

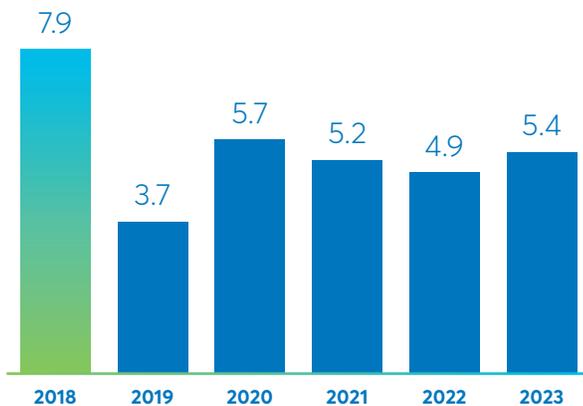
Onsite Services
Chemical Management

Developing Comprehensive Solutions to Chemical Management Challenges



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The modern chemicals industry and the products it produces are fundamental elements of business success and performance for companies across the globe. Chemicals are essential to much more than major industrial segments such as oil, gas and plastics. They're integral to major industries, such as pharmaceutical and biopharmaceutical production, healthcare, environmental testing and quality control as well as a broad range of research laboratories at universities, government agencies and private business. According to the American Chemistry Council, over 25 percent of the U.S. GDP is linked to chemical manufacturing.¹



Between 2019 and 2023, U.S. chemicals manufacturing revenue is expected to grow at an annual compounded rate of 5 percent.

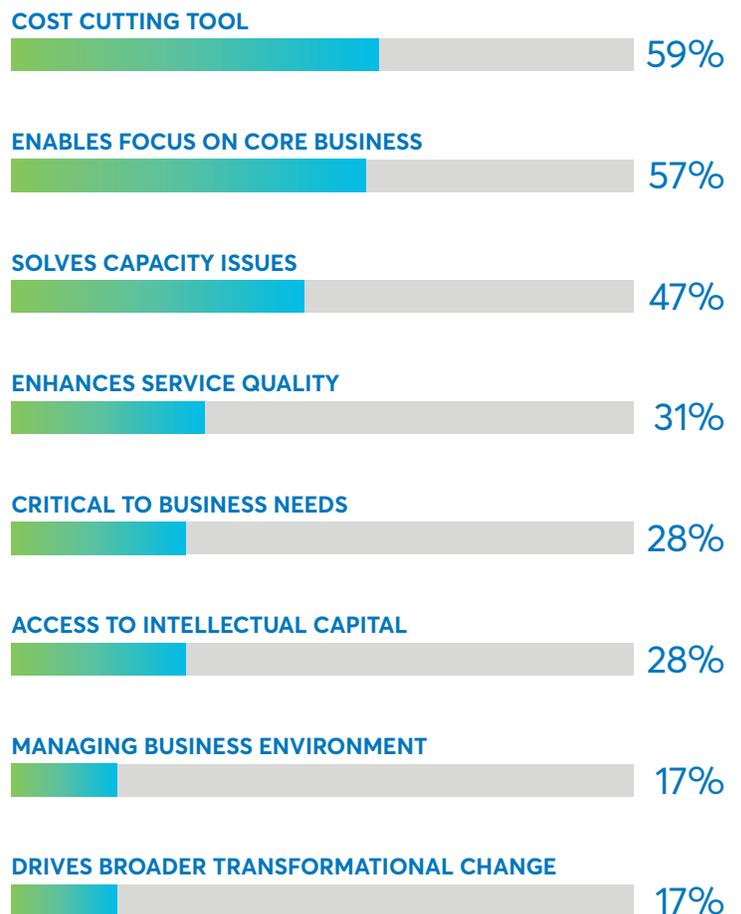
Source: First Research, Chemical Manufacturing, Industry Forecast.

For most of these end users, chemicals are said to serve in two ways:

- **As a resource:** Chemicals are vital to an extremely broad range of manufacturing processes and end products, from catalysts in chemicals manufacturing, buffers, chromatographic resins and excipients in biologics production or reagents in automated laboratory testing systems.
- **As a tool:** Chemicals for research and laboratory applications, such as analytical chromatography materials, histological, hematological and immunological testing systems and clinical trial kits.

Given the critical role chemicals play for these industries, many companies and organizations are investigating the value of implementing comprehensive chemical management solutions, either fully outsourced or in partnership with chemical management experts. Chemical management solutions are in line with a greater outsourcing trend that affects all industries.

REASONS FOR OUTSOURCING



Companies choose specialized management solutions to control costs, focus on their core missions, reduce storage and much more.

Source: Deloitte's 2016 Global Outsourcing Survey.

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There are several reasons why full-scale chemical management solutions are being considered:

- **Solve persistent challenges:** From cost overruns on purchases to poor chemical inventory tracking and management to increased regulatory, safety and documentation requirements, many companies face repeated challenges establishing effective processes for managing their chemical supplies to optimum effect.
- **Obtain economies of scale:** All global companies and research organizations are under constant pressure to control costs and make more efficient use of resources. Whatever the size of the organization, many procurement operations are seeking tools to manage the cost factors of their chemicals, seeking better insights and visibility into what materials are purchased, when and to what purpose those chemicals are used and how that usage is accounted for.
- **Focus on core competencies:** Many of the most successful businesses and organizations recognize the long-term value in focusing on their people's time, efforts and resources on their core mission or purpose—whether it's manufacturing semiconductor chips or researching new cell-based cancer therapies—and outsourcing non-core but necessary tasks to specialists in those fields.

For example, a few decades ago, drug makers did their own discovery work, along with every other element of getting a drug or medical device to the marketplace. But today, nearly anything that a pharmaceutical, biotechnology or medical-device business needs to do—from designing assays to planning and running clinical trials—can and may be outsourced to contract research organizations. In a survey across all industries, 57 percent of businesses indicated that outsourcing provides them with the ability to focus on what matters for their core mission.²

From IT services to human resources, specialized management solutions and outsourcing are potent tools for helping businesses streamline their operations and improve their bottom line. To understand how a comprehensive chemical management solution can deliver the same benefits, it's important to have a fuller appreciation of the common trends and challenges many organizations face in the ways they plan for and utilize chemicals in their operations.

INDUSTRY TRENDS AND CHALLENGES

Demand for greater efficiency and better information flow

The need for chemical management services can vary significantly, depending on the industrial segment. Many large-scale manufacturers in segments that make heavy use of chemicals—oil and gas, plastics, food processing operations—have made long-term investments in understanding and integrating the management of their chemical inventories, costs and documentation into their core processes. In part, this is possible because their chemical needs are highly predictable, based on longer-term plans related to production.

Other operations—especially laboratories and research organizations—have less predictable or changing chemical needs that are more difficult to predict. These organizations often have internally developed chemical management practices that can be inconsistent, less than fully efficient and not completely attuned to the needs and workflows of their researchers and other end users.

One key challenge research operations face, compared to manufacturers, is more variable chemical use patterns. Researchers begin studies with an initial understanding of the chemical requirements, but they can't be finely detailed or fully projected. The specific kinds of chemicals a research team may need can change over time, as well as the quantities.

Many labs also face what could be considered an "oversupply" problem. The chemicals that researchers need are often only supplied in large volumes: A minimum size might be 500 grams, but a researcher may only need 35 grams for their work. The amount needed is taken, then the remaining material is put into that research location's storage; if proper tracking processes aren't well established, questions can arise later about the stability of the chemical while it's been stored, which can lead to researchers requesting fresher supplies and potentially disposing of valuable chemicals.

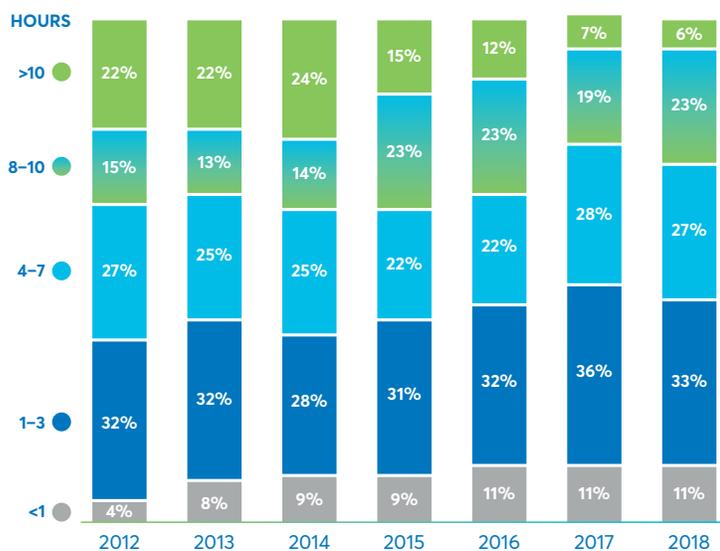
The result: Many labs face the problem of uncontrolled storage. Having a lot of chemicals stored in many places over the years with no good visibility into what is stored where, especially with regular changes in staff, systems and activities, is a big safety risk.

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The opposite can also be true: If a start-up in the biopharma segment expands or adds lines of research, moves to a new facility and needs to begin research/production operations, the new facility may implement its own chemical supply chain without fully determining how the rest of the operation's inventory could be reallocated to serve their needs. A big hurdle of chemical management today is completing a comprehensive and accurate inventory of chemicals, which have "organically grown" in quantity over many years.

Increased regulatory scrutiny

One of the most complex and time-consuming challenges companies and organizations face is responding to significant increases in regulatory supervision, compliance management and documentation requirements associated with chemical environment, health and safety (EHS) issues. Nearly a quarter of companies across all industries dedicate between 416 to 520 hours per year to managing regulatory compliance. This has led to about the same percentage of outsourcing all or part of their compliance management.³



Almost a quarter of compliance teams across all industries spend 8 to 10 hours a week managing regulatory compliance.

Source: Thomson Reuters Regulatory Intelligence, Cost of Compliance 2018.

There are multiple challenges associated with fully managing regulatory compliance. A major one is the sheer multiplication of regulatory requirements, depending on the country, regulatory agency, local regulatory requirements on top of national ones and the fact that different chemicals have less or more strict regulatory requirements. With renewed concern in many parts of the world associated with increasing worker safety and reducing the risk of environmental damage due to improper chemical handling and disposal, there are much greater demands on all users of chemicals to properly manage:

- The source of chemicals purchased
- Raw materials used to create those chemicals
- Understanding the potential safety risks and proper safe handling and storage of the chemicals they use
- All requirements associated with safe disposal
- Documentation of all these aspects of chemical use, including proper documentation covering requirements from source jurisdictions and jurisdictions of end use

In addition, for the biopharmaceutical industry, there is an added level of concern around biological materials. With the growth of segments such as gene and cell therapy, there are new and demanding regulations regarding the sourcing and movement of human and mammalian cells between suppliers, researchers and end users.

Ensuring that all these complex tracking, documentation and safety practices are fully established and woven into every organization's workflow is a daunting management task—and many operations lack the expertise, training and information management systems necessary to assure continued compliance. However, the costs and risks of non-compliance are very significant and need to be fully understood and addressed in a systematic manner.

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Impact of global chemical supply chains

One major chemical management challenge is the result of the successful efforts made by many chemical suppliers and end users to develop secure and robust global supply chains. These investments have been done to help lower costs, increase operational flexibility and supply global researchers and manufacturers with products and reliable inventory close to the locations where they operate.

Chemical suppliers and their customers count on these supply chains to enable agile responses to requests for new products or to replenish inventories. Once suppliers establish a clear understanding of continuing customer requirements, a robust supply chain management system enables suppliers to schedule and deliver the products they need, when they need them, so that neither research nor production are impacted.

However, in some cases, end users either cannot fully project the types of products they need, in the proper volumes or configurations or due to confidentiality restrictions choose not to provide that information in sufficient time. In those situations, having an agile supply chain with both primary and secondary sources of key products is vital.

For highly regulated industries, such as pharmaceutical and biopharmaceutical production, having reliable chemical sources can create a further challenge: Chemicals need to be manufactured according to cGMP principles and regulatory requirements, including complete validation of the source materials the manufacturer used to produce the chemical. If a trusted supplier of the fully validated product has a shortage, there is a risk that secondary suppliers may not be able to supply the fully validated product in the desired timeframe. For many operations that seek to operate using just-in-time supply principles and prefer not to keep significant inventories on hand, the potential for production disruption or extra time getting proper documentation in order can impact costs and productivity.

Movement to select outsourcing of chemical management

In response to these and other chemical management challenges, there is growing interest by many companies and organizations to have non-core chemical management tasks handled by outside resources. In fact, there are several aspects of chemical management that are already routinely outsourced:

- There are now multiple companies specializing in providing material safety data sheet (MSDS) aggregation services to aid end users in safety documentation. While this can be helpful, it is a narrow focus and still requires the end user to properly manage how the MSDS materials are distributed and used within their organizations.
- Professional chemical disposal companies with expertise in all aspects of handling and properly, safely and legally disposing of chemicals are now commonly entrusted by a wide range of end users to handle this important task.
- There is already some outsourcing of chemical purchasing and inventory management for large manufacturing operations, particularly those with multiple facilities in both traditional segments, such as oil and gas, as well as some drug manufacturing companies, but no consistent trend has become established similar to the wide use of CROs and CMOs.

However, among science-driven companies and organizations with heavy dependency on research and development operations, there is a growing focus on reorganizing operations and turning to professional chemical management resources, in order to renew their focus on core competencies, so scientists and research teams can devote less time to management and more time to what scientists are best at: doing science.

In addition, for companies like biopharmaceutical manufacturers, operations and production executives want to simplify and right-size the number of vendors they use, so they can focus valuable time and resources on their production challenges—not on managing multiple sources of chemicals.

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SOLUTION

Comprehensive chemical management programs

In response to these challenges, there are now comprehensive chemical management solutions being developed by major companies with deep insight into the key principles called for to successfully manage all the key elements of end users' chemical needs, whether in manufacturing segments, university-affiliated research organizations and environmental testing and quality control laboratory segments.

To be effective, these chemical management solutions need to be scalable and flexible enough to match the wide range of needs different companies and organizations have. They should provide the personnel, processes, technology and expertise to fully manage these challenges to help reduce costs, improve safety and efficiency and comply with regulations around the world.

Ideally, a chemicals management solution would provide a range of services covering five major aspects of chemical management:

- **Collaboration and development services** that ensure all unique chemical needs are clearly identified and efficiently served, and can include custom chemical manufacturing in cGMP facilities, optimization of how process chemicals are used and custom packaging to streamline research and production processes.
- **Distribution and delivery services** to multiple sites with different operating procedures and requirements. From warehousing and storage to procurement and distribution, companies with long-standing logistics expertise and well-established procedures for handling international chemical transport can help ensure deliveries are properly documented and arrive on time.
- **Onsite management** of chemical inventory, safety and disposal. The best solution would cover all major tasks, from procuring materials to receiving, labeling, tracking, delivering and staging waste for disposal, and would include state-of-the-art digital management tools that are cloud-based and provide an excellent tool for collaboration between the chemical

management service provider and end users. This helps build comprehensive plans to optimize chemical storage and usage, especially for multi location operations.

- **Disposal services** also play a vital role in a comprehensive management solution. They should cover the entire waste cycle and waste management should be tailored to individual location requirements, existing facilities' capabilities and local, regional and/or national environmental regulations.
- **Chemical operations consulting** can provide an in-depth analysis of every aspect of chemicals procurement, utilization and planning, focusing on specific ways to optimize processes—either by identifying waste and bottlenecks at existing facilities and getting them back on track or by helping establish best practices at new facilities.

While it is possible to have different companies handle different aspects of chemical management outsourcing, there are distinct benefits from working with a single solutions provider who has comprehensive responsibility for all aspects of chemical management processes. There are also benefits from working with a solutions provider who has:

- Actual chemical manufacturing plants and in-depth chemical production expertise, to enable more efficient custom chemical production, packaging and delivery.
- Proven inventory management and distribution experience, including personnel who work onsite with customers to supply their research and production needs.
- Global experience with cGMP production and supply chain requirements, as well as demonstrated experience handling regulatory, compliance and documentation requirements.

As with other successful outsourcing solutions, comprehensive chemical management solutions can help companies and organizations that have an ongoing and vital need for the right chemicals, in the right quantities, in the right locations at the right time be properly supplied through processes that maximize efficiency, proper and safe use and help end users leverage the value of the chemicals they use for maximum success.

1 American Chemistry Council, *Jobs and Economic impact*, accessed on June 20, 2019, <https://www.americanchemistry.com/Industry-Impact/Jobs-Economy/Overview/>

2 MicroSourcing, *The Ultimate List of Outsourcing Statistics*, accessed on June 20, 2019, <https://www.microsourcing.com/blog/the-ultimate-list-of-outsourcing-statistics.asp>

3 English, Stacey and Susannah Hammond. *Cost of Compliance 2018*. Thomson Reuters.