

Medical Device Manufacturing

Successful operation of a medical device 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 health and safety 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 and engineering 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 medical device 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 Services

Are you up-to-date with all of your EH&S compliance and management goals? Could you use additional EH&S assistance but cannot commit to adding another person to your payroll? Did you know that having compliant EH&S programs will lead to fewer incidents, increased productivity, and improved employee morale?

CAPACCIO's EH&S On-Site Compliance Management Program can complement existing staff or be used to alleviate temporary or long-term workloads. This is a great way to get expertise when needed without 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. There may also be construction, renovation or decommissioning projects where an extra hand or additional expertise is needed; or you may choose to use our services just to get your company up to date with its compliance needs.

Environmental, Health and Safety Compliance

- Compliance monitoring reports
- Contingency and emergency response plans
- Hazardous waste generator training
- Bloodborne pathogens and exposure control programs
- Chemical and biological safety compliance
- Chemical hygiene programs
- Development of environmental management tools (e.g., environmental compliance calendar)
- DHS chemical facility anti-terrorism standard compliance assistance
- Emissions reports
- Facility set-up and closure assistance
- Flammable storage permits and licenses
- 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
- Medical surveillance programs
- Product safety
- Radiation and laser safety
- Recycling program development
- Spill prevention, control, and countermeasures (SPCC) plans and training
- Stormwater pollution prevention plans and training
- Tier II reporting
- US DOT registration and site security plans
- Wastewater treatment system operation and maintenance assistance and operator training

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 screenin
- ASTM Phase I environmental assessments
- Groundwater investigations

Product Compliance

- International Waste Electronic and Electrical Equipment (WEEE)
- International Restriction of the Use of Hazardous Substance (RoHS)
- European Union (EU) Registrations, Evaluation, and Authorization of Chemicals (REACH)

QUALIFICATIONS

CAPACCIO professionals are:

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

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