



SERVICES FOR PHARMACEUTICAL/BIOTECHNOLOGY COMPANIES

Current and future environmental issues will continue to significantly affect pharmaceutical facilities throughout the United States. Federal, state, and local agencies implement environmental regulations, policies, and fees. This causes the development and operation of pharmaceutical facilities to be more costly and burdensome. The environmental factors affecting industrial facilities seem to grow more demanding every year. Important federal regulations include the Pharmaceutical Effluent Guidelines and the Pharmaceutical MACT (air). Heritage has significant ongoing experience with both.

Wastewater issues include limitations and standards for four pharmaceutical manufacturing subcategories: A (Fermentation), B (Extraction), C (Chemical Synthesis), and D (Mixing, Compounding, and Formulating). EPA has published final direct and indirect discharge standards for the four subcategories, as well as final MACT standards under the Clean Air Act. The MACT standards final rule controls emissions of hazardous air pollutants. There have been and will continue to be new and modified regulatory and policy documents issued by EPA in both the wastewater and air segments.

Heritage Technical Services, Inc. is an environmental engineering consulting firm that has been providing professional service to pharmaceutical/biotechnology facilities since its founding in 1988. Heritage works extensively with environmental regulations and permitting issues, and also performs resulting feasibility studies. Environmental requirements can result in substantial impacts, potentially affecting pharmaceutical facilities in the next several years and beyond. In this regard, Heritage has worked with numerous healthcare industrial companies, including Centocor, Merck, Unigene Laboratories, ImClone Systems, Johnson Matthey Pharmaceuticals, KVD Pharma, and Ethicon/Johnson & Johnson, to ensure that environmental restrictions are appropriate and to address some or all of the above-noted issues. One pharmaceutical company has been a client on a largely ongoing basis since the early 1990s.

The extensive background of Heritage in environmental regulations, as well as in water, wastewater, and similar infrastructure systems, allows careful but effective application of pressure on behalf of industrial clients with the appropriate regulatory and control agencies to implement only necessary regulations. Consulting advice is also provided to assist pharmaceutical/biotechnology facilities in complying with the resulting appropriate requirements. Heritage has had significant success on behalf of its clients in providing such assistance for more than twenty years, often saving clients substantial amounts of capital and/or operating costs in the process.

Finally, Heritage is a member of the Air & Waste Management Association, Water Environment Federation, and American Water Works Association. This helps to ensure that issues important to pharmaceutical facilities are addressed in an appropriate, understanding, and cost-effective fashion.