Development of Efficacious Cleaning and Disinfecting Products in Healthcare Settings

Drug Development Considerations for the Prevention of HealthCare-Associated Infections FDA and CDC Virtual Public Workshop August 30, 2022

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Innovative Products For Home. Work. Life.

Difference Between Disinfectants, Sanitizers, Sterilants, and Cleaning Products

Disinfectant

- Kills Bacteria, Viruses and Fungi on Surfaces
- Regulated by EPA under FIFRA

Sanitizer

- Kills 99.9% Bacteria on Surfaces
- Regulated by EPA under FIFRA

Sterilants

- Eliminates All Microorganisms on Surfaces
- Regulated by FDA when used on critical or semi-critical devices
- Regulated by EPA for all other applications

Cleaners

- Removes Dirt, Grime, and Other Organic Matter from Surfaces
- Does NOT Claim to Kill Bacteria or Viruses
- Regulated by CPSC or OSHA Depending on End-User

Product Performance



Testing is very dependent on the claims and the surface type to be treated which results in determining who has overall jurisdiction.

Disinfectants, Sanitizers and Sterilants

- For EPA Registered Products Series 810, Product Performance Test Guidelines https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-810product-performance-test-guidelines
- FDA Guidance for Medical Device Sterilants https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-and-format-premarket-notification-510k-submissions-liquid-chemical-sterilantshigh-level

Cleaning Products

- Don't Have Similar Agency Guidelines
- Various Industry Standards
 - HCPA's Cleaning Methods & Guidance can be Found https://www.thehcpa.org/resources/#1517763764230-684f8504-0955

How to Select the Appropriate Product?



- In ALL Cases, Read and Follow Label Directions
- Questions to ask
 - What am I Trying to Accomplish / Intent?
 - Do You Need to Disinfect/Sanitize or is Cleaning Sufficient?
 - On What Type of Surface(s)?
 - If to Disinfect or Sanitize, are there Particular Bacteria or Viruses for Which You Want to Kill? If Yes, Confirm it is Listed on the Label.

Thank You



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