503B Outsourcing Facilities

Operations of a 503B Outsourcing Facility

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About the Presenter

Douglas Cammann has been a pharmacist for 29 years and has worked in Retail Pharmacy, Managed Care, Hospital, Consulting, and Compounding Pharmacy settings

Licensed in 21 states

Entered the compounding space in 2009 to operate a 503A pharmacy and Medical supplies distributor

Joined AnazaoHealth in 2013 and oversaw transition of the 503A operations to FDA registered 503B outsourcing facility

Currently serves as Vice President of Operations for AnazaoHealth's FDA registered 503B outsourcing facility in Las Vegas Nevada and Consults for 7 ambulatory surgery centers

Operations

- 503B operations
  - Products
    - What Products do we produce?
    - What Patients do we serve?
  - Operations
    - Differences in regulatory oversight
    - What makes us different from a traditional 503A compounding pharmacy?
  - Processes/Quality
    - CGMP operations

What Type of Products do 503B Facilities Produce?

- Sterile Injectable Products
  - Hormone Injections
  - Vitamin Injections
  - Intravenous Solutions (Hospitals)
  - Manufacturer Shortage Products
- Sterile Implantable Products
  - Implantable Hormone Pellets
  - Naltrexone Pellets
- Topical Products
  - Numbing Creams
- Dental Products
  - Oral Rinses for in office use

What patients do we serve?

- 503B outsourcing facilities serve patients with many different needs
  - Hormone replacement Patients
  - Wellness Patients
  - Hospital Patients
  - Patients whose needs cannot be met due to shortages in commercially available drug products
  - And many other patients

Regulatory Comparison

- 503A compounding pharmacies are licensed and regulated by the State BOP's
- 503B outsourcing facilities have dual licensure
  - Registered with the FDA and Licensed by BOP's
- 503As – USP<797> and USP<795> govern the compounding quality
- 503Bs – Current Good Manufacturing Practices for quality (CGMP)
- 503B outsourcing facilities serve a different purpose in the drug supply chain.
  - Perform large batch production in quality equivalent to pharmaceutical manufacturers

CGMP Operations

- CGMP requires the implementation of a robust and thorough system for ensuring that our drug products are consistently produced and controlled according to quality standards
    - Many Hired Consultants from Big Pharma to assist
- 503B's follow CFR 210 and CFR 211 that describe the requirements for manufacturing of drugs and finished pharmaceuticals

CGMP Operations (con't)

- CFR Part 210 – Outlines the minimum GMP requirements covering manufacturing, facilities, and controls for the manufacture, processing, packing, and holding of all drugs in a way that meets the guidelines for safety, quality, and purity.

- CFR Part 211 – Outlines the minimum GMP requirements for finished drug products.
  - Covers the operations of the facility
  - Gives all encompassing direction
  - Examples…

CGMP Operations (con't)

- Buildings, Facilities, and Equipment
  - Sets up requirements for operation, maintenance, and validation of all potential equipment and facilities that are used in the manufacturing of drug products
- People
  - Sets up the need for a quality control unit and training and qualification of personnel used in production of drug products
- Processes
  - Sets up requirements for written procedures for production that assure drug products produced have the identity, strength, quality, and purity they purport or are represented to possess

CGMP Operations (con't)

- CGMP Produced Drug Products
  - Products made under a CGMP system are:
  - Consistent
    - Meet release criteria for potency
  - Safe
    - Meet release criteria for Sterility and Endotoxin limits
  - Effective
    - Vital in the treatment of tens of thousands of patients nationwide

503B Outsourcing Facilities

Thank you!