

Case Study: Compliance Ready – Biotech Start-up Challenges



Challenge:

Building Biotech manufacturing capacity is arduous, expensive, and must often be undertaken in a very compressed time - frame, to coordinate facility build-out with the drug approval process. This creates a situation where everything; construction, process development and validation, quality control procedures, and staffing, and compliance programs must be developed concurrently. This places a severe strain on existing team resources, and often creates conflicts within the interdependent developmental nature of the startup. Biotech manufacturing start-up challenges include:

- Manufacturing capacity development and build-out must be done concurrent with product approval and market development
- Facilities, equipment, utilities, and procedures must be created and developed in compliance with FDA, EPA, OSHA, DOT, State and local regulatory requirements
- Build-out, program development/compliance and staffing are all interdependent
- Resources are often in short-supply and under stress
- Many critical programs such as Safety and Health are not "built-in" due to the need to focus on facility start-up targets

Pisano & Associates LLC can take on the responsibility and remove the stress of identifying, creating and maintaining EHS compliance programs during a biotech's manufacturing start-up phase; freeing up the valuable company resources to concentrate on other priorities. During program development P&A can work with you, to build a scalable, sustainable resource model that meets long term EHS compliance objectives.

Our client, a global biopharmaceutical company, is engaged in the discovery, development and commercialization of therapeutic products aimed at treating patients with a wide array of severe disease states. Working rapidly to meet manufacturing start-up deadlines, our clients found themselves falling behind on EHS compliance program development, implementation, and training. Pisano & Associates was brought in to supplement the client's start-up team and take on the development of all EHS programs.

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Solution:

Pisano & Associates, LLC conducted a comprehensive EHS compliance audit. Reviewed all processes, identified all Federal and State compliance requirements; EPA, OSHA, & DEM. A resource plan and timeline were developed to ensure facilities 'compliance-ready' at manufacturing launch.

- Audit lead to the development and customization of more than (30) EHS programs including:
 - Hazard Communications Program
 - Respiratory Protection Program
 - Cryogenics Program
 - Fire Prevention Program
 - Emergency Action Plan
 - Flammable Liquid Safety
 - Fall Protection
 - Electrical Safety
 - Blood borne Pathogens
 - Personal Protection Equipment (PPE)
 - Laboratory Safety – Chemical Hygiene Plan
- A P&A team member worked on site at the client facility during program development.
- P&A utilized the ISO 14001 Environmental Management System and OSHA's Voluntary Safety & Health Management System Guidelines 18,001 as models for their approach in creating EHS programs.
- Each program is customized to the client's facility and includes a written program including policy, procedures, inspection and recordkeeping forms, and a comprehensive training presentation
- All EHS Programs were then uploaded to the EHS Intranet SharePoint for access by all employees.



Result:

- Client met all manufacturing start-up deadlines with no EHS compliance issues or exposure.
- All EHS programs in place communicated and documented.
- Successfully implemented a comprehensive EHS Management System.
- On-going compliance training was launched.
- New hire orientation training plan is in place for anticipated growth.
- Team consistency and continuity assured 24/7 end to end access to all EHS program information through integration with client intranet

About Pisano & Associates LLC:

Founded in 1998, Pisano & Associates LLC is an Environmental, Health, Safety & Ergonomics consulting and outsourcing company headquartered in Pawtucket, Rhode Island. Combining unparalleled experience, technical expertise and comprehensive capabilities, P&A collaborates with clients to help them rationalize their approach to EHS regulatory compliance.

For More Information:

To learn more about how Pisano & Associates can help your company build scalable, sustainable Environmental, Safety, Health and Ergonomic compliance strategies and programs, contact Cynthia Davis at 401.527.7047 or cdavis@pisanoassociates.com

