

Biotechnology, Life Science, and Pharmaceutical Manufacturing

Successful operation of a biotechnology, life science or pharmaceutical manufacturing facility requires integration of environmental, health and safety (EH&S) compliance requirements into facility management systems. CAPACCIO has extensive experience in delivering EH&S services to Facility and EH&S Managers. We serve our clients with facility set up and closure protocols; occupational safety and health compliance; preparation and submittal of environmental permits and registrations; design of manufacturing process and laboratory air and water pollution control systems; development and delivery of health safety training services; hazardous waste management; and the availability of on-site EH&S professional staff.

CAPACCIO's services are designed to seamlessly assist your staff in all EH&S areas. We have experience with complex facility operations and EH&S needs. Our staff of engineers, scientists, and regulatory specialists are experienced in a variety of biotechnology, life science and pharmaceutical manufacturing and facilities processes. We enjoy being part of your team and ensuring your facility's success. Keeping manufacturing in the U.S., and "helping industry and the environment prosper" is our mission. Let us show you how we can add value to your operations.

Environmental, Health and Safety On-Site Assistance

CAPACCIO can complement your existing staff or alleviate temporary or long-term workloads with our unique Environmental, Health and Safety on-site Management Program (EHSMP). With EHSMP, you receive the expertise when you need it without hiring new staff and paying a full time salary and benefits. Whether it is one day a week, five days a week, or one day a month, our EH&S professionals can fill gaps resulting from maternity/sick leave, vacation/holiday periods, overseas assignments or employee transition periods.

Environmental, Health and Safety Compliance

Our compliance services include:

- Compliance monitoring reports
- Contingency and emergency response plans
- Chemical and biological safety compliance

- Development of environmental management tools (e.g., environmental compliance calendar)
- DHS chemical facility anti-terrorism standard compliance assistance
- Emissions reports
- Hazardous waste generator training
- Health and safety compliance reviews
- Health and safety training
- Industrial hygiene sampling
- Industrial ventilation design and review
- ISO 14000 and OHSAS 18000 program development and assistance
- Product safety
- Stormwater pollution prevention plans and training
- Spill prevention, control, and countermeasures (SPCC) plans and training
- Tier II reporting
- US DOT registration and site security plans
- Wastewater treatment system operation and maintenance assistance and operator training

Life Science/Biotechnology

- Biological waste management
- Chemical hygiene programs
- Recombinant DNA/DNA handling programs
- DEA controlled substances compliance
- BL-1/BL-2 laboratory set-up
- Facility set-up and closure assistance
- Flammable storage permits and licenses
- Select agent import registrations
- Recycling program development
- Bloodborne pathogens and exposure control programs
- Medical surveillance programs
- Radiation and laser safety

Sustainability Services

- Assessments (Current and Future State)
- Awareness Training
- Benchmarking
- Corporate Customer, Investor, and Stakeholder Reporting
- Management Systems (ISO 9001, ISO 14001, OHSAS 18001)
- Program Development and Implementation

Environmental Permitting

- Permit application preparation for:
 - air pollution control systems and process ventilation
 - water treatment and wastewater treatment systems
 - fuel burning equipment including emergency generators
 - permit application preparation for surface water discharges under the National Pollutant Discharge Elimination System (NPDES) program
- License applications for chemical storage
- Professional engineer's certification of above and underground storage tanks (AST, UST)
- Determinations for Lowest Achievable Emission Rate (LAER), Best Available Control Technology (BACT), and Reasonably Available Control Technology (RACT)
- Total Maximum Daily Load (TMDL) review and consultation

Design and Construction Assistance

- Facility/process review and evaluation
- Design of air and wastewater pollution control/treatment systems
- Design of local exhaust ventilation
- Drawings and specifications
- Treatability and feasibility studies
- Pilot testing
- Bid assistance
- Contaminated soil and groundwater management
- Resident inspection and system start-up

Site Selection

- Identification of development restrictions posed by state environmental regulation and local environmental by-laws
- Identification of special local permit requirements
- Identification of surrounding land use such as residence and other sensitive users
- Assessment of local regulations



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Due Diligence

- Property transaction screening
- ASTM Phase I environmental assessments
- Groundwater investigations

Product Compliance

- European Union (EU) Registrations, Evaluation, and Authorization of Chemicals (REACH)

QUALIFICATIONS

CAPACCIO professionals are:

- Certified Industrial Hygienists
- Certified RABQSA Auditors
- Certified Environmental, Health & Safety Trainers
- Certified Safety Professionals
- Certified Hazardous Materials Managers (CHMM)
- Licensed Professional Engineers
- Licensed Site Professionals

WHAT CLIENTS IN THIS INDUSTRY ARE SAYING ABOUT CAPACCIO:

"CAPACCIO has been very proactive in keeping us informed of new regulations as they come down the pipeline and in putting together any programs we need to stay in compliance. CAPACCIO's work is also very thorough. They always make sure to cross all their t's and dot all their i's."

David Goodwin, Applied Biosystems

"CAPACCIO'S team of professionals utilized the concept of value engineering exceptionally. This resulted in cost savings for the project."

Robert D. Young, Millipore Corporation