

BBJ Group Experience Overview Medical Device Manufacturing Services

BBJ Group Practice Areas

- Remediation and Site Restoration
- Real Estate and Transaction Support
- Regulatory Compliance Assistance
- Risk and Liability Management
- Ecosystem Services and Sustainability

Managing Risk Despite Decreasing Budgets

EHS Managers are tasked with maintaining company brand value by meeting compliance requirements, reducing injury time, and avoiding disasters that would put their companies in the headlines. However, competing pressures to cut costs result in plant-level turnover and an accompanying loss in institutional knowledge. This reduction saddles overworked EHS managers with extra tasks or shifts those demands to unqualified plant level personnel.



BBJ Group supports the directives of EHS Managers at Medical Device Manufacturing Facilities, by leading or supporting EHS program development, conducting audits, record keeping, and developing plans and programs required by regulation or as part of ISO 14001 programs.

Industry Snapshot

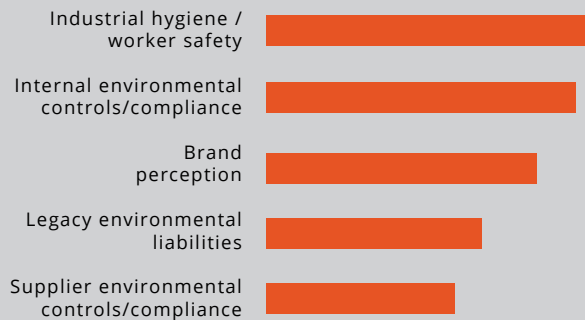
An EHS Compliance market leader, BBJ Group surveyed clients across job functions and industries.

Executives value safety and compliance as a means to maximize brand value

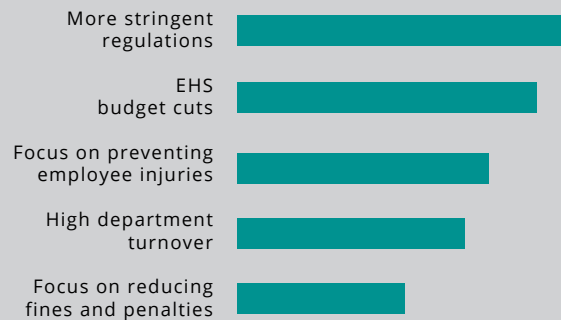
But...

EHS Professionals face budget cuts, high turnover, and more stringent regulations

Top 5 EHS Priorities for Executives¹



Top 5 Concerns of EHS Leaders²



1 - Source: BBJ Group Seminar Poll "What Keeps the Board Room Up at Night," September 2015 .

2 - Source: BBJ Group Seminar Poll "EHS in Crisis," May 2016.

Medical Device Manufacturing Services



Outsourced Compliance Assistance

BBJ Group provided outsourced compliance assistance at a 32-acre medical device manufacturing facility. Tasks included analyzing H&S programs, developing a CAPA Plan, conducting Job Safety Analyses and Personal Protective Equipment assessments, implementing a proactive EHS Management System, generating an online tracking system for H&S safety equipment, and creating new Standard Work Instructions and training programs. BBJ Group met the objectives of on-site and corporate EHS Directors in less than six months.



Fire Safety Regulation Inspection and Compliance

BBJ Group conducted a visual inspection of stored flammable materials and fire suppression design features within facility storage and production areas to evaluate compliance with applicable fire regulations.

As a result of the inspection, multiple distinct "control areas" were identified which allowed for a significant increase in flammable materials storage capacities at the facility, reducing the client's need and costs for structural changes.



Legislation Analysis

A medical device client relied on clean water sources to assure the purity of its product. BBJ reviewed pending fracking legislation in multiple states to evaluate possible impacts to their water sources.

BBJ identified six at-risk facilities, which were scored using a rubric. BBJ then advised the client regarding which facilities could be most impacted, which then informed the client's lobbying expenditures.

Other Recent Experience

COMPANY	Auditing	Waste Management	Waste Reduction	Program Development	Process Inventory Analysis	ISO 14001	Air Inventory / Permitting	Legacy Management	Health and Safety	Regulatory Negotiation	Regulatory Filings	JHA / SOP Development	Training	Site Investigation / Remediation	Cost Estimation
EHS Program Development	✓			✓	✓	✓	✓		✓		✓	✓	✓		✓
Fire Safety Assessment	✓			✓	✓	✓			✓	✓	✓		✓		✓
Product Lifecycle Analysis	✓	✓	✓	✓	✓	✓	✓								✓
Legislation Analysis / Lobby Support				✓			✓			✓	✓				
Legacy Site Superfund Remediation		✓						✓		✓					✓
Portfolio Medical Facility Audit	✓	✓		✓	✓		✓		✓		✓	✓	✓		✓
Medical Facility EHS Training				✓	✓				✓		✓		✓		
"Clean Room" Facility Audit & Remediation	✓				✓		✓	✓	✓	✓				✓	✓
Legacy Landfill Remediation		✓					✓		✓	✓	✓			✓	
Medical Device Facility Chemical Inventory	✓	✓	✓	✓	✓										