

Sigma-Aldrich | SAFC Cleveland

Village of Cuyahoga Heights | Featured Business | 2017



Sigma-Aldrich | SAFC Cleveland

4353 East 49th Street, Cuyahoga Heights, Ohio 44125

Toll-Free 800-321-0570 | Technical Service 800-334-0144

www.sigmaaldrich.com/safc/facilities/cleveland-ohio.html

SAFC Center of Excellence

SAFC Cleveland is SAFC's Center of Excellence for biological buffers, cell culture media components and reagent compound manufacturing used in the biopharmaceutical and diagnostic industries. This chemical production facility consists of laboratory, intermediate and bulk chemical areas capable of producing a broad range of batch sizes, quality control laboratories and dedicated packaging facilities operated under ISO9001 and cGMP IPEC guidelines.

Core Technologies

- Bulk scale chemical processing equipment is a multi-use, multi-vessel set up with equipment redundancy
- Pilot and laboratory-scale chemical synthesis capabilities
- Dedicated and segregated packing facilities
- Fully equipped and staffed QC department for testing products and raw materials
- Molecular biology laboratory for chemical testing

Sigma-Aldrich | SAFC Cleveland

Village of Cuyahoga Heights | Featured Business | 2017

Core Competencies

- Biological buffers
- Amino acids, derivatives and peptides
- Cell culture components
- Diagnostic reagent components
- Pack sizes up to 125 kg
- Batch sizes up to 3,000 kg
- Chemicals produced have a long history of successful use as components in biopharmaceuticals, cell culture media, diagnostic reagents, life science research and specialty chemical markets

Capabilities/Equipment Overview

- Provide responsive customer service and unsurpassed quality in our products
- Multi-scale, robust chemical processes that produce high quality, reproducible biological buffers and biochemical reagents that exhibit high clarity, superior solubility and minimal trace metal content, with lot-to-lot consistency
- All processes use non-animal derived raw materials
- Full lot traceability in manufacturing and the supply chain
- Chemical-based processes provide material that is inherently low in bio-burden and endotoxin contaminants
- Custom services for chemical synthesis, formulation, packaging and analytical/MB testing
- Processing equipment in Manufacturing Facility is a multi-use, multi-vessel set up with equipment redundancy and vessel sizes ranging from 30-2,000 gallons

About SAFC

SAFC is a trusted manufacturer of specialty chemicals and biologics for commercial life science applications. We provide unique and innovative technologies and services for customers requiring a reliable partner throughout the development and manufacturing process.

Sigma-Aldrich | SAFC Cleveland

Village of Cuyahoga Heights | Featured Business | 2017



Biopharmaceutical Expression Systems

SAFC offers multiple levels of support for your biopharmaceutical expression systems needs with a focus on increasing production titer and decreasing development timelines. In addition to our long history of reliability in supplying high grade critical raw materials, our offerings are backed by top notch technical support by Ph.D. level scientists and comprehensive protocols for ease of use. Decrease your time to market and costs by leveraging the CHOZN manufacturing system.

<http://www.sigmaaldrich.com/safc/biological-manufacturing.html>



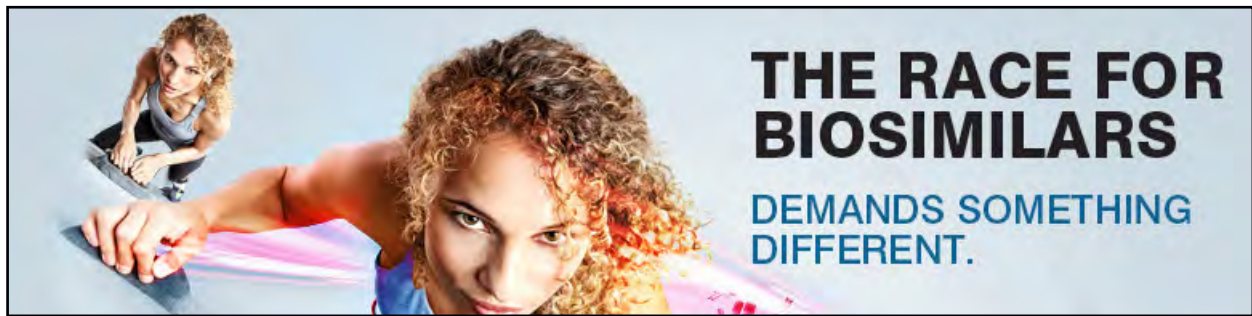
Bioprocess Products & Services

Global cell culture-based manufacturing operations for vaccine, biotherapeutic and diagnostic products have relied on SAFC as a primary supplier since 1971. This long-standing presence in the biopharmaceutical industry as a leading developer and manufacturer of critical raw materials has positioned SAFC to meet the ever changing demands associated with raw material supply.

<http://www.sigmaaldrich.com/safc/bioprocess.html>

Sigma-Aldrich | SAFC Cleveland

Village of Cuyahoga Heights | Featured Business | 2017



Biosimilar Products & Services

Get there first. In the push to market, the biosimilar that's approved first wins the race. That's why SAFC offers CHOZN®, an off-the-shelf, and customizable platform proven to accelerate cell line development timelines by 8 weeks. The CHOZN platform seamlessly integrates with EX-CELL® Advanced™ cell culture media and feeds, and EX-CELL® Glycosylation Adjust (Gal+), a protein quality supplement that jumpstarts profile matching. In a competition where everyone is the same, the only thing that matters more than speed is expertise. See how the experts at SAFC can help you win the race to market.

<http://www.sigmaaldrich.com/safc/biosimilars.html>



Contract Manufacturing Services & Solutions

SAFC is a complete pipeline partner for pharmaceutical and biopharmaceutical companies developing and commercializing complex small-molecule APIs and biologic drug substances. The company combines world-class, "single point of contact" project management with proven processes and procedures and offers analytical and process development support at all stages of drug development and manufacture.

<http://www.sigmaaldrich.com/safc/contract-manufacturing-services-and-solutions.html>

Sigma-Aldrich | SAFC Cleveland

Village of Cuyahoga Heights | Featured Business | 2017



Testing & Support Services

SAFC, through its BioReliance business, provides testing and support services for the development and manufacturing of large and small molecule therapeutics. Since 1947, BioReliance has offered industry leading quality, scientific knowledge and regulatory expertise. In addition, a focus on operational excellence and project management ensures clients that their critical timelines will be met successfully.

<http://www.sigmaaldrich.com/safc/testing-and-support-services.html>



Quality & Regulatory Support

SAFC has multiple cGMP manufacturing locations worldwide for biochemical production and manufacturing of complex organic APIs and key intermediates. Therefore, SAFC must meet many different regulatory requirements globally. Our Quality Systems are designed to meet stringent regulatory requirements, but flexible enough for us to customize many specific items for your needs.

<http://www.sigmaaldrich.com/safc/quality-and-regulatory-support.html>

Sigma-Aldrich | SAFC Cleveland

Village of Cuyahoga Heights | Featured Business | 2017



Global Project Management – Commercial

SAFC is dedicated to providing quality project management to our clients. Each project is unique in terms of scope and challenge, which are dependent upon your unique development and manufacturing requirements. However, we have found that a systematic approach using best practices across all of our worldwide locations is key to exceeding customer expectations. SAFC uses a single-point of contact project management approach that fosters an environment of collaboration, communication and flexibility. The Project Manager is responsible for driving the project to completion professionally; on-time with the quality and quantity the client expects. SAFC's project managers facilitate the timely communication of important technical information and production timelines.

<http://www.sigmaaldrich.com/safc/project-management.html>



Sourcing Services | CHESS™ Program

Let your development chemists concentrate on the development of new products, not the search for raw materials. Allow your purchasing group to streamline the multiple and ever-changing requests for raw materials and intermediates. Let SAFC develop a single-partner, customized sourcing program designed specifically to fit your needs.

<http://www.sigmaaldrich.com/safc/sourcing-services.html>

Sigma-Aldrich | SAFC Cleveland

Village of Cuyahoga Heights | Featured Business | 2017

Clinical Trial Laboratory Services

Clinical trials for biological products may require additional tests beyond the standard clinical chemistry and hematology. Many of these analyses involve the development of specialized assays that are not routinely performed by most Clinical Research Organizations or Reference Labs. To complement our significant experience in the testing of biological therapeutics, SAFC, through its BioReliance business, offers these assays as part of its Clinical Trial Laboratory Services. All assays are performed according to the principles of GLP.

<http://www.sigmaaldrich.com/safc/clinical-trial-laboratory-services.html>