

# EHS SERVICES FOR PHARMACEUTICAL COMPANIES



## Integrating environmental and engineering resources for real-world solutions

Barr's team of environmental health and safety (EHS) and engineering professionals have experience in the pharmaceutical industry, including people who held positions with responsibility for environmental compliance at pharmaceutical sites. Our fields of expertise include air and water quality permitting, waste compliance, wastewater treatment, and environmental remediation.

Our team has implemented multi-media environmental compliance programs and assisted clients with developing flexible Title V permits for large R&D sites—encompassing one million square feet of laboratory space and a power and steam-generation plant.

We develop and implement waste management programs addressing RCRA hazardous, pharmaceutical, biohazardous, and medical waste and conduct hands-on compliance-program implementation and management for facilities ranging from biotech operations to large R&D campuses.

Barr's EHS group develops environmental plans for pharmaceutical operations addressing pollution prevention, storm-water-pollution prevention, refrigerant management, and waste management. In addition, we handle all forms of environmental reporting to local, state, and federal government agencies, including air



emissions, RCRA biennial reports, Toxic Release Inventory reports, and Tier I/Tier II Community Right-to-Know reports for hazardous-materials use and storage.

## Air quality permitting and compliance

Understanding air emissions and regulatory applicability can be a significant challenge for pharmaceutical and biotech companies due to unique equipment and processes, along with dynamic batch operations and complex federal, state, and local regulations. Many operations use custom-designed equipment and chemical processes that can generate air pollutants, including volatile organic compounds (VOCs), hazardous air pollutants (HAPs), and particulate matter (PM).

Barr leverages our experience in air permitting to help our clients understand their unique processes, develop the best methodologies to assess air emissions, develop flexible permitting strategies, and navigate the complex regulatory landscape, which includes the pharmaceutical Maximum Achievable Control Technology (MACT) standard along with the chemical manufacturing area source rule. We've successfully permitted new manufacturing facilities, existing liquid and solid dosage formulation operations, and new and existing nucleic acid manufacturing operations to accommodate new products or production increases. Barr has negotiated flexible permitting provisions, including the ability for pilot operations at a Michigan facility to

accommodate new state air toxics through a self-implementing evaluation and notification process in lieu of permit modifications.

Barr has also successfully completed air permitting projects for facility support operations such as boilers, emergency generators, and wastewater treatment. With in-house expertise in dispersion modeling, health risk assessments, air-quality-control system cost-effectiveness evaluations, and compliance stack testing, Barr can execute complex permitting projects and help design emissions- and material-tracking systems to support post-permit compliance.

### **Rinse water and wastewater management**

Equipment rinses and other wastewater containing active pharmaceutical ingredients (APIs) often require targeted management to accommodate the diverse and bioactive nature of ingredients. Many APIs have downstream aquatic toxicity impacts, so treatment targets for whole effluent toxicity (WET) may need to be considered. Barr offers many water management services to the pharmaceutical sector, including alternatives analysis, pretreatment negotiation with local wastewater utilities, NPDES permitting, bench- and pilot-testing, WET studies, and full-scale design and commissioning for water treatment systems.

### **Engineering design of air pollution control equipment**

Barr's experience with air pollution control systems allows clients to continue working with a single firm—from permitting through equipment specification and installation. For example, a confidential biomanufacturing client hired Barr to assist with the procurement of three electric catalytic oxidizers (ECOs) for one of its facilities. The ECOs were installed to reduce volatile organic compound emissions. Barr

helped with selection of the air-quality control system technology, corresponded with suppliers, reviewed proposals, and recommended a supplier. Barr also performed detailed balance-of-plant design, including design of mechanical ducting and booster fans, electrical power supply, and controls integration of the ECO PLC to the facility's control system via network and communication link. Barr developed a general-notes drawing to document installation and material specifications and prepared a conceptual stack drawing for use during the bidding process and designed a new stack foundation and additional ductwork.

### **EHS compliance and management-system audits**

Because we have substantial experience conducting audits at R&D and manufacturing facilities, we understand their intricacies. When undertaking audits, we work with you to balance cost control with useful feedback. We develop scopes of work that match your budget and schedule by focusing on what's most important to your operation. We can also integrate EHS regulatory compliance and management-system audits (e.g., ISO 14001) to improve efficiency. Our audit schedules minimize interruptions and save time and energy. Barr also specializes in facility-specific reviews for compliance with federal, state, and local regulations that govern almost any environmental program (e.g., air quality, the emergency planning and community right-to-know act, hazardous and solid waste, and wastewater).

### **The bottom line?**

Barr makes your job easier and helps your operation avoid compliance problems, allowing your company to keep its resources focused on developing and manufacturing new products.