

White Paper

Consistency in Raw Material Supply: Benefits of Partnering with a Customer- Centric Supplier

Introduction

Biopharmaceutical manufacturing processes today are critically dependent upon the ability of suppliers to provide consistent, on-time supply of quality raw materials. Therapeutic manufacturers are increasingly concerned about potential downtime associated with underperforming materials and are consequently looking for customer-centric suppliers who can help develop collaborative solutions that meet a variety of supply chain challenges.

The Challenge

A therapeutics manufacturer discovered lot-to-lot variations during production through in-process testing. Further manufacturer analysis revealed that the root cause was disparities in purity among lots of Bis(2-hydroxyethyl) amino-tris(hydroxymethyl)methane (Bis-Tris) from their original supplier. These variations in raw material were adversely affecting quality and yields of their finished product lots. To resolve this issue, the manufacturer wanted to 1) find a supplier who could consistently provide raw materials that met their quality requirements and 2) identify a secondary supplier to limit risk from being sole-sourced.

The Solution

Through an existing relationship with SAFC based upon support of upstream raw materials and reagents, a Bis-Tris challenge was revealed. As a primary manufacturer of biological buffers with a Quality Management System based upon selected elements of ICH Q7A (Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients), SAFC was able to provide technical representation to investigate the challenges.

Analytical testing was performed and revealed that purity profiles of industry supplied Bis-Tris material varied noticeably from lot-to-lot. This finding initiated a more extensive investigation to determine how to remove the unwanted impurities. A process development team from SAFC's biological buffer manufacturing facility identified additional purification techniques that could be performed during production to reduce the lot-to-lot variation and provide a more consistent product with regard to its purity profile. As with all good quality systems, the Quality Assurance team guided incorporation of the changes into the manufacturing process and ensured that modifications were documented in accordance with standard procedures.

Qualification samples were provided to the customer to confirm the Bis-Tris manufactured from SAFC's new process met the customer's specifications. After the qualification samples were approved, large-scale lots of material were supplied for commercial manufacturing.

Results

New product specifications developed not only significantly helped this manufacturer, but also resulted in SAFC offering more robust material to other customers by meeting more stringent specifications.

Several significant benefits by outsourcing the manufacture of Bis-Tris to SAFC were realized, including:

- Security of supply - strategic sourcing with a partner capable of identifying and correcting raw material problems provided a more consistent product.
- Raw material cost savings - the customer did not have to use additional raw materials to adjust in-process steps and therefore saved 26% on raw material costs by using a more consistent product.

United States

SAFC Biosciences, Inc.
13804 W. 107th Street
Lenexa, Kansas 66215
USA
Phone +1 913-469-5580
Toll free-USA 1 800-255-6032
Fax +1 913-469-5584
E-mail info-na@sial.com

Europe

SAFC Biosciences Ltd.
Smeaton Road, West Portway
Andover, Hampshire SP10 3LF
UNITED KINGDOM
Phone +44 (0)1264-333311
Fax +44 (0)1264-332412
E-mail info-eu@sial.com

Asia Pacific

SAFC Biosciences Pty. Ltd.
18-20 Export Drive
Brooklyn, Victoria 3025
AUSTRALIA
Phone +61 (0)3-9362-4500
Toll free-AUS 1 800-200-404
Fax +61 (0)3-9315-1656
E-mail info-ap@sial.com

- Process development resource savings - by freeing up process development resources, the customer was able to focus more attention on maximizing the process rather than on troubleshooting issues relating to raw materials.
- Manufacturing resource savings - not having to adjust process parameters reduced the production time by an estimated 6%.
- Risk Management/Quality Assurance - by supplying material that consistently meets specifications, the risk of batch failures and write-offs was reduced. And, due to the elimination of use-testing raw materials and regulatory concerns, the customer was free to devote more resources to internal quality systems.

Outcome

This project demonstrates the mutual benefit of partnering with a trusted supplier to provide consistent supply of quality raw materials. SAFC's goal was to provide best-in-class quality and service for the customer/partner and, in return, become a leading supplier for the material. Because of the responsiveness and professionalism in handling the customer's problems and expertise as a primary manufacturer of Bis-Tris in the United States, the customer named SAFC as primary supplier and extended the majority share of annual volume requirements of Bis-Tris.

Working collaboratively with the customer and demonstrating flexibility and commitment to quality at every step of the project are key factors in SAFC maintaining this successful partnership. As a result of this project's success, new opportunities are in progress to proactively address any raw material issues to alleviate unwanted supply chain risks.

About SAFC Biosciences: SAFC Biosciences is a leading provider of cell culture materials and development services for upstream and downstream processes in the biopharmaceutical industry. Providing an integrated services package in mammalian cell culture media development, along with analytical and regulatory support, SAFC Biosciences employs a wealth of industry experience and scientific know-how to deliver reliable, consistent solutions that accelerate customer success – from development through to commercialization. The unit has a 35-year history as a manufacturing partner providing leading biopharmaceutical companies with the broadest range of highly customized products and services possible.

About SAFC: SAFC is the custom manufacturing and services group within Sigma-Aldrich that focuses on high-purity inorganics for high technology applications, cell culture products and services for biopharmaceutical manufacturing, biochemical production and the manufacturing of complex, multi-step organic synthesis of APIs and key intermediates. SAFC has manufacturing facilities around the world dedicated to providing manufacturing services for companies requiring a reliable partner to produce their custom manufactured materials. SAFC has four focus areas – SAFC Pharma®, SAFC Supply Solutions®, SAFC Biosciences®, and SAFC Hitech® – and had annual sales of \$624 million in 2008. SAFC is one of the world's 10 largest fine chemical businesses. For more information about SAFC, visit www.safcglob.com.

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www.safcbiosciences.com

United States

SAFC Biosciences, Inc.
13804 W. 107th Street
Lenexa, Kansas 66215
USA
Phone +1 913-469-5580
Toll free-USA 1 800-255-6032
Fax +1 913-469-5584
E-mail info-na@sial.com

Europe

SAFC Biosciences Ltd.
Smeaton Road, West Portway
Andover, Hampshire SP10 3LF
UNITED KINGDOM
Phone +44 (0)1264-333311
Fax +44 (0)1264-332412
E-mail info-eu@sial.com

Asia Pacific

SAFC Biosciences Pty. Ltd.
18-20 Export Drive
Brooklyn, Victoria 3025
AUSTRALIA
Phone +61 (0)3-9362-4500
Toll free-AUS 1 800-200-404
Fax +61 (0)3-9315-1656
E-mail info-ap@sial.com