

## Key Services for 503B Pharmaceutical Outsourcing Facilities

### Industrial Hygiene and Environmental Solutions for Pharmaceutical Outsourcing Facilities

VERTEX offers comprehensive services to support the unique needs of 503B pharmaceuticals facilities. Our expert team ensures compliance, safety, and optimal performance in your critical environments.

### Facility Design and Design Plan Review

- Collaborate with architects and engineers to optimize facility layout
- Review plans for compliance with USP <797>, <800>, and cGMP requirements
- Recommend improvements for workflow efficiency and contamination control
- Ensure proper site installation of primary engineering controls and supporting systems

### Cleanroom Certification

- Perform comprehensive cleanroom testing and certification
- Evaluate HEPA filter integrity and room pressurization
- Conduct particle counting and air exchange rate measurements
- Provide detailed reports and recommendations for maintaining cleanroom standards

### Environmental Monitoring

- Develop and implement robust environmental monitoring programs
- Perform viable and non-viable air sampling
- Conduct surface and personnel monitoring
- Trend and analyze data to identify potential issues before they become problems
- Provide forensic risk-based investigations into microbial excursions

### Work Practice Evaluations

- Assess current standard operating procedures (SOPs) for effectiveness
- Observe personnel practices and recommend improvements
- Identify potential sources of contamination or inefficiency
- Develop tailored training programs to address identified gaps

### Employee Safety and Health Training

- Deliver comprehensive training on aseptic techniques
- Educate staff on proper gowning procedures and cleanroom behavior
- Provide hazard communication and personal protective equipment (PPE) training
- Offer customized safety modules for handling hazardous drugs and chemicals



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## Primary Engineering Controls (PEC) Performance Testing

- Evaluate biological safety cabinet (BSC) and laminar airflow workstation performance
- Conduct smoke studies to visualize airflow patterns
- Perform HEPA filter integrity testing on PECs
- Assess containment capabilities for hazardous drug compounding areas

## Surrogate Containment Verification Sampling

- Utilize non-hazardous surrogate powders and novel tracers to simulate API handling
- Conduct air and surface sampling to evaluate containment effectiveness
- Identify potential exposure risks and recommend control measures
- Validate engineering controls and work practices for personnel safety

## Additional Services

- Indoor air quality assessments
- Ventilation system evaluations
- Microbial investigations and remediation
- Ergonomic assessments for compounding areas
- Noise level monitoring and control recommendations
- Chemical inventory management and safety data sheet (SDS) review
- Waste management and disposal consultations
- Regulatory compliance audits (FDA, EPA, OSHA)
- Emergency response planning for chemical spills or exposures

## Why Choose VERTEX?

1. **Expertise:** Our team of Certified Industrial Hygienists (CIHs), registered cleanroom certifiers, and environmental professionals specialize in pharmaceutical facility requirements.
2. **Comprehensive Approach:** We offer end-to-end solutions, from facility design to ongoing monitoring and training.
3. **Cutting-edge Technology:** VERTEX utilizes state-of-the-art equipment and methodologies to ensure accurate and reliable results.
4. **Customized Solutions:** We tailor our services to meet the unique needs of your 503B facility, considering your specific processes and products.
5. **Regulatory Compliance:** Our services are designed to help you meet and exceed regulatory requirements, including USP <797>, <800>, and cGMP guidelines.
6. **Continuous Improvement:** We don't just identify issues; we work with you to implement lasting solutions and drive ongoing improvements in your facility.
7. **Client-Focused Approach:** VERTEX prioritizes clear communication, timely reporting, and collaborative problem-solving to ensure your success.

Contact VERTEX today to learn how we can support your 503B pharmaceuticals facility in maintaining a safe, compliant, and efficient operation.



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