



Services for Pharmaceutical/Biotechnology Companies

Current and future hydrology and 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. Important federal regulations include the Pharmaceutical Effluent Guidelines and the Pharmaceutical MACT (air). Heritage has significant 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 a hydrology and environmental engineering consulting firm that has provided 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. Hydrology and 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 hydrology and environmental restrictions are appropriate and to address some or all of the above-noted issues. One pharmaceutical company was a client on an ongoing basis for almost 20 years before encountering major financial problems in the recession starting around 2008.

Heritage has provided expert witness services for litigation concerning facilities involved with research, development, and manufacturing of pharmaceuticals and/or biotechnology products. The issues addressed include groundwater, potable water, aquifer, hazardous waste, spills, contamination, solid waste, landfill, industrial waste, modeling, regulations, and Standard of Care. The firm has also provided expert opinions on regulatory issues to similar facilities addressing waste minimization/pollution prevention, industrial (wastewater) pretreatment, contamination, wastewater treatment, sanitary sewage, regulations, drinking water, and monitoring.

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.