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THIS PRESENTATION  
IS AVAILABLE BY EMAILING  
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# The Cleanroom Mindset

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Protecting Your GMP Facility Environment Seminar  
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# What is a mindset?

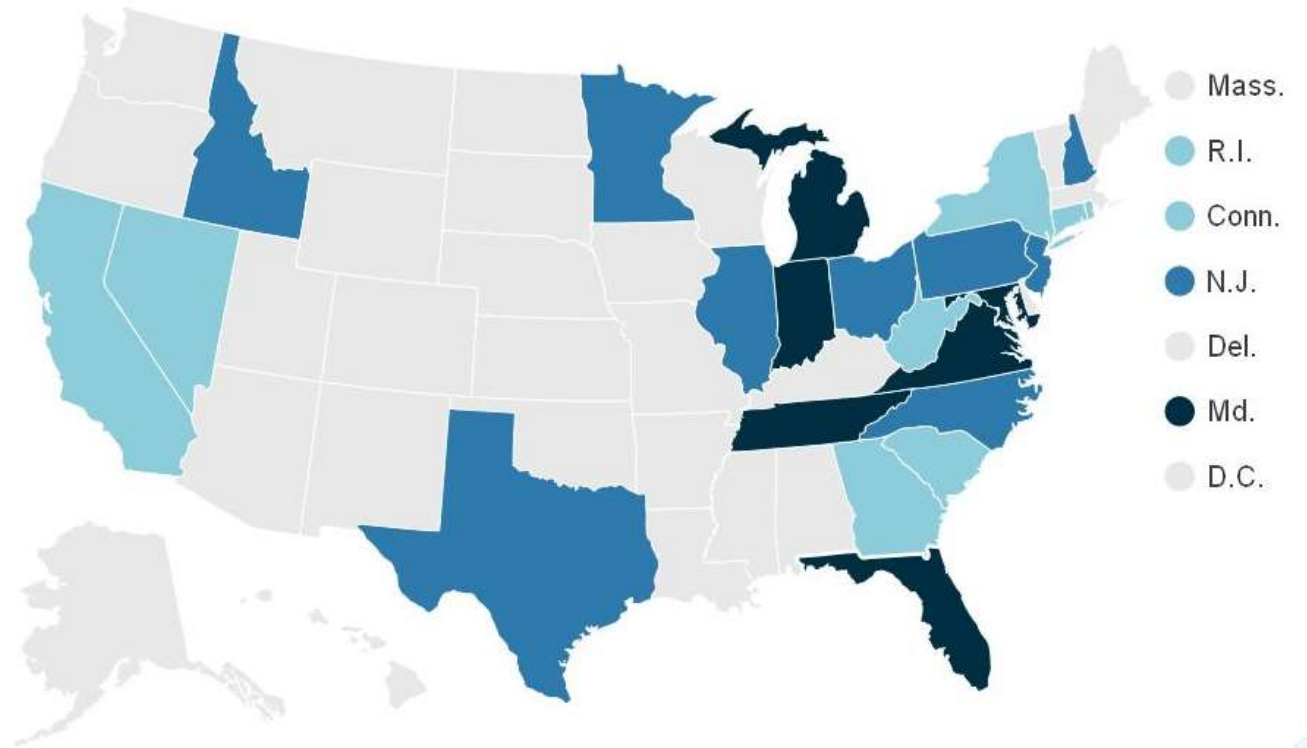


A set of assumptions and methods that is so **established** that it creates a **powerful incentive** for a person to **adopt** or **accept** behaviours, choices, or tools.

# New England Compounding Chemist (NECC)



● No outbreaks reported ● Sickened ● Deaths



**Fungal meningitis outbreak in 2012 linked to steroid injections resulted in 753 cases across 20 states with 64 people dead.**

# Who cleans your cleanroom?



**Production staff**

**In-house cleaners**

**Contract cleaners**

# Gauging your cleaners' cleanroom mindset



- ✓ What equipment do they use?
- ✓ Are they trained in its correct usage?
- ✓ Who keeps up with equipment innovations?
- ✓ If it is not a consumable, where is the item stored?
- ✓ How are items introduced into your cleanroom?
- ✓ Are the chemicals being used actually the ones specified in your SOP?
- ✓ Whose job description includes checking expiry dates?
- ✓ Do your cleaners provide exception reports?

# Gauging your cleaners' cleanroom mindset



- ✓ How are vacations and sick leave handled?
- ✓ What happens when cleanroom cleaners turn up sick for work?
- ✓ Is there a team with back-ups ready to come in on short notice?
- ✓ How often is training held?
- ✓ How often is the cleaning SOP reviewed?
- ✓ Do you use your training records to identify gaps in knowledge?
- ✓ Do you also apply a cleanroom mindset to your documentation and reporting?

# Documentation and reporting



# Improving the cleanroom mindset



**Knowledge**

**Communication**

**Recognition**

**Competition**



# BACS

CONTAMINATION CONTROL



## The Cleanroom Mindset

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