

# 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

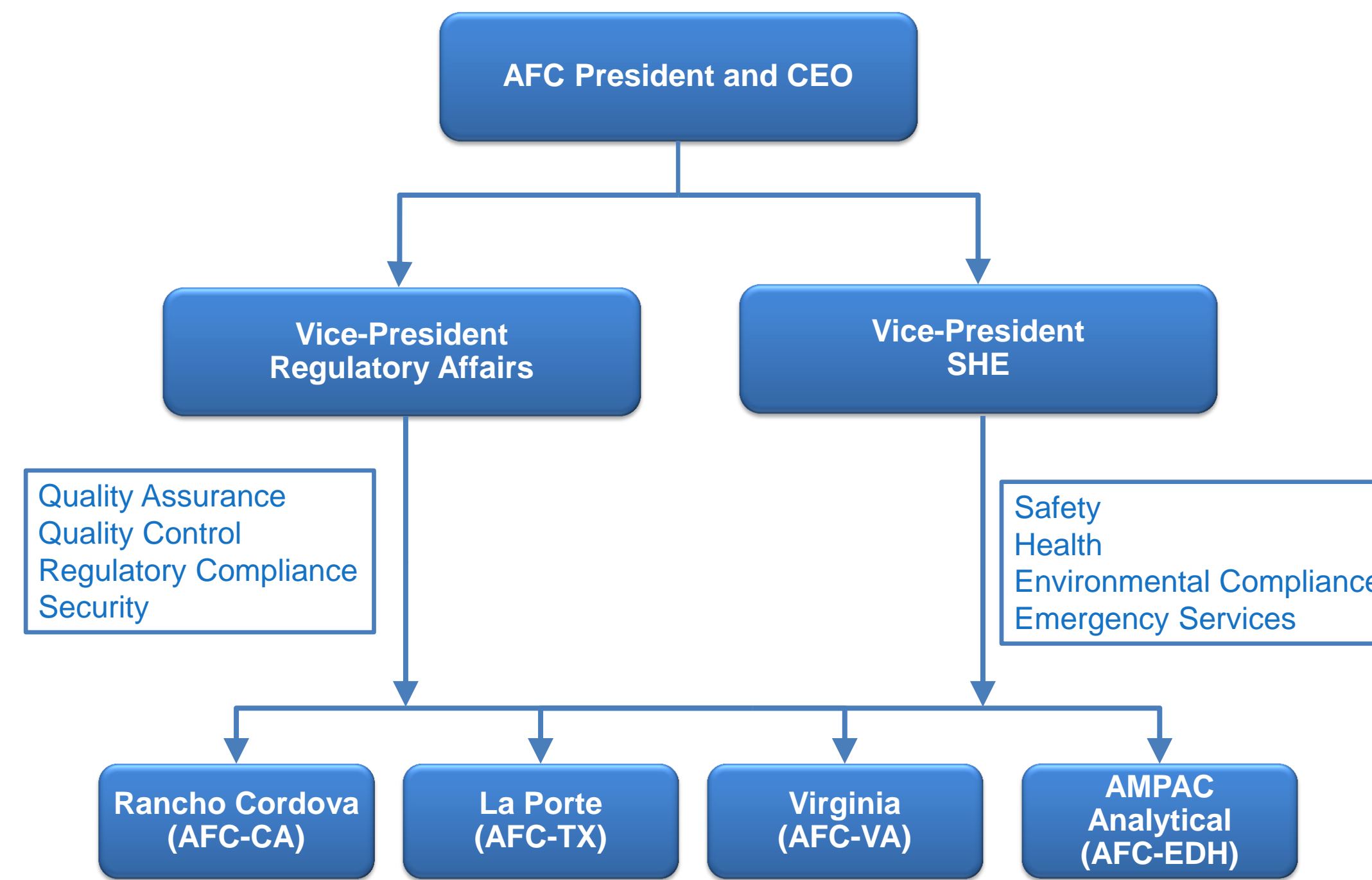
### Quality Policy

- 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 insure 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



### 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, isopropyl ether, isopropyl acetate, n-heptane, ethanol
  - Solvents recycled externally: dichloromethane
  - External recycling: precious metal catalyst

### Active recycling programs:

- Pallets (wood and plastic)
- Cardboard and Chipboard
- Paper (all types)
- Glass
- Plastics
- Drums (steel and poly)
- Totes
- Computer parts and accessories
- Oils (motor oils, hydraulic oils, pneumatic oils)
- Batteries (Ni-Cad, Lithium, Lead Acid)
- Tires
- Mercury (thermostats and thermometers)



### Potable Water Reduction Program in place since May 2015

- Leak detection and repair
- Reduced Consumption by 35%
- Savings to date – 6,900 gal/mo.



### Continuous Quality Improvement is a Core Value of AFC

QUALITY TOTEM POLE		
Southline Quality Totem		
MTM Minutes That Matter	Actual	Target
Complaints	0	0
Scrap / Rework / Reprocess	0	0
Batch RFT	69%	95%
Batch Record RFT	75%	95%
Variances	0	0.2
Overdue CADAS	3	0
Recordable Injuries	0	0
Environmental Releases	0	0

- 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

Lean Manufacturing Continuous Improvement Initiatives		
Area	Project Types	# of Projects In Progress or Pending
Engineering	War on FOD	44
Operations	SS, Guidance Documents, Efficiency, Changeover, War on FOD	16
IT	Automation, Controls Upgrades, Network Infrastructure	20
AFC TX	War on FOD, Throughput/ Yield and Efficiency	6
Maintenance	Maximo, Bottom Valves, PM's/Annuals, Docking System	10
Total		96

### 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
- Awards from the US Department of Energy for **Energy Reduction Achievements in 2009, 2010, and 2013**
- 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's CEO Dr. Aslam Malik Receives the CICC Pollution Prevention Recognition Award



## 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

- Most recent audit: Jan 2014 by HPRA/Bavarian Authorities
- EDQM and Romanian Authorities Audit: May 2011
- GMP Certificates issued following both inspections



#### Multiple Audits by International Agencies

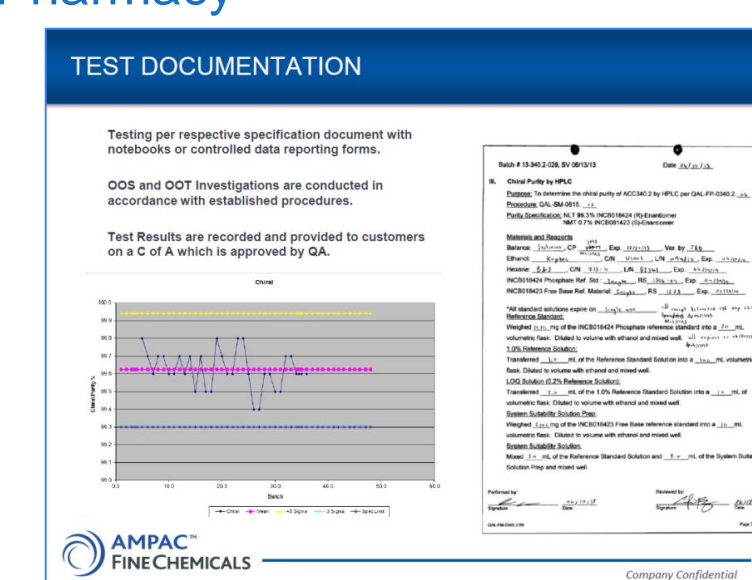
- PAIs by Korean MFDS in 2010 and 2015
- Routine Desk Top Audits by TGA and Health Canada
- PMDA Accreditation following physical audit in 2006
  - Accreditation Renewed May 2016



### 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)

