

Environmental Compliance for the Pharmaceutical Industry

Whether operations consist of sterile product manufacturing or biopharmaceutical production, pharmaceutical industries are typically subject to environmental regulations due to chemicals used in production, various wastes, or process streams. During economically challenging times, many organizations do not have adequate internal resources or time to manage more complex environmental regulation requirements, including planning, permitting, and reporting. As a result, some questions are problematic such as: Which regulations are applicable? What information do I need to provide for a permit application? How do I collect samples in accordance with my permit?

BB&E has the experience to guide organizations through the regulatory maze and strives to develop efficient solutions. We have provided compliance support in all 50 states and Puerto Rico, including over 90 private sector facilities and over 10 years of continuous support for pharmaceutical companies. Our work is tailored for each situation; for instance, during a recent flow meter installation, solar power was utilized allowing the facility to use sustainable technology while also decreasing the maintenance requirements of a typical battery powered unit. BB&E's staff of environmental professionals can assist your operation's environmental compliance needs at the precise level of effort you require, and our low overhead and flexibility allow for unique, innovative, and cost effective solutions.

Our specific environmental compliance experience includes:

- Analyzing operations to maximize exemptions to environmental regulations;
- Determining applicability and reporting requirements for air, storm water, wastewater, and/or storage tank permits;
- Publicly owned treatment works (POTW) negotiations, permitting, compliance sampling, and reporting;
- Implementation of flow- and time- proportional sampling per permit requirements;
- Automated wastewater sampling per discharge permit requirements;
- Conducting stack testing in compliance with facility air permits;
- Air emissions reporting and calculations;
- Gas turbine cogeneration systems permitting, reporting, and testing;
- Preparing and submitting required regulatory reports such as Tier II, TRI, annual air emission reports, and wastewater monitoring reports;
- Preparing and certifying required plans such as Hazardous Waste Contingency Plans; Hazardous Waste Management Plans; Spill Prevention, Control, and Countermeasure Plans (SPCCP); Storm Water Pollution Prevention Plans; or combining all plans into a federally approved Integrated Contingency Plan (ICP) format;
- Conducting third-party, objective, environmental compliance audits.



For additional information or to speak to someone regarding BB&E's environmental capabilities, please contact Mr. Aaron Etnyre at 248-489-9636 x303, or email aetnyre@bbande.com

