Transforming industrialization
A new paradigm for pharmaceutical development

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Introduction

The revolution in the biomedical sciences that has taken place over the past few decades reached the public eye with the completion of a draft map of the human genome in 2000. Yet, the advances that have been made in the laboratory still have to be translated into safe, effective and affordable new medicines.

In March 2004, the U.S. Food and Drug Administration (FDA) acknowledged the extent of the difficulties facing the pharmaceutical industry (Pharma) when it launched an initiative to improve the product development process. “Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products,” the white paper published at the time of the launch, spells out the technological gulf between discovery and development. It also calls for the creation of a better “product development toolkit.”

The initiative is a logical extension of the FDA’s earlier efforts to modernize the regulation of pharmaceutical manufacturing and product quality. In August 2002, the agency embarked on a two-year program to revise the guidelines for current good manufacturing practice, called “CGMPs for the 21st Century: A Risk-Based Approach.”

Clearly, however, manufacturing is the culmination of a complex set of activities that includes the physical design of a drug, the development of a robust method for manufacturing it and the shift from small-scale experimentation to full-scale production. The FDA has called this the “industrialization process” – and here Pharma is struggling. As the regulator notes, “Problems in physical design, characterization, manufacturing scale-up, and quality control routinely derail or delay development programs and keep needed treatments from patients.”

The FDA is therefore promoting a new paradigm that has the potential both to provide patients with better, safer medicines and to enhance Pharma’s bottom line dramatically. Research conducted by IBM suggests that improving pharmaceutical development and creating a manufacturing method that is stable from the moment a drug reaches the market could help to accelerate the point at which sales peak by up to five years. That, in turn, could increase the revenues a billion-dollar drug generates over its lifetime by as much as US$1.6 billion.
The slowdown in innovation
The sequencing of the human genome sparked hopes of a new era in the prevention and treatment of disease and stimulated greater investment in biomedical research. Between 1993 and 2003, U.S. pharmaceutical companies increased their expenditure on research and development (R&D) by about 150 percent (see Figure 1). This trend is likely to continue; CMR International predicts that Pharma’s global R&D spend will reach a staggering US$67 billion by 2007.4

Figure 1. Biomedical research spending has increased dramatically over the past decade.


Yet, boosting the industry’s investment in R&D has done nothing to increase the flow of new drug and biologic approvals. The number of small molecules approved by the FDA has fallen steadily since 1996 – and, as data from the Tufts Center for the Study of Drug Development (CSDD) show, the few drugs biotechnology has produced have not been enough to offset this decline (see Figure 2).5

Figure 2. New drug approvals have fallen steadily since 1996.

Note: SMD = small molecule drug; rDNA = recombinant protein; mAb = monoclonal antibody
A study recently conducted on behalf of the U.K. Economic and Social Research Council is even more critical. It claims that over the past quarter-century biotechnology has produced only 15 significant therapies (defined as drugs with sales of more than US$500 million in 2002/2003). “The translation of this science into new technology is far more difficult, costly and time-consuming than many policy makers believe,” the authors conclude.⁶

**Greater product complexity**

Nevertheless, even though the biomedical sciences have not yet fulfilled their promise, the direction in which the industry is heading is indisputable. As IBM Business Consulting Services argued in its November 2002 white paper “Pharma 2010: The threshold of innovation,” a better understanding of the molecular sciences and massive advances in computing power will eventually enable the industry to make targeted treatment solutions – or healthcare packages for people with specific disease subtypes (see Figure 3).⁷

**Figure 3.** Scientific and technological advances will provide the means with which to make targeted treatment solutions.

The move toward targeted treatment solutions has profound implications for product development, for it will require reinvention of every step of the R&D value chain. These therapies will include drugs, diagnostic tests, and delivery and monitoring devices; so, both the therapies and the processes used to manufacture them will be much more complex than traditional, mass-market medicines. They will also be made in much smaller quantities than conventional drugs and, since these therapies will retail at higher prices, tracking technologies will be required to curb counterfeiting and theft.
There is already some evidence of greater product complexity and the challenges it creates in industrialization. A growing number of medicines on the market are drugs with novel delivery mechanisms like electronically controlled patches, sustained-release injections, inhalers or pumps (see sidebar titled Slow and steady). Such products are sometimes a more effective means of getting drugs into the bloodstream than conventional formulations, and often result in better patient compliance and safety. They also have several commercial advantages. New delivery techniques can be used to extend the lifecycle of drugs that are reaching the end of their patent life, to reach fresh markets and to differentiate competing products. This is because it is much harder to copy complex extended-release technologies than it is to reproduce straightforward tablets, and the techniques are usually patented. In short, drug delivery technologies are an invaluable way of managing and prolonging product lifecycles.

However, the more complex a product is, the more difficult it is to design and manufacture. Many of the new drug-device combinations amalgamate different scientific disciplines; to design and produce an inhaled drug, for example, requires an understanding of materials science, mechanics and plastics engineering, as well as pharmaceutics. Moreover, most drug makers do not develop delivery devices in-house, so they need to collaborate with other companies specializing in such technologies. That, in turn, means they must synchronize their activities – and where multiple devices are used to deliver multiple formulations, product development becomes very difficult indeed.

Thus the industrialization process increasingly involves a network of technology suppliers. It is also likely to include contract developers and manufacturers. All these external parties must be aligned from an early stage in product development, but managing such relationships is not easy. In a 2003 IBM Business Consulting Services survey of strategic licensing practices, respondents reported
that between 20 and 50 percent of the their companies’ alliances did not live up to expectations – with ineffective communications and lack of realism among the most frequently cited obstacles.11

**The current approach to product development**

The FDA recognizes that product development is now the weak link in what it calls the “critical path” from scientific discovery to commercial product. In essence, the agency argues, that path can be divided into two distinct stages: discovery and “translational research.” The latter consists of three elements: *in-vitro*, animal and human testing to determine that a molecule is safe; computer modeling and testing to establish that it is efficacious; and the development of robust processes for manufacturing it on a large scale (see Figure 4).

**Figure 4. Product development is the weak link in the critical path from scientific discovery to commercial product.**

Pharma has extensive experience in testing drugs for safety and efficacy. It is also gradually devising techniques for improving its performance in clinical development, such as the use of adaptive trial design, electronic data capture and investigator relationship management systems to recruit trial patients.12 However, it is much less skilled at making the transition from the laboratory to the factory floor. This is partly because very few people possess the hybrid scientific and engineering skills required to bridge the gap between the two, but it is also because the industry is desperately in need of a new generation of performance standards and predictive tools, as the FDA points out.
Pharmaceutical development (the formulation, process and analytical activities required to bring a drug to market) involves designing a medicine that can be consistently mass produced. First, the product must be designed in a way that best meets the needs of the market for which it is intended; for example, a tablet that has to be taken five times a day is clearly not suitable for elderly patients with poor memories or anyone suffering from a serious psychiatric disorder. Second, it must be formulated with excipients to convert it into a stable dosage form that can be manufactured and administered to patients. And third, it must possess all the attributes that are critical to quality – in accordance with the FDA's new guidelines on drug manufacturing.

After the product has been designed, it must be piloted on a small scale and characterized to test the manufacturing processes that are being used to make it. Both the product and the processes must then be repeatedly refined until they are sufficiently reliable to scale up for mass production.

Numerous difficulties are associated with these steps. Scale-up is one of the biggest hurdles, particularly with biologics, where fermentation and the subsequent separation and purification steps can be even less predictable than the corresponding processes for traditional molecules. As Peter York, professor of physical pharmaceutics at the University of Bradford, notes: “poor and ill-defined scale-up from laboratory via pilot plant to manufacturing scale is inefficient, expensive and wasteful…”

However, even when a product has successfully migrated into full production, problems frequently arise. One common issue is that different batches of excipients often vary slightly, causing significant variations in the end product. At present, drug manufacturers generally work out a standard blending time for an active product and its excipients based on the typical physical and chemical properties of the ingredients and how they interact with each other. They do not perform tests to establish the precise properties of each batch and adjust the blending time in realtime. By contrast, in the semiconductor industry run-to-run process controls are used to measure and etch wafers on an individual basis.

Drug-device combinations are also subject to considerable manufacturing problems because they are intrinsically more complex than conventional therapies. But it is sometimes simply a mixture of minor variations in different ingredients, machinery and unit operations that causes trouble – and when a problem is “spread” across the process in this way, it can be very hard to detect and rectify.
The need for a new product development paradigm

In short, the existing model of product and process development is inefficient, and the trend toward more complex medicines is straining it further. Liam Feeley, director of pharmaceutical R&D at Abbott Laboratories, estimates that as many as half of the factors causing attrition in drug development are related to chemistry, manufacturing and controls. Problems with industrialization are also responsible for a substantial number of the delays that occur in getting new drugs approved.

The FDA acknowledges that it has unintentionally contributed to this situation. Pharmaceutical companies have historically been hesitant about introducing new sciences and technologies into their manufacturing processes, fearing that the FDA would refuse to accept them. However, over the past two years the agency has actively started encouraging the use of process analytical technologies (PAT) and other modern manufacturing techniques for improving production. In addition, it has promised to regulate companies that use such tools and clearly understand the scientific foundations of what they are doing with a lighter hand than those that persist with traditional manufacturing methods. The agency has thus removed one of the greatest obstacles to the development of better manufacturing practices.

Of course, the FDA has also recognized that industrialization is now on the “critical path” to the marketplace. At one time, the protracted nature of Phase III trials meant that the pharmaceutical development team had plenty of time in which to resolve any problems, but drugs that address an urgent medical need can now be filed much more rapidly – and the method by which they are manufactured must therefore be stable at a much earlier point in the development timeline.

Under the FDAs accelerated approvals program, for example, promising new drugs for life-threatening diseases can be launched before the completion of clinical studies. The regulator has approved 20 such drugs over the past nine years, including Gleevec (for the treatment of leukemia and certain gastrointestinal tumors); Eloxatin (for the treatment of cancer of the colon or rectum); and Bexxar (for the treatment of non-Hodgkin’s lymphoma).

Other reforms have also helped to reduce lead times dramatically. Indeed, a study conducted by the Tufts CSDD shows that, between 1998 and 2003, the FDAs fast track program cut the average time required to develop a new drug and win approval by almost three years (see Figure 5). The number of disease indications included in the program increased over the same period and the center predicts that this trend will continue.
Figure 5. The FDA’s fast track program has substantially accelerated the launch of important new medicines.

Shorter clinical development times clearly increase the pressure to produce robust formulations and manufacturing processes much earlier in the overall product development cycle. Other changes in the nature of clinical testing could reinforce the need for faster, better industrialization. The introduction of “in-life testing,” using remote monitoring devices and mobile telecoms or wireless networks, is one such instance; in-life testing would provide a more comprehensive and more realistic means of testing drugs than conventional Phase III trials. Sir Tom McKillop, chief executive of AstraZeneca, recently proposed something similar when he called for a system of conditional approval, under which new drugs would be prescribed by medical specialists and closely monitored for side effects before receiving a full marketing license.

For various reasons, then, what Pharma now needs is a new paradigm for developing medical products. If it is to capitalize on the progress that has been made in biomedical research, it must move from an empirical to a more mechanistic and predictive mode of working.

Building a better industrialization process

More specifically, Pharma needs to manufacture products that are increasingly complex; it needs to develop the processes for manufacturing them increasingly rapidly; and it needs to verify the processes are stable prior to launch. Three elements are especially important in achieving these changes: cross-functional data-sharing; “quality by design”; and systematic building of process capability.
Cross-functional data-sharing

A lot of the basic data the pharmaceutical development team requires to do its job are ascertained in discovery and early clinical studies. Information about how a drug behaves in the body over a given period of time is clearly vital in establishing its safety and efficacy in early human trials, but it is equally important in designing the route of administration, dosage form and processes used to manufacture the product.

At present, very few development teams have the tools to collaborate closely. The discovery, clinical development, pharmaceutical development and manufacturing teams meet regularly, but they do not share crucial data on a day-to-day basis. However, sharing such data throughout the industrialization process allows the pharmaceutical development team plenty of time to solve any problems with the drug candidate (see Figure 6). Collaboration with the manufacturing function is also essential to confirm that the team does not design a product which cannot ultimately be manufactured.

Figure 6. Sharing data between clinical development, pharmaceutical development and manufacturing facilitates the creation of more robust manufacturing processes.

Quality by design

If cross-functional data-sharing is vital, so is scientific development of a manufacturing process that reduces or mitigates the risk of making products which lack the features that are critical to quality. Experience in other industries shows that the starting point for quality by design is the preferred technology platform.

In fact, most pharmaceutical companies do use the same technologies on a regular basis. The pharmaceutical development team typically goes through its records to see whether it has manufactured similar molecules and selects the technology platform that has previously worked best for making such drugs. But this is usually an ad hoc exercise relying on individual expertise and is often poorly aligned with manufacturing. If Pharma is to make increasingly complex products targeted at specific patient subpopulations, and make them in a completely scientific manner, it needs to adopt a much more formal approach (see Figure 7).

Figure 7. The starting point for quality by design is the preferred technology platform.

Illustrative example:
Preferred technology platforms for Oral Solid
1. Coated tablet
2. Mixing and wet granulation
3. Pharma Matrix™ (Aeromatic-Fielder)
4. Plasdone™ (ISP)
5. PVC Blister (Kalle Pentaplast/Lawson Mardon Packaging)

Creating preferred technology platforms that are implemented throughout the entire company has several advantages (although it certainly does not preclude the need for a technology strategy to accommodate drugs that simply cannot be formulated or processed using traditional approaches). It enables companies to standardize the equipment, materials and processes they employ, thereby reducing investment in resources and optimizing the use of those resources. This approach also facilitates the development of a knowledge base that can ultimately be used to predict how technologies will perform.

Preferred technology platforms are equally important in designing a pharmaceutical development plan which can then be implemented across the organization. Again, however, most companies are only halfway there. They have development manuals which document their preferred modes of working, but these do not generally incorporate interactive templates that can be tailored to a given project and automatically updated to accommodate the latest experimental results – features necessary to facilitate the transition to fully scientific development and manufacturing.

**Systematic building of process capability**
Moreover, using preferred technology platforms and development plans only produces a basic manufacturing equation. The ultimate aim is to design “right first time” in more than 99 percent of cases – which means building robust pharmaceutical development and manufacturing processes to consistently deliver medicines with the features that are critical to quality throughout their entire product lifecycle.

There are various ways of measuring process capability, including the six sigma methodology. For each step involved in a particular technology platform, calculating the process capability, or $C_{pk}$ – the mean performance of a process relative to the spread between the upper and lower limits of the product specification – shows how reliable the process is (see Figure 8). $C_{pk}$s are typically lower in manufacturing than in development, since the processes are then exposed to multiple sources of variability on a continuous basis. This is why it is important to aim for a high $C_{pk}$ at the point of transfer.
Process measurement can also be used to acquire a better understanding of technology platforms. Suppose, for example, that the pharmaceutical development team wants to learn more about dry blending. It might employ manufacturing data generated through the application of PAT to correlate variations in materials, environmental factors and equipment with variations in the finished product. It could then use the data to refine the performance of the processes prior to the transfer to manufacturing. As its level of understanding increases, a company can eventually create a set of mathematical models to predict and continuously refine the performance of its technology platforms and manufacturing processes (see Figure 9).

**Figure 9.** A company’s development culture determines the extent of its knowledge about its technology platforms.

<table>
<thead>
<tr>
<th>Development culture</th>
<th>Technology platform knowledge</th>
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<tbody>
<tr>
<td>5. Ability to predict and refine processes based on mathematical models of the interaction of critical control parameters</td>
<td>First principle knowledge</td>
</tr>
<tr>
<td>4. Understanding of critical control parameters and mechanisms by which they affect process</td>
<td>Mechanistic knowledge</td>
</tr>
<tr>
<td>3. Understanding of how process outcomes are affected by critical control parameters</td>
<td>Causal knowledge</td>
</tr>
<tr>
<td>2. Correlational understanding of process behavior under defined circumstances</td>
<td>Process knowledge</td>
</tr>
<tr>
<td>1. Trial and error experimentation</td>
<td>Descriptive knowledge</td>
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Source: IBM Business Consulting Services.
However, building process capability and understanding at the levels of mechanistic and first-principle knowledge is almost impossible without ready access to historical process data, primarily data generated in manufacturing. The ability to predict the most likely sources of variation and what changes might reduce them is arguably one of the greatest benefits of using PAT (see sidebar titled Extrapolating from the past).

A pharmaceutical development process that aspires to quality by design is thus one that stimulates experimentation in order to build a mechanistic understanding of how critical control parameters influence processes and, ultimately, the quality of the finished product. It starts with the features that are critical to quality from the perspective of patients; translates them into the features that are critical to quality in the manufacturing process; and then defines the critical control parameters for producing a drug with the right specification (see Figure 10). The end result is an equation that shows how each step in the manufacturing process must be performed, given the particular circumstances that prevail. It also shows how the critical control parameters can be varied to consistently produce a drug with the right specification.

Figure 10. The aim of quality-by-design in pharmaceutical development is to build a mechanistic understanding of process capability and variability.

Pharma is currently a long way from this point. IBM research suggests that most pharmaceutical companies can develop repeatable processes based on prior experience and manufacture to an average of two sigma, but they are far behind other high-tech industries like microelectronics, which are capable of manufacturing to six sigma or more.
The benefits of process understanding

Yet, process understanding through the collection and manipulation of vast quantities of development and manufacturing data has real business value. The FDA has already promised that it will lessen the regulatory burden for those companies that can show they have a firm scientific grasp of the processes they are using. There are other benefits, too. A better comprehension of processes can deliver substantial improvements in operational efficiency. For instance, Pfizer reports that it has reduced the average cycle time for one drug manufactured at a foreign plant where it has introduced PAT to 14 days – compared with the 60 days it takes to make the same product in the United States – and the company is confident it can cut the cycle time still further.18

Better process understanding can also mitigate the risks of product recalls, with all their attendant damage to a company’s bottom line. In summer 2004, for example, Boston Scientific wrote off US$43 million when it was forced to recall 165,000 drug-coated and bare metal stents.19 Above all, process understanding can help to accelerate the time new products take to reach their sales peak, and thus increase the overall amount of revenue generated over their lifecycle.

Of course the duration and shape of the pharmaceutical product lifecycle varies considerably among products. Some drugs may experience very rapid sales growth, especially if they are the first effective treatments for life-threatening conditions. Others may be slow to take off or may enjoy a surge later on if, for example, they are approved for new indications or studies show that they are more effective or safer than was previously thought. Nevertheless, as a rule, sales of a drug now peak about 10 years after it has been launched (see Figure 11).20

Figure 11. Sales of a drug usually peak about 10 years after it has reached the market.

Source: H. Grabowski et al. "Returns on research and development for 1990s new drug introductions."
However, it is not just the degree of demand in the marketplace that determines how quickly sales of a new drug rise; it is also the stability of the processes used to produce it. Most pharmaceutical companies launch products before they have fully optimized the processes for manufacturing them, learn from practice and submit post-approval changes to the regulators as they refine their techniques. In other words, they spend the first year or two ironing out any problems before ramping up production.\(^{21}\)

Therefore, in the early part of the product lifecycle, companies are far more likely to suffer from shortfalls in supply – either because they have been forced to halt production temporarily as a result of manufacturing problems or because they cannot scale up rapidly enough to exploit unexpected opportunities. When Boston Scientific had to recall so many stents, for example, archrival Johnson & Johnson could not supply enough of its own drug-coated stents to meet demand and capitalize on its competitor’s misfortune.\(^{22}\) As a result, Boston Scientific recovered very rapidly and secured more than 70 percent of the market by the end of September 2004, only 12 weeks after the first wave of recalls.\(^{23}\)

IBM research suggests that improving new product and process development to produce robust manufacturing processes prior to the launch of new products could help to reduce the period from launch to peak sales by as much as five years. That, in turn, would unlock an enormous amount of additional value. As Figure 12 shows, a drug with peak annual sales of US$1 billion could generate an extra US$1.6 billion over its lifetime.

**Figure 12.** Bringing the point at which sales peak forward by five years could add US$1.6 billion to the lifetime value of a product with US$1 billion annual peak sales.

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For a product with US$1 billion annual peak sales:
10 years to peak sales: NPV = US$2.9 billion
5 years to peak sales: NPV = US$4.5 billion
Delta = US$1.6 billion
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An architecture suitable for product lifecycle management

The transformation of the industrialization process has potentially huge financial advantages but it is dependent on the ability to capture data from the very start of the product lifecycle and store those data in the “corporate memory” as they emerge. The term “product lifecycle management” (PLM) has different meanings in different industries. In this context, however, the emphasis is on data management.

More particularly, PLM is the electronic backbone that facilitates the flow of data on products and processes between development and manufacturing (see Figure 13). It provides an integrated framework for regulatory compliance, strategic sourcing, product specification and data management, manufacturing and corrective actions, and control of product safety and quality.

Figure 13. Product lifecycle management is the electronic backbone enabling the flow of product and process data to and from manufacturing.

The key feature of this electronic backbone is that data flows in both directions. First-rate industrialization is not simply a matter of feeding data from development to manufacturing; it is equally important to pass data back from manufacturing to development to inform the design of new products and processes, particularly as these products and processes become increasingly complex. PLM therefore covers both structured data, such as those generated by in-line PAT monitoring and unstructured data, like exception and out-of-specification reports.
Most pharmaceutical companies have already recognized the value of connectivity in discovery and clinical development and have started building systems that provide a richer picture of the issues with which the scientists are working. Very few currently think in terms of linking pharmaceutical development with manufacturing, yet it makes perfect sense for building process capability.

The architecture used to support PLM integrates multiple applications in a single hub that makes data readily available to scientists and process engineers throughout the organization. Input from different development projects and manufacturing plants is captured via the manufacturing execution systems (MES), laboratory information management systems (LIMS) and enterprise content management systems (ECMs). It is then fed into a central hub, or corporate memory, which includes a structured data warehouse and an unstructured ECM.

An analytics tool enables users in both development and manufacturing to export the structured data for multivariate or causal analysis, while the ECM holds end-state submission documents. The integration of the data warehouse and ECM allows experimental results to be automatically imported into regulatory documents. In this way, data that are currently collected in a document management system solely or largely for the purposes of regulatory compliance can be extracted, stored in the corporate memory and manipulated to improve the industrialization process and generate value for the company collecting them.

**Figure 14. An integrated architecture facilitates data management throughout the product lifecycle.**

In short, PLM will play a major role in the industrialization process of the future. It can help bench scientists and their managers to plan, execute and transfer robust and innovative development projects that focus on critical-to-quality attributes. The sidebar titled Smart development in 2010 shows what it could ultimately deliver.

**Conclusion**

Pharma has traditionally treated pharmaceutical development and manufacturing as the “poor relations” to discovery and clinical development. However, as the drugs it makes and the processes it uses to manufacture them become increasingly complex, so the status of the chemistry, manufacturing and controls function is being slowly elevated. The FDA has reinforced this trend with its drive to protect patients more effectively – for example, through its two-year program to improve the regulation of pharmaceutical manufacturing and its more recent initiative to transform the industrialization process.

As a growing number of industry executives are beginning to realize, manufacturing is no longer a standalone activity to be conducted in isolation from what happens in the laboratory. It is, rather, part of a continuous research and development loop. The transformation of the industrialization process from art to science will remove some of the roadblocks in getting new drugs already in the pipeline to market and enable companies to develop better products in future. It can also help them to unlock far more value from the products they make.
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References


For further information on this concept, see “Pharma 2010: The threshold of innovation,” p.39.


