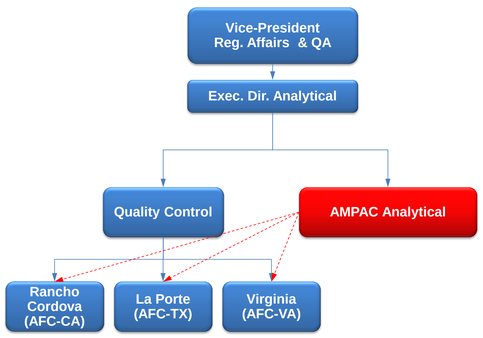
A Strong Analytical Team to Support the Manufacturing of APIs

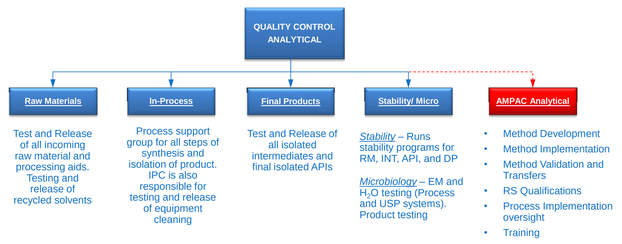
A Single Quality System Approach to Favor a Unique Quality Culture

AMPAC Analytical is Integrated within the cGMP Quality Control Function at AFC

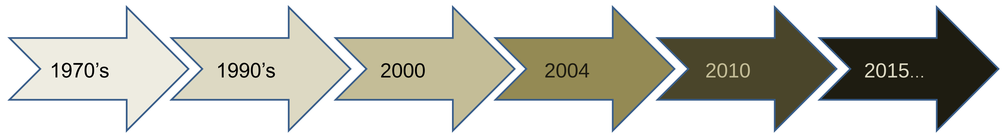


One Quality system across all AFC sites

- Global implementation of SOPs
- Weekly Analytical meetings between all sites
- Weekly site reports allows for transparency of activities
- Frequent site visits and training



AMPAC Analytical is Rooted in the Company Foundation



Quality Control and analytical support

AMD built from **experienced** QC chemists

Expanded AMD as part of the **Quality Organization** Growth period

AMD services opened up to our clients for products manufactured at AFC

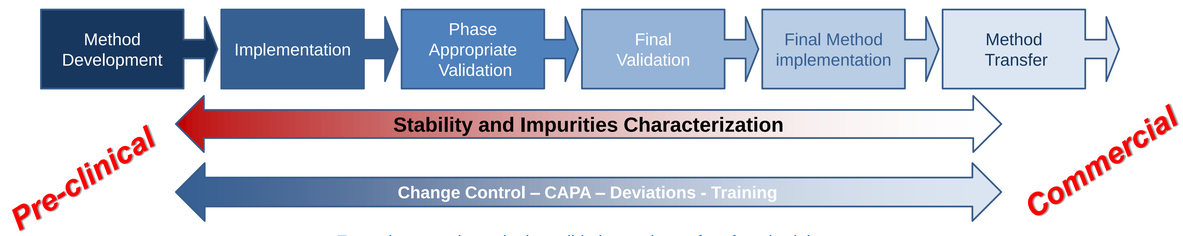
Laboratory services opened up to existing and new clients as a contract lab

AMPAC Analytical structured to focus on Contract Laboratory work. Increased Lab ft^2

cGMP Foundation

AMPAC Analytical Provides Support Throughout the Life of the Product

AMPAC Analytical Covers All Aspects of Analytical Requirements for API's and Drug Product



- Extensive experience in the validation and transfer of methodology to support pharmaceutical testing of APIs & drug products from clinical to commercial stage
- Validation protocols and reports to support regulatory filings
- Stability for Intermediates, API's, and Drug Product
- Impurity identification and characterization
- Plant support post commercial launch
- Method troubleshooting

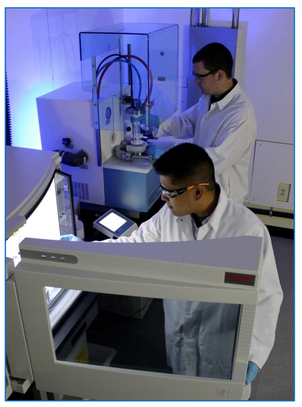
AMPAC Analytical Provides High Quality Service at a New Location

- ❑ The new 13,000 ft^2 facility in El Dorado Hills increases AFC's analytical footprint
- ❑ More than 80 analytical professionals, including development and validation team of >20 experienced analytical scientists
- ❑ Equipped with state-of-the-art analytical technologies
- ❑ Support for development and commercial stage programs
- ❑ 24/7 operation in support of production schedules

- ❑ Development of "phase appropriate" analytical methods
- ❑ Method implementation, qualification, validation, and transfers
- ❑ Analytical Testing – broad range of equipment
  - Reference Standard Qualifications
  - Release Testing – raw materials, API, and Drug Product
  - ICH Stability Studies

AMPAC Analytical is Well Positioned for ICH Q3D Transition (Trace Metal Analysis)

- ❑ Helping our clients align with USP <232>, <1232>, and ICH Q3D
- ❑ Premier site for development, validation, and routine testing of Elemental Impurities
- ❑ Equipped with latest ICP systems
  - ICP-MS, iCAP-Q, iCAP-RQ systems
  - Microwave digester, Ultrawave Digesters
  - Heat Block digestions
- ❑ Cytotoxic/Potent and Controlled Substances testing capabilities
- ❑ Digestion methods developed for multiple types of matrices



AMPAC Analytical has Unique Capabilities to Support HPAPI Production

- ❑ Analytical scales within glove boxes for sample weight and dilution
- ❑ Room dedicated for analytical sample preparation only
- ❑ Single pass HEPA filtered air
- ❑ Air lock for gowning/de-gowning
- ❑ Sample pass-through
- ❑ Separate disposable chutes for solids and liquids within each hood
- ❑ Negative differential air pressure in processing rooms relative to surrounding areas

AMPAC Analytical Includes a Wide Array of Analytical Services in Support of API Production

AMPAC Analytical Uses the Latest Analytical Techniques for Release Testing for APIs& DPs

Characterization and Assay

- ❑ Appearance/Description
- ❑ Infrared Spectroscopy – ATR, Salt Pellets, and Salt Plates (for liquids)
- ❑ Nuclear Magnetic Resonance (NMR)
- ❑ LC detection by VWD, DAD, CAD, RID, FLD, and MS (MS/MS system by Q-TOF)
- ❑ GC detection by FID, TCD, ECD, and MS
- ❑ Ion Chromatography (IC)
- ❑ Mass Spectrometry (MS)
- ❑ Ultra Violet Spectroscopy (UV)
- ❑ ICP-MS and ICP-OES for Elemental Impurities (UPS <232/233> / ICH Q3D)

Pharmacopeia Testing

- ❑ Qualify and implement monographs and testing chapters from the various pharmacopeias and standards including USP, EP, BP, JP, FCC, ACS, etc.

Other Physical Properties

- ❑ Density
- ❑ Refractive Index
- ❑ pH
- ❑ Water Content by Karl Fischer Titration (Coulometric and Volumetric)
- ❑ Color and Clarity of Solution
- ❑ Conductivity
- ❑ Optical Rotation
- ❑ Differential Scanning Calorimetry (DSC)
- ❑ Thermogravimetric Analysis (TGA)
- ❑ Dissolution Testing
- ❑ Osmolality
- ❑ Particle Counting
- ❑ Particle Size Distribution (Wet and Dry)
- ❑ Polymorph identification (XRPD)
- ❑ Compendial Tests
- ❑ Chromeleon Data Collection

AMPAC Analytical Provides Support to Regulatory Filing

Stability Studies

- ❑ ICH stability storage and testing
- ❑ Stability storage for drug product packaged in semi-permeable containers, as well as, DEA schedule II –V controlled substances
- ❑ Multiple ICH Storage Conditions with flexibility to adapt to customer request:
- ❑ Available Stability Services:
  - Long Term, Intermediate. and Accelerated Testing
  - Forced Degradation Studies
  - Temperature Excursion/Cycling Studies
  - Protocol and Report writing

Impurity identification

- ❑ Detection, identification, and quantitation of impurities
- ❑ Forced degradation studies to determine most likely path of degradation
- ❑ Typically performed during method development and validation to assure impurities are not missed due to peak overlap or deficiencies in choice of detectors
- ❑ Analysis typically starts with an UPLC or HPLC method using an appropriate detector, followed by analysis with a universal detector, such as a MS
- ❑ NMR available for structure elucidation
- ❑ Synthesis of impurities for structure confirmation available