



## WE'VE GOT APIs DOWN TO AN EXACT SCIENCE

### POWER API PRODUCTION WITH GLOBAL, COST-EFFECTIVE DEVELOPMENT AND COMMERCIAL MANUFACTURING

We support the chemical development and cGMP manufacture of complex APIs, including, but not limited to, potent and cytotoxic compounds and controlled substances. Our world-class facilities in North America, Europe and Asia provide the scale and technology to serve your needs from development to manufacturing, for small to commercial-sized batches. We have a track record of quality and compliance with the FDA, AIFA, PMDA and other regulatory agencies and more than 200 API dossiers filed worldwide.



#### API Manufacturing

AMRI is one of the largest independent developers and suppliers of APIs to the life sciences industry. Leverage our complete suite of capabilities, plus analytical and global regulatory support for your custom, complex APIs.

## DELIVERING COMPLEX SCIENCE AND EXPERT SOLUTIONS

We have a robust portfolio of both market-leading APIs and generics, as well as world-class capabilities in niche and high-barrier-to-entry technologies. Our offerings include:

- More than 240 commercial APIs
- Sterile and high-potency APIs, steroids, hormones, monobactams, boronic acids and controlled substances
- Expert custom synthesis and contract manufacturing via a global network of facilities
- Analytical research and testing services, including solid state chemistry and container closure integrity testing
- Opportunities to vertically integrate your projects with our complete suite of discovery and drug product solutions



Complex Science. Expert Solutions.

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## Specialized Technology Expertise

- Hydrogenation
- Fermentation
- Photocatalytic chemistry
- Biotransformation
- Industrial chromatography
- Flow chemistry
- Spray drying

## High-Potency APIs (HPAPI)

We offer more than 25 years of expertise in the production, handling and containment of cytotoxic and other highly potent compounds.

- State-of-the-art, SafeBridge-certified facility
- Equipment including cGMP-compliant glove box isolators and reactors capable of handling materials with OELs under 1 ug/m<sup>3</sup>
- Manufacturing capabilities up to 1200 L reaction scale with batch sizes of 50–100 kilograms
- Large-scale cryogenic capabilities

## Controlled Substances

AMRI is an industry leader in the development and manufacture of DEA-controlled substances and derivatives.

- Expert manufacturing of Schedule I–V compounds
- DEA-licensed to import Schedule II narcotic raw material for the manufacture of opium-derived products
- Product classes including phenidates and amphetamine derivatives and precursors
- Dedicated aseptic fill and finish facility licensed to handle Schedule II, IIN, III, IIIN, IV and V controlled substances

AMRI is a global contract research and manufacturing organization that has been working with the life sciences industry to improve patient outcomes and quality of life for more than 25 years.