Automating the Pharma Workforce: Conversations on Quality
SPECIAL REPORT

Automating the Pharma Workforce:
Conversations on Quality

CONTENTS

3  Reducing Variability in the Pharma Workforce
5  Managing Life Sciences Workers in Real Time
9  Temporary Workers: Pharma’s Contingency Planning
12 Is Pharma Management Getting the Hang of M&A’s?
NO MANUFACTURER’S workforce is static. Those who understand the variable nature of their workers, and manage that variability, gain competitive advantage, says John Frehse, Partner and Owner at workforce management consulting firm Core Practice Partners. Reducing workforce variability is not only a key to increasing quality and reducing costs in drug facilities, Frehse says, but also to improving worker morale. Automating and applying metrics to workers and their performance is a first step. Pharmaceutical Manufacturing spoke with Frehse to learn more.

PhM: When you speak of reducing “variability” in the workforce, what are you really talking about?

J.F.: There are two types of variability that we are concerned about. The first is created by the shape of the demand curve for the products and services offered by the company. As demand changes, the need for variable levels of staffing are also needed. Without the right labor strategies, this variability can be costly as overtime and idle time become larger when management teams can’t adapt labor effectively to these adjustments.

The second form of variability is much more dangerous. Quality can be compromised when employees are asked to be flexible with their work hours. The variability in an employee’s alertness, rest level, and consistency have become major realities in the life sciences sector. Removing human error and providing an environment that fosters focus must be given more attention. This means deploying the right labor strategies with heavy respect for the physiological effects of shift work and also deploying the right workforce management software to monitor results.

PhM: What are the keys to reducing variability in the pharma manufacturing workforce?

J.F.: We cannot reduce the variability associated with launching new products, demand spikes, and seasonal requirements, so we have to focus on the areas we can control. Consistent quality should be the focus. To accomplish this, employers need to take a fresh look at labor practices. Employee morale plays a large role and every workforce is different. Survey your employees to understand what they like and do not like about the current operation. Find out what motivates them. You will be surprised that often the answer has little to do with money. Then design a scheduling system with labor strategies that not only work for their lives, but also have health and safety factors built in to maximize alertness levels and reduce variability.

PhM: When you look at the workforces of drug manufacturers, what glaring weaknesses jump out at you?
J.F.: Drug manufacturers have long believed that the answer lies in the length of the shift. This simply is not true. If they have 8-hour shifts, companies may adjust to 12-hour shifts thinking that it will solve morale problems. They may be successful, but they may also increase payroll costs in the process. Due to federal labor laws, employers may increase payroll costs by over 2% in this transition because overtime occurs in some weeks and working less than 40 hours occurs in other weeks. We call it the “44th Hour Problem” and it is rampant.

Other work and pay policy adjustments (or lack of adjustments) can lead to millions of dollars in additional costs. We do not, however, think that overtime is a bad thing. Healthy levels of overtime should be used where needed. Although we do not advocate spending money for no value (the 44th Hour), we do advocate using overtime as an effective tool to manage spikes in demand.

PhM: Where are drug manufacturers in terms of automating their workforce oversight, and what’s holding back the laggards?

J.F.: Drug manufacturers are excellent at measuring and monitoring everything—except the workforce. Although software and other forms of technology have been heavily implemented to improve quality, consistency, and the supply chain, many management teams are still using Excel, pencil and paper to manage shift workers. It just does not make sense. Few can identify labor best practices, top performers, and detailed labor inefficiencies and are left managing to the status quo. The laggards are too comfortable with current practices and will not change unless they are hit with a catastrophic event. Of course at that point, it is too late.

PhM: What does real-time management of a workforce mean? What key factors are being monitored and manipulated?

J.F.: Real-time management of the workforce means that management teams can look at effectiveness throughout the day and not just a week later when reports have been tabulated. It allows management teams to look at key performance and productivity measures and understand success while also making immediate course corrections as employees deviate from best practices. In summary, it is a way to maintain the highest levels of labor quality all the time. The basic views typically surround productivity (how many, how fast, for how much effort). As advances in data integration have improved performance analytics have thrived. The question of “how many” and “how fast” have been augmented, but not replaced, by “how well.” This is the key to managing quality and not just cost. Units produced per hour can now be units with zero defects produced per hour. Microbial counts can be integrated as well where applicable. The move to quality-based analytics (and not just quantity) have driven lower-cost, higher-quality solutions for both businesses and consumers.
Managing Life Sciences Workers in Real Time

A TALK WITH GREGG GORDON, SENIOR DIRECTOR OF MANUFACTURING INDUSTRY MARKETING AT KRONOS, INC., ABOUT HOW DRUG MANUFACTURES CAN, AND SHOULD, AUTOMATE THEIR WORKFORCE MANAGEMENT.

PhM: Where are drug manufacturers at in terms of automating their workforce management? In your opinion, is this an area of largely untapped potential?

G.G.: Drug manufacturers as a whole are one of the more progressive segments within the industrial sector. They have adopted technology at a higher rate than other industries due to the nature of their business. That being said, there are two aspects of the industry that have resulted in drug manufacturers not capitalizing on workforce opportunities to the same degree as other segments in manufacturing.

The first is the patent protection on drugs. Branded pharmaceuticals usually carry higher prices than generics. This price premium is used to amortize the R&D expense and risk over the patented life of the drug. Because the labor and material costs of producing these patented drugs are low compared to the price, operating efficiencies will have less of an impact on contribution margins. Instead manufacturers have prioritized efforts such as ensuring inventory, compliance and improving the effectiveness of R&D.

Secondly, the higher percentage of professional employees (often exempt) in drug manufacturing are often excluded from traditional workforce management initiatives. There can be significant losses in terms of unreported vacation and leave as well as miscalculations in benefits that are being overlooked by manufacturers who rely on the honor system or manual tracking.

These drivers of the business are changing as generic manufacturers, who sell into a significantly more competitive market and earn a profit purely from the efficiency of their operations, are focusing on labor productivity and demonstrating that there is significant opportunity in actively managing the workforce beyond calculating an accurate paycheck.

PhM: What’s driving leading drug companies to improve and automate their workforce management? Is it more cost and productivity, or more of a compliance issue?

G.G.: Interesting question, Compliance leads, but it also straddles the cost and productivity driver . . . let me explain.

An acute lack of compliance in quality and safety is translated to significant cost so quickly that management will address this with the necessary adjustments to the business. Whether it’s a process change, training or investment in technology, compliance is not an option for any manufacturer that wants to maintain health and safety for its customers and employees. For workforce management this can mean accurately tracking skills, certifications and hours of experience at a particular operation to ensure safety and product quality.

General cost and productivity of labor come next in prioritization. As companies lean out they look through their expenses and figure out ways to reduce labor costs
and inventory and increase productivity. For the workforce, the fastest ROI comes from the elimination of payroll inflation, which is pay without associated productive output, whether through manual processes or time abuse by employees. The next level of ROI, which has bigger benefits, but is more difficult to achieve is through improved productivity. An example of this effort recently is from a company that realized it needed a more flexible and agile workforce as it cut inventories and had to respond faster to smaller orders of its products. Make-to-Stock is giving way to pull systems and the workforce must adjust too.

Finally compliance comes into play again, but this is often latent pain. Manual systems and processes that are built to ensure compliance become unwieldy over time. Eventually it becomes apparent that the processes should be consolidated and automated. The realization might come from an internal suggestion or driven by an employee lawsuit, union grievance or Department of Labor audit. These projects are often justified through administrative savings or trying to avoid the next lawsuit or fine. This is a tricky area for companies because it’s difficult to measure the ROI until a lawsuit occurs. And while the investment is easy to justify at that point to executives, the savings has already been spent. This is where Six Sigma tools such as Failure Mode and Effects Analysis can

---

**We need to shorten our R&D cycles.**

**A** Yes.

**B** Patents. Schmatents. We’ve got all the time in the world.

You have to get to market as quickly and efficiently as possible. Which means your people have to be working at maximum productivity. At Kronos, we understand your workforce management issues and what it takes to address them. Which is why all our solutions deliver complete automation, high-quality information, and are easy to own. With thousands of installations in organizations of all sizes — including over half the Fortune 1000® — we’re proving workforce management doesn’t have to be so hard.


---

© Kronos Incorporated 2010
be helpful. Most financial analysis focuses on tangible costs. FMEA also considers the ability of a process to actually detect a defect (such as a gap with compliance) and can therefore be used to prioritize investments in improving processes that have few quality issues, but when they do, are significant in terms of cost.

**PhM:** Are M&A’s, layoffs, relocations, etc., driving drug manufacturers to automate their workforce management, or preoccupying them so much that they’re dragging their feet?

**G.G.:** Kronos is seeing an increase in interest in workforce management due to these issues. The industry is consolidating and through M&A, companies are being purchased at premiums, often with debt. The justification of these premiums and assumption of debt are that synergies and efficiencies will occur at the new larger company. One of the fastest ways to increase efficiency and improve insight to new synergies is to focus on the workforce. Understanding labor capacity and capability can be achieved through a centralized workforce management system. This investment can be justified by the efficiencies gained through consolidation of the myriad HR, timekeeping, attendance and payroll systems typically found at the dozens of locations within the US and internationally.

**PhM:** You told me previously that metrics can be used to help companies empower their workers rather than just “manage” them. Can you elaborate upon this?

**G.G.:** Empowering the workforce means more than just providing authority to make decisions. Individuals must have visibility to the process, understand the impact their decisions have on other dependent operations, and finally they must know when a process requires a change. Metrics such as Overall Labor Effectiveness that are aligned to the success of the operation provide the signals to employees that something needs to be addressed. Metrics also show the impact of a decision on the process. Without metrics, employees are forced to build judgment and experience about decision making over time. That translates into increased costs and lower productivity for companies that don’t use metrics to assist in decision making.

**PhM:** What metrics are most drug manufacturers relying upon to gauge their workforce productivity (particularly operations professionals)? Are these the right metrics to focus on, or is there other information they might want to pay attention to?

**G.G.:** Manufacturers are often using the right workforce metrics within their operations; labor utilization, labor costs, quality, attendance, and turnover are all common and important metrics. Additionally they have production related metrics such as on-time delivery and yield. The opportunity for manufacturers is that these metrics are usually measured in different systems. Some are collected on spreadsheets, some within ERP and others in a variety of other software applications such as their timekeeping

### ADDITIONAL RESOURCES:

- **A Fact-based View of the Workforce: Essential to M&A Success**
- **Video: Tracking Your Workforce: A Market Intelligence Report**
- **From Discovery to Production: Increasing Operational Efficiencies in the Pharmaceutical Industry**
systems. Because of this, supervisors manage to each individual metric and cannot see the dependencies throughout the process. For example, a manufacturer might measure machine effectiveness using Overall Equipment Effectiveness (OEE). This is a common and valuable metric, but if management is not careful, its focus on OEE will cause supervisors to use excess labor to ensure the OEE score stays high. So while throughput might be increasing, labor costs are increasing faster due to scheduling only senior employees to the operation. Because these metrics are captured in different systems, it can be difficult to correlate the increase in labor costs with the OEE score and identifying opportunities for improvement are difficult.

With respect to workforce management in operations, the top level metric is Overall Labor Effectiveness. This key performance indicator (KPI) measures the total effectiveness of an operation or department, it is the cumulative effect of labor utilization, performance and quality. By measuring this benchmark KPI over time, operations managers can quickly see an issue and then drill down into why labor effectiveness is dropping.

**PhM:** Ideally, manufacturers that identify productivity gaps or weaknesses would integrate this information with training programs. Are you seeing this? Can you offer some suggestions on how manufacturers can better integrate training needs with training that is carried out?

**G.G.:** Training is challenging because it is difficult to measure the return on investment. Training driven by regulatory requirements is an exception to that, but in general it doesn’t increase an manufacturer’s competitiveness either.

This is a good example of why it’s valuable to use lean metrics that provide visibility to the entire process. Most employees will say they like training, aside from learning something new, it provides a change of pace from their every day work. But that doesn’t help management understand what training is required and which training programs have had an impact.

The question always remains, was the workforce more productive after the training than before? And if they are, how often should this training be repeated to account for the slow loss of lessons learned through turnover and the eventual return to less than ideal practices. By mapping training events over time against production key performance indicators, a comparison of the impact to production efforts are visible and ROI can be calculated. If training occurs on a productivity improving topic and throughput for that group of employees does not increase, then however popular the training session was, the company yielded no benefit from that investment.

To determine training needs, looking at existing data in a new way can uncover opportunities where training can deliver financial benefit. By measuring overtime by skills or intraday transfers, management can see exactly which skills are in shortage and are increasing operational expense to cover. Because certain employees are personally benefiting from this shortage by earning overtime, the need might not be highlighted to management. Analysis of the situation can provide guidance to what training can increase the flexibility of the workforce and reduce premium pay.

**MOST EMPLOYEES WILL SAY THAT THEY LIKE TRAINING, BUT THAT DOESN’T HELP MANAGEMENT UNDERSTAND WHAT TRAINING IS REQUIRED AND WHICH PROGRAMS HAVE HAD AN IMPACT.**
TEMPORARY WORKERS: PHARMA’S CONTINGENCY PLANNING

CONSULTANT STEVE SAWIN ANSWERS OUR QUESTIONS ABOUT MANAGING CONTINGENT LABOR.

BY PAUL THOMAS, SENIOR EDITOR

**DRUG MANUFACTURERS** are turning to temporary workers to fill gaps in production, and to save on salary costs. This leads to serious training issues. “In a regulated environment like ours, the matter of training is usually pretty well addressed—with the exception of the contingent labor piece,” says Steve Sawin, president of Operon Resource Management, a firm which helps life sciences companies manage part-timers. “Many companies do a poor job in terms of process and product training of the contingent worker, especially up front prior to placement.”

The challenge for manufacturers? “How do we make this resource ready to hit the production floor to make a contribution initially and to meet the expected learning period?” he says. “On the premise that quality and compliance can otherwise be maintained, it becomes a financial trade-off: learning curve attainment to idle labor cost.”

Managers will say, “Why do I want to invest the time in training this person when they are only going to be with me a short period of time?” Sawin continues. “Another underlying reason is that these group leaders or supervisors just do not have the time. In the interest of cost-take-out, their numbers have been reduced or their scope of work has been increased.”

Sawin recommends that manufacturers have an established, comprehensive “on-boarding” process that includes a thorough qualification screening, tailored company orientation and process training, and close management and supervision of those workers once they’re on site.

Our interview with Sawin follows.

**PhM:** What are the biggest labor issues that drug manufacturers have today (particularly within their facilities), and how are these issues related to training?

**S.S.:** Cost! White House to Your House healthcare costs are an issue. Cost pressures are either at the manufacturer’s doorstep or they’re coming! Margin squeeze will force manufacturers to look at all cost drivers and few are bigger than labor. So I see one of the biggest challenges that drug and device manufacturers will be to do more for less in terms of labor. And one way to do that is by developing a flexible workforce; so you only use what you need and you only pay for what you use. And clearly a tool to accomplish that is contingent labor.

But back to the issue of “training and labor”: In a regulated environment like ours the matter of training is usually pretty well...
addressed; with the exception of the contingent labor piece (or temporaries). Too often, because of the “temporary” nature of the worker’s tenure, many do a poor job in terms of process and product training of the contingent worker; especially up front prior to placement.

PhM: Is the issue of contingent labor training becoming more significant for drug manufacturers in light of recent trends towards leaner, more nimble workforces? Has it also become a more significant regulatory issue in your estimation?

S.S.: 

HOW DO WE MAKE THIS RESOURCE READY TO HIT THE PRODUCTION FLOOR TO MAKE AN IMMEDIATE CONTRIBUTION?

S.S.: You know, I am not as close to the drug manufacturers as I am to the device folks. But I have to believe that the forces of cost reduction are the same. For any operation in the manufacturing process that has a relatively short ramp-up or learning period, and where demand for this resource is not always steady, contingent labor is an option. Then that issue is how do we make this resource ready to hit the production floor to make a contribution initially and to meet the expected learning period. On the premise that quality and compliance can otherwise be maintained, it becomes a financial trade-off: learning curve attainment to idle labor cost.

In terms of a current regulatory issue, I don’t know! But we can all be sure that if the labor that we put on the production floor does not meet regulatory or quality systems standards they will make it an issue.

PhM: What do manufacturers really struggle with, specifically, regarding the training of part-time or outsourced workers?

S.S.: I think they really struggle with the fact that generally speaking the outsourced provider does not provide the needed general process or maybe even product training that they need, so they, the manufacturer is faced with doing it themselves. And the reaction typically is ‘why do I want to invest the time in training this person when they are only going to be with me a short period of time’. Another underlying reason is that these group leaders or supervisors just do not have the time. In the interest of cost-take-out their numbers have been reduced too or their scope of work has been increased.

PhM: What few basic practices do drug manufacturers need to put in place to meet these challenges? How can training become as flexible and thorough as staffing needs to be?

S.S.: That’s a good question; and I am assuming you mean in terms of contingent or temporary labor? I think it varies widely depending on where the manufacturer in terms of their internal training program or training culture; and where their staffing provider is in term of their value proposition. There are some very good examples on the medical device side on how they have addressed this. And at the risk of inserting a commercial here, we have worked with several organizations to, not only address training of temporary labor but to address the whole “on-boarding” process for manufacturing labor. This has included:

- Tailored Application & Qualification
- Tailored company Orientation
- Tailored Process Training
- On-site labor placement, optimization and management

So it could be as easy as selecting the right partner who brings the proper value proposition to the relationship.

PhM: Have you seen an increase in on-site training—where consultants or solutions providers come in-house to accelerate or perform on-demand training?
S.S.: Not really. But there is a reasonable dose of the “not invented here” culture... we know our needs best so we will do it ourselves. And this may be more visible in the bigger organizations.

**PhM: Are web-based training services and modules expanding and helping?**

S.S.: I see a lot of web-based training materials being developed and a lot of it is very good stuff. But I don’t see it as much in terms of manufacturing workers. However, I would suspect that too will change in time.

**PhM: As workforces become more global and diverse, language becomes an obstacle to training. To your knowledge, have regulators raised concerns about whether training materials can be understood by workers? What are proactive manufacturers doing to make sure their materials are understood by speakers of various languages?**

S.S.: I don’t know what issues regulators have raised regarding the language issue, but I see more and more (almost all) organizations instituting an English-Only environment. And I see them backing that with English Comprehension testing. The speaking and understanding skills are important too..... and are usually assessed during the balance of the on-boarding process (orientation & training).

**PhM: Do manufacturers seem to have a handle on exactly who is performing what tasks, and if they’re even qualified to do so?**

S.S.: Boy, that one is all over the board! I think for the most part manufacturers have designated responsibilities by function—for example, the group leader or department manager is responsible for ensuring an understanding of cGMP’s.

**IF THE LABOR THAT WE PUT ON THE PRODUCTION FLOOR DOES NOT MEET REGULATORY OR QUALITY SYSTEMS STANDARDS, [FDA] WILL MAKE IT AN ISSUE.**

PhM: Related to the above, are paper-based training records a problem, and is automating training and recordkeeping something most manufacturers need to do more of?

S.S.: Yeah, most are electronic records of the training requirement. Matter of fact many have unique barcodes assigned to individual operators. When the barcode a work-order for a certain product, it will indicate whether they are qualified in terms of process, product or machine training.

In other environments that we work with that are more manual the DMR has a daily start-up checklist that prompts the operator and the supervisor to go to the training record in the DMR to determine compliance. i.e., is this operator trained on this part or product.

---

**WANT TO KNOW MORE ABOUT KRONOS?**

- Life Sciences Workforce Management at Kronos
- How Will Your Week Work?
IS PHARMA MANAGEMENT GETTING THE HANG OF M&A’S?

IF THE “SERIAL ACQUIRERS” DON’T KILL US, THEY’LL MAKE US STRONGER.

By Paul Thomas, Senior Editor

MOST OF our biggest drug companies are what Mary Cianni, Global Practice Leader for M&A of the consulting firm Towers Watson, calls “serial acquirers,” who make a habit of snatching up smaller prey for sustenance. Drug pipelines are no longer developed but bought. Doddering big pharmas become burgeoning biotechs overnight through the magic of M&A. The serial acquirers must be forgiven for this—it’s in their business blood.

So it must be sheer hell out there for many of you, their past, present, or future employees. Conventional wisdom holds that whenever a company undergoes a merger or acquisition, employees suffer. First, there’s the emotional strain of whether or not you’re going to keep your job, or whether that job will irrevocably change for the worse—the new boss a tyrant, your workload doubling, your best work buddies shipped off to another site. Our worst fears come calling. Maybe you’ve already been told you’re out of a job, in which case you don’t want to hear about silver linings.

Sheer hell . . . or so I thought until talking with Cianni and colleague Frank Giampietro, a managing consultant, about studies Towers Watson has done of workers who have been through mergers and acquisitions. According to these studies, here is the drug industry’s general response to an M&A, in comparison with other industries: been there, done that.

A megamerger? A hostile buyout? A spinoff snatch-up? We’ve seen it before. There’s a “sense of resiliency” among pharma employees in regards to major upheaval, says Cianni. Workers tend to say, “We’re used to it. We’ve been doing this for a while now.”

In pharma, it’s not as if the down economy started the whole feeding frenzy. It goes back more than a decade. In the Towers Watson surveys, greater numbers of pharma workers reported no “direct impact” as a result of a merger or acquisition. “The majority of folks are still doing the same job, with the same ‘comp and ben’ as they had prior to acquisition,” says Giampietro.

In addition, says Cianni, pharma’s professionals tend to be optimistic about M&A’s, that this change may “offer more global experiences, in new therapeutic areas, and translate their skills and experiences into new opportunities and challenges.”

THE REST OF THE STORY

But Cianni qualifies this rosy data: Because the survey was conducted via employers, the respondents are those who are employed and, theoretically, have not been badly burned.

Also, Towers Watson data shows that while pharma employees may handle a merger or acquisition period deftly, that doesn’t mean they don’t fret about what the future holds. For instance, those pharma workers who

ADDITIONAL RESOURCE:

➥ How Pharma Handles Mergers and Acquisitions: A Talk with Towers Watson Experts

➥ A Fact-based View of the Workforce: Essential to M&A Success
have gone through the M&A wringer express more uncertainty about their futures and their potential for advancement, and are thus more open to possible job offers, than do those who have remained under a single, consistent employer. They also express doubts about whether or not their new (or newly structured) company can meet their desires in terms of pay and long-term security.

To alleviate such fears, Cianni and Giampietro say that workers are looking for an “emotional connection” with their superiors during times of transition. Emotional connection? Is it reasonable to expect some kind of special bond between shop-floor Stu and C-suite Cheryl?

No, says Cianni. Workers just want to know that their execs are there for them. “When senior leaders are making decisions, is there a recognition of what the human impact on employees will be?” she asks.

Pharma execs, it seems, know this. “Many of our clients who are serial acquirers take away lessons learned from each merger or acquisition on how to do it better,” Cianni says. “There has been a learning along the way on how to lead through change.”

This learning now needs to be communicated to middle management. They’re the ones who serve as both conduit and buffer between the majority of workers and executives. If they break down, the M&A can break down.

“Senior management now understands how important it is to be visible all the time and make that emotional connection all the time,” says Giampietro. “Now it’s a matter of understanding not only how they need to lead but how they can support other managers in leading.”

We need to shorten our R&D cycles.

A Yes.

B Patents. Schmatents. We’ve got all the time in the world.

You have to get to market as quickly and efficiently as possible. Which means your people have to be working at maximum productivity. At Kronos, we understand your workforce management issues and what it takes to address them. Which is why all our solutions deliver complete automation, high-quality information, and are easy to own. With thousands of installations in organizations of all sizes — including over half the Fortune 1000® — we’re proving workforce management doesn’t have to be so hard.


© Kronos Incorporated 2010