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Your True Cost of Compliance: Do You Know It?

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Agenda

- Elements of a Compliance Program
- Correlation of Increasing Regulations and Compliance Cost
- Most Common Results of State Audits and FDA Inspections
- Non-Compliance: Audit Findings and Quality Events
- Cost of Investigation and Remediation

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What is the Cost of Compliance??

- Your Entire Business!

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Elements of Compliance - REGS

State Regulations & Licensing (Personnel and Facility)
FDA - FD&C Act, Section 503A
USP 797, 795, 800
FDA Guidance (Insanitary Conditions)
OSHA - 29 CFR 1910.1020 and 29 CFR 1910.1200
EPA - RCRA of 1976

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USP Cost Case Study

- USP <797> / <800> compliance costs were evaluated for a 30-chair infusion clinic
- Costs included: competency assessments, personal protective equipment, closed system transfer devices, labels, cleaning supplies, and environmental monitoring. One-time costs included initial cleanroom construction and renovations.
- **Recurring annual costs were calculated to be $785,207**. One-time costs associated with initial construction and renovations were estimated to be **$1,365,207–$1,535,207 for initial construction and $965,207–$1,005,207 for renovations**.
- Reference: https://journals.sagepub.com/doi/full/10.1177/10781552211048871#:~:text=Recurring%20annual%20costs%20for%20a,and%20%24965%2C207%E2%80%93%241%2C005%2C207%2C%20respectively.

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Elements of Compliance - OPS

Process (SOPs)
Personnel
Facility
Lab / Measurements
Equipment
Materials
Quality System

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Heightening Regulations = Rising Costs

- NECC
- Others

	What	When	Where	Why
Pharmacy 1	-*Serratia marcescens* contamination -Injured 11 -Killed 3	California	2001	-Autoclaving step not performed -Improper facility design -Insufficient training and supervision -Poor labeling
Pharmacy 2	-*Exophiala dermatitidis* -Injured 6 -Killed 1	South Carolina	2002	-Improper autoclaving -Lack of release testing -Poor cleanroom procedures
Pharmacy 3	-*Pseudomonas fluorescens* -Injured 80	Texas	2005	-Sterility test not performed -QA and production issues
Pharmacy 4	-Gram negative bacilli and endotoxins -Injured 11 -Killed 3	Maryland	2005	-Poor EM program -Insufficient training -Inadequate QA -Equipment not maintained
Pharmacy 5	-*Serratia marcescens* -Injured 19 -Killed 9	Alabama	2011	-Faucet water to clean mixing receptacle -Mixing procedures not detailed -Deficient filter and sterility tests
Pharmacy 6	-*Streptococcus mitis* and *Streptococcus oralis* -Injured 12, permanent vision loss	Florida	2011	-Single-use vials used for days/weeks after initial puncture -Inadequate EM and training programs -Non-sterile materials used

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Non-Compliance

Audit Findings

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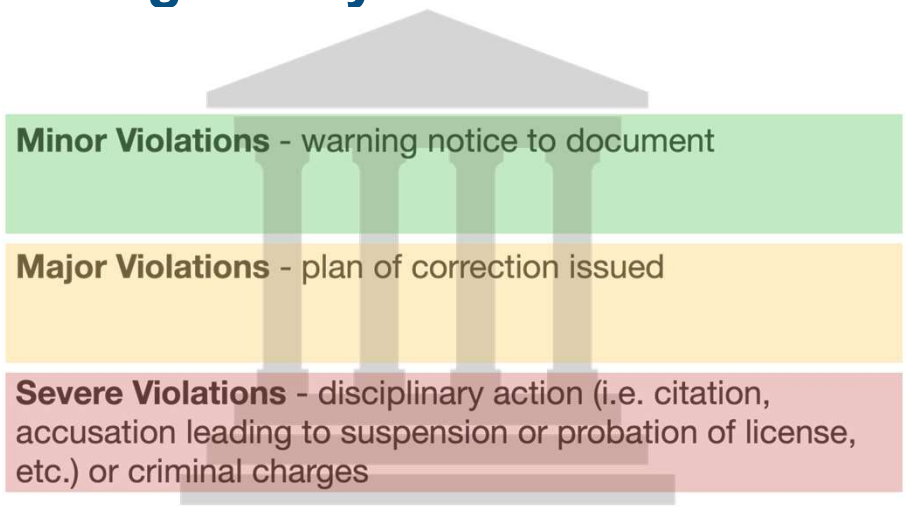
State Regulatory Audit Results



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Most Common State Deficiencies

- Noncompliance with facility or equipment
- Incomplete master formula requirements
- Lacking process validations
- Incorrect or unjustified beyond used date assignments
- Insufficient quality assurance program
- Failure to maintain appropriate records

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Federal Regulatory Audit Results

Common Theme: Insanitary Conditions

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FDA 483s – Non-Sterile Compounding

- "Your firm produced hazardous drug products using shared equipment and utensils, and there was inadequate containment and segregation to prevent cross--contamination of non-sterile drug products."
- "Vermin was observed in an area immediately adjacent to your production area."
- "You produced hazardous drugs without providing adequate cleaning of work surfaces and cleaning of utensils to prevent cross-contamination."
- "Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils and/or personnel to prevent cross-contamination."
- "Your firm cleans product contact equipment, glassware, and utensils with household cleaners after they are used for production of hazardous and potent drugs. There is no assurance that household cleaning detergent is effective in cleaning and removal of product and cleaning agent residue from shared production equipment, glassware, and utensils used in the production of hazardous and potent drugs to prevent cross-contamination."
- "Your firm has not demonstrated appropriate air changes per minute are established and ensured negative pressure is maintained during compounding of Hazardous Drugs."
- "You produced hazardous drugs without providing adequate segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination… All hazardous and non-hazardous drug products produced onsite use shared production and cleaning equipment…We observed operators routinely touching ancillary equipment, such as calculators, keyboards, computer mice, and printers, that contained apparent white powder while producing drug products. These pieces of ancillary equipment are not routinely cleaned and are not product dedicated… We observed operators placing their gloved hands inside of [these] bags to dispose of waste. These bags are not changed between different product formulations… Operators do not change gloves between different product formulations."

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Non-Compliance

Quality Events

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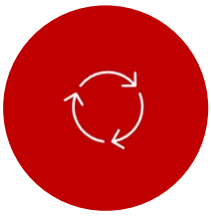
Quality Related Events

COMPLAINTS

ADVERSE EVENTS



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Warning Letter – ADE Related to Undeclared & Elevated Drug Content

- "FDA received MedWatch reports in April 2020 regarding adverse events experienced by 74 patients associated with Finasteride Plus capsules produced by your firm that were labeled as containing 1.25 mg per capsule. FDA analysis of a sample of this product found that it contained an average of 1.49 mg of finasteride per capsule. Additionally, FDA analysis of this sample found that the capsules contained undeclared minoxidil, an antihypertensive drug, at an average of 127.86 mg per capsule, which greatly exceeds the amount found in FDA approved products."

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Recall Cost Case Study

- Safety, sanitary problems prompt scores of drug recalls
  - Drug: Compounded Calcium Gluconate Injection
  - Contaminated with: Rhodococcus equi bacteria
  - 15 sickened, 2 died
  - Reported by: USA Today, Oct. 7, 2014
- "**The company lost about $2 million on the recall**, according to spokesman… and it has suspended all compounding of sterile medications until the FDA approves its plan to resume production."
- Reference: https://www.usatoday.com/story/news/nation/2014/10/07/compounding-pharmacy-recalls-inspections-contamination/16472741/

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Case Study
Cost Savings With Error Reduction

- Can a robot reduce health care costs by preventing errors that can cause adverse drug events?
- An average of 1,000 simulations resulted in the prevention of 5,420 medication errors and associated savings of $288,350 per year.
- Reference: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4252201/#:~:text=Thus%20it%20provided%20a%20reliable,savings%20of%20%24288%2C350%20per%20year.

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Cost of Investigation & Remediation

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Cost of Investigations

- Lost time to production
- Opportunity loss
- Waste of human resources

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Cost of Compliance Personnel

Personnel	Hourly Fee Range	Example
Designated Person (RPh)	$80-$150	Annual Salary: $166,400 - $312,000
Consultant	$250-$500	10HR Gap Analysis: $2,500 - $5,000 80HR 483 Remediation: $20,000 - $40,000
Attorney	$600-$1200	Retainer for 50HR $30,000 - $60,000 Retainer for 400HR $240,000 - $480,000
Expert Witness	$400-$750	Retainer for 80HR $32,000 - $60,000

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Cost of Expenditures

CapEx / OpEx	Hourly Fee Range
Facility Construction	$1,000s-$100,000s
Equipment Purchase	$100s-$10,000s
Material Purchase	$100s-$1,000s
Laboratory Costs	$100s - $10,000s
Additional Human Resources	$10,000s-$100,000s

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Cost of SOP Updates & Training

- Requires time away from production to:
  - Draft changes
  - Peer review changes
  - Approve changes
  - Train on changes

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Indirect Costs of Non-Compliance

- Damaged reputation
- Competitor opportunity
- Loss of market share
- Distractions from growth

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Resources – Standards & Guidance

- USP <1163> – Quality Assurance Program
- USP <795> Pharmaceutical Preparations – Nonsterile Preparations FAQs
- USP <797> Pharmaceutical Preparations – Sterile Preparations FAQs
- FDA Guidance for Industry – Insanitary Conditions
- FDA Web Page - Compounding Inspections, Recalls, and Other Actions

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Thank You!

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