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A presentation for HealthTrust Members

March 31, 2021

An Alternative Channel of Drug Manufacturing: 503B Outsourcing Explained

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Disclosures

- Neither the presenter nor his preceptor have conflicts of interests related to this presentation.
- Note: This program may contain the mention of suppliers, brand products, services, or drugs presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes only and should not be perceived as an endorsement of any particular supplier, brand, product, service, or drug.

Learning Objectives

Pharmacists & Supply Chain Professionals

- Discuss the standards of the 503B Current Good Manufacturing Practices (cGMP)
- Outline the regulations that determine what drugs can be manufactured in 503B facilities
- Describe the 503B audits that were conducted by the Food and Drug Administration (FDA)

Learning Objectives

Pharmacy Technicians

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Background

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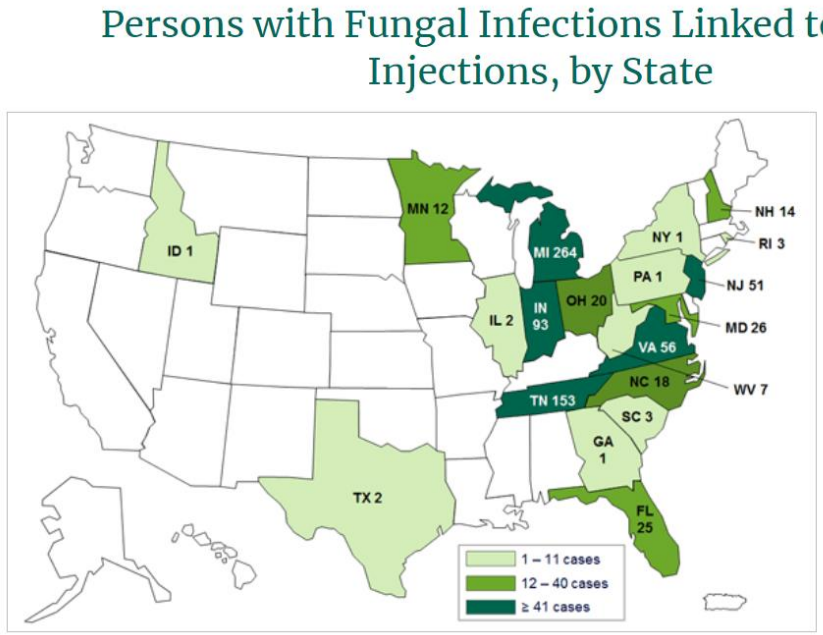
Background

- In 1998 “Congress exempted compounding pharmacies from the oversight of the Food and Drug Administration. The theory was, mixing drugs one prescription at a time shouldn't require federal inspection.” [1]
- In 2001 11 patients were sickened with meningitis[2]
  - Betamethasone injections
  - Terminal sterilization practices
  - Resulting in 3 patient deaths
- Between 2001 and 2012 problems persisted[3]
  - 11 separate incidents occurred
  - 207 patient reported adverse events
  - Resulting in 11 deaths.
- The New England Compounding Center (NECC) in 2012
  - Fungal meningitis
  - Multi-State Outbreak
  - 793 patients impacted
  - Resulting in 64 deaths



https://www.cdc.gov/hai/outbreaks/meningitis-map-large.html

1. “Lethal Medicine Linked to Meningitis Outbreak.” *CBS News*, CBS Interactive, www.cbsnews.com/news/lethal-medicine-linked-to-meningitis-outbreak-10-03-2013/4/.
2. Civen, R., Vugia, D.J., Alexander, R., et al. Outbreak of Serratia marcescens Infections following Injection of Betamethasone Compounded at a Community Pharmacy. *Clinical Infectious Diseases*, *Volume 43,* Issue 7, 831–837, (2006).
3. Staes, C., Jacobs, J., Mayer, J. et. al. Description of outbreaks of healthcare associated infections related to compounding pharmacies, 2000-2012. Am J Health Syst Pharm. 2013 Aug 1;70(15):1301-12. doi: 10.2146/ajhp130049. https://bit.ly/3mzhy4N

New England Compounding Center

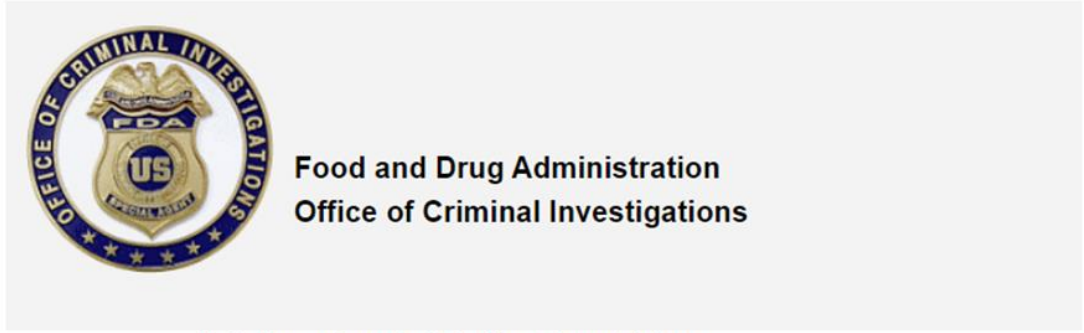
"We became a manufacturer overnight" – Joe Connolly

- Scott Pelley from 60 Minutes interviewed Joe Connolly and an anonymous salesman on national television
- Starting in 2009, Joe started working at New England Compounding Center (NECC) in what was called "Clean Room 1"
  - NECC became greedy, overextended and sloppy
  - NECC sales reps bragged about the amount of business they were bringing in
    - ✓ NECC had a call center with 30 sales reps
  - Drug output increased by a factor of 1,000
  - Mold in the clean room
  - 503A legislation requires compounded preparations to have an RX connected to a patient
    - ✓ Scott Pelley: "And when you got the prescriptions with Bart Simpson's name and Homer Simpson's name you went back to that client and said what?"
    - ✓ Salesman: "Can you please, you know, give us legitimate names, or people that you know? Sometimes they'd take a phone directory within their office and scribble out their extensions, and fax it over to us."

The content described above is directly from Scott Pelley's 60 Minutes interview with former staff members, and does not reflect the opinions of the presenter or HealthTrust

1. "Lethal Medicine Linked to Meningitis Outbreak." *CBS News*, CBS Interactive, www.cbsnews.com/news/lethal-medicine-linked-to-meningitis-outbreak-10-03-2013/4/.

New England Compounding Center Outcome



Food and Drug Administration
Office of Criminal Investigations

U.S. Department of Justice Press Release

For Immediate Release
January 31, 2019

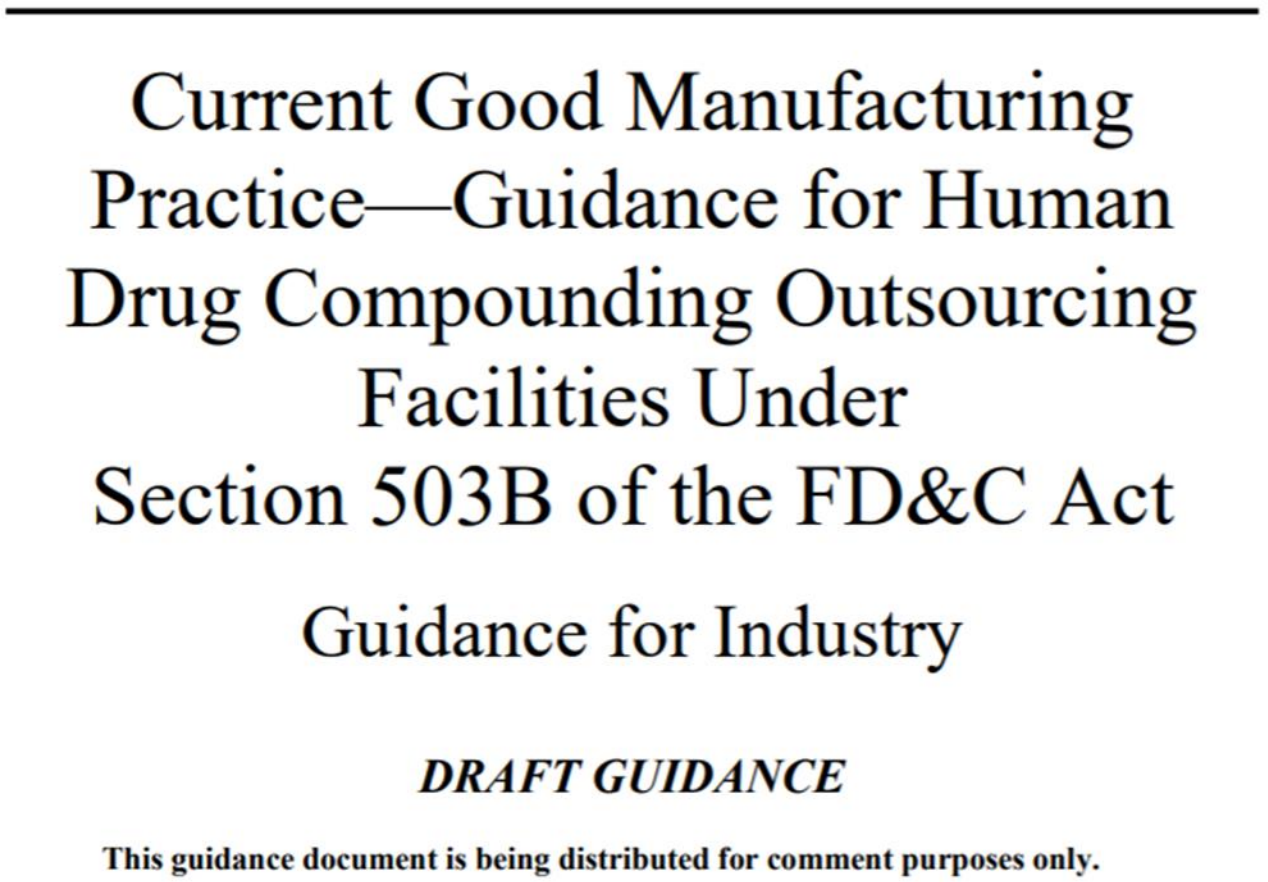
United States Department of Justice
District of Massachusetts

Boston -- The former supervisory pharmacist of New England Compounding Center (NECC) was sentenced today in connection with the 2012 nationwide fungal meningitis outbreak that killed 64 and caused infections in 793 patients.

Glenn Chin, 49, of Canton, Mass., was sentenced by U.S. District Court Judge Richard G. Stearns to eight years in prison, two years of supervised release, and forfeiture and restitution in an amount to be determined later. In October 2017, Chin was convicted by a federal jury in Boston of 77 counts, including racketeering, racketeering conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead.

U.S. Department of Justice Press Release. Food and Drug Administration. Jan. 31, 2019. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/january-31-2018-new-england-compounding-center-pharmacist-sentenced-role-nationwide-fungal

"Under section 501(a)(2)(B) of the FD&C Act, a drug is deemed to be adulterated if it is not produced in accordance with CGMP."



Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Center for Drug Evaluation and Research. "Current Good Manufacturing Practice-Guidance for Human Drug Compounding." *U.S. Food and Drug Administration*, FDA, www.fda.gov/regulatory-information/search-fda-guidance-documents/current-good-manufacturing-practice-guidance-human-drug-compounding-outsourcing-facilities-under.

503B Current Good Manufacturing Practices (cGMP)

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cGMP – Guidance for Industry

Table of Contents

Quality Assurance Activities

- Purpose is to ensure that proper procedures are consistently followed and that the end product is of high quality and safe for the patient
- Quality Control Unit
  - Independent Unit: Sole responsibility is to ensure quality in compounding procedures and products
  - Adequate staffing of Quality Control Unit
  - Sterility Sampling & Testing
  - "The quality control unit must periodically (at least annually)…"
    - ✓ Results of environmental monitoring
    - ✓ Results of personnel monitoring
    - ✓ Where water is used as a component in the drug product, results of water system testing for water that is purified/processed on-site, or if water is purchased as an incoming component, testing results from the supplier or results of testing conducted by the outsourcing facility
    - ✓ Results of finished drug product testing
    - ✓ All media fills/process simulations performed since the last review
    - ✓ Periodic scrutiny of operations to ensure adherence to procedures and proper aseptic technique
    - ✓ Complaints, discrepancies, failures and yield variation

Quality Assurance Activities (*continued*)

- Discrepancy and Failure Investigations
  - Institute changes in processes as necessary
- Testing (not limited to)
  - Sterility
  - Endotoxin levels
  - Content assay
  - Impurity assay
  - Particulate matter
  - Reconstitution time
  - Content uniformity
  - Perseverative content testing
  - Microbial enumeration
  - Tests for specific microorganisms
  - Weight/Volume/Counts
  - Container closure integrity testing
- Investigate complaints related to drug products

https://www.edupliance.com/blog/post/3175

Facility Design

"The design of a facility should consider the products produced and must provide the necessary level of control to prevent mix-ups and contamination"

- Clean & Sanitary
- Sterile Drugs – Critical Area must be ISO 5 or better
- Facility Layout
  - Room separation
  - Process flow
- Critical Area must be adjacent to ISO 7
- Alternative Compounding Areas
  - Isolator, adjacent should be ISO 8
  - Restricted Access Barrier, adjacent area should be ISO 7
- Terminally Sterilized Drugs
  - ISO 8 or better

Table 1. ISO Classification of Particulate Matter in Room Air*

ISO Class Name	Particles/m^3
3	35.2
4	352
5	3,520
6	35,200
7	352,000
8	3,520,000

*Limits are in particles of 0.5 µm and larger per cubic meter (current ISO) measured under dynamic conditions. Adapted from ISO 14644-1:2015, Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness by particle concentration.

ISO = International Standards Organization

Facility Design (*Continued*)

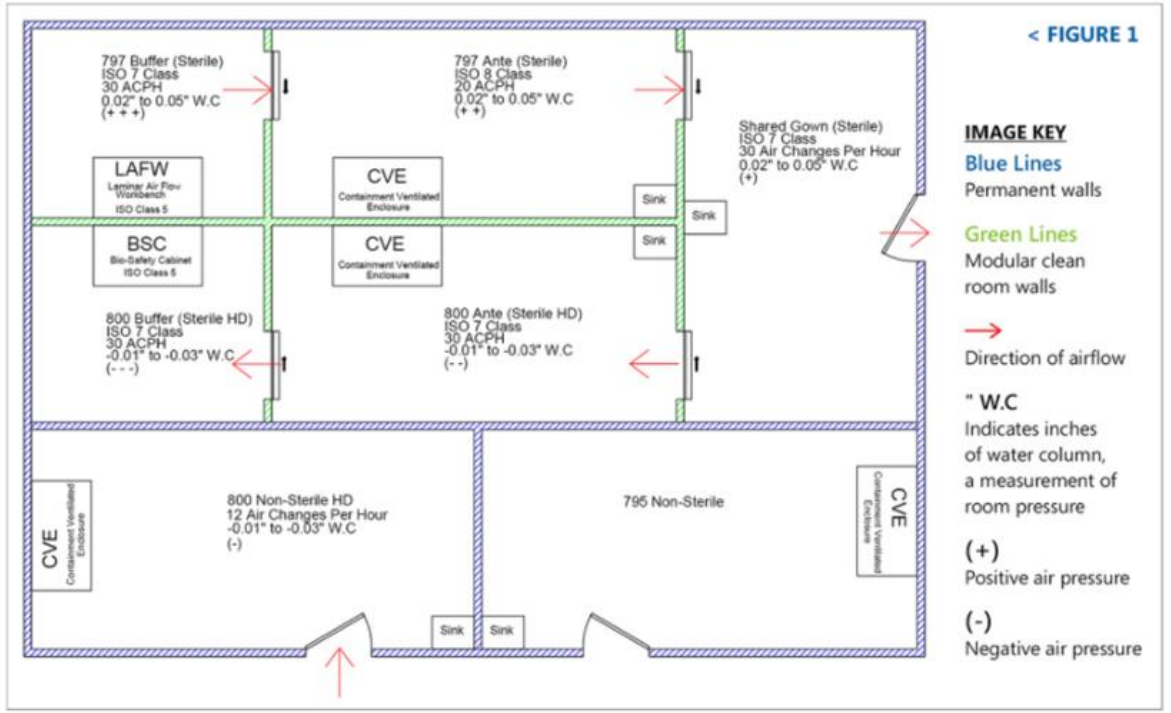
ISO 5 Critical Area Testing

- Air flow studies under operational conditions
- HEPA periodic testing/recertification at least twice a year
- Air velocities
- ISO 5 Unit relocation and requalification

https://edgepharma.com/products/

Control Systems & Procedures for Maintaining Suitable Facilities

- Separate or defined areas for facility operations
- Assign responsibility for sanitation
- Detailed cleaning schedule
  - Cadence
  - Methods
  - Equipment
  - Materials and cleaning agents used
  - Validated program
- Multi-use facilities and non-dedicated equipment
- Sterile vs purified water for rinsing equipment and utensils



https://www.pccarx.com/Blog/important-considerations-for-clean-room-design-rssid

Environmental & Personnel Monitoring

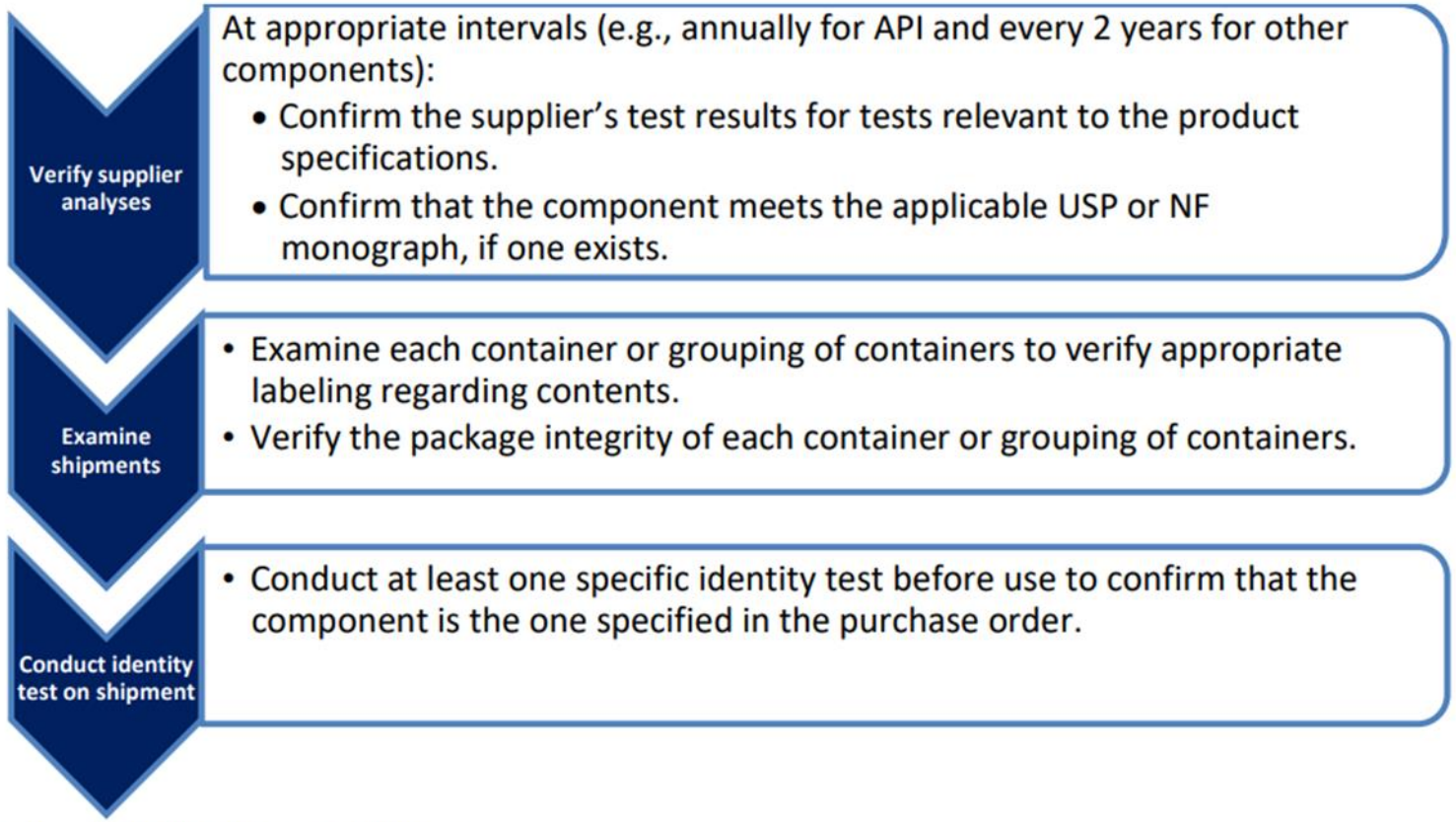
- Should be commensurate with the risk to product quality
  - Aqueous based vs non-aqueous based non-sterile
  - Sterile drugs (at least daily)
  - Product residue
- Procedures should be well defined, documented and supported by scientific literature
- Cover all production shifts
- Daily ISO 5 zones during operations
- Established actions when excursions occur
- Personnel
  - No exposed skin in ISO 5 area
  - Critical sites
  - Monitoring should take place before planned disinfection

Equipment, Containers & Closures

- Equipment must be qualified as capable of performing its intended functions or operations before 1st use
- Outsourcing facilities may choose to use single-use disposable equipment
- Containers and Closures must:
  - Be scientifically sound and appropriate
  - Tested under proper storage conditions over the expiry period
  - Examined and tested before use
  - Stored to protect sterility and integrity
  - If excursions occur, containers must be retested for integrity
- Containers and Sterility
  - Suppliers packaging
  - If pre-sterilized containers are not used

Components

Figure 1. Using a Supplier's COA in Lieu of Testing*



* See §§ 211.84(d)(2) and 211.82(a).

API = Active Pharmaceutical Ingredient

Production & Process Controls

- Written procedures for consistent production
- Visually examine all equipment, components, containers before production
- “Process Loss”
- General Production and Process Controls
  - Reduce bioburden
  - Minimize holding time in process
- Drug Product Sterilization
  - Terminal sterilization
  - Aseptic processing
    - ✓ Sterilize immediately before filling into the final container
    - ✓ Personnel training
    - ✓ Personnel techniques to maintain sterility
    - ✓ All aseptic manipulations, should be performed under unidirectional flow that is ISO 5 or better
    - ✓ Media fills to validate process

Release Testing

- Finished drug products are required to be tested
- Quality Control Unit responsibility
- Specifications to ensure quality of finished product
  - Identity and strength of the active pharmaceutical ingredient
  - Purity
  - For drug products purporting to be sterile and/or nonpyrogenic, sterility and a limit for bacterial endotoxins of the drug product
  - Antimicrobial effectiveness for sterile drug products labeled as multiple dose and for aqueous non-sterile drug products labeled as multiple dose
- Additional quality testing to meet USP monograph
  - Color, clarity
  - pH, if applicable (e.g., for aqueous formulations)
  - For drug products that are not solutions, content uniformity
  - For drug products that are non-sterile, microbial testing
  - For drug products that are solutions purporting to be sterile, a limit for visible particles and subvisible particles (10µm-100µm)

Stability/Expiration Dating for Compounded Drug Products

Table 2. BUDs for Non-Sterile Compounded Drug Products, by Aggregate Batch Size

Aggregate Batch Size (over 6-month reporting period)	Default BUD (no testing)	BUD Based on Limited Stability Testing
≤5,000 units	Default BUD, which may be further limited by literature or other scientific information. See Appendix B for the conditions that must be met.	Data-driven stability program. See Appendix B for the conditions that must be met.
>5,000 units	N/A. Default BUDs are not applicable to large aggregate batch sizes.	Data-driven stability program. See Appendix B for the conditions that must be met.

Table 3. BUDs for Sterile Compounded Drug Products, by Aggregate Batch Size

Aggregate Batch Size (over 6-month reporting period)	Default BUD (no testing)	BUD Based on Limited Stability Testing
≤1,000 units	Default BUD, which may be further limited by literature or other scientific information. See Appendix B for the conditions that must be met.	Data-driven stability program. See Appendix B for the conditions that must be met.
>1,000 units	N/A. Default BUDs are not applicable to large aggregate batch sizes.	Data-driven stability program. See Appendix B for the conditions that must be met.

Stability/Expiration Dating for Compounded Drug Products (*Continued*)

Default BUD (No Testing) for Non-Sterile Drug Products: Aggregate Batch Size ≤ 5,000 Units

- Water activity Testing

Type of Product	Storage Conditions	
	Controlled Room Temperature (20° to 25°C)	Refrigerator (2° to 8°C)
Solid dosage forms	180 days	N/A
Water activity >0.6	Preserved: 30 days Unpreserved: Not applicable	Preserved: 30 days Unpreserved: 14 days
Water activity ≤0.6	90 days	N/A

Stability/Expiration Dating for Compounded Drug Products (*Continued*)

Default BUD (No Testing) for Sterile Drug Products: Aggregate Batch Size ≤ 1,000 Units

Processing Conditions	Contains a Preservative?	Storage Conditions		
		Controlled Room Temperature (20° to 25°C)	Refrigerator (2° to 8°C)	Freezer (-25° to -10°C)
• Finished drug product is aseptically processed; and • A sterility test has not been completed before release	No	6 days	9 days	45 days
	Yes	28 days	42 days	45 days
• Finished drug product is terminally sterilized; • A validated sterilization cycle that uses physical, chemical, or biological indicators is employed; and • A sterility test has not been completed before release	No	14 days	28 days	45 days
	Yes	28 days	42 days	45 days
• Finished drug product is aseptically processed or terminally sterilized and has a completed, passing sterility test before release	No	28 days	42 days	45 days
	Yes	42 days	42 days	45 days

Stability/Expiration Dating for Compounded Drug Products (*Continued*)

- Enforcement Policy Regarding the Use of Limited Stability Testing to Assign a BUD
  - Incorporate stability-indicating test methods that are reliable, meaningful and specific
  - Evaluate samples of the drug product in the same container-closure system and with the same label that will be affixed
  - Evaluate samples for stability that are representative of the batch
  - Suitable storage conditions
  - BUD is no longer than 12 months
  - Many tests including nondestructive tests, destructive chemical tests, microbiological tests, sterility or container-closure integrity tests

Stability/Expiration Dating for Compounded Drug Products (*Continued*)

- Bracketing
  - If 3 or 4 drug product strengths, concentrations, or volume presentations are produced, test the high and low extremes
    - ✓ (e.g., if available strengths include 2.0 mg/mL, 3.5 1745 mg/mL, 5.0 mg/mL and 10.0 mg/mL, test 2.0 mg/mL and 10.0 mg/mL)
  - If 5-10 drug product strengths, concentrations, or volume presentations are produced, test the high and low extremes and 1 intermediate case.
  - If more than 10 drug product strengths, concentrations, or volume presentations are produced, test the high and low extremes and 2 intermediate cases.

Packaging & Labels

- Packaging and labels must be appropriate to maintain integrity until it is administered to the patient
  - Protection against foreseeable external factors
  - Controls to examine labels and separation of labeling of different products
  - Packaging records
  - Label of finished product examined prior to release

COMPANY ANNOUNCEMENT

Meitheal Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Cisatracurium Besylate Injection, USP 10mg per 5mL Due to Mislabeling

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/meitheal-pharmaceuticals-inc-issues-voluntary-nationwide-recall-cisatracurium-besylate-injection-usp

Reserve Samples / Complaint Handling

- Reserve Samples
  - Reserve sample that is representative of each lot must be retained and stored under conditions consistent with product labeling
    - ✓ Reserve sample is held for at least 30 days following expiration date
    - ✓ Quantity held consists of amount to run all necessary tests required at release
- Complaint Handling
  - Outsourcing facilities must have procedures for handling complaints that they receive about their compounded drug products
    - ✓ Complaints must be reviewed by the quality control unit to determine if an investigation is needed
    - ✓ If it is determined that an investigation is needed, it will be evaluated by the quality control unit and appropriate additional personnel
    - ✓ Complaint handling procedures must include provisions for review to determine whether the complaint represents an adverse event that must be reported to FDA

503B Drug Selection

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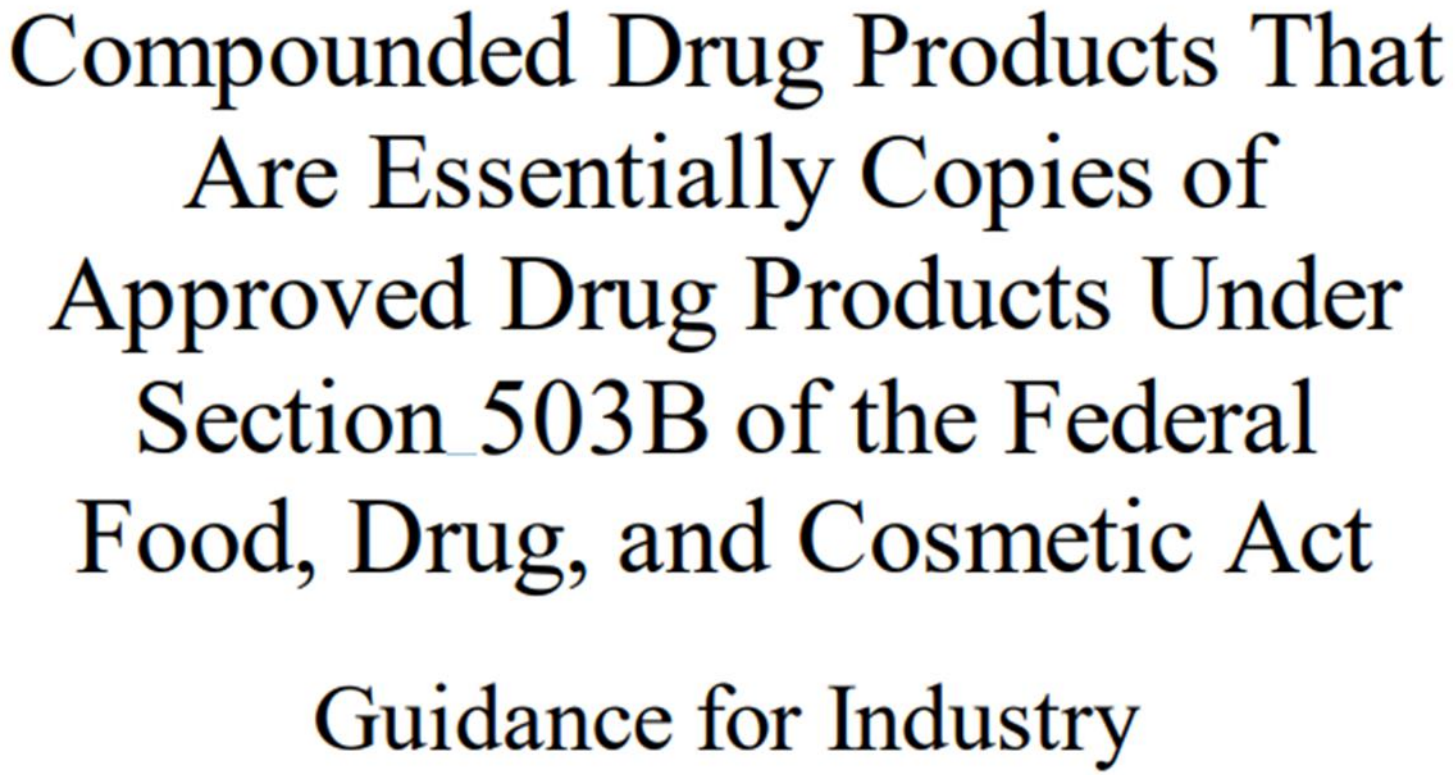
Bulk Drug Substance List

- Outsourcing facilities, which register with FDA, compound under section 503B and may only use bulk drug substances in compounding that:
  - Are used to compound drug products that appear on FDA's drug shortage list at the time of compounding, distribution and dispensing; or
  - Appear on FDA's list of bulk drug substances for which there is a clinical need (the 503B bulks list)
- August 2020 – FDA's announcement affects the following bulk drug substances:
  - To be excluded: (1) diazepam, (2) dobutamine hydrochloride (HCl), (3)dopamine HCl, (4) edetate calcium disodium, (5) folic acid, (6) glycopyrrolate, (7) hydroxyzine HCl, (8) ketorolac tromethamine, (9) labetalol HCl, (10) mannitol, (11) metoclopramide HCl, (12) moxifloxacin HCl, (13) nalbuphine HCl, (14) polidocanol, (15) potassium acetate, (16) procainamide HCl, (17) sodium nitroprusside, (18) sodium thiosulfate and (19) verapamil HCl
  - To be included: (1) diphenylcyclopropenone (DPCP), (2) glycolic acid, (3) squaric acid dibutyl ester (SADBE) and (4) trichloroacetic acid (TCA)

1. Center for Drug Evaluation and Research. "Bulk Drug Substances Used in Compounding." *U.S. Food and Drug Administration*, FDA, www.fda.gov/drugs/human-drug-compounding/bulk-drug-substances-used-compounding.
2. "FDA Moves to Exclude 19 Bulk Drug Substances from 503B Bulks List: Perspectives: Reed Smith LLP." *FDA Moves to Exclude 19 Bulk Drug Substances from 503B Bulks List | Perspectives*, www.reedsmith.com/en/perspectives/2020/08/fda-moves-to-exclude-19-bulk-drug-substances-from-503b-bulks-list

Essentially Copies



The 1 Mile Radius Rule

Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

Guidance for Industry

COVID-19 503B Temporary Guidance

Contains Nonbinding Recommendations

Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised)

Guidance for Industry

503B Audits Conducted by the Food and Drug Administration (FDA)

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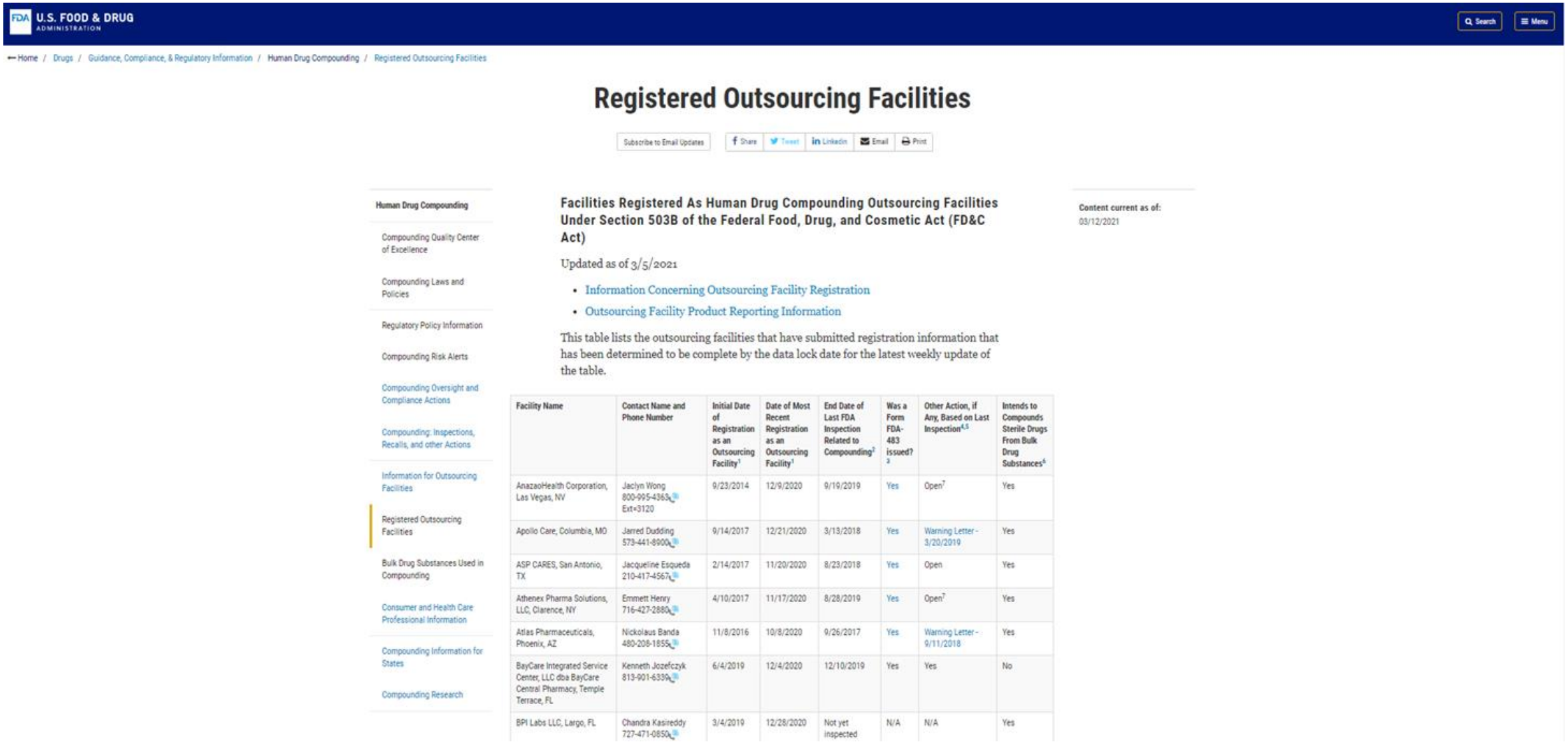
Registered Outsourcing Facilities

https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities



U.S. FOOD & DRUG ADMINISTRATION

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Registered Outsourcing Facilities

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Human Drug Compounding

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- Compounding: Inspections, Recalls, and other Actions
- Information for Outsourcing Facilities
- Registered Outsourcing Facilities
- Bulk Drug Substances Used in Compounding
- Consumer and Health Care Professional Information
- Compounding Information for States
- Compounding Research

Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Content current as of: 03/12/2021

Updated as of 3/5/2021

- Information Concerning Outsourcing Facility Registration
- Outsourcing Facility Product Reporting Information

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing Facility[1]	Date of Most Recent Registration as an Outsourcing Facility[1]	End Date of Last FDA Inspection Related to Compounding[2]	Was a Form FDA-483 issued?[3]	Other Action, if Any, Based on Last Inspection[4,5]	Intends to Compounds Sterile Drugs From Bulk Drug Substances[6]
AnazaoHealth Corporation, Las Vegas, NV	Jaclyn Wong 800-995-4363 Ext=3120	9/23/2014	12/9/2020	9/19/2019	Yes	Open[7]	Yes
Apollo Care, Columbia, MO	Jarred Dudding 573-441-8900	9/14/2017	12/21/2020	3/13/2018	Yes	Warning Letter - 3/20/2019	Yes
ASP CARES, San Antonio, TX	Jacqueline Esqueda 210-417-4567	2/14/2017	11/20/2020	8/23/2018	Yes	Open	Yes
Athenex Pharma Solutions, LLC, Clarence, NY	Emmett Henry 716-427-2880	4/10/2017	11/17/2020	8/28/2019	Yes	Open[7]	Yes
Atlas Pharmaceuticals, Phoenix, AZ	Nickolaus Banda 480-208-1855	11/8/2016	10/8/2020	9/26/2017	Yes	Warning Letter - 9/11/2018	Yes
BayCare Integrated Service Center, LLC dba BayCare Central Pharmacy, Temple Terrace, FL	Kenneth Jozefczyk 813-901-6339	6/4/2019	12/4/2020	12/10/2019	Yes	Yes	No
BPI Labs LLC, Largo, FL	Chandra Kasireddy 727-471-0850	3/4/2019	12/28/2020	Not yet inspected	N/A	N/A	Yes

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Inspection Citations

- FDA Form 483
  - Issued at the end of the inspection
  - Observations of any condition that may constitute a violation of the FD&C Act
  - Clear, specific and significant observations
  - These are inspectional observations and do not represent a final agency determination regarding compliance
  - Companies are responsible to take corrective action to address the cited objectionable conditions and any related non-cited objectionable conditions that might exist
  - 503B facility is encouraged to respond in writing

483 Example

483 issued

OBSERVATION 3

Employees engaged in the manufacture, processing, packing, and holding of a drug product lack the education, training, and experience required to perform their assigned functions.

Specifically, there are no documented training records prior to 1/9/18 for your personnel who were involved in processing operations of (b)(4) lots of sterile injectable product between 10/17/17 and 1/9/18. This includes distributed products Vancomycin 1250 mg in 250 mL of 0.9% Sodium Chloride lot (b) (4) and 8.4% Sodium Bicarbonate Injection 50 mEq (1mEq/mL) 50 mL Syringe lot (b) (4).

Warning Letter Example

"During the inspection, the investigator noted that drug products you produced failed to meet the conditions of section 503B of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain provisions of the FDCA. In addition, **the investigator noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.** "

- Failure to Meet the Conditions of Section 503B
- Violation of the FDCA
- Misbranded Drug Products
- Failure to Report Drugs
- Corrective Actions

"You should take prompt action to correct the violations cited in this letter. **Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.**

"Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations."

Conclusion

"The Drug Quality and Security Act, signed into law on November 27, 2013, created a new section 503B in the Federal Food, Drug and Cosmetic Act. Under section 503B, a compounder can become an outsourcing facility.

The law defines an outsourcing facility as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B."

Center for Drug Evaluation and Research. "Information for Outsourcing Facilities." *U.S. Food and Drug Administration*, FDA, www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities.

Assessment Questions

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Assessment Question #1

Which citation is more severe to a 503B manufacturing facility?

- Complete Response Letter
- Warning Letter
- FDA Form 483
- Manufacturing Ticket

Assessment Question #1 – Correct Response

Which citation is more severe to a 503B manufacturing facility?

A. Complete Response Letter
B. Warning Letter
C. FDA Form 483
D. Manufacturing Ticket

Assessment Question #2

Quality Assurance Activities includes which of the following:

A. An independent quality control unit
B. Where water is used as a component of the drug product, results of water system testing for water
C. Investigations and corrective action of failures and discrepancies
D. Each batch of finished drug product is sampled and tested
E. All of the above

Assessment Question #2 – Correct Response

Quality Assurance Activities includes which of the following:

A. An independent quality control unit
B. Where water is used as a component of the drug product, results of water system testing for water
C. Investigations and corrective action of failures and discrepancies
D. Each batch of finished drug product is sampled and tested
E. All of the above

Assessment Question #3

503B facilities may compound an approved drug by the FDA if the drug is on the FDA's drug shortage list.

A. True
B. False

Assessment Question #3 – Correct Response

503B facilities may compound an approved drug by the FDA if the drug is on the FDA's drug shortage list.

A. True

B. False

References

Slide 7:

1. "Lethal Medicine Linked to Meningitis Outbreak." *CBS News*, CBS Interactive, www.cbsnews.com/news/lethal-medicine-linked-to-meningitis-outbreak-10-03-2013/4/.
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Thank you!!

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