Chemical Strategies Partnership

CMS in New Sectors: Potential for CMS in the Pharmaceutical and Biotech Industries

Laura Wolfson and Jill Kauffman Johnson, Chemical Strategies Partnership

Executive Summary

With the emergence of the Chemical Management Service (CMS) model in a variety of sectors ranging from aerospace to electronics to utilities and research institutions, the non-profit Chemical Strategies Partnership (CSP) evaluated the feasibility of CMS in the pharmaceutical and biotech sectors. After assessing specific economic, environmental and organizational criteria, we believe the time is ripe for CMS adoption in the pharmaceutical and biotech sectors.

Methodology

CSP developed this paper based on secondary research, informal discussions with industry leaders, and our experience in the field.

Introduction

What is Chemical Management Services (CMS)?

CMS is a business model in which a customer engages with a service provider in a strategic, long-term contract to supply and manage the customer's chemicals and related services. Traditionally, suppliers' profits are tied to chemical volume – the more chemicals sold, the more profit generated. Under the CMS model, the providers' compensation is no longer based on chemical volume, but on the quality and quantity of services delivered. Instead of purchasing chemicals, the customer purchases chemical management services: assistance in purchasing, managing, and tracking of chemicals. This shift to chemical services often aligns the incentives of the supplier and its customer to reduce chemical use and costs. Results to date indicate that the CMS model lowers total chemical costs, and both parties achieve bottom line benefits via reduced chemical use, costs, and waste.

The Emergence of CMS & Market Penetration

Roughly twenty years ago, the automotive industry began working with their chemical suppliers to develop a cradle-to-grave approach to chemical management at their sites. Recognizing that chemical manufacturers have significantly more expertise in chemical management than they do, the auto industry decided to move towards a new relationship with their suppliers: auto manufacturers began paying their suppliers to assist in purchasing and managing their chemicals rather than just supplying chemicals. The supplier was compensated per car out the door, rather than per container of chemical. In such a relationship, both parties have the same financial incentives: to produce a quality car with the least possible amount of chemicals.

What started out as a business model utilized by automotive companies alone has spread to numerous other sectors, including aerospace manufacturing, air transport maintenance, electronics, steel manufacturing, energy and utilities, food and beverage, and research and laboratories.

According to the CMS Industry Report Update 2005, 45% of CMS Providers reported serving three or more sectors.[1]

With the rapid adoption of the CMS model into these new sectors, the non-profit Chemical Strategies Partnership (CSP) decided to evaluate whether CMS could work in the pharmaceutical and biotech industry.

The Viability of CMS in the Pharmaceutical and Biotech Sectors

Key Criteria

Broadly speaking, determining whether an industry holds an opportunity for CMS is no different from determining what the opportunity is for any business venture. The current, past, and anticipated future marketplace need to be considered. The industry and the forces that impact its profitability need to be understood: Is there a good customer base? Is it a growth or mature industry? Which companies are leaders or laggards? Is it a buyers or sellers market? Who has the leveraging power in the industry? The answers to these questions define the health and strength of the industry overall.

While considering all of these broader questions, CSP developed a set of specific criteria to help determine whether CMS is a viable business model for the pharmaceutical and biotech industries. CSP surveyed CMS Providers and industry representatives from the biotech and pharmaceutical sectors to understand particular opportunities and barriers for the industry.

The criteria identified fall into the following categories: economic, environmental, and organizational (see Table 1 below). These categories are defined by the following questions which, if answered positively, make an industry sector particularly ripe for CMS:

1. Can a CMS program in this sector be financially self-sustaining? (Economic)
2. Does CMS have the potential for broad and permanent environmental improvement in this sector? (Environmental)
3. Is the sector open to adoption of the CMS model based on cultural/external factors? (Organizational)

Table 1: Criteria for Determining CMS Viability within an Industry

Economic	Environmental	Organizational
High chemical volume	High toxic chemical use	High proportion of chemical use not embodied in final product
High chemical cost	High toxic chemical release or disposal	Some level of supply chain management sophistication
Large facility size	Environmental regulatory pressure	Openness to outsourcing
Cost reduction pressure		Some CMS provider experience in related manufacturing

[1] *CMS Industry Report Update 2005,* Chemical Strategies Partnership, San Francisco, CA, October 2005, Slide 3, http://www.chemicalstrategies.org/pdfs/Industry_Report_Update_2005.pdf

Opportunities to Apply CMS

Most CMS customers to date do not consider chemicals and their management a core competency. Hence, they partner with a CMS provider to assist them in managing their chemicals. However, in the pharmaceutical and biotech industries, chemistry *is* their business. So what opportunities are there for CMS? While CSP sees little opportunity for traditional "process efficiency improvements" as they relate to production, CMS has much to offer in supply chain logistics and possibly educating researchers on less toxic alternatives.

A simplified way to characterize operations at a pharmaceutical or biotech company is to divide the activities into Good Manufacturing Practices (GMP) and non-GMP. GMP operations generally comprise pharmaceutical production activities that are strictly regulated by the Food and Drug Administration (FDA). Every ingredient that goes into making a drug must be meticulously tracked from its origin. Thus, the inventory tracking and reporting for these materials is highly systematized and great attention is devoted to accuracy. In addition, since the formula and production of pharmaceuticals is reviewed and approved by the FDA, there is little room for changing production processes. Because of this scrutiny, the potential for pollution prevention or continuous process improvement through a CMS program is limited. The only area that appears to be an opportunity for CMS is in the supply chain function – improving forecasting, purchasing, and inventory management.

The non-GMP side of the business includes activities such as research and development (R&D) and quality control testing. These activities resemble an academic setting where there are hundreds of labs, a high diversity of chemical use, and a large population of chemical users. From interviews and site visits we conducted, it appears there is opportunity for a CMS program to deliver high value for this side of the business. Compared to GMP, there are fewer resources and less focus devoted to the chemical purchase, delivery, inventory management, and efficiency issues. Thus, CSP primarily focused on opportunities for introducing CMS to the non-GMP set of activities, understanding that the scope of a CMS program may expand to include GMP activities down the road.

Economic Assessment. For a pharmaceutical and biotech R&D facility, there is a significant volume of chemicals and they comprise a higher proportion of operating costs than seen in other CMS customer environments. In conversations with representatives from both industries, there was consistent acknowledgement that cost reduction pressures are growing. In the past, there was more focus on developing new products at any cost since time to market was of the utmost importance. However, in the past few years, there is a move toward cost containment and conserving cash, and one of the areas high on the radar screen is supply chain and inventory management.

Pharmaceutical and biotech companies procure thousands of different types of chemicals and make tens of thousands of products, which means facilities require a lot of resources to deal with the complex nature of managing a highly diverse set of chemicals. Several industry representatives noted there was potential to cut down transaction costs in the purchasing function through the consolidation of the chemical supplier base. There is also opportunity to reduce the unit cost of chemicals through analysis of annual purchases and leveraging chemical pricing. Several customers we spoke with acknowledged that on the non-GMP side, there has not been focused attention on reducing costs by the purchasing function.

In addition, there is opportunity for a CMS program to make improvements in chemical delivery and inventory management. Researchers request a wide variety of chemicals, some of which have strict handling requirements. There needs to be a strong management process for receiving the chemicals, storing them, transporting them to the lab, and final delivery to the user. This is a matter of lab safety and researcher confidence in the system. Finally, the greatest opportunity for cost reduction is likely in improving inventory management. Like any lab environment, hundreds of researchers are ordering chemicals from the bench. Often, other colleagues have the chemical they need or it is already stocked in inventory. Without a robust inventory management system, there is duplicative buying, excess chemicals accumulating in labs, and hoarding supply to assure it is available. Implementing a system that could allow users to share chemicals and quickly obtain materials in inventory would reduce researchers' time in buying chemicals, reduce costs for the company, and reduce the proliferation of chemicals on-site.

Beyond the supply chain function, one supplier suggested that the biggest opportunities for cost savings may lie in environmental management functions such as MSDS tracking, general reporting, wastewater treatment processes, and waste disposal. Thus, streamlining the information and management systems around environmental reporting and tracking could bring additional efficiencies.

Environmental Assessment. There is growing awareness of the need to improve chemical and hazardous materials (HazMat) management and companies are scrambling to figure out what to do. One of the primary drivers to improve HazMat management in the past several years is increasing attention by local Fire Marshals regarding chemical inventory, storage, and transportation in research facilities. This is forcing companies to evaluate the robustness of their information systems, upgrade chemical storage areas, and pay close attention to chemical inventory issues. For the biotech industry in particular, as they have grown, they face space constraints and the need to "clean house". Getting the house in order is starting to prompt a more proactive stance toward active HazMat management.

From a waste perspective, the root of primary production processes consists of inefficient basic chemistry that has not changed in over a hundred years. This fact makes it difficult for the industry to achieve efficiency improvements in its GMP processes through optimized chemical management, because a more efficient process is not a matter of improved chemical management but of discovering more efficient chemistry. One industry representative estimated that <1% of chemical input becomes part of the product output, which at first blush is a breakdown that would point towards CMS viability. However, as mentioned previously, due to the highly formulaic and exact nature of the chemical synthesis processes, it would be difficult for a CMS provider to reduce chemical usage, substitute chemicals, or make efficiency improvements, and thus reduce costs.

Organizational Assessment. In non-GMP pharmaceutical and most biotech operations, the current state of HazMat management programs is generally disjointed and not highly managed. The programs tend to be modular (e.g., some do tracking or have an on site pharmacy or have a good handle on waste) and generally have "no single owner" with oversight of HazMat management. This is largely due to cultural issues in a lab/research environment where researchers are very independent and activities are not typically coordinated. Also, at large pharmaceutical companies, the non-GMP is a small part of their business. Thus, less attention is paid to the chemical management infrastructure at the R&D operations.

Traditionally, many companies have developed their own software for HazMat management. These homegrown systems are partially responsible for the modular approach – a system to address each set of needs (e.g., structure search, MSDS, inventory management, etc.). While there are many homegrown systems still today, there is a movement toward implementing commercial software. For IT professionals within a pharmaceutical or biotech company, maintaining and upgrading the HazMat management system is not a top priority. Adopting commercial software provides the advantage of a specialized solution with continuous upgrades, the cost of which is shared by other software customers. However, tailoring the software to interface with the enterprise information system has been challenging. In addition, with no one "process owner", the data collected is not always analyzed for potential improvements.

In summary, implementation of a CMS program would allow pharmaceutical and biotech companies to leverage the expertise of a CMS provider to optimize purchasing, inventory management, chemical delivery, MSDS tracking, waste disposal and wastewater treatment. These benefits could be attractive for companies that face intense market pressure to trim cost and boost production efficiency.

Lessons Learned from the Research/Lab Sector. The academic research and laboratory sector is a recent adopter of the CMS model. The CMS model has had success in this environment, particularly at the Stanford Linear Accelerator Center (SLAC). The CMS program at SLAC kicked off in August of 2005. In the first six months of the program, there were more than 1600 different chemicals in the catalogue with over 90% of the items ordered on request. There are approximately 170 users in 35 work areas who order off of the central ordering system provided by the CMS Provider. The CMS Provider exceeded the goals for on-time delivery for both "min-max" and "order on request" material requests. In addition, the program has reduced scrap and spoilage in inventory. Savings have already been realized in material purchase costs, inventory carrying costs, MSDS management, EHS labor, and annual hazardous material inventory activity. The success at SLAC is a good indicator that CMS could be applied successfully to non-GMP activities in pharmaceutical and biotech industries.

In addition, one biotech company recently released a "request for proposals" for assistance in developing a CMS program. If a contract is awarded, it would mark the first CMS program in a biotech company.

Conclusion

Economic, environmental and organizational factors point towards the readiness of the pharmaceutical and biotech industries for adopting the CMS model. The recent success of CMS in a research and lab environment also suggests a ripe opportunity. CSP believes that the pharmaceutical and biotech industries would benefit greatly from implementing CMS as a best-in-class business practice.