

Keeping you "in the know" in the ASC industry

got compliance?

a pharmacist's insights for success!

Gregory Tertes, R.Ph. ASC Pharmacist Consultants, Inc. 510-710-3640

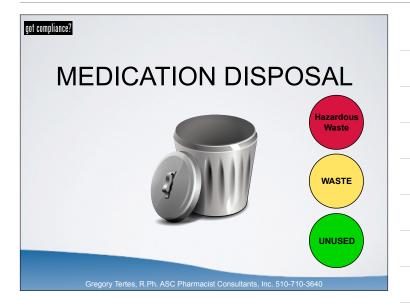


LEARNING OBJECTIVES

- Understand the many regulators and rules of pharmaceutical waste disposal.
- Know how to comply with the essentials of Drug Enforcement Agency paperwork.
- Understand the changing rules for compounding pharmacies, and how to properly vet one for safety and accuracy.

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TOPICS • Medication Disposal • DEA Paperwork Best Practices • DQSA/Compounding Pharmacies • Consultant Pharmacist What to expect!





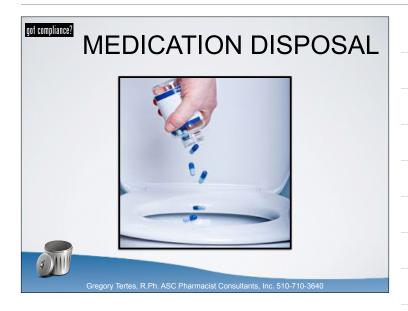
Why do we care about it?

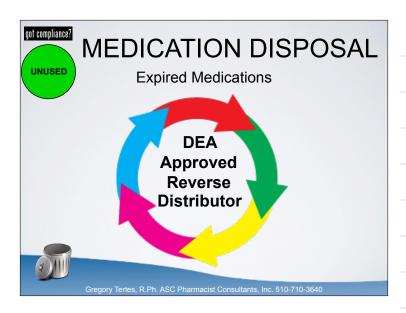
- To comply with Federal, State, and Local Laws and Regulations
- To comply with accrediting agency standards
- To protect patients and staff
- To protect the environment

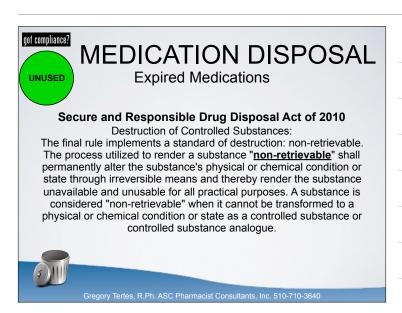


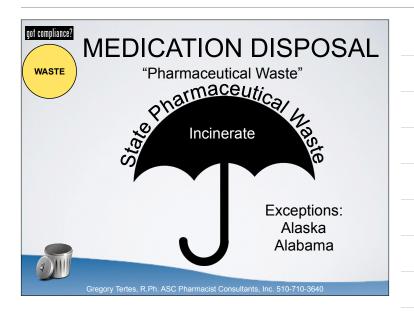




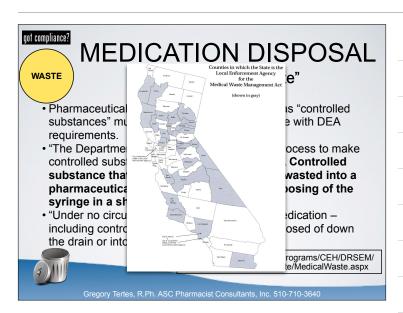




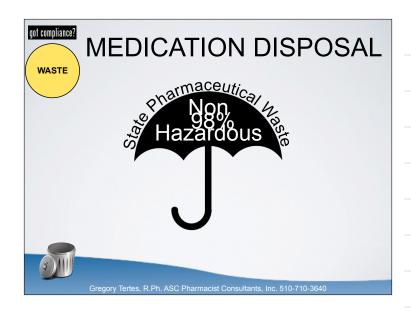


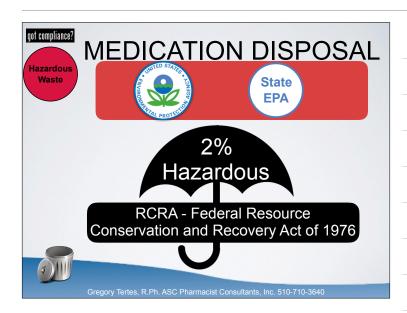


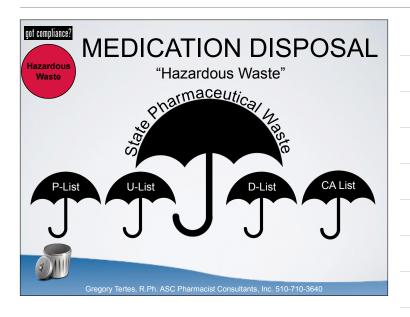


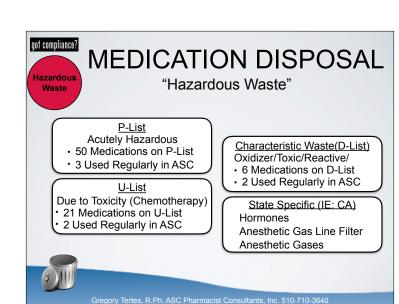


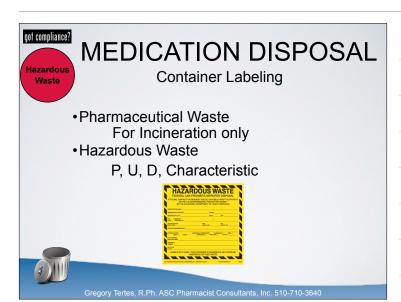


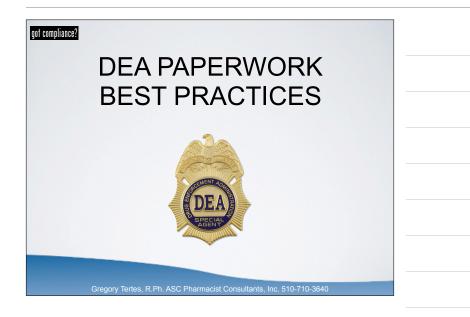












DEA PAPERWORK

DEA 222 Form (Schedule II Order Form)

- Store Securely
- · Consider keeping a log.
- Complete DEA 222 forms correctly
- Power of Attorney (POA)





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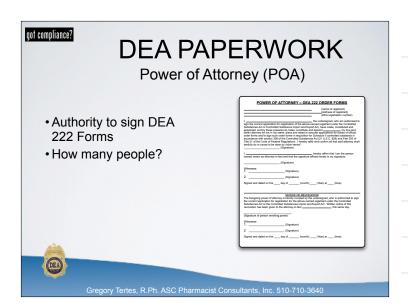
DEA PAPERWORK

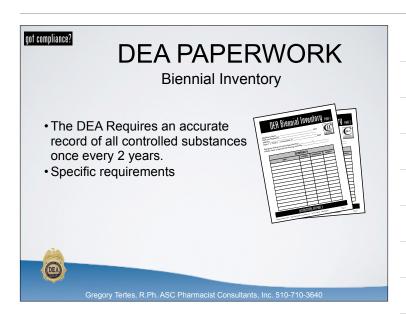
DEA 222 Form (Schedule II Order Form)

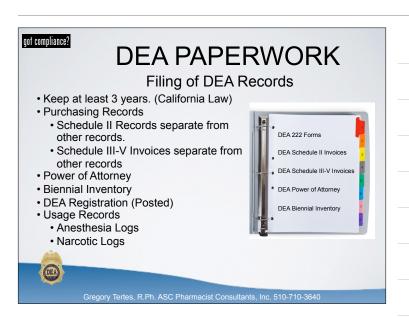
- Store Securely
- Consider keep
- Complete DEA correctly
- Power of Attorn

TO BE FILLED IN BY PURCHASER		
No. of Packages Received	Date Received	
5	9/7/17	
5	" "	
2	" "	









DEA PAPERWORK

- Paperwork
- DEA Registration
- √ Biennial Inventory
- **√POA/CSOS**
- **√DEA 222 Forms**
- ✓ Invoices
- · Daily AM/PM Count
- · Safe Monthly Count

- Security
 - Double Lock
 - Refrigerator
 - Lock Carts
- Audit Anesthesia Log Correlate to Controlled Substance Log.
- Physician Security Forms



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Drug Quality and Security Act of 2013 and Compounding Pharmacies



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Drug Quality and Security Act of 2013

The bill was written in response to the New England Compounding Center meningitis outbreak that took place in 2012, which sickened over 800 people and killed 64 people.

This is the first time the FDA has jurisdiction over Compounding Pharmacies.



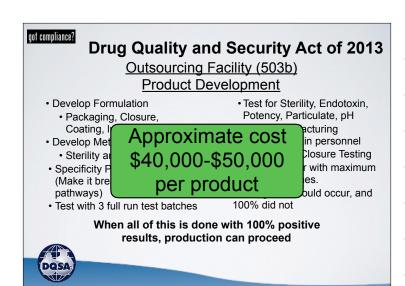
June 27, 2017 - Former New England Compounding Center owner Barry Cadden sentenced to 9 years for deadly meningitis outbreak case.

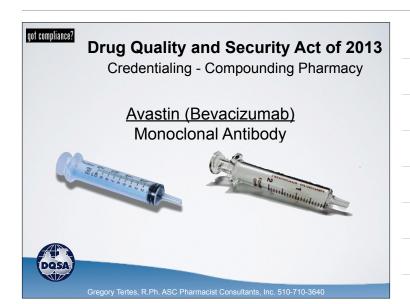
got compliance? **Drug Quality and Security Act of 2013** Title I Compounding Quality Act Compounding Pharmacy (503a) Outsourcing Facility (503b) Registered with FDA Sterile Compounding Pharmacy- Traditional Test every product for Compounder sterility • "For office use" Some sterility testing • Drug product is compounded Much More for an identified individual patient noever your compounding • Much More armacy is, be sure to check their credentials! DQSA

got compliance? **Drug Quality and Security Act of 2013 Credentialing** - Compounding Pharmacy Compounding Pharmacy (503a) Outsourcing Facility (503b) PCAB Accredited • FDA Website for Registered Board of Pharmacy **Outsourcing Facilities** • Form FDA-483 New Regulations Compounding Questionnaire • Interpret the results and Interpret the results and ask ask more questions! Site Visit more questions! Site Visit • Letter stating compliance with cGMP • Engage your Consulting Engage your Consulting **Pharmacist Pharmacist** $\underline{\text{https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/}}$

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pharmacycompounding/ucm378645.htm





Drug Quality and Security Act of 2013 DALLAS NEWS April 28, 2017 Patients lose vision after routine cataract surgeries at Dallas Key-Whitman center • The issue has been traced to a combined steroid and antibiotic injection prepared by Guardian Pharmacy Services, a Dallas compounding



pharmacy.

Drug Quality and Security Act of 2013 DALLASNEWS Update: June 15, 2018 • FDA identified multiple substances in Guardian's product, including poloxamer 407 and poloxamer 407 degradants. FDA prepared in-house samples of Guardian's product and found that autoclaving and sonication caused the poloxamer 407 to degrade. • The amount of poloxamer 407 in Guardian's product (12%) is much greater than the maximum amount of poloxamers in FDA-approved ophthalmic products for topical administration (0.1-0.2%) • The safety profile of drug products intended for intravitreal injection containing poloxamer 407 is unknown.

Drug Quality and Security Act of 2013 DQSA Title II Drug Supply Chain Security Act • Challenge the influx of counterfeit drugs that may ultimately reach end users or be provided by "dispensers" • Requires a "pedigree" attestation (Track and Trace) Pedigree Pedigree | Pe

CONSULTANT PHARMACIST, WHAT TO EXPECT! Safe Medication Solutions Gregory Tertes, R.Ph. ASC Pharmacist Consultants, Inc. 510-710-3640

YOUR PARTNER FOR SAFE MEDICATION SOLUTIONS

SUPPORTING YOU TO BE SAFE EVERY DAY, NOT JUST SURVEY DAY



ASC Pharmacist Consultants, Inc. 248 3rd Street, Suite 606 Oakland, CA 94607 510-710-3640 www.SafeMedicationSOlutions.com

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THREE FOUNDATION PRINCIPLES



Patient Safety



Survey Success

\$ave Money



got compliance?

SPECIALIST IN ASC

SERVICES			
	Pharmacist	ASC Pharmacist Consultants	
Check Refrigerator Log	✓	✓	
Review Controlled Substance Log	✓	✓	
Benchmarking		✓	
Assistance with Drug Shortages		✓	
Cost Containment Opportunities		✓	
Newsletters		✓	
Regulatory Guidance		✓	
Chart Review		✓	
QI Studies		✓	
Educational Services		✓	
Easy Access		✓	
Controlled Drug Management		✓	
Policies and Procedures		✓	
Quarterly Reports		V	
Quarterly Audit with over 100 items			
Knowledge of Accreditation Standards		✓	
Medication Safety Focus		✓	



QUARTERLY VISIT AND EXIT MEETING

- · Chart Review
- OR and PACU Inspections
- Controlled Drug Management
- Quarterly Audit with over 100 items
- Active Staff Engagement Questions Encouraged!!
- Exit Meeting
 - Review findings from audit (No Surprises)
 - Review General Comments

Annual

Policy & Procedure Review Formulary Review



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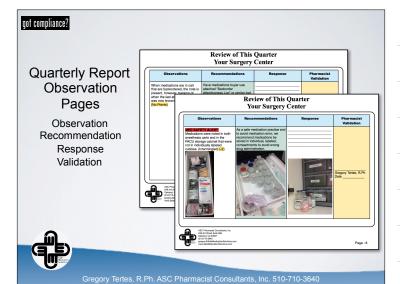
QUARTERLY REPORT

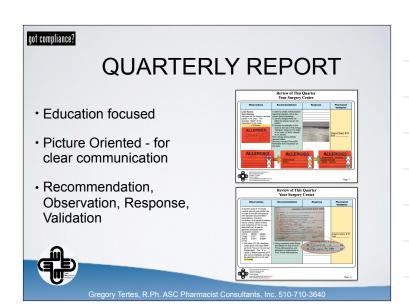
- · Observation oriented
- Four Areas of Review
 - Observation
 - Recommendation
 - Response
 - Validation
- Provides numeric score for comparison between quarters within a facility and between facilities

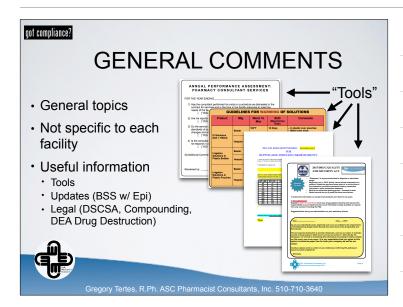


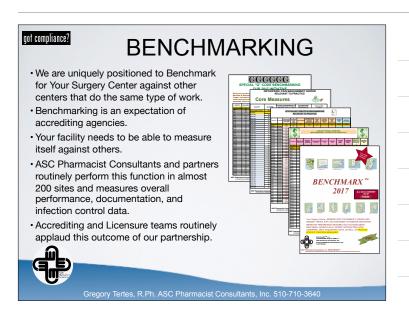
Voter Stragery Center
Planmany Services Review for the This Quarter
Share and Services Review for the This Quarter
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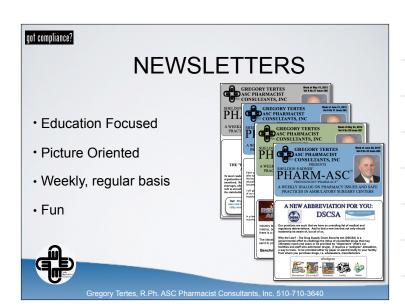
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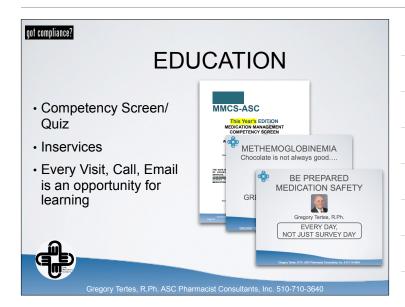








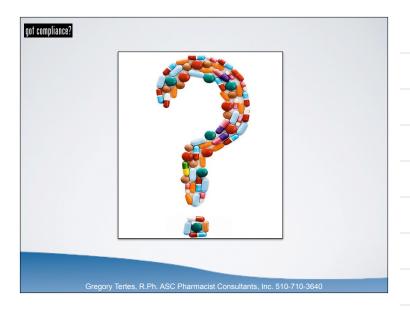




CUSTOMIZED EXPERIENCE

- No "Cookie cutter" package. If there is something you need, let me know.
 - · Diversion Prevention Training
 - · QI Studies
 - Case Observation for Safe Injection Practices
 - Meetings with Anesthesia
- Screen for regulatory and accreditation compliance along with best practices
- Available daily for you and your team on a PRN basis. Calls are routinely returned within one to a few hours 365 days a year.





Continued Education Credit

- •1 CE contact hour per licensed attendee.
- Complete course evaluation by Friday June 29 link provided in email following webinar.
- Allow 2 weeks for processing of your certificate.
- Any questions regarding continued education contact
 lyn@pss4asc.com



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Join the Community!

CLICK LINKS BELOW TO DOWNLOAD
 Medication Compounding Clarification
 PCAB Accreditation Manual
 Choose an Accredited Pharmacy Fact Sheet

- For the resources referenced today and SO MUCH MORE...
- •Request your free web demo today
- •www.progressivesurgicalsolutions.com/esupport
- Email us at info@pss4asc.com
- Or call us! (855) 777-4272



Mark your Calendars!





Friday August 24, 2018 11AM PT/ 2PM ET INFECTION CONTROL RISK ASSESSMENT

Phenelle Segal, RN, CIC Infection Control Consulting Services

Friday October 26, 2018 11AM PT/ 2PM ET ASK THE CLINICAL DIRECTOR/ADMINISTRATOR PANEL

Minda Soria, RN April McElheny, RN Joan Conine Jared Abel

Mark your Calendars!



Friday July 23, 2018 11AM PT/ 2PM ET

QI STUDY REVIEW Vanessa Sindell, MSN, BSN, RN

Friday September 17, 2018 11AM PT/ 2PM ET WORKING EFFECTIVELY WITH YOUR MEDICAL STAFF

Alison Galloway, BSN, RN LaPeer Surgery Center

Get the Full Line Up!

For the full 2018 Webinar Line up visit our website:

https://progressivesurgicalsolutions.com/progressive-webinars/

