

White Paper

Gaining Process Efficiencies in Vaccine Production while Maintaining Regulatory Compliance

Introduction

Implementing lean manufacturing practices in the vaccine industry can exert positive impact on manufacturing processes. Traditionally, vaccine manufacturers have accepted a certain level of inefficiencies in manufacturing operations, however increased competition is forcing them to identify cost-effective efficiencies in production processes, while maintaining regulatory compliance.

The Challenge

To add value to their organization, a leading vaccine manufacturer faced the task of implementing a lean manufacturing strategy to achieve a more efficient workflow that would deliver high-quality products to market quicker while controlling costs and reducing waste.

To achieve these goals, the manufacturer set out to reduce its workload by partnering with its external supply chain members for raw materials used in the downstream process. The manufacturer recognized the importance of maintaining quality and integrity of critical raw materials, while ensuring regulatory compliance. Key concerns related to outsourcing downstream products and other critical raw materials included identifying a supplier with the following competencies:

- Capability and capacity to manufacture many different products with customizable packaging.
- Quality to meet both specifications and regulatory requirements for vaccine manufacturing.
- Consistent track record for providing products on time.

The Solution

The vaccine manufacturer entered into discussions with SAFC Biosciences® to design a solution that would reduce costs, remove resource constraints and improve collaboration between the organizations. Initial steps included a technical visit to a SAFC Biosciences manufacturing facility to determine if outsourcing was theoretically possible with regards to capacity and capability. The initial visit proved that the collaboration was technically feasible. A formal audit was then performed to confirm that SAFC Biosciences had the expertise to meet requirements by manufacturing products to cGMP standards. Both parties agreed on quality standards and product specifications based on process requirements. The result of this initial effort enabled a scope of work to be created and the project was initiated.

Following the successful audit, extensive validation work was carried out to ensure these products met the client's batch manufacturing specifications. SAFC Biosciences provided samples for qualification and, following approval, supply and quality agreements were established, allowing the start of commercial manufacture. Further quality audits were conducted at agreed-upon intervals to ensure that process and quality standards were maintained to the highest levels.

Results

Collaborative work between the partners resulted in vaccine manufacturer's workload reduction by removing the sourcing of critical raw materials and preparation of downstream products thereby leaving the manufacturer with additional resources to focus on its core competencies.

SAFC Biosciences developed this successful partnership by working closely with the customer and demonstrating its capabilities, flexibility and commitment to quality at every

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step of the project. Effective tech transfer from the client to SAFC Biosciences ensured a smooth process flow with minimal production downtime during change over. As a result of this project's success, the customer is now preparing to transfer the manufacture of additional raw materials to SAFC Biosciences. Specific benefits of this outsourcing collaboration include:

- **Capital equipment investment** - The customer did not have to tie up expensive production equipment for raw materials hydration and saved on equipment utilization by having pre-made, sterile downstream solutions delivered and ready-to-charge directly into processing vessels.
- **Optimal use of facility space** - Following a just-in-time inventory strategy, the previous need to store finished downstream products and unused raw materials was eliminated through outsourcing. In addition, the customer only has to store ready-to-use products, or simply transport them just prior to final manufacturing.
- **Manpower** - Significant savings were realized in manpower formerly used for raw materials production, some of which was redeployed in higher value areas. The customer benefited from a 16% reduction in man-hours to achieve the same throughput, allowing an increase in production without increasing manpower.
- **Reduction in logistics and vendor management** - SAFC Biosciences supply of products effectively removed the management of multiple suppliers from the client's responsibility. A supply agreement enabled SAFC Biosciences to purchase needed reagents as required to ensure continuity of supply at scheduled intervals.

In summary, vaccine manufacturers can achieve greater efficiency with personnel and facility utilization by outsourcing non-value added process steps. SAFC Biosciences has the resources, capacity and expertise to supply customized downstream purification reagents to the global vaccine community allowing vaccine manufacturers to focus on their core competency.

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.safcglobal.com.

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