CONTAMINATION CONTROL CASE STUDIES

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Presentation Overview

- Mold Contamination/Spores/Propagules
- Mold Growth Factors
- Traditional/Other Methods of Control
- New Method
- Case Studies – Mold Prevention
- Case Studies – Bacteria Prevention
- Why Choose Something New?
- Ozone and how it works
- Ozonated Water

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MOLD CONTAMINATION

- It is now appreciated that mold is a very serious contaminant and should be eliminated as soon as possible.

- Mold traditionally is viewed as an allergen and rarely as a pathogen, but the mycotoxins released by mold pose a threat to pharmaceutical products, patients and therefore pharmaceutical operations.
Mold Spore

Death Star
The Number One Problem Is Mold Spores(or is it?)

Spores Are Everywhere:

- Ceilings, above ceilings
- On your clothes
- In your hair
- In the air
- Walls, behind walls
- In anything brought into the room
- Any crack or fissure
Mold Growth

- Septum
- Hyphae
- Apical growth
Fungal Propagules

- Discovered that fungal fragments are aerosolized simultaneously with spores from contaminated agar and ceiling tile surfaces

  - Concentration measurements with an optical particle counter showed that the fragments are released in higher numbers (up to 320 times) than the spores
Mold GROWTH FACTORS

- Most importantly a source of moisture and proper nutrients
- Temperature
- Proper nutrients
- Light/Dark
Challenges to Mold Control

- **Moisture** - accumulates on lower floors, cracks in building, high outside humidity, human bodies, wet clothes underneath gowns
- **Temperature** – can only make it so cold
- **Nutrients** – wall board, paint, organic cleaning materials, pollen, plastic
- **Light / Dark**
Traditional ways to control mold contamination:

- Control of the environmental conditions to prevent mold contamination and growth (clean rooms, filters, humidity control)

- Application of physical method (mechanical, thermal, and electrical fields) to remove mold cells and spores

- Application of antimicrobial products (chemical warfare)
ENVIRONMENTAL CONTROL

- Mold will grow in water saturated air (100% relative humidity (RH) without any additional moisture)

- At a RH of 97% and below, surface wetting is necessary for the growth

- Between a RH of 64% to 97% variations in the type of the surface material have not affected mold growth responses

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### Chemical agents include:

- Phenol and perchlorate based
- Perchlorates based
- Quaternary ammonium compounds ("Quats") based
- Phenol and "Quat" based
- Peroxide and phenol based
Problems with Antimicrobial Products

- They do not prevent mold
- The oxidizers oxidize themselves
- Oxidizers damage equipment
Advantages of Alternatives

MOLDGuardian

- Eliminates mold
- Prevents mold for one year
- All natural, biodegradable
- Harmless to stainless steel
Case Study - Mold- #1 Arizona

- Large Pharmaceutical - Injectables
- 4 Stability Chambers
- 20’ x 15’ x 10’

Large Air Duct Above
Massive Accumulation of Water
Collapsed Over Weekend
Case Study Mold- #1 Arizona

- Flood in Chamber 115° F
- Open Door Monday- Observe water and mold
- Design a Plan to Clean
- Use VHP, Chlorine Dioxide, Quats
- One Year- Mold Hits
- May 12, 2014
- Spray Filter Housing, Vent
- Entire Room, Shelves, Into Holes

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Why Use Something New?

- Nothing Else Worked
- Chemical Warfare
- Tried Every Known Weapon
Case Study Mold- #1 Arizona

- Today (May 18, 2016) no Mold Hits
- WHY? Used a different kind of product.
- Nutrient- Trojan Horse applied
- Eliminates Live Mold and Mold Spores For One Year.
- Harmless to stainless, humans etc.

No hits as of May 2015 when reapplied
How Does It Work?

- Nutrient- Studied for 6 Years
- All Mold/Fungi Have Same Method of Absorption of Nutrients
- Mixed Similar, but Different Ingredients
- Trojan Horse
Case Study Mold #2

- Pharmaceutical Facility - Purchased Building with Leaking Roof
- Toward end of construction - sprinkler head failure. Water was everywhere.
- Very concerned about Mold, more leaks
- Used same product - inside wall spaces, on bare sheetrock, floors and everywhere in area.
Case Study Mold #2

- Over One Year - no mold detected
- Now used in 6 facilities for PREVENTION
- Includes facilities in Puerto Rico and Singapore
Case Study Mold- #3

- Walk-In Refrigerators

- Mold on Door Seal and Fan Housing

- One Application- No return of mold as of six months

- Must Reapply After Cleaning with strong oxidizers
Case Study Mold # 4

- Pharmaceutical Company
- Huge Drive in Cold Rooms
- 200’ x 50’ x 20’
- 4 Large Refrigerator Units
- 3 blower fans each
Case Study Bacteria # 1

- Large Pharmaceutical Company
- Manufacture Animal Supplements
- Non Sterile Facility

- Large Vats- Pour in Protein Powder
- Dust Everywhere- High Likelihood of Bacteria Present
- Mix API With Other Powders in the same area
Case Study Bacteria # 1

- Add Water, Mix with Auger
- End of Run

- Spray walls, vats, equipment with chemicals
- Long process, dwell times, rinse
- Corrosion, residue
- Bacteria detected
What is Ozone?

Forms in stratosphere – ultra violet and electrical action
Reproduce via Technology – electric discharge dielectrics
Known since 1840 for its powerful oxidizing properties
First application in 1900 for microbiological safety in water treatment
FDA GRAS recognition in 2001, USDA organic 2007, AB 1427 California (food code)
How does Ozone Work?

Through a process of rapid oxidization ie: *cell lysis*

Destroys cell walls, and the pathogen on contact
No ‘immunity’ develops – as in emerging pathogens
Ozonated water will always be effective

Because ozone is highly reactive natural oxidizer
- The process has a very short contact time
- Destroys bacteria, virus, molds and mildews
- No residues are left - smell or taste
- Super hydrates leafy greens

*PureQuest*
OXYGEN EXISTS AS O$_2^-$ – 2 OXYGEN ATOMS JOINED BY A STRONG BOND
ELECTRICAL ENERGY BREAKS THE BOND AND RELEASES INDIVIDUAL OXYGEN ATOMS

SOME OF THE INDIVIDUAL OXYGEN ATOMS RECOMBINE AS $O_2$ (REGULAR OXYGEN) AND SOME AS $O_3$ OZONE (SUPER OXYGEN)
OZONE – SUPER OXYGEN ATTACKS THE CELL WALLS OF BACTERIA
SUPER OXYGEN BREAKS THE BACTERIA CELL WALLS AND THE BACTERIA CYTOPLASM SPILLS OUT – THE BACTERIA ARE DEAD
Why Choose Ozone Technology?

- Microbes cannot develop resistance to Ozone or Ozonated water
- Sterilizes the smallest pores, and is highly reactive, while getting into the nooks and crannies that chemical molecules can’t reach
- Uses ambient water and instantly kills microorganisms, while eliminating the use of dangerous chemicals with no harmful byproduct
- Safe for equipment and operators, as ozone system monitors, can assure operational efficacy
An additional high tech hand wash process for pathogen and cross contamination control

Effectively use the dispensed soap and reduce waste with Ozonated water anti-microbial rinse

Proven sanitizer generated into the water source for POU (Point of Use)

Creates no residue and reverts to oxygen O2 while killing germs

Pathogens cannot develop immunity or resistance to Ozonated water

Organic chemical free rinse that is 99.999%, effective on a wide range of pathogens
Ozonated water systems are USDA and FDA approved.

ROI- Savings in employee time to clean with chemicals, dwell time, rinse time. Only need to rinse with ozonated water after surfactant used.

Reduction of water use and waste discharge and heated water reducing carbon footprint.

Offers enhanced safety with the employees desired use of Ozonated water hand washing

Digital Ozone Meters available inline. ORP Meters (Oxidation Reduction Potential) reading by digital meter is used to measure efficacy

USP 1229.6 –recognizes O3 as a liquid sterilant
Ozone
Ozonated Water
Why Did They Consider Ozonated Water?

- Time taken to apply chemicals
- Dwell time of chemicals all over walls, equipment
- Time taken to rinse
- Corrosion
- Residue
- Surfactant and scrub to remove powder.
- Spray walls, ceilings, vats, equipment floors with Ozonated Water. Fill Sinks with Ozonated water for soaking tools.
- Able to wheel from one room to another.
Currently Used As Portable

- Decision Made to Change all SOPs to use Ozonated Water.
- Permanent skid system currently being installed for 2 rooms.
- Will retain portable unit for backup and other areas within facility.
Bacteria #2 Hand Sinks

- Pharmaceutical Company

- Hand Sinks- Wash/Scrub/Rinse
- Rinse water not purified
- Install hand sink ozone unit
- Retrofit
- 4 log reduction observed on coupon testing
Bacteria #3
Compounding Pharmacy

- Hand Sink Outside Clean Room
- Regulator requires sterile water
- Municipal Water Source
- Not Sterile
- Installed Ozone Generation Unit
Reference

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