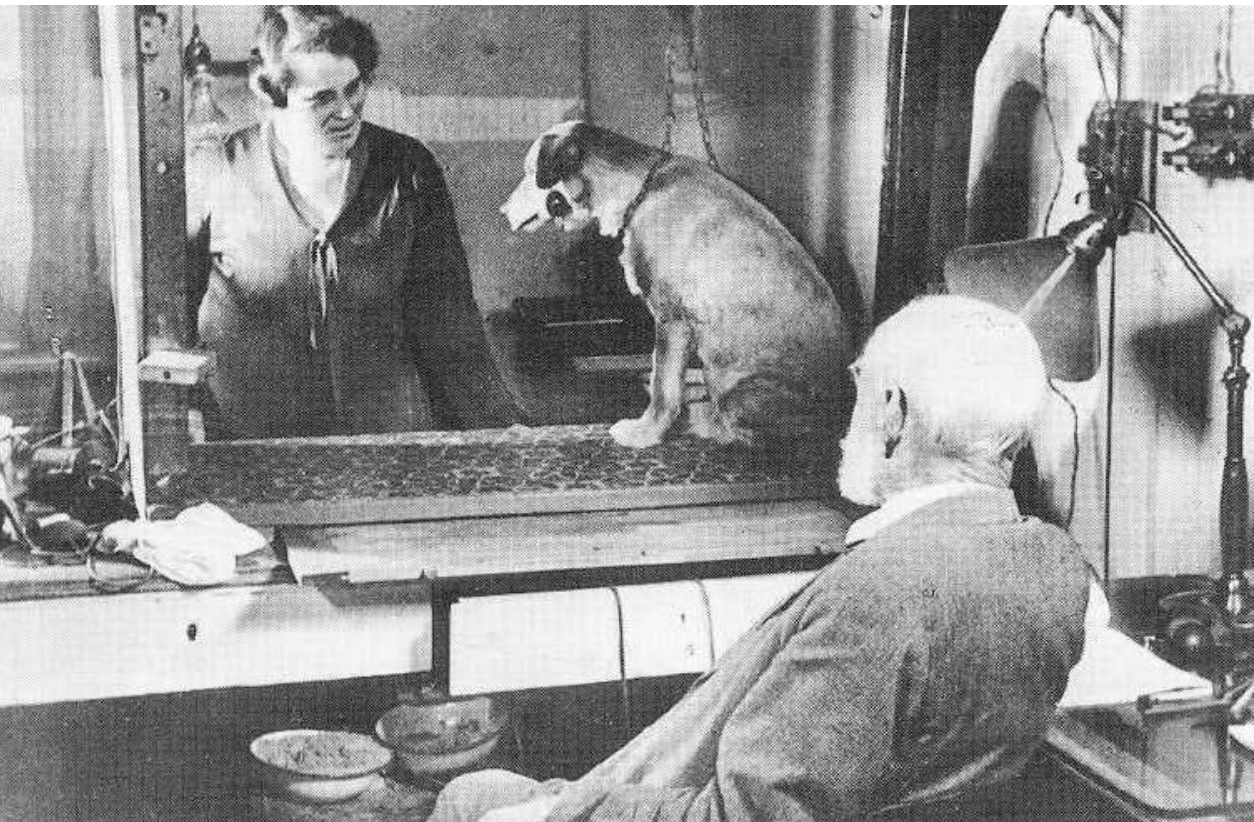
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Adult Learning Theories



Behaviorism



- Learner is conditioned based on stimuli/experiences
 - Include repetition to build mastery
 - Provide rewards/recognition and feedback



Putting it into Practice: Behaviorism



- Repetition of tasks: observation of activities or skills that require precision
- Feedback: provide immediate feedback and recognition for proper execution

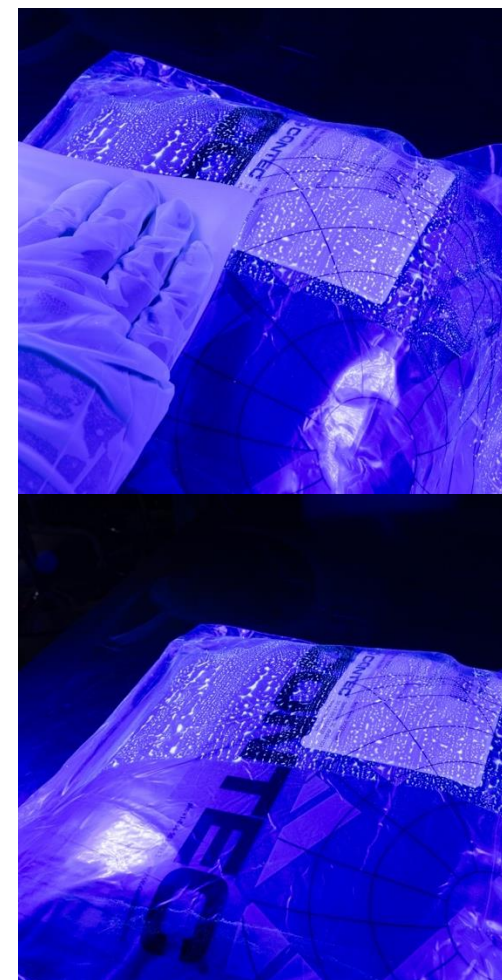


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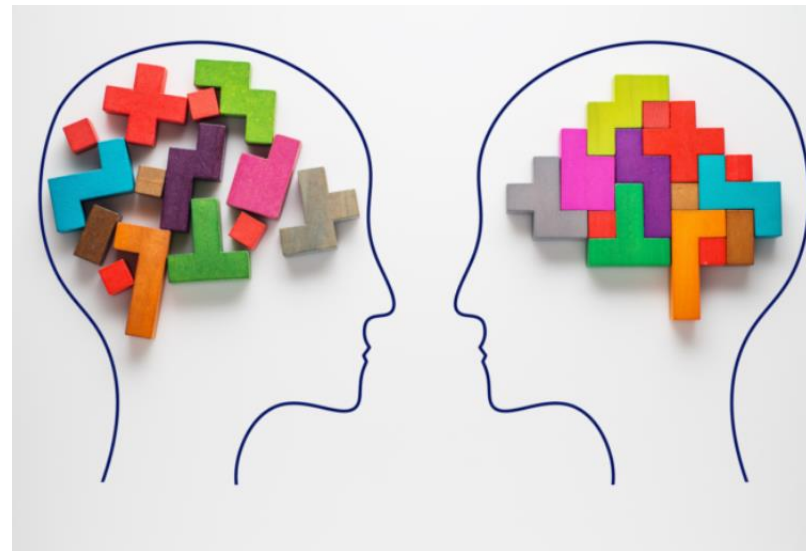
Putting it into Practice: Behaviorism





Cognitivism

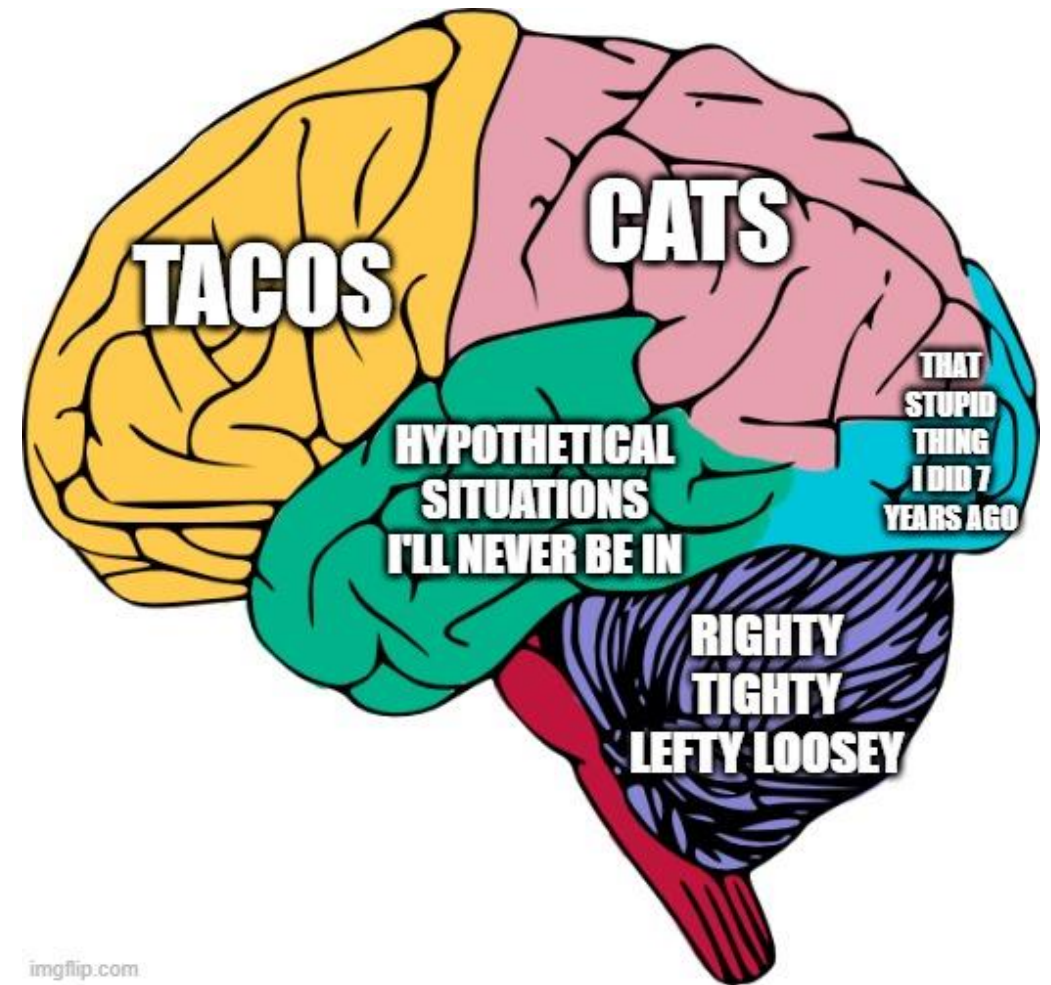
- Theory places emphasis on what occurs in the learner's brain rather than observable behaviors
- Mental processes involved in learning such memory, problem-solving, thinking





Cognitivism

- Cognitive load
 - The brain can only handle a limited load of information at a time
 - Intrinsic Cognitive Load: complexity of the material
 - Extraneous Cognitive Load: the way that information is presented to learners (poor design choices can contribute)





Putting it into Practice: Cognitivism

- Organize content logically and break it into manageable portions
 - Consider creating a syllabus
- Use mnemonics or visuals to aide learners in retention and retrieval

Disinfection TIME

T Top to Bottom 

I In One Direction (Unidirectional) 

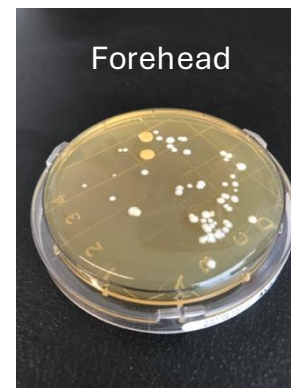
M Make Strokes Overlap 

E Ensure Contact Time 



Putting it into Practice: Cognitivism

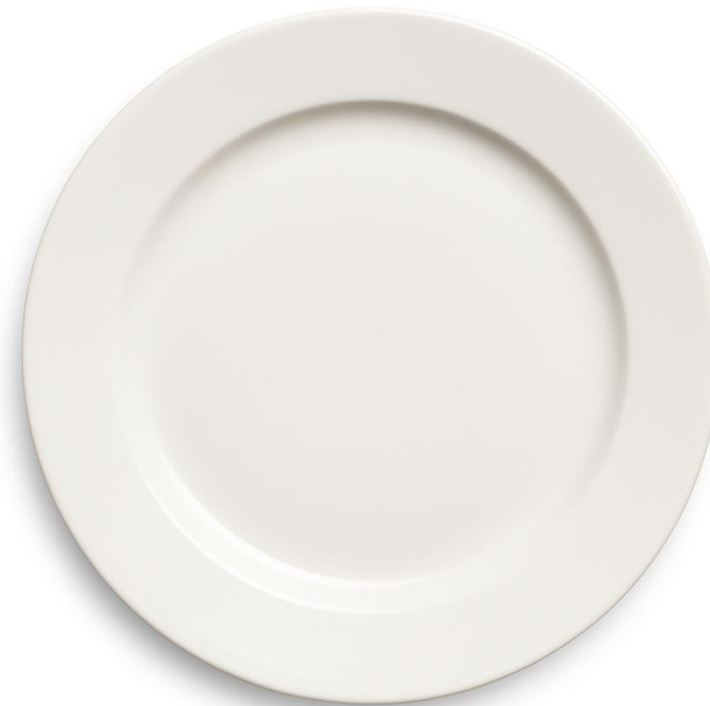
- Connect new information with prior knowledge





Putting it into Practice: Cognitivism

- Connect new information with prior knowledge





Constructivism

- Learners construct their understanding and knowledge based on real-life experiences or simulations and active engagement
 - Previous experiences will be used to interpret new knowledge – learner constructs their own knowledge
 - Learners use newly acquired knowledge to rebuild schemas



Putting it into Practice: Constructivism

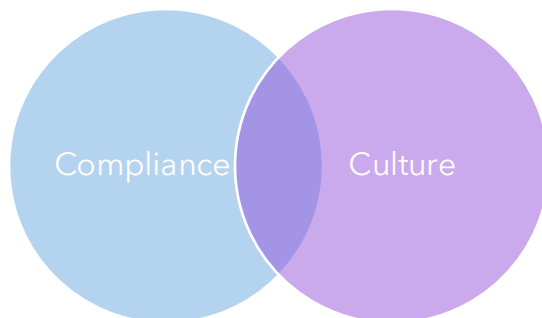


- Create opportunities for operators to problem-solve
 - Case-studies / investigations
- Experimentation w/ guided support
 - Provide scenario-based activities to reflect real-world challenges
 - Allow collaboration and sharing through discussion



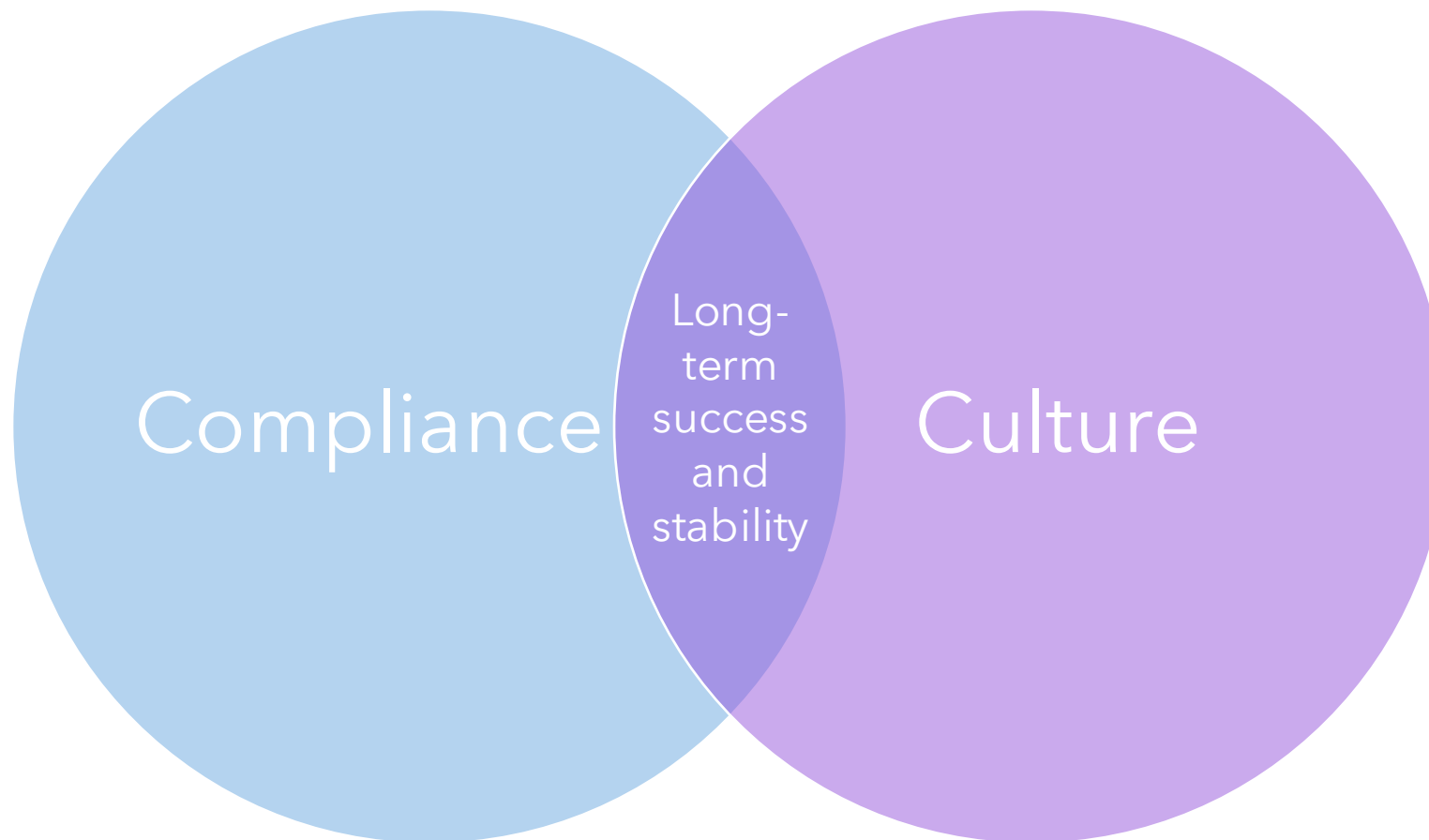
Contamination Control Culture

- Compliance: The Framework
 - Control
 - Following the rules, regulations, policies, procedures etc.
- Culture: The Motivation and Commitment
 - Values and beliefs
 - Guiding behavior and decision-making, even in the absence of strict rules





Contamination Control Culture





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Thank you!



SCAN ME

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