

GOT DATA?

Using informatics to protect and improve your business

In 2012, *Harvard Business Review* put data science on the map, calling it the “sexiest job of the 21st century.”¹ But what is it exactly and how does it align with analytics, informatics, process intelligence and all the other terms you’re seeing in the business press these days?

While there’s no single definition, all these terms refer to a specific discipline that involves:

- Gathering and aggregating multiple types of data from multiple sources
- Making that data available across an organization
- Subjecting it to statistical analysis
- Extracting knowledge from it, and
- Using that insight to correct problems and capitalize on opportunities

Marketing leads the way

Interest in data science is growing in the life science sector, particularly among sales and marketing teams. Some companies are using big data to predict which physicians are most likely to prescribe their products. Once a target population has been identified, the data can be mined again to determine the combination of marketing messages that will be most meaningful to the individual physicians—and most apt to result in sales. This type of targeting is not new, but the amount of data available to do it is increasing, along with the tools and systems needed to aggregate and analyze that data.²

Next up: manufacturing

Life science companies are also benefiting from informatics in the manufacturing side of the business. Effective use of data can help an organization:

- Optimize efficiency—cutting cycle times, reducing waste, increasing yields
- Meet FDA guidelines for Continued Process Verification
- Facilitate technology transfer
- Protect Intellectual Property
- Identify and mitigate manufacturing risks that could impede FDA compliance and even require disclosure under SEC regulations

Utilize Full Capabilities of Informatics

The payback is there for those who invest in manufacturing informatics. There’s insight hiding in your manufacturing data. Find it and use it to protect and improve your business.

Despite these benefits, the move to data-driven decision making is happening at a relatively slow pace in life science manufacturing. When Pharmaceutical Manufacturing surveyed operations professionals about spending priorities in 2015, fewer than 15% reported working at firms that were investing in informatics and data management technologies.³

Even companies that have made a commitment to informatics aren't always getting full value from their investments. Some don't have effective master data management strategies. Others haven't done enough training. And many have not fully embraced a data-driven culture.

—○ GOT DATA? Start using it

Are you ready to use data and analytics to improve decision making?

There are things you can do now to get started:

- Develop a master manufacturing data management strategy that supports your business objectives
- Assess your IT architecture and software portfolio, identifying strengths and weaknesses
- Review terms of CMO agreements pertaining to data ownership, sharing and visibility
- Evaluate staff capabilities and conduct regular training
- Bring in an expert to guide you through the change management process

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1. <https://hbr.org/2012/10/data-scientist-the-sexiest-job-of-the-21st-century/3>
2. <http://www.pharmavoices.com/article/2015-11-digital-tools/>
3. <http://www.pharmamanufacturing.com/articles/2015/pharmas-search-for-operational-truth/?start=1>

Why the lag?

There are many reasons why life science manufacturers have been reluctant to make data science a higher priority. Unfortunately, many are based on perceptions that aren't completely accurate. Do you have the facts straight?

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PERCEPTIONS

FACTS

"We do a good job collecting data for compliance reports. That's all the manufacturing intelligence we need."

There's a big difference between *gathering* data for reporting and *using* data to determine what you're doing well, where your vulnerabilities lie and how you can improve. Collecting data for compliance reporting is a critical first step in a regulated environment. But using informatics can drive even bigger benefits such as higher yields, faster cycle times and less time spent on investigations and inspections.

"We're meeting quality and delivery targets, so our manufacturing processes are already efficient."

Most life science manufacturers do a great job delivering safe, compliant products. Yet large amounts of time and resources are often wasted in production operations. Manufacturing informatics can help identify inefficiencies so you can eliminate waste while you cut cycle time, increase yield, boost throughput and preserve your margin.

"We don't make the product, a contract manufacturer does. We count on them to control their processes and optimize efficiency."

The FDA is clear on this. In order to comply with regulations for Current Good Manufacturing Processes, life science manufacturers must control both their own production processes and those of their manufacturing partners. It's your legal responsibility to know everything you can about CMO production processes. Without shared ownership of information and shared visibility of data, it will be nearly impossible for you to do that.

"We don't have the budget or the time to attack all our problems with informatics."

We don't advocate trying to solve all your problems at the same time. Your best bet is to start with a key product with the greatest variability in yield or a critical product in which stability varies the most. Focus your efforts, find the relevant data, bring it all together and apply informatics principles. An incremental approach will allow you to build skills, acquire expertise and expand your capabilities—efficiently and economically.

"We don't capture data electronically so we can't do complicated analytical work."

Electronic data capture makes informatics work faster and easier, but it's not essential. In fact, given the time it takes to buy, implement and validate new systems, it doesn't make sense to wait for data to be available electronically. A better plan may be to collect data manually and make it available (in accordance with 21 CFR Part 11) electronically so it can be analyzed and acted upon. This "lean" approach has produced great returns for global and emerging life science companies.

"We don't have a lot of in-house expertise in using data and analytics to solve problems."

Many life science manufacturers are in the same boat. It's hard to attract and retain people for this critical job. Getting an independent consultant involved may be your best option. Look for one with a proven track record in life science manufacturing and a history of using data and analytics to solve complex operational problems.