

Onsite Services Science as a Service

Helping labs operate at peak efficiency to foster innovation



Current industry trends and forecasts for the lab of the future indicate that the demand for increased quality, efficiency, and speed-to-market has never been greater. But, as scientists strive to accelerate innovation and discovery, the burden of repetitive protocol-based work increasingly hinders their productivity. To meet this growing obstacle, many organizations are turning to outsourced solutions, searching for services that provide scientific assistance. This "Science as a Service" model harnesses the knowledge of highly-qualified career professionals in providing a support network to assist labs with quality processes, performance metrics, and technological advancement. Spurring innovation through collaboration is Avantor Services driving focus, guaranteeing scientists maintain control of their scientific vision.

Table of contents

Authors

Page 3

Part 1

Outsourcing No Longer a Trend, but an Undeniable Truth

Pages 4-5

Benefits of Outsourcing

Pages 6-7

Part 2

Reducing Complexity, Creating Value Pages 8 Part 3

Delivering Science as a Service to the Lab of the Future

Pages 9

Accelerate Discovery with Avantor Services

Pages 9-11

References
Pages 11

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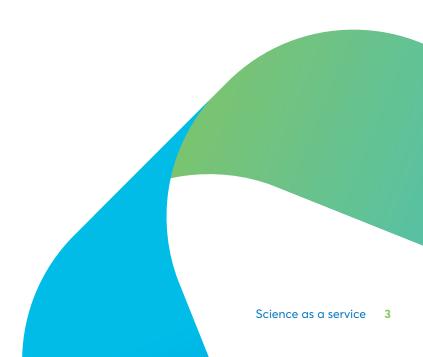
She is passionate about developing the business processes and support infrastructure to help clients for the laboratory of today and the future.



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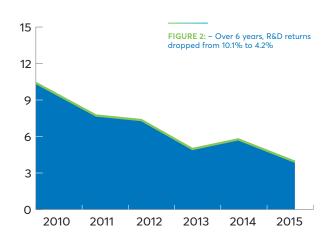
Outsourcing no longer a trend, but an undeniable truth

Science, as Vannevar Bush wrote¹, is an endless frontier. Bush, the founder of Raytheon and Director of the Office of Science and Development at its inception in 1941, pushed the U.S. government to invest heavily in research – leading to a renaissance of advancement in science and technology. Unfortunately, as more and more businesses have realized, the resources to explore that frontier are not endless. Although the pursuit of knowledge and scientific advancement knows no limits, the price tag for carrying out research is too often strictly defined and increasingly prohibitive. Simply put, science costs a lot of money.

The Tufts Center for the Study of Drug Development recently estimated the cost for developing and marketing a new drug at over \$2.5 billion². A recent study³ tracking 12 leading companies in the pharmaceutical industry revealed that in a span of six years, costs to develop a scientific asset rose 33%, while the projected sales, or return on investment (ROI) of those assets, declined by 50% [Fig. 1]. These industry leaders have seen their R&D returns drop from 10.1% to 4.2% in the same time span [Fig. 2]. Global pharma sales of conventional products are forecasted to drop almost 10% by 2020⁴ [Fig. 3]. The era of the "blockbuster" drug – medicines that brought in billions of dollars a year – led



FIGURE 1: – Over 6 years, costs to develop product went up 33%, while projected sales declined 50%



to pharmaceutical companies pouring vast amounts of money into infrastructure to support the burgeoning success in research. Changes in the market are causing companies to transform their approach and adapt to stay viable.

Many innovative drugs have already been discovered and pushed to market while others are running up against the patent expiration clock. In 2017 alone, the patent of at least 20 drugs representing over \$9 billion in estimated annual revenue expired⁵. Losing patent protection is costly; it's estimated that 90% of sales are lost to generic drugs⁶.

Available time and resources have only added to the difficulty faced by labs. Scientists spend, on average, 42% of their time handling non-core, administrative tasks⁷ – time that is taken away from discovery and innovation [Fig. 4].

Despite these obstacles, demand is growing. With the rise of specialty drugs and personalized medicine, the biotechnology

sector is forecasted to realize a near 50% increase in sales⁸. Aging populations living longer and an expanding global market push growth further, as the amount of clinical trials tracked by the NIH have nearly quintupled in the past decade⁹ [Fig. 5]. Pharmaceutical sales have increased by 22.6% in the fast-industrializing market of BRICS countries (Brazil, Russia, India, China, and South Africa) as many barriers to free trade have recently been removed through economic and policy changes in global trade¹⁰.

Thus, constricting profit margins, matched with a growing demand and time constraints, are leading to a greater focus on the bottom line. Companies want to propel innovation and discovery while offsetting costs through business tactics and strategies¹¹ - seeking ways to tighten the belt. Doing so has become a game of analyzing every "loop" in the "belt" of research.

In any major research and development program, there's a long chain of diversely talented professionals that lead to the ultimate success or failure of the outcome - technologists, scientists, researchers, directors, managers, medical doctors, etc. For each

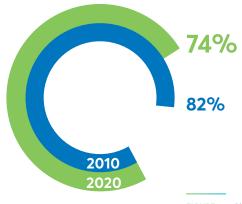


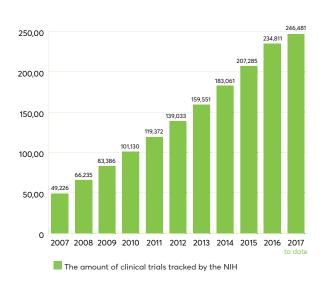
FIGURE 3: – Global pharma sales of conventional products are forecasted to drop almost 10%, from 82% to 74%, by 2020



42%

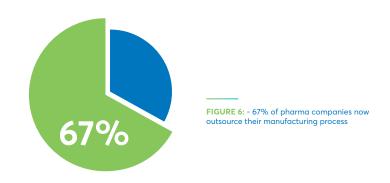
FIGURE 4: – Scientists spend, on average, 42% of their time handling non-core, administrative tasks





one of these resources, another resource must be situated to manage the asset and the process¹³ [Fig. 6].

It is through critical evaluation of this R&D value chain that organizations across the research spectrum are able to realize gains. Costs are lowered and efficiency improved as more companies outsource routine lab and science work to third-parties and CROs. Experts believe that companies will soon outsource all aspects of drug research and development, in addition to clinical trials and manufacturing, thereby creating virtual pharma organizations¹². To date, roughly 67% of pharma companies now outsource their manufacturing process¹³.



Case Study: No Longer Tasked with Cell Bank Management, Scientists Gain Time for Research

CHALLENGE

A pharmaceutical company needed its researchers to be relieved of the time-consuming demands of managing their variety of cell lines

SOLUTION

A well-qualified, degreed scientist was implemented by Avantor Services to fulfill the company's cell banking process.

RESULTS

The cell bank needs of more than a hundred researchers is supported through Avantor Services, recovering researcher time equal to one full-time employee. Consistent and reliable quality has been delivered and is monitored through customer feedback and process metrics, and the cell bank program now includes assisting researchers with routine cell-based assay setup.

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Outsourcing also allows for greater agility in meeting heavily fluctuating project pipeline demands, while maintaining regulatory compliance with the increasingly stringent protocols required to ensure patient safety. Issues with regulatory compliance can result in costly project delays and adversely affect a company's ability to bring its product to market efficiently.

In order to meet a growing market demand, and offset decreasing ROI, companies have turned the trend of outsourcing lab work into an important business truth: science is now a service needed to propel companies forward.

Benefits of Outsourcing

There are six main factors driving pharmaceutical and biotech companies to outsource their laboratory experiments, clinical trials, and manufacturing production work. These areas cause additional complexity that is often difficult to address by a scientific organization alone.

Bottom line pressure. data in the graphs above show, the business environment is growing more complex with patents expiring, innovation and discovery becoming more targeted to smaller populations leading to less blockbuster drugs, and ROI diminishing related to asset R&D. This has led more companies to offload research, development, quality, and production costs to reliable third parties and CROs.

Physical transformation. With the cost of a new lab now reaching over \$1,000 per square foot¹⁴, it's clear that space is a premium

in today's laboratory [Fig. 7]. Organizations are moving away from traditional labs that once sequestered small teams who focused on a single project. Now, the emphasis is on open and flexible space, or even virtual labs. The open-space lab facilitates interdisciplinary interaction and collaboration – connecting areas of scientific specialization under one umbrella to truly master innovative technology for the advancement of science. Doing so also centralizes complex, high-cost equipment (like automation used in high throughput screening & high content biology platforms), reducing overhead and maintenance costs. reduce costs. Virtual labs focus on modeling and simulation¹⁵, requiring communication between many resources spread out globally.

Furthermore, organizations are seeking to be closer to target patient groups¹⁶ for therapeutic research and clinical trials, requiring labs and scientists to be available to emerging global communities.

Technology-driven evolution. As a new generation enters the world of research, the expectation for technology-based process and communication increases, giving rise to a digitally-driven workforce¹⁷. Labs must evolve to keep up with the latest technologies that allow for more immediate collaborative communication between remote/regional/international associates, cloud-based data for large data-set storage and analysis, and an easily searchable repository of shared intellectual discovery. The costs to keep up with the ever-expanding technological advancement can become overbearing.

Compliance. The overhead costs related to staying compliant with all regulations and regulatory bodies in an increasing global market is complex. Managing the oft-moving rules, staying aligned with organization values, and operating efficiently in cGMP and GxP environments is a constant challenge of which it is difficult to stay ahead.

Managing resources. Recruiting and hiring skilled employees, and getting them trained in time to be effective becomes a management task outside of the core science. Many labs can no longer keep temporary workers for more than two years due to stringent laws preventing long temporary work, thus, turnover can be high, restarting the time-consuming cycle of hiring and training. Training can become expensive, particularly for high-content biology and gene array profiling technologies. Companies are

finding it fruitless to invest in temporary employees who offer no long term value.

Additionally, new Department of Labor laws require increased pay for postdocs – whom many labs rely on – due to improved overtime rules¹⁸, causing a further strain on tight salary allotments. As temporary staffing can be time-prohibitive, CROs are becoming more cost-prohibitive

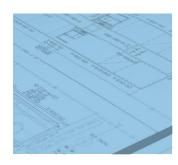


FIGURE 7: – Cost of a new lab now reaching over \$1,000 per square foot

and inflexible to the evolving needs of labs. One recent survey of over 300 global clinical operations leaders revealed that delays in CRO data analysis and reporting lead to an average delay of three months and over \$100,000 per CRO change order¹⁹.

Driving efficiency. Streamlining data management, workflows, global operations and logistics, along with managing employee productivity and quality output in compliance with myriad regulations can swiftly become overbearing. Balancing all of these essential elements all while driving down costs turns an organizations focus away from innovation and discovery.

With the benefits of outsourcing clear, the question organizations must ask then is not if they should outsource, but to whom should they outsource? Finding a trusted, reliable third-party with a proven track record is critical to success with the outsourcing model.

Part 2 Reducing Complexity, Creating Value

Among all of the obstacles faced by the pharmaceutical industry, R&D productivity remains the greatest challenge²⁰. An increasing demand to deliver innovation and value leads to advancement of technologies and automation that can, however, lead to even more complexity. With advanced automation comes advanced data. Now, R&D teams are forced to handle and analyze an enormous amount of generated data in order to positively influence on-going experimental processes as quickly as possible.

Case Study: Integration with Biotech Customer Meets Bulk and Specialty Solution Requests

CHALLENGE

Scientists at a major biotech subsidiary were spending too much time mixing solutions for experiments, delaying the concept-to-market timeline for novel therapeutics.

SOLUTION

Avantor Sciences built an on-site Scientific Solutions Laboratory for media and buffers, supported by well-qualified scientists.

RESULTS

The Avantor Sciences team is now fully integrated with both scientists and the work streams at the biotechnology subsidiary, exclusively preparing all media for R&D projects and experi-ments utilizing the company's trademarked antibody. By attending strategic meetings to discuss the solution preparation queue, plan experiments, and meet preparation demands, the scientists consistently meet 100% of on-time delivery requests for all solutions.

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As scientists strive to maximize the value of their work within a company's growth strategy, they need ample opportunity to focus on data analysis, decision making, collaborating with colleagues on new models of discovery, and other value-generating activities.

With over 40 years of experience, Avantor Services is well-equipped to meet these needs by providing high-quality scientific services; after all, it is run by scientists, for scientists.

Like all valuable processes and projects, success begins with the people involved. Avantor Services strategically hires, cultivates, and maintains a staff of qualified, collaborative professionals with the requisite lab experience and background in chemistry, biology, and engineering to work closely with onsite customer scientists, or in a Avantor Services core lab. These experienced, degreed professionals are further developed through the Avantor Services "career ladder" - a system designed to harness exceptional talent with dedicated training and promotion based on knowledge and experience. Doing so creates an expanded support system, so that highly valued life science professionals can focus more on decision-making, innovation, and value. This in turn creates opportunities for significant improvement in an organization's project delivery timeline.

Avantor Services supports all levels of scientific requirements by offering staff at different career levels. Lab assistants are available for scientific preparation and lab readiness; lab technicians provide basic- to medium-level lab support; degreed scientists are ready to assist at the bench; and researchers with advanced degrees can assist with larger, strategic challenges. Avantor Services associates are not in the lab to replace existing scientists and researchers, but instead augment and assist them in their scientific vision.

Avantor Services consults the customer to identify work streams that can be standardized and delegated to support staff. Scopes of work are defined and carefully designed to deliver results so customers can make the decisions that give their organization a competitive edge.

Part 3

Delivering Science as a Service to the Lab of the Future

As business in innovation and discovery progresses forward through the limitless frontier, so must the environment and technology in which science is conducted. Organizations must be prepared to bring a modern lab into the advanced age, allowing their scientists and researchers to excel in the lab of the future. Doing so, means adjusting to the major factors driving the need for the lab of the future.

Marketization. Quickly turning innovative research into a marketable product has never been more important. Improving productivity and increasing efficiency in processes and protocol-based work returns valuable time to researchers in achieving scientific discovery, ramping up a lab's speed to market.

Globalization. Organizations are realizing cost savings by relocating R&D throughout the world. Harnessing the economic advantages of emerging markets demands clear and immediate communication between multiple internationally-situated sites, resources, and personnel, as well as a reliable global supply chain and logistics network.

Digitization. As the world grows more digital, technological advances are affecting every area of research. More sophisticated tools are enhancing the role of the researcher while digital solutions are revolutionizing the entire supply procurement and management process. Furthermore, a new generation of younger scientists entering the field are well-acquainted with technology, which instills them with a more flexible approach to work. This new generation has come to view aspects of work like remote access, flexible work environments, and digital tools and solutions, as the norm instead of the product of future advancements.

Knowing what needs to be done, unfortunately, is not the same as actually bridging the gap from the current lab to the lab of the future. That's where Avantor Services, a trusted service provider, can help.

Accelerate Discovery with Avantor Services

Avantor Services enables science by providing it as a service. Scientists, spared from routine procedural work, can then spend more time on innovation and discovery. Take for example the emerging need for cold-chain bio-sample management. Discovery depends on the integrity of test samples and analysis, but managing the process is time-consuming, tedious, and costly.

Avantor Services trained specialists remove scientists from the logistical process, while also optimizing in-lab space for researchers. Specialists can provide immediate archival and delivery of any test sample or analysis via an advanced database inventory system on demand.

Case Study: Freezer Management Program **Delivers Cost Avoidance**

CHALLENGE

A large pharmaceutical R&D facility was facing increasing freezer program costs.

SOLUTION

Avantor Sciences developed controls and processes to reclaim freezer space, refocus scientists' time, and ensure effective preventative maintenance planning.

RESULTS

Five freezers worth of open space was regained from inventory clean-up and reorganization, avoiding costs of \$70,000 that would come from purchasing additional freezers. The company was able to refocus end-user time from sample inventorying and searching back to science, recovering 432 hours per year. The success of this freezer management program resulted in adoption of the program by additional groups within the organization.

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Avantor Services team of skilled, experienced experts with real-world lab experience enable researchers to focus on their core business tasks by performing essential, non-core, protocol-driven science directly tailored to support the vision and strategy of each unique customer and support new and efficient ways of working in the modern laboratory. As a result, Avantor Services can assist in getting your products to market quickly with technological advancements and an unmatched global reach – bringing you into the lab of the future.

Stability. Avantor Services delivers stable and compliant provision of non-core tasks through recruiting, employing, and managing highly talented personnel, from lab technicians to career scientists, and developing a career ladder for associates to expand their skill set. This approach provides stable, trusted services from a competent team devoid of the high turnover and lowered engagement endemic to temporary staffing agencies.

Flexibility. Flexible deployment models allow for Avantor Services staff to address shifting priorities quickly, meeting any and all requests. Additionally, Avantor Services offers modular services - a tailored "platform" approach that allows labs to add service capabilities based on targeted needs and unique requirements. Choose from onsite or offsite managed services that extend from the stockroom to the laboratory bench.

Quality, Safety & Compliance. The Avantor Services team is wellversed in regulatory compliance as all associates receive detailed GxP and GLP training. These experts excel at documenting processes including scope of work, working instructions, and SOPs; manage training matrices and job safety profiles; integrate onsite specific EH&S programs; and support audit programs. The focus on process excellence sets Avantor Services apart from other service providers - driving efficiency and utilizing metrics to ensure that a lab and scientists are able to operate at peak efficiency.

Reduced Operating Costs. Various hard and soft cost savings - from inventory and procurement management to employee training and HR management – are realized by labs working with Avantor Services. Leaner, standardized processes boost efficiency and return time to scientists and researchers to focus on discovery. Quality of science is assured through measurable services and metrics, allowing labs to readily track returns on investment.

Technological Advancements. Through the use of proprietary digital tools (Inventory Manager, Chemical Manager, and Equipment Manager), Avantor Services takes the time-consuming and error-prone paper process away, allowing for more organized collaborative reporting, swift accounting of product inventory, and timely equipment calibration/validation.

A comparison of Avantor Services managed services with an average temporary staffing agency

Avantor Services managed service	Temp staff augmentation
Service provider commits to take responsibility for a defined business process.	Supplier commits to providing resources with specific skills.
Productivity and service quality commitments are made by the service provider.	Supplier only commits to employee attendance.
Service provider is responsible for the delivery model, including managing people, processes, and tools.	Client is responsible for the delivery model.
Service provider is financially incentivized to drive operating efficiencies.	Supplier is not financially incentivized to improve efficiencies.
Service provider shares in operational risks.	All operational risks remain with client.

By integrating a talented team of skilled professionals with bench scientists and labs throughout the world, Avantor Services harnesses the shared experience of the scientific community to drive the next generation of operational excellence, enabling the advancement of science. Behind every service and support system stands a dedicated community of highly trained specialists, committed to and passionate about delivering excellence at every step of the supply chain and scientific workflow.

Avantor Services' proven history and portfolio of custom managed services meet the needs of a wide range of chemistry and biology labs, helping scientists spend more time on innovation and maintain their scientific vision.

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