

# **CONTAMINATION CONTROL CASE STUDIES**

**Brian Hubka  
Contamination Prevention Technologies, Inc.**

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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

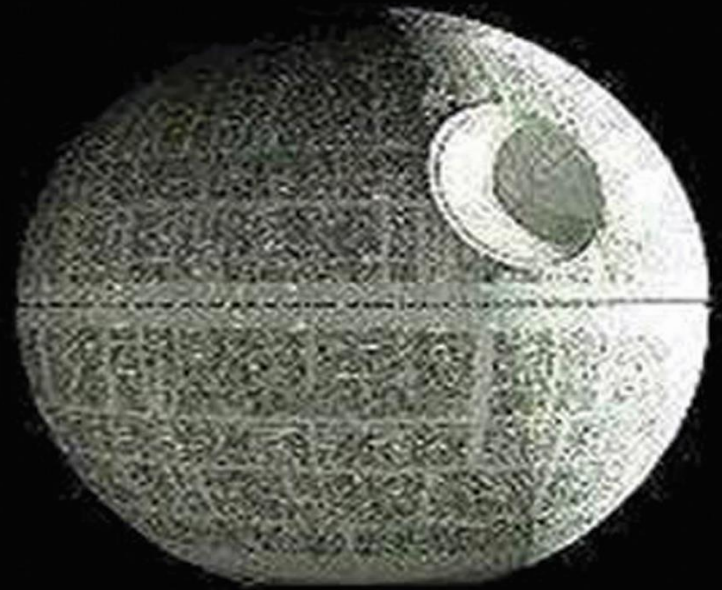
# MOLD CONTAMINATION

- 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

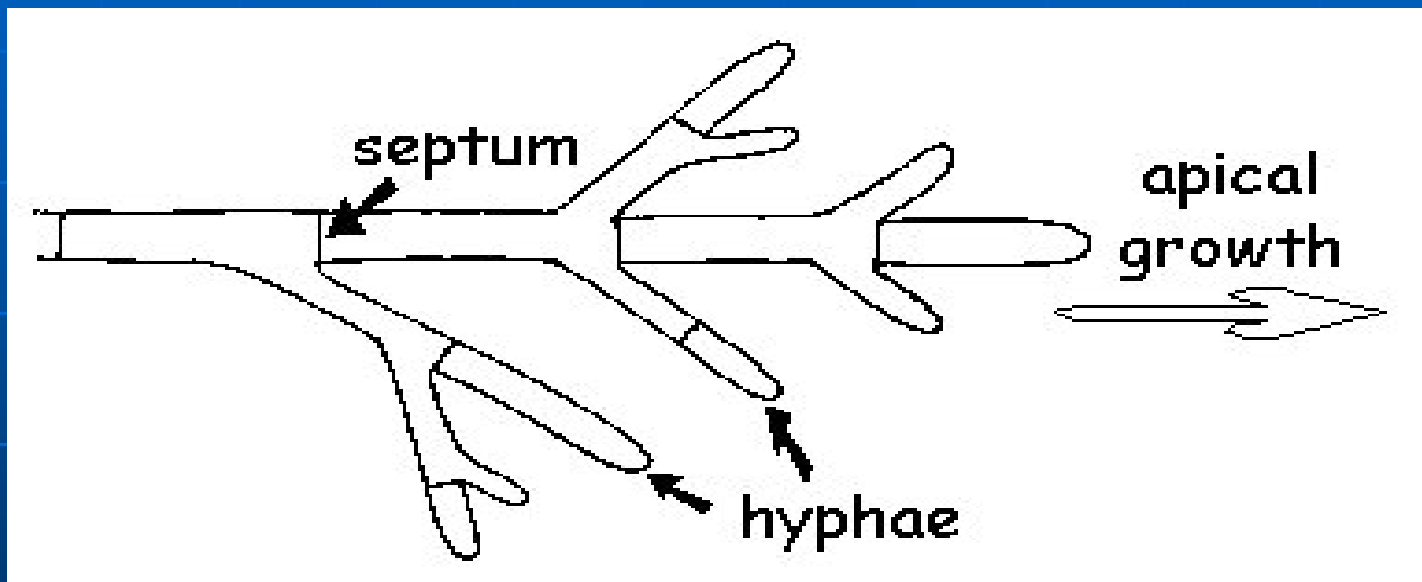


# The Number One Problem Is Mold Spores(or is it?)

## 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



# 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

# CONTAMINATION CONTROL

## 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**



# ANTIMICROBIAL PRODUCTS

## 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



# 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

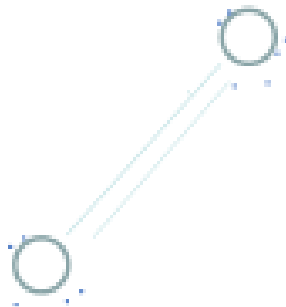


# Case Study Bacteria # 1

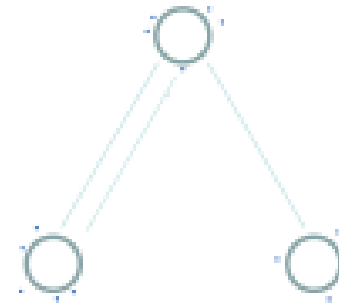
- Add Water, Mix with Auger
- End of Run
- Spray walls, vats, equipment with chemicals
- Long process, dwell times, rinse
- Corrosion, residue
- Bacteria detected

# What is Ozone?

Oxygen  $O_2$



Ozone  $O_3$



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

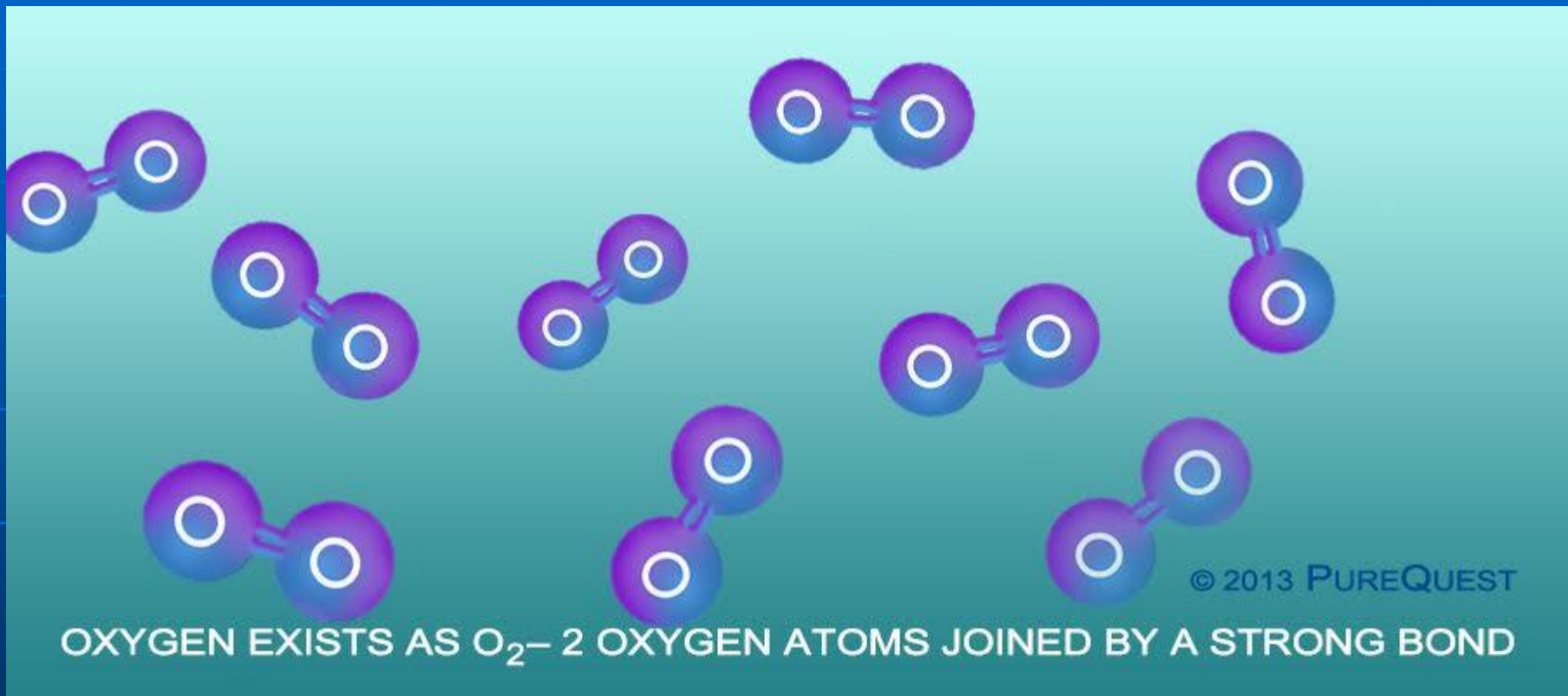
Destroys cell walls, and the pathogen on contact

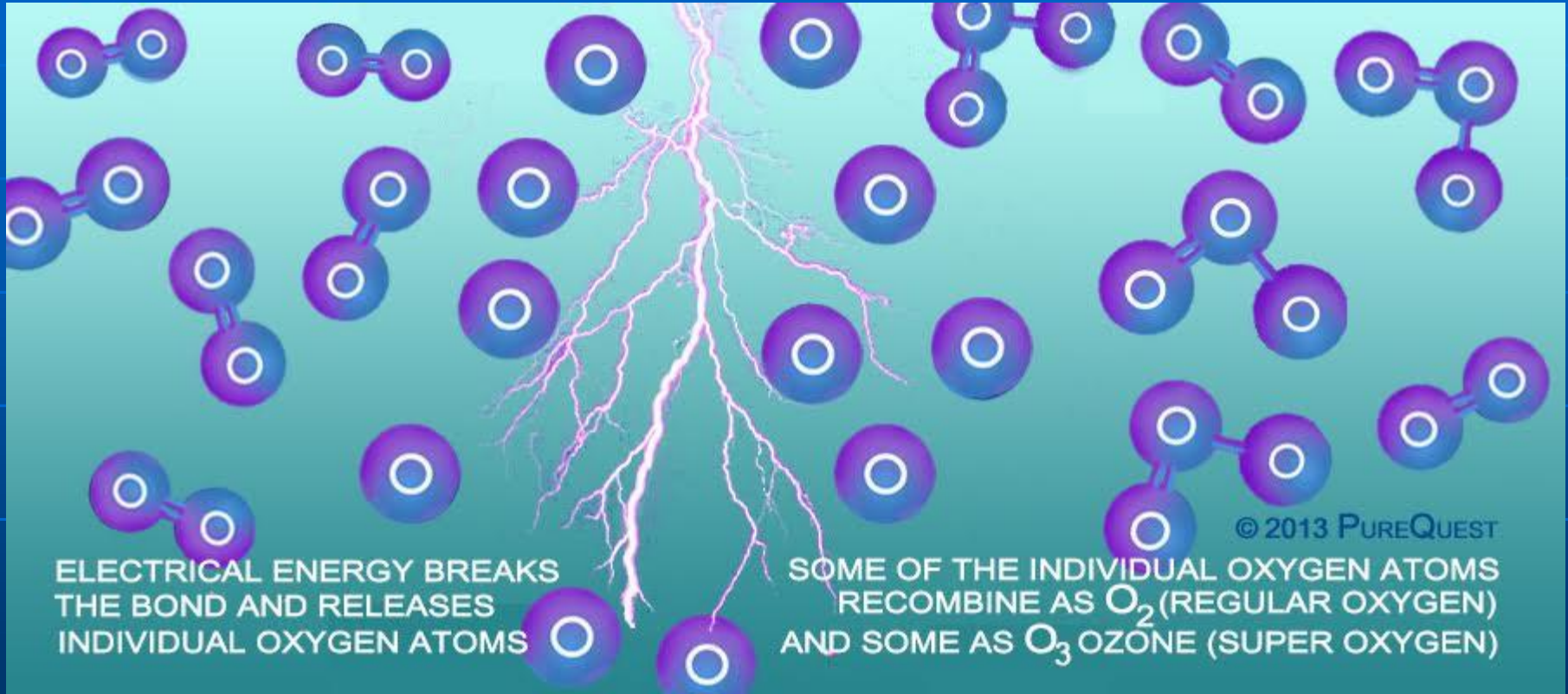
No 'immunity' develops – as in emerging pathogens

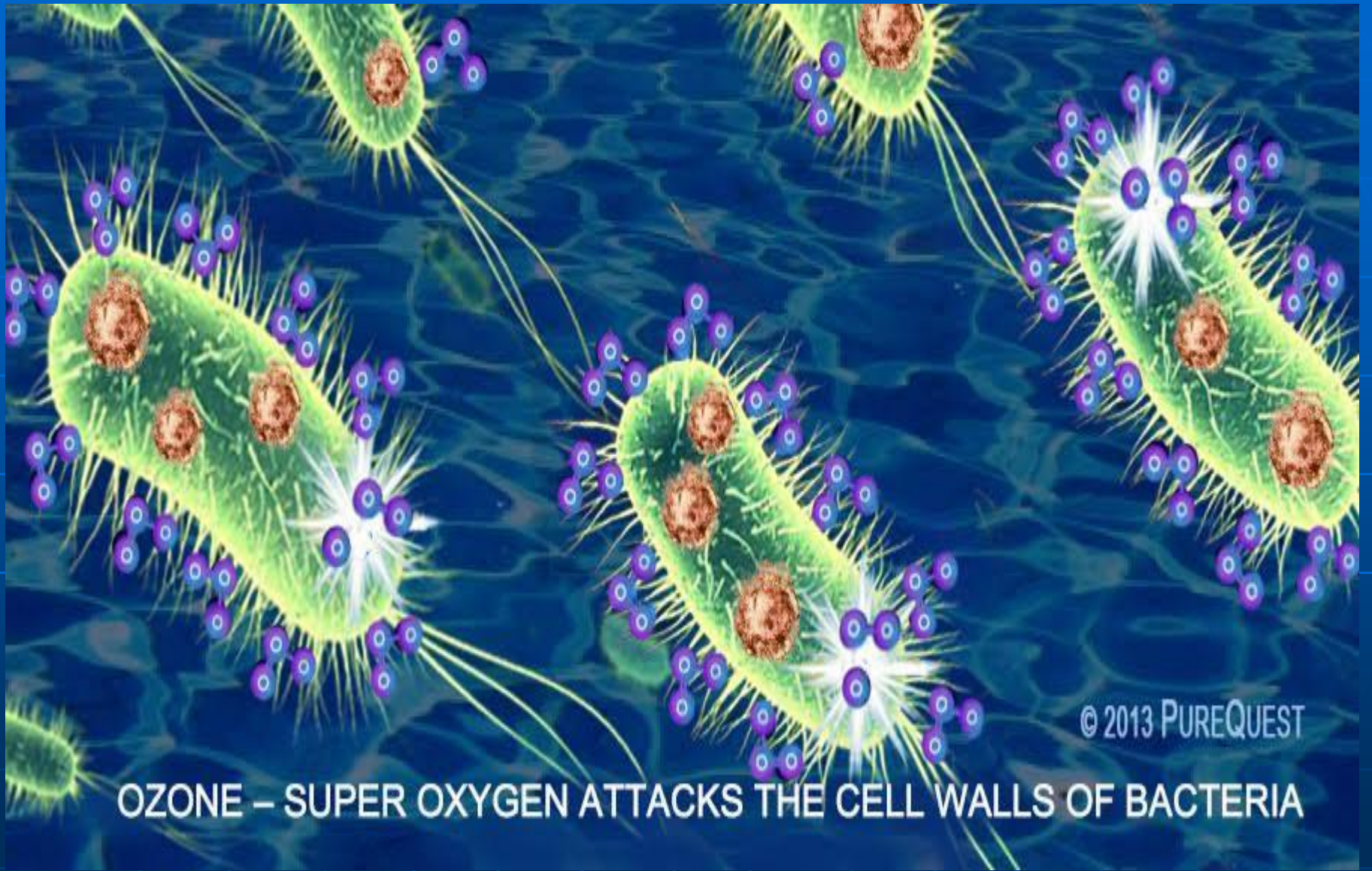
Ozonated water will always be effective

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

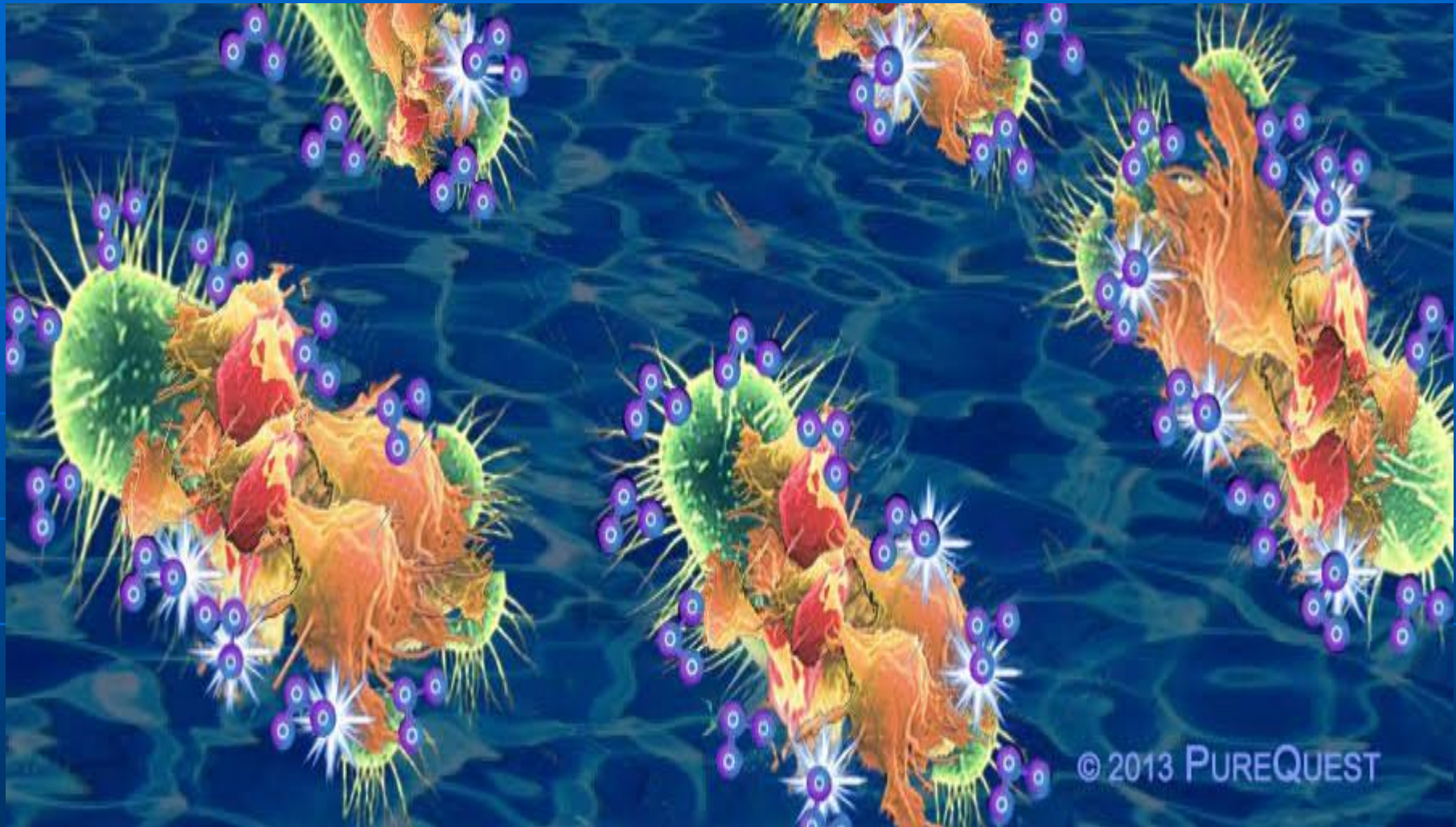






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**OZONE – SUPER OXYGEN ATTACKS THE CELL WALLS OF BACTERIA**



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**SUPER OXYGEN BREAKS THE BACTERIA CELL WALLS AND THE BACTERIA CYTOPLASM SPILLS OUT – THE BACTERIA ARE DEAD**

# Why Choose Ozone Technology?

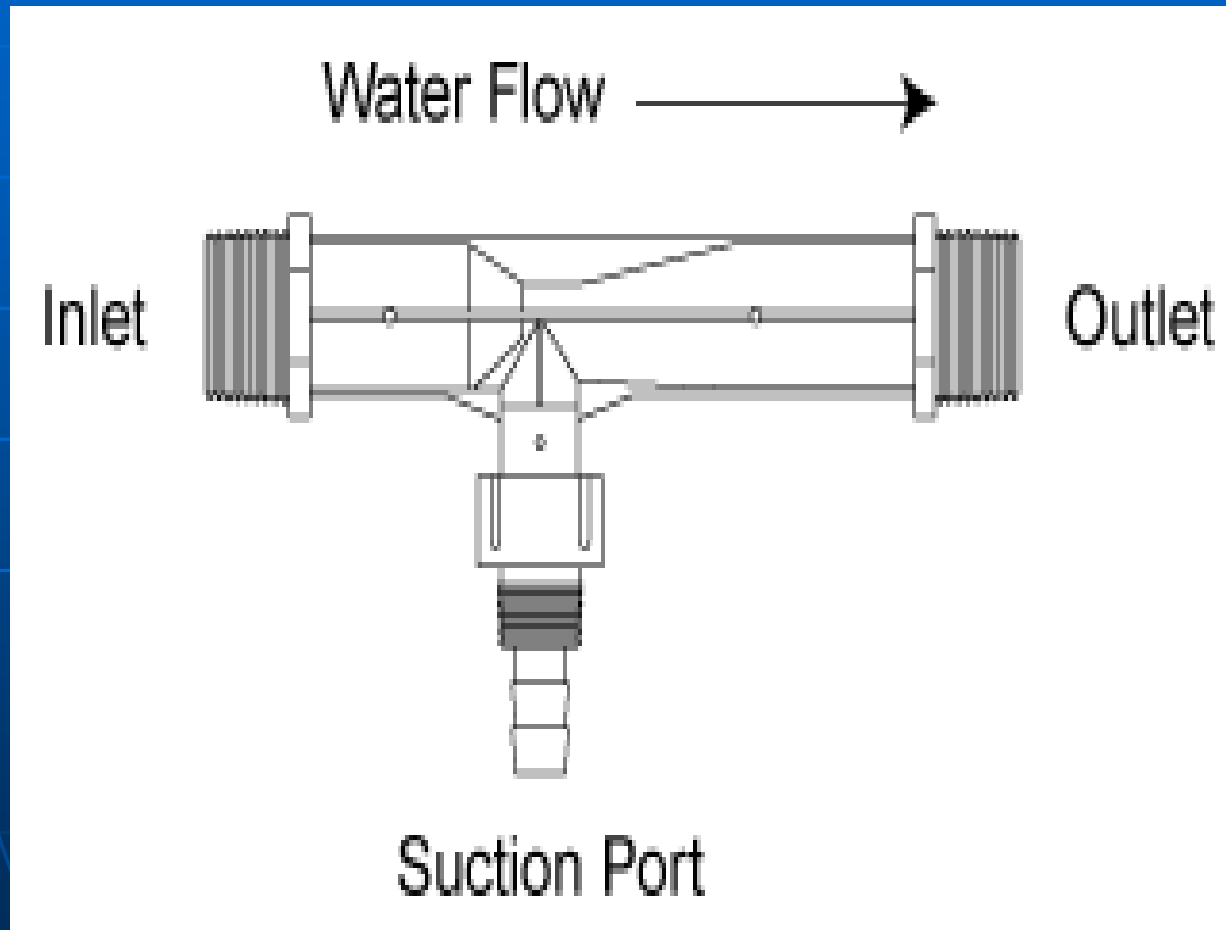
- Microbes cannot develop resistance to Ozone or Ozonated water
- Sterilizes the smallest pores, and is highly reactive, while getting into the nooks and crannies that chemical molecules can't reach
- Uses ambient water and instantly kills microorganisms, while eliminating the use of dangerous chemicals 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 O<sub>2</sub> 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 O<sub>3</sub> 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













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- 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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# Questions

**Thank you**



# Contact

Brian G. Hubka

702-858-7245

[bhubka@contaminationprevention.com](mailto:bhubka@contaminationprevention.com)

[www.contaminationprevention.com](http://www.contaminationprevention.com)