AFC Principles Focus on Quality, Safety, Security, and Environment

Universal Quality and EH&S Systems are Applied to all AFC Sites, Facilities, Operations, and Products

quality Policy

- It is the policy of AFC to implement and maintain a
  quality Management System
  that will assure our ability to reliably supply our customers with the highest
  quality material and services available.

- The objective of the AFC System is to provide the means to produce a
  product that consistently exceeds customer expectations, prevents
  pollution, injury, and ill health.

- This will be achieved by continually improving our products and services and
  complying with applicable legal and regulatory requirements.

SHE Policy

- Provide and maintain facilities, operations and working conditions, which are safe for employees, visitors, contractors, and the public.
- Provide appropriate information and employee training to enable all activities to be conducted in a responsible and effective manner that promotes involvement and accountability.
- Communicate with and engage our employees, business partners, and the community to foster a greater understanding of environmental, health, and safety matters.
- Make EH&S, pollution prevention, risk mitigation and loss prevention priority considerations in planning and decision making for all current and future products and processes.
- Comply with applicable laws and regulations and establish and maintain programs and procedures to assure that those laws and regulations are known and followed by our employees.
- Minimize any undue risk to health, safety, or the environment in connection with the conduct of its business.
- Promote product stewardship throughout a product’s lifecycle, including exerting a positive influence on the EH&S performance of contract manufacturers and key suppliers.
- Cooperate with relevant authorities and other key stakeholders in resolving issues and improving performance.
- Continuously strive to use resources efficiently and minimize waste.

AFC Embraces Safety, Quality, and Environmental Compliance as a Way of Doing Business

AFC Approach to Quality and SHE

- Provide the Appropriate Resources to Each and Every Project
  Deliver the right people, products, and services at the right time and place
- Operate as a disciplined, process-oriented, learning organization to assure continuous and measurable improvement
- Achieve AFC’s priorities of operational excellence and company growth
- Continuously Striving for Process Improvement aligned with our customers systems and needs to
  Improve process capability, cycle time, and reduce variability
- Minimize/prevent pollution and waste
- Provide a safe environment

- Nurture Relationship and Provide a Desirable Work Environment
  • AFC values diversity, empowerment, open communication, accountability, safety, environmental responsibility, teamwork, training, personal growth, achievement, and recognition
  • Maintain a relationship of trust with our customers, employees, owners, suppliers, and community
  • Become the supplier of choice through best practices, teamwork, and partnerships
  • Maintain compliance with Federal, State, and Local requirements

Continuous Quality Improvement is a Core Value of AFC

- Lean Manufacturing Cultural Enhancement
  • Multiple Kaizen events with diversified teams
  • Joint process related Kaizen events with customers
- War on Foreign Objects and Debris (FOD)
  • Dedicated cross functional teams focused on eliminating FOD sources
- Right First Time: Quality and Documentation
  • Quality Totem Poles provide transparency and continuous feedback
  • Capacity Enhancements
    Focus on equipment uptime and minimization of changeover time
  • Improved Supply Chain Management
    Preventing disruption of manufacturing to assure on-time delivery

AFC Supports Strong Sustainability and Conservation Programs

- Reduced hazardous waste generation average of 2.5 million pounds per year since 2009 and an
  annual average savings of $2.5M
  • From 2013 through 2016, the site recycled over 6M pounds of
    internal solvent for reuse
  • Solvents recycled internally: acetone, isopropl ether, isopropl acetate, n-heptane, ethanol
  • Solvents recycled externally: dichromethane
  • External recycling: precious metal catalyst

- Potable Water Reduction Program in place since May 2015
  • Leak detection and repair
  • Reduced Consumption by 35%
  • Savings to date – 6,900 gal/mo.

AFC has been Recognized for its Safety and Environmental Programs

- CA Department of Toxic Substances Control (DTSC) and the Chemical Industry Council of California (CICC) awards in the Pollution Prevention Challenge Program in 2007, 2008, and 2009 for solvent recycling
- Received in 2009 and 2012 highest overall environmental recognition awards from multiple California Industry Associations for pollution prevention and green chemistry achievements
- Society of Chemical Manufacturers and Affiliates (SOCMA)
  • National Silver Award for Pollution Prevention and Environmental Stewardship in 2010
  • ChemStewards® Certification national Bronze Award for overall environmental achievement in Environmental Sustainability 2014
  • Silver Awards for Training and Environmental Stewardship 2015
  • Bronze Award for Environmental Sustainability 2016

AFC Demonstrates a Strong Compliance Culture through Successful Regulatory Activities

- Frequent Regulatory Inspections with Positive Outcomes
  • FDA Inspections: 16 PAIs (all products approved) since 2008
    4 Successful General Inspections since 2011
    Most recent FDA audit: November 2016
  • EMA Inspected: Jul 2011
  • Multiple Audits by International Agencies
    PAIs by Korean MFDS in 2010 and 2015
    PMDA Accreditation following physical audit in 2006
    Accreditation Renewed May 2016

- Strong Relationships Developed With Regulatory Agencies
  • FDA Training
    Training Sessions Provided by AFC in 2014, 2015, and 2016
    Attended by over 50 employees of FDA and CA Board of Pharmacy
- Two-day Training Events:
  • Poster Board Sessions Provided on Warehouses, Laboratories, Production Plant, and Development Facilities
  • Presentations on GMP Topics of interest

- Excellent Relationship with Other Agencies
  • Frequent interaction with state and local environmental agencies
  • HAZMAT partnership with local emergency responders
  • Voluntary enrollment in CA-OSHA safety enhancement program
  • Direct interface with local US DEA office

- AMPAC Maintains Proven Security Capability
  • Security System
    • Fully fenced US DoD perimeter
    • Two guarded gates to enter facility
    • Armed security guards 24/7
    • CCTV across campus with continuous monitoring and recording
    • High security CS facility with secure vault and alarmed fencing
  • Biometric access to key processing areas
    • CS processing and storage areas
    • Cytotoxic processing areas

- Fully Vetted Security
  • Inspected annually by DEA for registration renewal
  • Inspected biannually by DEA for CS compliance
  • Inspected annually by US Department of Homeland Security
  • Prior inspections by DHS CA and BARDA (US HHS)