

Welcome to  
**“The Dirty Secrets of Cleaning Medical Devices”**  
 We will begin soon...






7/1/2020  
 PQCWebinar with Alconox

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**“The Dirty Secrets of Cleaning Medical Devices””**






Ask your questions using  
the **Q&A** button



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# “The Dirty Secrets of Cleaning Medical Devices”

## Featuring Alconox



**WEBINAR**  
ALCONOX  
Critical Cleaning Experts

The PQCW offers practical, hands-on and independent, training in cleaning.



**Darren Williams**  
Cleaning Research Group at SHSU  
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BFK Solutions  
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**Jeff Phillips**  
Alconox  
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## Webinar Hosts

### The PQCW Team




**Barbara and Ed Kanegsberg - “The Cleaning Lady and the Rocket Scientist”**

- BFK Solutions - Consultants in Critical Cleaning
- Authors and Editors of the two-volume CRC Handbook for Critical Cleaning
- Independent evaluations and recommendations
- Co-chairs of the Product Quality Cleaning Workshops
- barbara@bfksolutions.com and ed@bfksolutions.com



**Darren Williams - “The Professor”**

- Professor of Physical Chemistry at Sam Houston State University
- Leader of the Cleaning Research Group
- Co-chair of the Product Quality Cleaning Workshops
- Performs cleaning trials and formulates cleaning chemistries
- williams@shsu.edu



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## Product Quality Cleaning Workshops

- ▶ Workshops
- ▶ Webinars
- ▶ Resources for more effective cleaning processes
- ▶ More information
  - ▶ [shsu.edu/pqcw](http://shsu.edu/pqcw)
  - ▶ [bfksolutions.com/manufacturing-minds-pqcw/](http://bfksolutions.com/manufacturing-minds-pqcw/)

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Q: What was most valuable to you?  
A: "The general overview of cleaning and the introduction to cleaning processes."  
- a 2018 attendee

"The vendor demos were great."  
- a 2018 attendee

"All the lab activities were interesting and made me think about things I need to consider in my own lab work."  
- a 2018 attendee

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# ALCONOX

## About Jeff Phillips

Critical Cleaning Experts

- ✔ 20+ yrs, pharmaceutical industry, medical device industry, process optimization, troubleshooting, training, critical cleaning, analytical chemistry
- ✔ Alconox, Inc. (New York, USA)
- ✔ [JPhillips@alconox.com](mailto:JPhillips@alconox.com)
- ✔ +1 (914)610-3029
- ✔ Senior Director, Technical Marketing & Commercial Development
- ✔ Very funny guy....

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**ALCONOX**  
Critical Cleaning Experts

## Today's Talk

- Introduction
- Define Critical Cleaning
- Cleaning Chemistry
- Cleaning Methods
- Cleaning Validation/Verification
- Discussion and Questions

The screenshot shows the Alconox website with a navigation menu on the left. The website header includes the Alconox logo and the tagline "CRITICAL CLEANING EXPERTS". The main navigation menu includes: HOME, ABOUT, PRODUCT CATALOG, SUPPORT, SOLUTIONS, ASK ALCONOX, and TECHNICAL NOTES. Below the navigation menu is a large image of industrial cleaning equipment with the text "The Critical Cleaning Experts" overlaid. At the bottom of the website, there are buttons for "Dealers", "Downloads", and "Support".

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**ALCONOX**  
Critical Cleaning Experts


## Introduction

- Privately held 70+ yr old company
- Third generation family ownership
- Detergent manufacturer serving
  - Laboratories
  - FDA: pharma, medical device, healthcare, food
  - Precision manufacturing: solar, aerospace, electric
- Over half a century of global distribution
- Over 50 countries
- Expert technical support – Our pride

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## Define Critical Cleaning

### What is critical cleaning?

- ▽ Cleaning that impacts the value of the finished output from whatever is being cleaned
- ▽ Typically some observation, measurement or validation is done related to precision cleaning
- ▽ Critical cleaning in FDA or USDA regulated industries of components or substrates is the complete removal of undesirable contaminants to a desired preset level.
  - ▽ Cleaning validation acceptance criteria using risk assessment-based ADEs
- ▽ The preset level is normally the minimum level at which no adverse effects take place in a subsequent operation.

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## Define Critical Cleaning

### Why Precision Cleaning and Cleaning Validation is Important – Infamous Example

Cleaning failures can be very costly

- ▽ Inhouse cleaning/passivation process in house
  - ▽ < \$2.00/device
- ▽ Not properly validated → there was tragedy

There were many product failures...

- ▽ The company had to recall nearly 25,000 hip implants,
  - ▽ 17,500 of which had already been implanted in patients
- ▽ This catastrophic series of events lead to the destruction of this large medical device company as a stand alone company.


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## Chemistry of Cleaning

- Organic solvents
  - Alcohols
  - Ethers
  - Petrochemical
- Only clean residues that are soluble in them
- Volatile Organic Carbon Concerns
- Flammability Concerns
- Waste Disposal Concerns



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## Chemistry of Cleaning

### Water

- Only cleans things soluble in it
- Excellent where water alone will work

Commodity chemicals (aqueous)

- Caustic soda and potash (NaOH & KOH)
- Phosphoric and nitric acid
- Single cleaning mechanisms of alkaline or acid attack
- Require high concentrations, no synergistic cleaning
- Waste disposal concerns

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Detergent for Critical Cleaning

## Chemistry of Cleaning

- ▽ Aqueous – blend
- ▽ Surfactant – anionic, nonionic, cationic
- ▽ Builders – chelation, anti-redeposition, silicates
- ▽ Additives – enzymes, rinse aids

### HOW ALKALINE CLEANERS WORK

Water Molecule and Alkalinity Builders

Surfactant Molecule

Surfactant Lifting Oil Off Metal Surface (Forms Emulsion)

Surfactant Molecules On Surface

Metal Part Being Cleaned

Surfactant Micelle

Oil-Water-Surfactant Emulsion

Oil On Surface

Source: *Practical Cleaning Magazine*, June 1997.

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## Chemistry of Cleaning

### About the water....

- ▽ Water Hardness
  - ▽ Mg, Ca, Mn, Fe = Dissolved ions that cause water hardness
- ▽ Hardness ions lead to insoluble materials (scale or scum)
- ▽ Alconox, Inc.'s well built detergents typically unaffected
  - ▽ May decrease detergent solvency
- ▽ Water softening = replacement of "bad" ions by "good" ions (Sodium)
- ▽ Deionize, ultrafiltered or RO water


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## Cleaning Methods

- Manual
- Soak
- Agitated Immersion
  - Ultrasonic
  - Bubbled
  - Pump under immersion
- Spray in air (auto machine and CIP)



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## Cleaning Validation/Verification

**Validating the use of a cleaner:**


- ✔ Identify Cleaner Residues
- ✔ Select a Residue Detection Method
- ✔ Choose a Sampling Method
- ✔ Validate a Residue Detection Methods
- ✔ Construct Recovery Studies
- ✔ Set Residue acceptance criteria
- ✔ Validate the cleaning process with the new cleaner
  - ✔ Including design of experiments for optimal process
  - ✔ Including three consecutive cleaning trials
  - ✔ Including and Creating the Validation Report
- ✔ Write procedures and train operators



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**Critical Cleaning Experts**      **Cleaning Validation/Verification**


**Validating the use of a cleaner:**

Detergent Residue Detection

- ▽ Specific vs. non specific
- ▽ Specific ingredients:
  - ▽ high performance liquid chromatography (HPLC)
  - ▽ ion selective electrodes
  - ▽ flame photometry
  - ▽ UV spectroscopy
  - ▽ enzymatic detection
  - ▽ Titration
- ▽ Blend of ingredients:
  - ▽ total organic carbon
  - ▽ pH
  - ▽ conductivity

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**Validating the use of a cleaner:**

Detergent Residue Detection

- ▽ Preference for use of specific methods
  - ▽ non-specific methods accepted provided a scientific rationale for their use is determined.
- ▽ Specific methods are also preferred when investigating failures or action levels.
  - ▽ non-specific method for monitoring,
  - ▽ specific methods are used for investigating
- ▽ Specific method is also used for an initial validation
  - ▽ correlated with a non-specific method which
  - ▽ later used for retesting to maintain a validated state of manufacturing.

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### **Validating the use of a cleaner:**

- ▼ **Setting Residue Acceptance Criteria**
  - ▼ Residue acceptance limits may be set for a residue that affects biocompatibility, toxicity, or functionality of the finished device (anything that would affect fit, form or function).
  - ▼ This typically means residue acceptance limits need to be set for contaminants such as process fluids, polishing compounds, mold releases, bioburden, and cleaning agents
  - ▼ Such criteria are determined according to the potential a given residue has to affect biocompatibility, toxicity, or functionality of the finished device.
  - ▼ Any applicable historical data on residues from successful manufacturing processes can be used to set acceptable levels.

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**Critical Cleaning Experts**      **Cleaning Validation/Verification**

### **Validating the use of a cleaner:**

- ▼ **Setting Residue Acceptance Criteria**
  - ▼ For a new device, where no history is available, a study can be performed where a series of internally determined and justified worst case devices are spiked using defined residue amounts on the surface.
  - ▼ Each spiked device is then cleaned and cleanliness is measured.
  - ▼ The acceptability of this resulting worst case cleanliness is established by biocompatibility studies, toxicology calculations, or clinical data.

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## Cleaning Validation/Verification

### Summary

- ▼ The validation is done on critical cleaning steps effecting the quality, safety or manufacture of the final product/device (Form, Fit, or Function).
- ▼ Validation is achieved by proving that a process operates within predetermined parameters.

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## Cleaning Validation/Verification

- ▼ [Alconox® Powdered Precision Cleaner](#)
- ▼ [Liquinox® Critical Cleaning Liquid Detergent](#)
- ▼ [Alcojet® Low Foaming Powdered Detergent](#)
- ▼ [Detojet® Low Foaming Liquid Detergent](#)
- ▼ [Detergent 8® Low-Foaming Ion-Free Detergent](#)
- ▼ [Luminox® Low-Foaming Neutral pH Liquid Detergent](#)
- ▼ [Solujet® Low-Foaming Phosphate-Free Liquid](#)
- ▼ [Tergajet® Low-Foaming Phosphate-Free Detergent](#)
- ▼ [Tergazyme® Enzyme-Active Powdered Detergent](#)
- ▼ [Citranox® Liquid Acid Cleaner and Detergent](#)
- ▼ [Citrajjet® Low-Foam Liquid Acid Cleaner/Rinse](#)
- ▼ [Alcotabs® Tablet Pipet Detergent](#)
- ▼ [Detonox® Ultimate Precision Cleaner](#)
- ▼ [Keylajet® Low-foaming High Alkaline Liquid](#)


Alconox, Inc.  
free samples program  
Try it before you buy it!



Because they work!!

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## Things to Consider / Avoid

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- ▼ **Blind Holes**
  - ▼ Orient/rotate parts to release air under immersion
  - ▼ Rotate during rinsing to flush out loosened up residue
  
- ▼ **Thin tubes with small internal diameters**
  - ▼ Ultrasonics and chemical detergency will loosen residues
  - ▼ Need flush to remove
  - ▼ Circulate cleaning and rinsing solution along the tube.
  - ▼ Use same temperature rinse water to avoid deposition
  
- ▼ **Complex geometries**
  - ▼ Rotate or flush complex geometries during cleaning and rinsing for thorough cleaning
  
- ▼ **Any polycarbonate or acrylic materials of construction that could undergo stress cracking**
  - ▼ Surfactant-free detergent
  - ▼ Challenge when emulsification needed

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## Cleaning and Cleanliness Standards

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- ▼ **FDA**
  - ▼ Establishment Registration & Device Listing
  - ▼ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfr/rl.cfm>
  
- ▼ **ASTM**
  - ▼ F2459-12 Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis
  - ▼ F-3127-16 Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices
  
- ▼ **AAMI**
  - ▼ AAMI TIR30:2011 A Compendium Of Processes, Materials, Test Methods, And Acceptance Criteria For Cleaning Reusable Medical Devices
  - ▼ AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
  
- ▼ **ISO**
  - ▼ ISO 10993-17:2009 Biological evaluation of medical devices, Part 17: Establishment of allowable limits for leachable substances
  - ▼ ISO 10993-18:2020 Biological evaluation of medical devices, Part 18: Chemical characterization of medical device materials within a risk management process

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**Critical Cleaning Experts**      **References**

- ▼ The Aqueous Cleaning Handbook by Malcolm C. McLaughlin, M.A and Alan S. Zisman, M.D and the Technical Services Staff of Alconox, Inc. Fourth Edition. AI Technical Communications, LLC White Plains, NY 2005.
- ▼ [www.cleansolutions.org](http://www.cleansolutions.org) - Toxics Use Reduction Institute Cleaning Lab - UMass Lowell
- ▼ [www.surfacefinishing.com](http://www.surfacefinishing.com)
- ▼ <https://alconox.com>
- ▼ <http://technotes.alconox.com>

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**Thank You for Attending**  
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**Product Quality Cleaning Workshops**  
**COME TO THE PQCW**

- ▶ **When?** To Be Announced
- ▶ **Where?** Sam Houston St. Univ., Huntsville TX
- ▶ **More Info?** Visit <http://shsu.edu/pqcw>

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**Q: What was most valuable about the workshop?**  
**A: "The general overview of cleaning and the importance of cleaning procedures - a 2018 attendee's perspective"**

... Solvent properties, cleaning verification, and analysis, acoustics

Don't type anything in the box on the screen

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**Have a great rest of your day**

**product quality cleaning workshops**

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