

CMC Biologics - Seattle

Sustainability

2013 Highlights

At CMC Biologics we have a commitment to our customers, employees, the community and other environmental stakeholders to ensure that our business operations are carried out in an environmentally responsible fashion. This means that we will operate with the highest of ethical standards and behavior and expect the same of our suppliers and partners.



Road to ISO14001:2004 Certification

At the beginning of 2013, CMC Biologics began an initiative to create a structured environmental management system with the goal of achieving ISO14001:2004 certification by the end of 2014. The company has utilized a cross-functional team to design and implement this two-year strategy toward environmental management excellence. 2013 saw the implementation of the primary system elements required by ISO14001:2004 at CMC Biologic's Seattle facility. This included:

- Creation of a facility Environmental Policy
- Establishment of an Environmental Management System (EMS) and related procedures
- Development of internal environmental management audit and corrective and preventative action processes
- Identification of significant environmental aspects that could have a potential impact on the environment
- Assignment of objectives and targets to drive environmental improvement
- Utilization of a management review process to ensure effective implementation, function and ongoing continual improvement of the environmental management system

CMC Biologics selected BSI Group as its registrar to provide independent assessments of the environmental management system and certification to the requirements of ISO14001:2004. An EMS pre-assessment and Stage-1 EMS assessment were successfully completed in Q1 and Q2 of 2014. A Stage-2 certification assessment is planned for Q3 with the goal of attaining certification.

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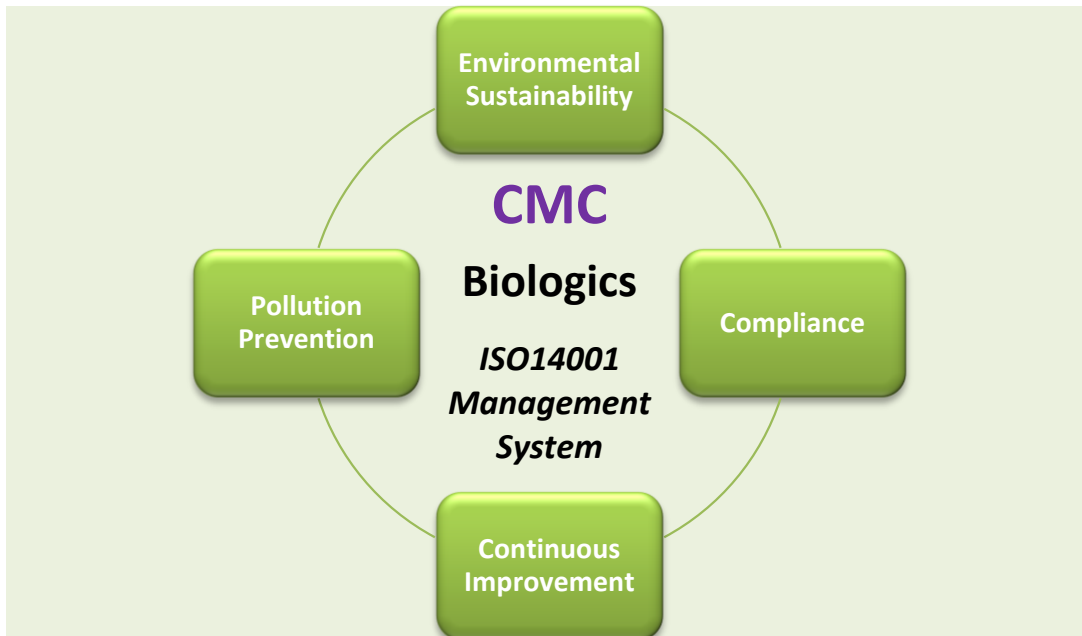
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Environmental Policy

Our environmental policy provides a foundation for our overall approach to environmental management and establishes the direction that the company has taken to drive continual improvement in environmental compliance, pollution prevention and sustainability. The policy has been approved by CMC Biologics senior leadership and adopted by the organization.



CMC Biologics – Seattle Environmental Policy

CMC Biologics is a contract biopharmaceutical manufacturing and development organization that is committed to meeting the needs of its clients, customers, and the community by operating in an environmentally responsible manner. To support this commitment, CMC Biologics will align continual improvement of the environmental management system with the organization’s mission, vision, and values. Essential to this commitment is a focus on pollution prevention, compliance with all environmental laws and regulations and environmental sustainability.

CMC Biologics believes that it has an important obligation to all company stakeholders as well as the local communities in which it operates to ensure excellence in environmental performance. This is accomplished through the establishment of an environmental management system that:

- effectively plans for pollution prevention and reduction
- establishes objectives and targets designed to demonstrate leadership in environmental management
- ensures the responsible use of energy across the organization through conservation, efficiency, and preference of renewable over non-renewable sources where feasible
- minimizes waste and utilizes viable alternative recycling approaches to conserve natural resources
- utilizes robust procedures, training, self-assessments, regular management review, and monitoring systems to ensure conformance with existing and future regulations
- maintains effective internal and external communications to foster awareness of the environmental policy and to facilitate prompt response to environmental inquiries or concerns

All employees and contractors are expected to adhere to this policy and immediately report any environmental concerns to CMC Biologics management so that prompt action can be taken to minimize environmental impact.



Environmental Aspects & Impacts

A rigorous process was used by the CMC Biologics ISO14001 implementation team to identify those aspects associated with the company's operation that could have a potential impact on the environment. These were looked at in further detail to determine those aspects having the potential for significant impact. Over 80 aspects were initially evaluated with the following aspects determined to be the most significant:

Service, Process or Product	Environmental Aspect
Waste neutralization, biological harvesting, buffer preparation, process equipment cleaning	pH of discharged water, Process wastewater generation/volume
HPLC operation, cell staining, analytical and general laboratory processes	Hazardous waste generation
Sink disposal of lab chemicals	Sanitary sewer disposal
Hazardous waste storage	Hazardous waste accumulation
Expired materials	Regulated and non-regulated waste generation
Neutralization system	Onsite transport of neutralization system chemicals (drums)
Storage of neutralization system chemicals	Chemical spill
Clarified product	Deactivation of biological materials
Disposal of unprocessed cell culture, biohazardous material, cell culture filtration	Biowaste disposal
Lab use of biological (BSL-2) materials	Release of BSL2 material (air)
Transferring hazardous waste external to buildings, emergency generator tank fuel filling, material loading/unloading	Spill to storm drain
Clean steam sampling, disconnecting cooling coil in bioreactor suites	Spill of chilled water (glycol)
Gas-fired boiler operation	Air emissions
Utilities (chillers, boilers, facility lighting, HVAC systems) and equipment use/maintenance.	Energy Use
Paper usage Use of recycled paper	Recycling
Disposal of single use technologies, packaging, Styrofoam	Recycling

2013 Objectives and Targets

CMC Biologics established environmental objectives and targets in 2013 and has made significant progress in the development of a robust environmental management system that addresses environmental aspects within the facility's laboratories, production processes and office environments. Objectives were developed considering identified significant environmental aspects as well as expectations of key stakeholders.

Objectives were reviewed and approved by CMC Biologics senior management as part of the company's environmental management review process. The following is a description of the objectives that were adopted in 2013 and a brief summary of accomplishments.

Objectives	Summary of Accomplishments
Develop an environmental management system (EMS) that conforms to the requirements of ISO14001:2004.	An implementation team was created and trained to design an EMS containing all of the elements required by ISO14001:2004. Major milestones attained included development of an Environmental Policy, procedures, internal audit system, corrective and preventative action system and management review process.
Ensure that the discharge capacity of waste neutralization system meets production demands without permit violations	A 20% increase in wastewater discharge volume was requested and granted by King County Waste Management to accommodate increases in manufacturing levels. There were two instances where daily water volume limits were above limits. However, subsequent control system improvements that were developed and implemented were highly successful and have been sustained.
Ensure compliance with pH discharge parameter through improved waste neutralization system design	There were no pH excursions during 2013 due to the effectiveness of a temporary system design modification that resolved issues with pH probe spikes. A permanent system design change is planned for 2014.
Provide for improved and more efficient storage and use of waste neutralization chemicals.	Procedures were created to address bulk fuel and chemical deliveries, tank filling operations and loading dock deliveries including spill prevention requirements.
Achieve Medium-Quantity Generator (180-Day) status through prevention and reduction strategies	Achieved MQG status throughout 2013 as a result of waste stream reductions and close monitoring and level loading of monthly waste shipments.
Reduce energy usage through an ongoing "green team" initiative. Achieve 5% reduction in gas usage and electricity	A Lean Green Team was formed and initiatives created with the goal of reducing energy consumption. Improvements were realized in building lighting and efficiency of air handling units, sterilizers and boilers. The company is currently in the process of performing a baseline energy evaluation to accurately determine energy improvements.
Minimize liquid corrosive waste shipped offsite for disposal	Procedures for performing onsite elementary neutralization of corrosive waste were established for laboratory operations.
Minimize the potential for spills to the storm water system	Storm drain covers were acquired and spill prevention procedures implemented for use when chemical and fuel shipments are received.
Ensure safety and compliance with waste accumulation requirements	Procedures were developed and improved for accumulating and bulking waste in the facility's 90/180 day hazardous waste accumulation room.

2014 Objectives

As part of our continuous improvement process, CMC Biologics has identified specific sustainability objectives for 2014 to drive environmental excellence within the organization and continue to reduce its impact on the environment. These efforts consist of the following:

Objectives	Target
Establish and certify through a registration body, an Environmental Management System (EMS) to provide the framework and means of carrying out the vision of the Environmental Policy	Successfully pass a 3 rd party registration audit and attain ISO14001:2004 certification.
Ensure that the discharge capacity of waste neutralization system meets production demands without permit violations	Work with the County to explore flexibility in daily maximum permit limits to account for peak production days. Identify all water sources and investigate opportunities to decrease water usage.
Ensure compliance with pH discharge parameter through improved waste neutralization system design	Install a permanent design change to the existing neutralization system to ensure proper pH control.
Provide for improved and more efficient storage and use of waste neutralization chemicals.	Plumb mini-bulk caustic/acid tanks in neutralization room to improve chemical storage, handling and containment.
Maintain Medium-Quantity Generator (180-Day) status through prevention and reduction strategies	Evaluate each waste stream to identify potential reduction opportunities and non-hazardous alternatives.
Identify and implement additional recycling opportunities	Investigate potential recycling of single-use technology bags. Evaluate opportunities for increased paper recycling.
Reduce energy usage through an ongoing "Green Team" initiative.	Achieve 5% reduction in gas and electricity usage. Complete a baseline energy evaluation.
Improve biomedical waste management process	Investigate discontinuation of onsite waste autoclaves and transition to biomedical waste vendor for transfer and offsite treatment/disposal if feasible.

Environmental Performance

CMC Biologics is committed to regulatory compliance, pollution prevention and reduction and sustainability. The following were areas of focus in 2013 which resulted in a reduction in our environmental impact. These efforts are ongoing into 2014 with plans to minimize waste resulting from expired materials as well as identifying and implementing additional recycling opportunities.

Hazardous Waste Management

CMC Biologics achieved its goal in 2013 to become a medium quantity generator (MQG) of hazardous waste. This was accomplished by reducing the pounds of hazardous waste generated by 54% when normalized by revenue and by closely tracking and level loading the waste shipments on a month-to-month basis.

Hazardous Waste Offsite Disposal	Year	Pounds Disposed (normalized by MM revenue)	Percent Reduction
	2012	408.5	54.0%
	2013	220.7	

Non-Regulated Waste Management

Waste shipped offsite for disposal that was classified as non-regulated waste was also significantly reduced in 2013 resulting in a 32.5% reduction in waste disposed normalized by revenue.

Non-Regulated Waste Offsite Disposal	Year	Pounds Disposed (normalized by MM revenue)	Percent Reduction
	2012	116.52	32.5%
	2013	37.87	

Effluent from Manufacturing Operations



Wastewater generation resulting from the Seattle facility's biological manufacturing process is closely monitored within the limits defined by an operating permit issued by King County. As a result of the company's sustained compliance with the terms and conditions of its industrial wastewater discharge permit in 2013 and its efforts to protect the public treatment works and water quality of the Puget Sound region, it was recognized with a "Gold Award" by the King County Department of Natural Resources and Parks Industrial Waste Program.

Recycling

At CMC Biologics, recycling is highly encouraged as an alternative to disposal. In 2013 we saw a 5.4% increase in recycled materials. By diverting recyclable materials from the general refuse waste stream, we were able to reduce our impact on local landfill capacity.

Additional recycling initiatives have been planned for 2014 including efforts to make recycling more convenient by increasing the number containers as well as exploring ways to recycle plastics associated with single-use bioprocessing technology.

Waste Recycling	Year	Tons Recycled (normalized by MM revenue)	Percent Increase
	2012	0.61	5.4%
	2013	0.64	

Energy Conservation

The end of 2012 saw the inception and kickoff of the Green Lean Project team with the goal of reducing energy consumption. The team identified and implemented a number of improvements in 2013 including:

- ✓ Instituting a program to limit the use of after-hour lighting along with replacement of light switches
- ✓ Reprogramming of gas pack air handlers for improved efficiency
- ✓ Changes to boiler operation including lowering of pressure, reducing usage during summer months, additional servicing and addition of controls to further conserve energy.

Emphasis was placed on additional team training in energy reduction methods to enable in-depth exploration of energy reduction strategies. To support this, the team leader was enrolled in a formal Building Operation Certification for Energy Efficiency program to enable the development of enhanced energy reduction strategies in 2014.

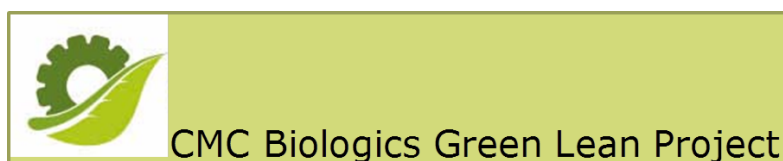
2014 Lean Green Focus

Energy consumption benchmarking to enable comparison of CMC Biologics with similar facilities.

Programming of air handlers for active occupancy efficiency.

Lighting evaluation and assessment of potential upgrades.

Addition of HVAC programmable controls to provide increased control and efficiency



Safe Workplace

CMC Biologics was awarded VPP STAR certification by the Washington State Department of Ecology in Q-4 of 2012 for its commitment to health and safety excellence and injury prevention. Since its initial certification, the site has seen continued growth in its safety culture, improvement in its health and safety management systems and processes, and sustained injury performance below the average for biopharmaceutical manufacturing industry.

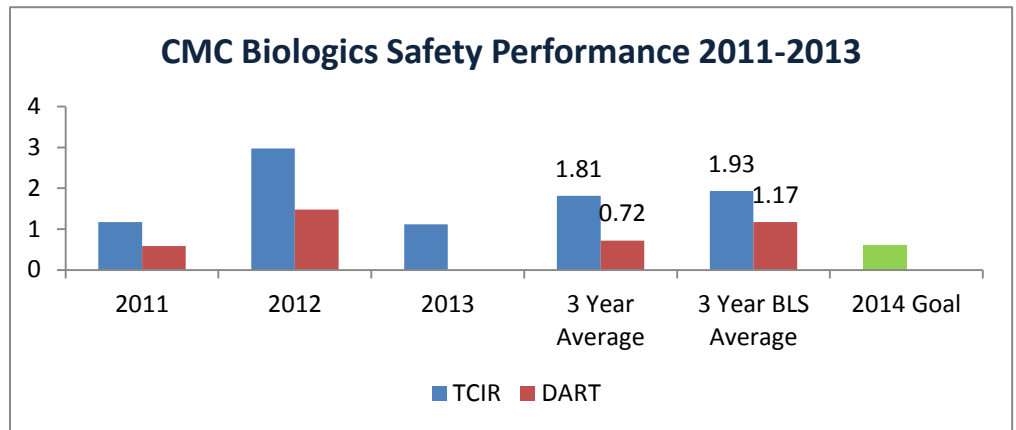
Through the efforts of the site’s employees and with support from senior leadership, initiatives and program enhancements were successfully undertaken in 2013 which included:

- ✓ Implementation of a Near Miss reporting program to identify and address upstream safety issues
- ✓ Safety evaluations of chemical and steam systems within the manufacturing process to identify opportunities for risk reduction
- ✓ Ergonomic training and workstation/work process evaluations
- ✓ Enhanced emergency team capabilities through advanced first aid training and certification
- ✓ Improved process for tracking of safety observations, audits and inspections



Safety Performance

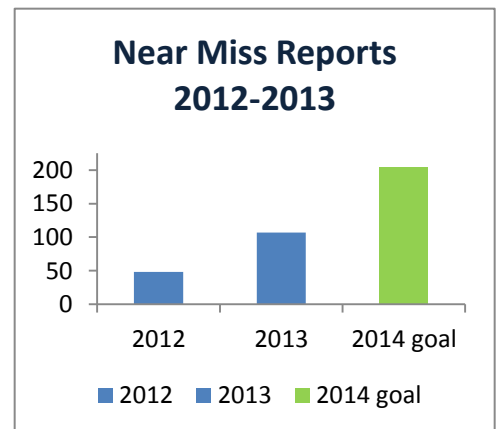
In 2013 there was significant improvement in both the total OSHA recordable case rate (62% reduction) and Day Away/Restricted rate (100% reduction) compared to 2012. The



3-year average for these rates was also sustained below the 3-year BLS average for the biopharmaceutical manufacturing industry.

Near Miss Reporting

A program was implemented to strongly encourage the reporting of near miss incidents to enable trending of workplace risks that could potentially lead to injury. The site set an aggressive goal of 200 reports for 2013. While this goal was not reached, the effort yielded a 127% increase in the number of reports submitted which supported risk identification and reduction efforts. The site has maintained its goal of reaching 200 reports through 2014 as part of its overall accident prevention program effort.



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CMC
biologics

Right. On Time.

About this Report

This report highlights the progress of CMC Biologic's Seattle facility in the area of environmental sustainability for the year 2013. Additional inquiries may be made by contacting the Seattle facility Environmental Health and Safety Department.