A UNIQUE POSITION

Ampac Fine Chemicals (AFC), formerly Aerojet Fine Chemicals, is a technology-focused contract manufacturer of active pharmaceutical ingredients (APIs) and intermediates. Our current capabilities—including process development, scale-up and cGMP production from kilograms to multi-tons—are based on more than 50 years of chemical production experience.

AFC's differentiating advantage lies in the positioning of unique technology platforms at a state-of-the-art U.S. facility near Sacramento, California. These platforms include production of high-potency intermediates and active pharmaceutical ingredients (HPAPIs), handling of hazardous materials and performing energetic reactions, production of nucleosides, simulated moving bed (SMB) chromatography, and continuous processing.

AMPAC Fine Chemicals produces accordance with current Good Manufacturing Practices at a state-of-the-art facility near Sacramento, California, in compliance with cGMPs. From kilogram to multi-ton scale, to your specifications, with your transferred process or a process developed at AFC—we provide the solution.
pharmaceutical chemicals in Manufacturing Practices (cGMPs).
AMPAC Fine Chemicals (AFC) manufactures active pharmaceutical ingredients (APIs) and registered intermediates in accordance with current Good Manufacturing Practices (cGMP) for a global market. From R&D and kilo-scale cGMP synthesis to commercial production under regulated quality standards, AFC uses the latest technology to support customers and ensure confidentiality, safety, and the timely delivery of the best overall solution.

With 49,880 gallons (188.8 m³) of capacity – from 20 to 4,000 gallon reactors – and seven Class 100,000 buildings, AFC’s state-of-the-art production facilities support the manufacture of intermediates and APIs from grams to multi-tons.

TECHNOLOGY-DRIVEN CHEMICAL SOLUTIONS

AFC’s Process Development Group provides the expertise to take a chemical synthesis from bench to commercial-scale production. The group designs and develops robust processes for customers’ products with a focus on safety, economics, scale-up feasibility, reliability and throughput optimization.

AFC’s chemists work closely with plant process engineers during process development to focus on chemically-engineered solutions that provide product to specification with a safe, economically-viable process. Our process chemists also provide full support to the production team and are continually testing new ideas in the lab to improve throughput. Process improvements are initially tested at 10 to 50 L scale and demonstrated at pilot scale (50 to 100 gallons), if necessary, before full-scale implementation.

THE AFC LEGACY

AMPAC Fine Chemicals LLC (AFC), formerly Aerojet Fine Chemicals, is a wholly-owned subsidiary of American Pacific Corporation (NASDAQ: APFC). AFC is uniquely situated on a single site, positioned in the center of a large, high security facility near Sacramento, California. AFC’s capabilities support a wide range of processes and technologies that have been developed during the past 50 years. AFC’s customers include multinational pharmaceutical and biopharmaceutical companies.

AMPAC Fine Chemicals is committed to continuously developing new technologies that provide added value
UNIQUE TECHNOLOGY PLATFORMS & CAPACITIES

AFC's technology platforms have evolved throughout the course of five decades and include:

- Development, scale-up and commercial implementation of energetic chemistries
- Production of highly potent compounds
- SMB separation for the manufacture of intermediates and APIs
- Application of continuous processing for commercial scale manufacturing of APIs and intermediates

ENERGETIC CHEMISTRIES

Energetic chemistries offer a rich palette of reactions that are clean, fast, reliable and scalable. AFC offers production capabilities from lab to commercial scale using energetic compounds including:

- Azides
- Diazomethane
- Aziridines
- Nitric Acid
- Isocyanates
- Hydrazines

HIGH-POTENCY ACTIVE PHARMACEUTICAL INGREDIENTS (HPAPIs)

AFC has produced numerous HPAPIs for various pharmaceutical customers at commercial scale and more than two metric tons of highly potent drug substances in a single year. Through a triple-containment strategy, AFC's facilities are capable of handling products with an OEL (Occupational Exposure Limit) as low as 0.2 microgram/m³. The facilities include:

- Three dedicated HPAPI production facilities separated from main plant buildings
- R&D laboratory dedicated to high-containment synthesis
- Separate SMB production facility for HPAPIs
- High-containment QC laboratory

SIMULATED MOVING BED (SMB)

SMB is a unit operation ideally suited for chiral separations, as well as for other types of binary separations such as diastereoisomers, cis/trans isomers, and the removal of “troublesome” impurities. Several APIs using SMB as unit operation in the manufacturing process have been approved by the FDA.

AFC has six SMB units, with columns ranging in diameter from 4.6 mm to 1,000 mm. These SMB units support all phases of drug development and commercial-scale production of intermediates and APIs.

CONTINUOUS PROCESSING

When it comes to pharmaceutical fine chemical production, continuous processing is a new frontier and AFC has been a leader in introducing continuous processing to the cGMP manufacture of intermediates and APIs. Based on its successful history of using continuous processes to produce thousands of metric tons of various energetic compounds for the defense industry, AFC's experienced team of engineers and chemists has extended continuous processing to cGMP production in particular for two of its technology platforms - SMB chromatography and energetic chemistry.

In order to meet the needs of pharmaceutical industry and to capitalize on the benefits of continuous processing, AFC has developed a “Zone Reactor” concept for producing small quantities of intermediates and APIs under cGMP. The Zone Reactor concept is very versatile and allows most batch processes to be conducted under continuous processing conditions. In particular, it allows parameters such as temperature, pressure, residence time, etc to be controlled independently in each zone and allows efficient handling of liquids, slurries, and gases.

SPECIAL TECHNOLOGIES

AFC also has the cGMP capability to handle difficult chemistries or compounds with restrictions such as:

- Mercaptans
- Methylene Chloride
- Chlorosulfonic Acid
- Diethyl Ether
- Phosphorous Oxychloride
- Ammonia
- Metal Hydrides

Ampac Fine Chemicals produces a wide range of pharmaceutical chemicals utilizing special technologies.

to continuously developing new technologies for our customers.
AMPAC Fine Chemicals (AFC) offers pharmaceutical and biopharmaceutical companies state-of-the-art technology platforms and resources at its facility near Sacramento, California. This single site optimizes security, quality management and confidentiality.

**AFC facilities support all phases:**

- **Kilo-scale Capabilities**
- **Glass reactors from 10 L to 30 gallons**
- Remote operation for energetic / hazardous chemistries
- **Bench-top SMB unit with 4.6 mm and 10 mm diameter columns**
- **8 x 50 mm SMB unit for Phase I/II materials**
- Preparative dynamic axial compression column (50 mm) for batch chromatography
- **“Zone Reactor” for developing continuous processes**

**Plants for Phase II and Phase III quantities**

- **8 x 100/200 mm SMB unit for Phase II/III quantities**
- Plants with glass and stainless steel reactors from 50 to 750 gallons
- Remotely-controlled facility for hazardous operations (e.g. diazomethane)
- Semi-works facility with 300 to 1000 gallon reactors, HF-600 Heinkel Hastelloy® centrifuge, and a Rosenmund filter/dryer (1.6 m³)

**Commercial-scale production plants**

- Total capacity of 49,880 gallons (188.8 m³)
- Three production trains with azide capability
- Glass, Hastelloy® and stainless steel reactors from 300 to 4,000 gallons
- Class 100,000 solids handling facility equipped with Hastelloy® Cogeim® (4 m³) filter dryers, 3 m³ glass tumble dryer, two 3 m³ Hastelloy® tumble dryer and a milling suite
- Class 100,000 general purpose chemical facility
- Commercial-scale diazomethane facility (750-gallon scale)
- Two high-containment facilities for cytotoxics, with 50- to 200-gallon glass reactors and Class 100,000 packaging areas
- High-containment facility with a 6 x 75 mm SMB unit, 2 x 20 gallon glass-lined reactors and a 13” Aurora filter dryer, and class 100,000 packaging capability.
- Two Class 100,000 facilities for SMB separation, with 6 x 800 mm and 5 x 1000 mm SMB units, falling film evaporators, and two stainless steel 5 m³ conical dryers per building
AMPAC Fine Chemicals produces a wide range of pharmaceutical chemicals utilizing special technologies.
AMPAC Fine Chemicals is proud of its excellent record of regulatory compliance.
QUALITY, EH&S AND PRODUCT MANAGEMENT

The design and operation of R&D and production facilities at AFC are in full compliance with federal, state and local regulations. At AFC, our dedicated quality unit consists of Quality Assurance, Quality Control, and Quality Engineering personnel to ensure that the production of pharmaceutical fine chemicals is conducted in accordance with current Good Manufacturing Practices (cGMPs).

A COMMITMENT TO QUALITY

AFC has a continuing record of successful regulatory inspections from the FDA, PMDA and other regulatory authorities, as well as customer cGMP audits that confirm our commitment to total regulatory compliance.

AFC’s quality control and analytical R&D laboratories are fully equipped with the state-of-the-art equipment to support production and ensure the highest level of quality in the product.

- Gas Chromatography (GC) – Static Headspace/Gas Chromatography (HS/GC) – Gas Chromatography/Spectrometry (GC/MS)
- High-Performance Liquid Chromatography (HPLC) and Liquid Chromatography / Mass Spectrometry (LC/MS)
- Ion Chromatography (IC)
- Nuclear Magnetic Resonance (NMR) (300 MHz)
- Fourier Transform Infrared (FTIR) – Ultraviolet-Visible Spectroscopy (UV-VIS) – Polarimeter
- Particle Size Analyzer
- Differential Scanning Calorimetry (DSC)/Thermogravimetric Analysis (TGA)/RC-1

Our Quality and Regulatory Services Include:

- Drug Master Files (DMFs): Preparation and Maintenance
- Input and review of the Chemistry, Manufacturing and Controls (CMC) section of New Drug Applications (NDAs)
- Development and validation of analytical methods
- Stability and microbiology testing

A COMMITMENT TO EH&S

AFC’s EH&S team ensures that operations in the laboratories and the plant are conducted in strict compliance with federal and state safety and environmental regulations. Scale-up of the processes from R&D to production undergoes rigorous process hazard analysis (PHA) reviews to mitigate potential safety concerns. Some of the programs implemented by AFC include:

- California Occupational Safety & Health Administration’s (Cal-OSHA) Process Safety Management Standard
- California Environmental Protection Agency’s (Cal-EPA) Accident Release Prevention Program
- Operation of a biological wastewater treatment system to process aqueous waste in accordance with the wastewater pretreatment standards for the pharmaceutical industry (40 CFR Part 439)
- Implementation of Green Chemistry/Engineering initiatives such as recycle and reuse of solvents and technology-based engineering solutions such as SMB to minimize pollution
- On-site HAZMAT response team and Fire Service Department to manage emergencies

A COMMITMENT TO SERVICE

At AFC, our goal is to provide best-in-class service to our customers and to truly understand and quickly respond to their needs. We work as a team with a “can-do” attitude that fosters implementation of value-adding processes. Our service-oriented philosophy is coordinated by our product management team which interacts closely with our customers and keeps them updated on our progress.

Close partnering is a key feature of this service-oriented philosophy. Every process specification or compliance-related change is approved by the customer prior to implementation. We believe in an open communication model and we share all project-specific data with our customers. We are committed to providing our customers with high-quality products that employ cost-effective strategies and solutions to reduce time-to-market.

AMPAC Fine Chemicals is proud of its excellent record of regulatory compliance.
Ampac Fine Chemicals manufactures pharmaceutical chemicals for the global market at our state-of-the-art facility located on a large security-controlled site near Sacramento, California. This single site optimizes security, confidentiality and seamless transfer of processes from lab to commercial scale. Customers are welcome to visit us to review the fully-integrated manufacturing infrastructure.

Our service-oriented philosophy involves understanding and responding to the needs of our customers, and working as a team with a “can do” attitude that fosters implementation of value-adding processes. AFC is committed to providing customers with high quality products that employ cost-effective strategies to shorten the time-to-market.