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COMPANY TO WATCH:
Acetylon p. 10

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Doing Business In

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Elevating IT At AstraZeneca

AZ creates an IT team of senior leaders "so that significant decisions could be made without additional layers of approval." p. 20

Angela Yochem, CTO, AstraZeneca

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20 FEATURE: ASTRAZENECA

"There is very little value in a technology deployment that is not directly linked to an outcome," explains Angela Yochem, CTO, AstraZeneca.

January 2013

Welcome to *Life Science Leader*

DEPARTMENTS

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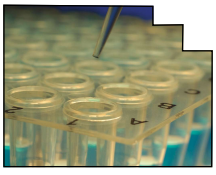

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My Top 10 Shows For 2013

In recent discussions with readers, I have been hearing a consistent message regarding their plans to attend trade shows in 2013. That message can be summed up in two words — highly selective. In the past, these executives may have attended half a dozen events a year. When you combine the global recession with the patent cliff, the result is a conservative approach to budgeting, including funding conference and trade show attendance. Perhaps we will see an increase in people attending virtual events. Only time will tell. Maybe I am just too old school, but I believe there to be greater value in attending shows in person. Though I see people not giving the event their full and undivided attention, I imagine trying to attend a virtual conference in your office, with the constant demands of doing your day job, would preclude you from giving even 1/10 of your attention.

Now, before I tell you about some of the shows I plan to attend in 2013, I want to share those which I found extremely valuable in 2012. Let me preface this by pointing out that last year I attended around 20 different events. From these, listed in alphabetical order, are the noninvitation-only events which provided interesting educational content, were attended by industry key opinion leaders, provided excellent networking opportunities, and led to editorial which appeared in *Life Science Leader* magazine throughout the year: BIO International; BPSA Single-Use Summit; CPhI Worldwide; DDP; DIA; Disruptive Innovations; Diversity, Inclusion, & Life Sciences Symposium; HBA WOTY; Interphex; Partnerships; and the WIB Annual Gala.

For 2013, I plan on attending around the same number of events. Like you, I plan to be highly selective. Personally, I don't select trade shows or conferences based on the venue or geographic location. The criteria I use for deciding which shows to attend is driven first by who will be attending/presenting and then the content. For a variety of reasons, I don't always attend the same shows from year to year. This could be a matter of logistics. Such is the case with this year's Interphex, Partnerships in Clinical Trials, and BIO International shows, which all take place in the same week. It could also be my desire to have a different experience. How can I tell you if I found a show valuable, if I haven't checked it out for myself?

Just because you don't see a show listed, doesn't mean it isn't valuable. Nor does it imply that someone from *Life Science Leader* won't be attending. It simply means that as I strive to manage my most precious resource — time — and my second most precious resource — sanity — these are shows I am personally planning to attend for 2013, listed in the order in which they take place throughout the year: DIA Euro; DCAT; Diversity, Inclusion, & Life Sciences Symposium; BIO International; HBA WOTY; DIA; Disruptive Innovations; CPhI Worldwide; ISPE; and FDA/CMS Summit. In case you are wondering, since I did mention I would be attending about 20 events, what are the other 10 shows? Well, a few are by invitation only. For the rest, I am waiting to gain some insight from you, our readers. Think there is an event I should consider attending in 2013? Drop me an email with some additional information, or better yet, pick up the phone and give me a call.

Rob Wright
rob.wright@lifescienceconnect.com
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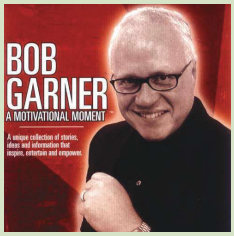

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Q: If you could implement a change at the FDA, what would it be?

The criteria for PDUFA (Prescription Drug User Fee Act) and MDUFA (Medical Device User Fee Amendments) provide the framework for a change I'd like to see implemented — an enhanced communication strategy developed by the FDA that includes all stakeholders. Why? As innovation in the industry has accelerated, so have the submissions for approval. For a number of reasons, the FDA has been challenged in meeting PDUFA timelines, leading to delays to the market. By executing a consistent, clearly defined communication plan, many of the obstacles along the path to drug approval can be overcome and ultimately, patient needs are served.

Ann Willmoth, M.Ed.
Ann Willmoth is the general manager of Blue Standard Consulting, a healthcare management consultancy, advising companies on business strategy and commercial approaches to the market.

Q: What's the future for a global harmonized regulatory approach to reduce supply chain costs?

In a word? Distant. Companies have accepted that meeting splintered regulatory requirements and reducing supply chain costs are often mutually exclusive undertakings. A global regulatory approach or standard to reduce supply chain costs, in my view, is a long way off because protecting patient safety trumps expense for implementation and practicability, and too often these considerations are not given enough weight. Many countries with specific requirements — and the need for national autonomy — have made harmonization under one overarching, harmonized standard seem an improbable and distant hope. Product and service suppliers to the industry have recognized this and have strategized to improve the "value-add" to their offerings as a means of leverage and gaining competitive advantage. Likewise, 3PL and 4PL service providers continue to expand the breadth and scope of their global operations and fulfillment options, all in an effort to compensate for this regulatory incongruity.

Kevin O'Donnell
Kevin O'Donnell is senior partner at Exelsius Cold Chain Management Consultancy US, an international provider of consultative, research, and training services to manufacturers, airlines, forwarders, and other stakeholders in the life sciences logistics sector.

Q: As a CEO/founder of a life sciences company, what is the biggest obstacle you struggle with, and how do you overcome it?

As a founder of an early-stage virtual start-up, one of the major challenges is balancing the scientific and business priorities of the company within the limited resources that are available. Essentially, a lot of it comes down to funding. Accomplishing company goals and staying on track with limited funding means tapping into every available resource and seeking out as much "free" help when necessary. It also means "wearing many hats" and learning how to do as many things as is possible yourself. Of course, success is not possible without good consultants and advisors. Finding the best consultants and managing them well is another challenge. Success comes from having a wide but valuable network to tap into when necessary. Staying well-organized, with daily prioritization, is the only way to stay in the game.

Dr. Laura Hales
Dr. Laura Hales has more than a decade of experience in biologics discovery research and is currently a founder of Extend Biosciences and The Isis Group.

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By Wayne Koberstein, contributing editor

Acetylon Pharmaceuticals

Taking HDAC inhibitors to a higher level in cancer and other diseases.

SNAPSHOT

Acetylon Pharmaceuticals calls itself an "epigenetics" company developing gene and protein modulating drugs — mainly selective histone deacetylase (HDAC) enzyme inhibitors for treatment of hematologic and solid tumor cancers and inflammatory, neurodegenerative, genetic, and parasitic infectious diseases. The company licensed its core technology from Harvard University and the Dana-Farber Cancer Institute. It completed lead optimization and preclinical development of its lead pipeline candidate, ACY-1215, in late 2010, and following successful completion of Phase 1a, it is now in two Phase 1b clinical trials, in combination with Revlimid (Celgene) and Velcade (Takeda/Millennium), for the treatment of multiple myeloma.

Walter Ogier, president and CEO

LATEST UPDATES

• July 2012: Initiated a Phase 1b clinical trial of ACY-1215 in combination with Celgene's Revlimid (lenalidomide) plus dexamethasone, for the treatment of relapsed and relapsed/refractory multiple myeloma. Also advanced ongoing clinical trial of ACY-1215 into Phase 1b in combination with Takeda/Millennium's Velcade (bortezomib) plus dexamethasone.

• Dec. 10, 2012: American Society of Hematology (ASH) annual meeting — announced ACY-1215 was well-tolerated in Phase 1a and demonstrates benefit in preclinical models of multiple myeloma bone disease and B-cell lymphoma in combination with proteasome inhibitors; positive results from a preclinical study of an HDAC 1/2 inhibitor for treatment of sickle cell disease and beta-thalassemia.

WHAT'S AT STAKE

I spoke with Acetylon President and CEO Walter Ogier at the BIO Investor Forum last October and then again more recently. There was already a trend noticeable at the event: therapeutic platforms for cancer, often alternatives to current "hot" approaches like targeted therapy, being developed for other disease areas. Acetylon is an exceptional but also exemplary case in point; its highly selective HDAC inhibitor platform seems to bridge several approaches in targeting a broad pathway in cancer cells by aiming at a specific HDAC which enables protein degradation to boost response rates and cut side effects. In comparison, the multi-HDAC inhibitors now on the market have notably traded only moderate response for major safety issues. Proteasome inhibitors successfully blocked the first route of protein degradation, but tumors are often resistant by utilizing the other main pathway: aggresomes, whose production depends on HDAC6.

Acetylon chose HDAC6 as its target based on the scientific founders' pivotal work to determine the critical HDAC that promotes degradation and disposal of waste proteins, versus current inhibitors that target multiple HDACs, leading to substantial side effects: suppression of blood platelets, major GI symptoms, and fatigue (usually on top of other chemo and disease complications such as cachexia). The early clinical trials of the company's lead candidate, ACY-1215, take the cautious approach of testing the drug's action in combination with two standard drugs for multiple myeloma — a wise choice considering how difficult it is to design trials of new cancer drugs that can show a significant OS or even PFS benefit used alone.

When I interviewed Ogier, we began by speaking of cancer immunotherapy, and I noted that quite a few companies pursuing that approach were also using their platforms to address other diseases as well. "In general, cancer has a lot to do with immune response and inflammation," he said. "That's where we got started down the path moving outside of cancer." He added that one of the potential modes of action of HDAC inhibitors, and particularly HDAC6 inhibitors, is to raise the immunogenic profile of cells which may have evaded immune system surveillance. HDAC6 inhibitors are thus being considered for augmenting treatment of cancers dependent on cell surface antigen immune recognition. HDAC inhibitors have also been proposed as a means for clearing the body of latent HIV viral reserves in combination with a standard anti-HIV treatment regimen. "Our research has now taken us quite a bit further in elucidating mechanisms of action for HDAC6 beyond inflammation," Ogier said.

VITAL STATISTICS

- Employees: 20
- Headquarters: Boston, MA
- Equity funding (total $50 million)
- Research partnership funding: nondilutive funding, $6 million, by the Leukemia & Lymphoma Society to support Acetylon's clinical development of ACY-1215, in 2011.
- Partnerships: Numerous sponsored research relationships with leading academic institutions and thought leaders, CRO and CRM collaborations; and continued involvement of scientific founders at the Dana-Farber Cancer Institute, Massachusetts General Hospital, and Harvard Medical School.

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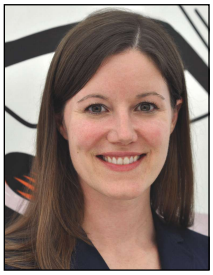
Options shown. 1. 2012 IntelliChoice, www.IntelliChoice.com; Popular Brand. Based on 2012 model year study. 2. Longevity based on Polk U.S. Vehicles in Operation registration statistics MY 1987-2011 as of July 2011. Full-line manufacturer based on car, SUV, minivan, compact and full-size pickup. 3. Fuel efficiency based on NHTSA Final Industry MY10 CAFE data for Toyota Motor Sales. 4. Based on Vincentric Best Fleet Value in America awards from 2006-2012. 5. For more information about the 2012 American-Made Index, visit Cars.com 6. MotorIntelligence.com, CY 2011 sales.



OUTSOURCING INSIGHTS

Quality And Reliability Will Continue To Drive Outsourcing Relationships In 2013

By Kate Hammeke, director of marketing intelligence, Nice Insight

In reviewing the past two years of Nice Insight data on outsourcing relationships in the drug development industry, we have noticed some subtle yet important differences in the preferences and behaviors of buyers of outsourced services. For a contract service provider, these variances reiterate the importance of differentiating one's business from the competition in order to develop strong customer awareness (CA) as well as the importance of targeted marketing that helps to shape prospective and existing customers' attitudes towards the company, or customer perception (CP).

RANKING OF MOST INFLUENTIAL ATTRIBUTES HAS SHIFTED

Each year, our team identifies the six most influential attributes when it comes to building new outsourcing relationships. These form the basis of a CRO's or CMO's customer perception score. Buyers of outsourced services rank the traits in order of their influence on partner selection, and then each company included in the research study is evaluated against these measures. Moving into 2013, the six traits remain consistent — innovation continues to be a primary concern among drug developers and edges its one-time predecessor in the top six — accessibility. But over the past two years, the ranking of pricing, productivity, and regulatory track record has shifted.

Two attributes tend to rise to the top of almost any list of desired attributes in an outsourcing partner — quality and reliability. Since Nice Insight's first survey, these two have maintained the top two rankings, and we expect them to continue to carry the most weight among sponsors assessing contract service providers. Benchmarks for quality and reliability — for both CROs and CMOs — increased from 2011 to 2012 by 1% and 3% respectively, which suggests that CROs and CMOs are making an effort to improve in these areas, and this is being recognized by the buyers.

The research results have helped to debunk some rumored theories regarding pricing. The notion that "it all comes down to cost, and the cheapest bid wins" loses credence when affordability drops from third to fourth in importance, and that businesses with higher prices (and lower affordability scores) frequently score better on the "Project Likelihood" measure than lower-priced competitors. Similarly, the belief that "maintaining compliant operations is a given in this industry" has been shattered with a number of major brands facing product recalls in the past two years, leading biopharma companies to reprioritize. This was reflected in our results, with regulatory track record moving up in ranking from fifth to third place. Contract businesses fared well among sponsors' perceptions, with the benchmark for regulatory compliance increasing by one percentage point among both CROs and CMOs.

OUTSOURCING BEHAVIOR CHANGES

In addition to the changes in preferences, our survey results have revealed some changes in outsourcing behaviors. Outsourcing spend rose slightly — coinciding with a 6% increase among outsourcers with a budget of $10M to $50M range, which was reflected in a 5% decrease among those with a budget under $10M. Respondents from Big Pharma, biotech, and specialty pharma companies indicated they outsourced more services than they had one year before, with Big Pharma showing the largest average increase, 1.4%. The average number of services outsourced appears likely to remain steady among emerging pharmaceutical or biotech companies.

Not only have there been changes in behavior and preferences on the buyer side, CROs and CMOs have made changes to the way they present their offerings to the market. In the past year, 30% of the businesses included in Nice Insight's brand index released new print advertisements, 17% launched new websites, and 6% updated their company logo. Marketing communications are one of the leading ways for a company to manage its reputation; thus launching a new campaign or restructuring information on a website in an effort to further influence perceptions of a business. While some may feel marketing materials are mostly cosmetic, the tools are often used to symbolize the changes occurring below the surface.

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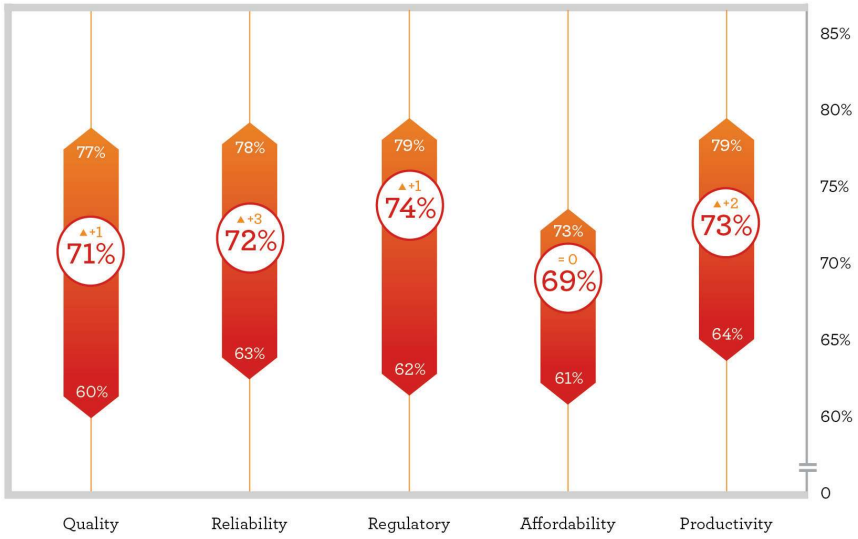
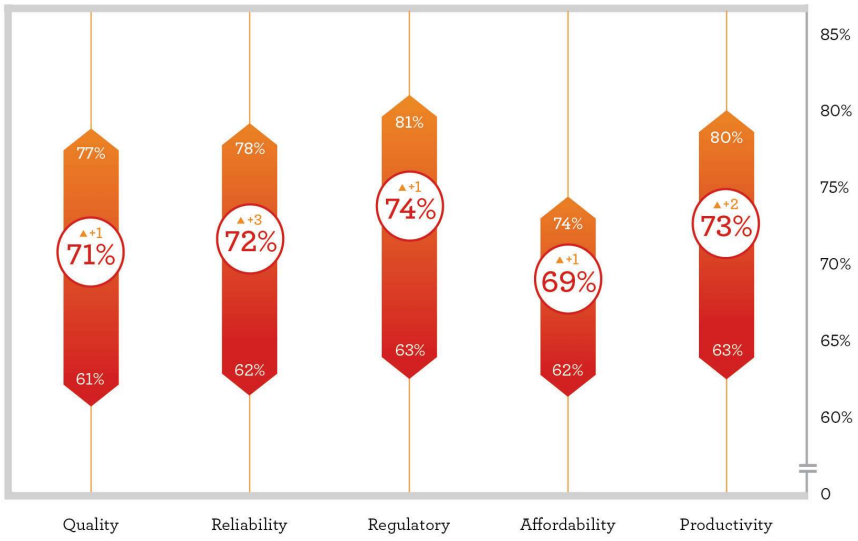
CRO Benchmarks



CMO Benchmarks



Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to outsourcing-facing pharmaceutical and biotechnology executives. The 2012-2013 report includes responses from 10,036 participants. The survey comprises 500+ questions and randomly presents ~30 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perceptions on the top 100+ CMOs and top 50+ CROs servicing the drug development cycle. Over 900 marketing communications, including branding, websites, print advertisements, corporate literature, and trade show booths are reviewed by our panel of respondents. Five levels of awareness from "I've never heard of them" to "I've worked with them" factor into the overall customer awareness score. The customer perception score is based on six drivers in outsourcing: Quality, Innovation, Regulatory Track Record, Affordability, Productivity, and Reliability.

Walker

If you want to learn more about the report or how to participate, please contact Nigel Walker, managing director, or Salvatore Fazzolari, director of client services, at Nice Insight by sending an email to niceinsight.survey@thatsnice.com.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BIO INNOVATION NOTES

New Technology Developments A Leading Trend For 2013

By Eric Langer, president and managing partner, BioPlan Associates, Inc.

In November 2012, we asked the 425 global subject matter experts and senior participants on our Biotechnology Industry Council (BIC) to evaluate the 2013 trends in bioprocessing and biopharmaceuticals. Trends the BIC expects in bioprocessing over the coming year are presented below. This is the first of BioPlan's monthly columns on how innovation in biopharmaceuticals, related bottlenecks, and regulatory hurdles to new technology adoption are affecting the industry.

A few of the 65 key microtrends identified by the Council include:

Analytical Methods; Assays

- Expect simpler assay processes that increase process knowledge and speed/simplify product release
- Expect more convenient, high-throughput assays that assess physicochemical properties, IgG clones for high-level expression, and therapeutic efficacy
- Innovators are developing assays to demonstrate biosimilarity and analytics to demonstrate equivalent product quality

Biosimilars

- Expect more models for demonstrating biosimilarity: lack of established definition and standards on "biosimilarity" regarding biochemical or biophysical characterization
- Process development for biosimilars that allows comparisons to innovator biologic
- Expect more quality by design for all products including generics/biosimilars

Biomanufacturing Process Improvements

- Expect higher workload, fewer staff, at higher quality, and shorter time frames
- Improved processing (especially downstream) to handle 10g/l and greater cell cultures
- Improved upstream process efficiency to reduce costs, increase productivity while ensuring compliance and quality

Biomanufacturing Downstream Process Improvements

- Alternatives to protein A will continue to be sought and developed
- Need for better performing chromatography resins
- Development of nonchromatographic recovery unit operations

Single-use Biomanufacturing

- Building more quality into single-use operations to further reduce regulatory activities/oversight
- Addressing problems of disposable bioreactors and devices that are creating inconsistent growth due to changes in resins, films, gamma irradiation, and cell line specificity
- SUS (single-use systems) downstream operations using membrane adsorbers
- Emergence of flexible and modular biomanufacturing facilities
- Establishing leachables and extractables guidance for testing and for cell growth
- Single-use devices facilitating large-scale bioproduction in China

Regulatory Compliance

- Creating processes and technologies that support lower costs of clinical and commercial supplies
- Continuous validation programs that link PD (process development) and manufacturing data
- Implementing process controls such as PAT (process analytical technology)

Supply Chain, Raw Materials: Control and Sourcing

- Development of international regulations for quality and raw materials sourcing
- Development of process controls that reduce impact of process or raw materials changes on quality
- Expect decreased product defects when manufacturing facilities relocate to lower production costs

THE INDUSTRY IS DEMANDING INNOVATION

These trends are supported by our *9th Annual Report and Survey of Biopharmaceutical Manufacturing, 2012*. For example, fully 40% of the 302 biomanufacturers surveyed expressed a desire for improved bags and connectors, the most basic components of single-use systems. More than a third (36.1%) need better disposable probes and sensors, and nearly a third showed a desire for improved single-use chromatography products (32.2%). In contrast with disposable equipment, only 10% indicated a desire for improvements in fixed stainless steel bioprocessing equipment.

Particularly needed in the industry is the development of new materials, improved plastics, and variations of current materials that enable major design innovations. Possible innovations

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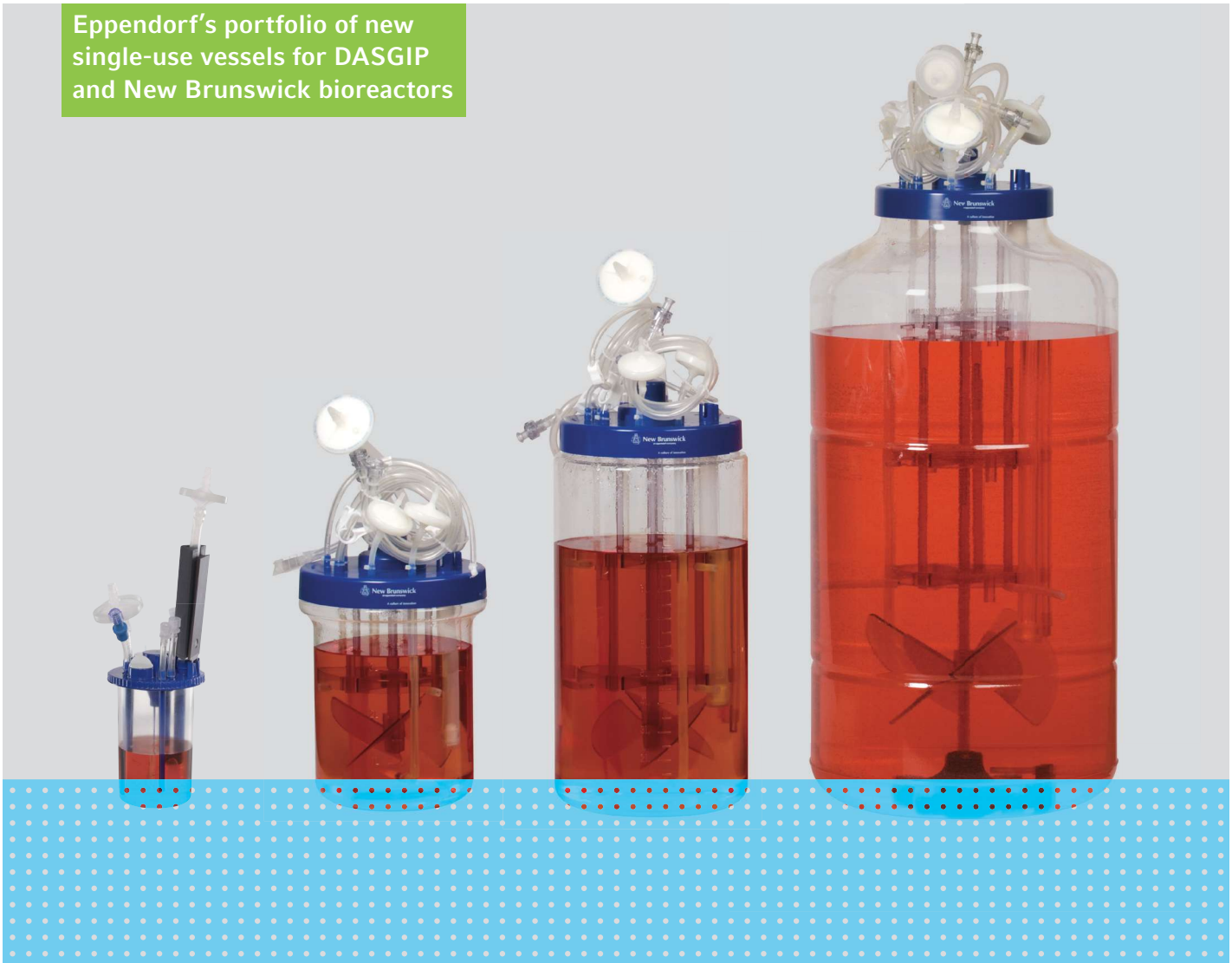

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IMPROVING THE NEW TECHNOLOGY EVALUATION PROCESS

Evaluating new technologies in the regulated pharma environment can be slow and costly to both innovators and the end users doing the beta or evaluation testing. To reduce these challenges, the new technology and product evaluation program (NTAP) spearheaded by BioPlan Associates is designed to help kick-start innovation in bio/pharma manufacturing segments. The program helps ensure that the best technologies are evaluated, even when innovators are small or resource constrained.

The program streamlines the evaluation process and cuts down on internal staff time, both at new technology innovators and at the bioprocessing facilities evaluating suppliers' new products. The program compresses external beta testing and postlaunch evaluations and takes the time-consuming responsibility for recruiting facilities and the costly process for managing the evaluation process out of the hands of technology innovators. By leveraging our network of evaluators and field testing staff and providing access to global commercial process development facilities, we free up innovators' staff from project and site management. This helps assure independent, cross-lab analysis and provides facility data comparability. It also cuts time to market and reduces site recruiting costs significantly.

The program benefits suppliers by providing high-value evaluations, getting new products into the right hands, and coordinating multisite testing with integrated, compiled data. The program benefits evaluators by giving them access to the most promising and cutting-edge technologies while eliminating the need to deal with multiple contacts from multiple suppliers. Rather than testing all technologies, BioPlan can provide available data from other commercial evaluations.

Innovation is the lifeblood of the biopharma industry, fueling new efficiencies, greater quality, and cost reductions in manufacturing processes. New ways of introducing new technologies are needed to allow facilities to focus on core aspects of R&D and to provide better evaluation methods that significantly cut down on time to market and streamline the testing process. There is a strong desire in the industry, as our study observes, for innovation and an accompanying sense that cost reductions and improved quality will come about for production of current biologics, biosimilars, and for production in emerging markets using flexible processes. Suppliers and technology innovators have repeatedly demonstrated their commitment to investment in innovation and new technologies, and industry demand will continue to support and fund suppliers' process improvements.

Selected New Product Focus Areas

Biomanufacturers' And CMOs' Top Areas Where Suppliers Should Focus Development Efforts

Survey Methodology: The 2012 Ninth Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production, in the series of annual evaluations by BioPlan Associates, Inc., yields a composite view and trend analysis from 302 responsible individuals at biopharmaceutical manufacturers and CMOs in 29 countries. The methodology also included 185 direct suppliers of materials, services, and equipment to this industry. This year's survey covers such issues as new product needs, facility budget changes, current capacity, future capacity constraints, expansions, use of disposables, trends and budgets in disposables, trends in downstream purification, quality management and control, hiring issues, and employment. The quantitative trend analysis provides details and comparisons of production by biotherapeutic developers and CMOs. It also evaluates trends over time and assesses differences in the world's major markets in the U.S. and Europe.

If you want to learn more about the report, please go to bioplanassociates.com.

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Angela Yochem, CTO, AstraZeneca

How AstraZeneca Is Transforming IT

By Rob Wright

If you have any experience in technology, then you are probably familiar with Moore's Law – the number of transistors on a chip will double approximately every two years. Interestingly, this exponential growth in computer processing power tends to decrease the cost of technology exponentially over time. Thus, the corollary for early adopters of technology is buyer's remorse. For example, that iPhone 4S you purchased just one year ago for $199 now costs just $99.

Perhaps quick technological obsolescence is why many pharmaceutical companies have historically viewed IT departments simply as cost centers. Yet in today's pharmaceutical world, IT is being viewed in a different light. Emerging markets and increased outsourcing trends are leading to the rapid spread of almost any size pharma company's technological footprint. Increased communication, both internally and externally, is no longer just a common business requirement — it's now a business differentiator, especially in the highly competitive drug development stages.

In 2011, AstraZeneca took a key step toward transforming its IT department when it convinced 20-year IT veteran Angela Yochem to leave her job at Dell and become the pharma company's new CTO. But when you have a company as large as AstraZeneca, the question becomes, where do you start?

Tie Technology Spend To Desired Business Outcomes

Yochem notes that technology is increasingly being viewed as a key enabler of many different types of businesses, which is very different from how it was viewed in the past. "Historically, we spent a lot of money on technologies specific to a line of business, sub-line of business, or a small geographic region." The result of this approach was duplication and redundancy, which meant it was not only expensive, but didn't offer improved business agility. "It's not good when you have umpteen number of different systems doing the same thing when you should probably just have one or two. If you have to make a change to a business process, having that type of inefficient system requires a tremendous amount of remediation work across many different system types," she affirms. To avoid falling into these bad habits when determining technology spend, Yochem advises that you make sure you can trace every expenditure to a desired, known, and accepted business outcome. "There is very little value in a technology deployment that is not directly linked to an outcome."

Creating The Right Team To Evaluate Technology Spending

Considering technology investment decision making requires a tremendous understanding of context and a broad perspective, one of Yochem's first tasks in her new job was to assemble a 23-member team of senior leaders called the enterprise architecture board, or EAB. "It's a terrible name," she confides. "Because in many companies, the EAB is not a team of senior leaders, but a group of people who write standard documents that get put on shelves and are often never reviewed again." That's not the role of this EAB, though. She wanted it to be a group of people who would determine and prioritize technology spending for AstraZeneca. That meant EAB members had to be people who weren't just business-savvy, but deep technology experts. They needed to understand not only the elements of a technology implementation, but also how to prioritize the project and the interdependencies between project components, which sometimes are not obvious. "Having strong technology expertise allows for accelerated decision making (e.g. knowing when to use commercially available technology versus when a custom solution might be necessary)," she explains.

The plan was to build a team of senior-level subject matter experts from each line of business, including procurement, portfolio managers, and even finance. "We built the EAB with such senior leaders so that significant decisions could be made without additional layers of approval," she states. "In addition, when you have senior leaders who are personally responsible and accountable for deliverables, that becomes a great mechanism for creating buy-in across the board."

When it came time to select team members, Yochem, being new to the company, sought recommendations from the CIO, the Information Services Leadership Team, and business line leaders. She would ask the person making the recommendation questions such as, "Tell me a little bit about this person's history. Why do you want them on the EAB? What sort of history does this person have with this level of authority? Are they going to be able to make these sorts of decisions? Do you trust them to make these sorts of decisions?"

Simplify, Then Prioritize

Once the team was compiled, its first task was to identify what level of technology capabilities were required to enable the company's

CTO Reveals Useful Tools

For Angela Yochem, AstraZeneca CTO, the availability of some useful tools helped in her quest to streamline the company's technology spending process. For example, frequently bringing together a globally dispersed enterprise architecture board (EAB) and its seven-member support team for in-person meetings can be cost-prohibitive. "We try to meet quarterly face to face and find the U.K. to be a fairly central location," she states. But in addition to in-person meeting, the team also took advantage of virtual meetings, via a tool called Lync, a fully integrated conferencing, instant message, workspace communication solution. This allowed the EAB to set up quick, on-demand video conferencing from desks or phones, incorporating a variety of technologies, including whiteboards.

Another useful tool AstraZeneca put in place is called TrouxView, an enterprise architecture software that allows you to look across multiple assets and capabilities and manage the linkages and interdependency. AstraZeneca also employed a tool called Apptio, a real-time dashboarding technology that facilitates your ability to manage the cost, quality, and value of IT. "We paired Troux and Apptio, because it is important that we think about how we're looking from the finance perspective, quarter-to-quarter," says Yochem. "It also allows for some projection capability. The linkage of the two of them has been very useful in managing the overall project."

business outcomes, which at the time, ranged between 5 and 10 for each line of business and functional area. As Yochem reviewed the number of business outcomes, she realized the importance of simplifying before prioritizing. She did this by first thinking about AstraZeneca's information system (IS) capabilities as consisting of two categories — core and differentiated. "There are about 200 core capabilities," she states. "To make them more easily adjustable and discussable, we grouped them into eight categories."

- End-to-End Process Management
- Application Lifecycle Management
- Information Lifecycle Management
- Information Visibility & Exploitation
- Externalization
- Collaboration
- Consumerization
- On Demand

The process of grouping the core capabilities into eight categories provided the EAB with a good view of the desired business outcomes. "That's when we could start the analysis process to see if we could link what technology capabilities, skills, processes, and so on would be needed to enable those desired business outcomes," says Yochem. "That's a big piece of work. In other companies I've seen it take a year or more, typically with a tremendous number of consultants involved."

Lessons Learned The Hard Way

In creating the EAB, Yochem admits not everything went as planned. For instance, she quickly learned the importance of the team behind the team. "When I first put together the EAB, I failed to get the right number of people in supporting roles lined up. It is not reasonable to expect senior leaders to be doing a lot of compilation work and lower-level analysis work, after the high-level analysis is complete. For that, we relied on our chief architect, Mark Brogden, and his team that he was slowly assembling over the course of the year. We still got the work done, but it was due to some heroics on the part of Mark and his team working in the background," she explains. "I think this put an unnecessary strain on that team."

Yochem learned another lesson, one which she viewed as being even more significant. "I wish I had personally spent more time with each line-of-business head along the way and keeping them informed," she confides. "Because while they were very receptive to the output (i.e. the multiyear plan showing what technology capabilities need to be in place to support the desired outcomes

for each line of business) of the EAB and seemed very pleased with it, I feel the updates that I have given have been, in some cases, surprising to them."

To avoid making the same mistake, Yochem recommends writing into your operating plan the time necessary to provide weekly or biweekly updates to each line-of-business owner on the specifics as to what is coming out of the EAB analysis. "I think richer and more frequent engagement would have made the process go more smoothly," she says.

> "When you have senior leaders who are personally responsible and accountable for deliverables, that becomes a great mechanism for creating buy-in across the board."
>
> Angela Yochem, CTO, AstraZeneca

If you take on the task of changing how you approach technology spending within your company, Yochem has some concluding thoughts. Stay plugged into your team, paying close attention to how they are doing, so as not to take them for granted. "Very sophisticated, master-level enterprise architects are hard to come by," she states. "It is something that you need to be very careful in sourcing. Invest legitimately and aggressively in that capability, because that's where what appears to be magic to everyone else is, in reality, tremendously sophisticated analysis." She explains that the analysis work required to identify the optimal end-to-end technology landscape over the next few years and identification and management of the various interdependencies across such a large estate can be quite tricky. The enterprise architects anticipate and measure impact, understand risks and trade-offs, and enable faster/better business decisions as a result.

The effects of AZ's IT plan are evident when you look at how the company enabled significant differentiated solutions for its business during the rapid delivery of FIPNet (fully integrated pharmaceutical network) this year. "FIPNet allows our R&D staff to locate experts and potential collaborators, quickly connect with them in a seamless way, then operate on very large data sets together over the course of a multilateral collaboration — a particularly important model for our virtual iMeds," explains Yochem.

For FIPNet, John Reynders, VP of R&D informatics, and his team were able to build or leverage core capabilities delivered for use across many lines of business, such as federated security, cloud-based email and document management, an AZ external connector (API), and interactive collaboration tools. Then they layered differentiated capabilities specific to R&D's needs, such as those necessary to support real-world evidence collection and growth, real-time pattern identification and matching, and a sophisticated rules engine that allowed them to orchestrate events across the multiparty ecosystem. "Rolling out something like FIPNet without the target-state capabilities (i.e. the overarching capabilities identified as being necessary to deliver the desired business outcomes) would have led to an unnecessarily constrained and expensive point-specific solution, taking longer to deliver and difficult to extend or leverage for other collaboration models in and outside of our industry," Yochem concludes.

The Sprint Approach To Analysis

Redesigning any process or department at a company the size of AstraZeneca is a huge undertaking. In terms of running, it would be a marathon, as opposed to a sprint. However, Mark Brogden, chief architect at AstraZeneca, introduced the concept of incorporating some sprinting within the marathon, specifically, when it comes to conducting analysis. According to Yochem, Brogden was charged with conducting the EAB analysis meetings. "At the start of the meetings, he would essentially say, we are going to meet for a day, and within this day meeting, we're going to have five sprints," she explains. He would then explain to the EAB how long each sprint would be for each topic. "By placing time constraints around the amount of time allocated to each topic and then cutting the discussion off immediately at the allotted time, every member of the EAB was incented to be as crisp and focused as possible," says Yochem. Although, while cutting off the discussion at the allotted time is indeed important, agreeing that the topic will be resolved according to where the discussion lands at cut-off time is a strong motivator. In general, the pace at which the team was able to deliver a significant piece of analysis, pretty early on, was amazing." Yochem advocates that if you are in the process of conducting team-oriented analysis, consider using a sprint-based approach to provide focus and make greater utilization of your most precious resource — time.

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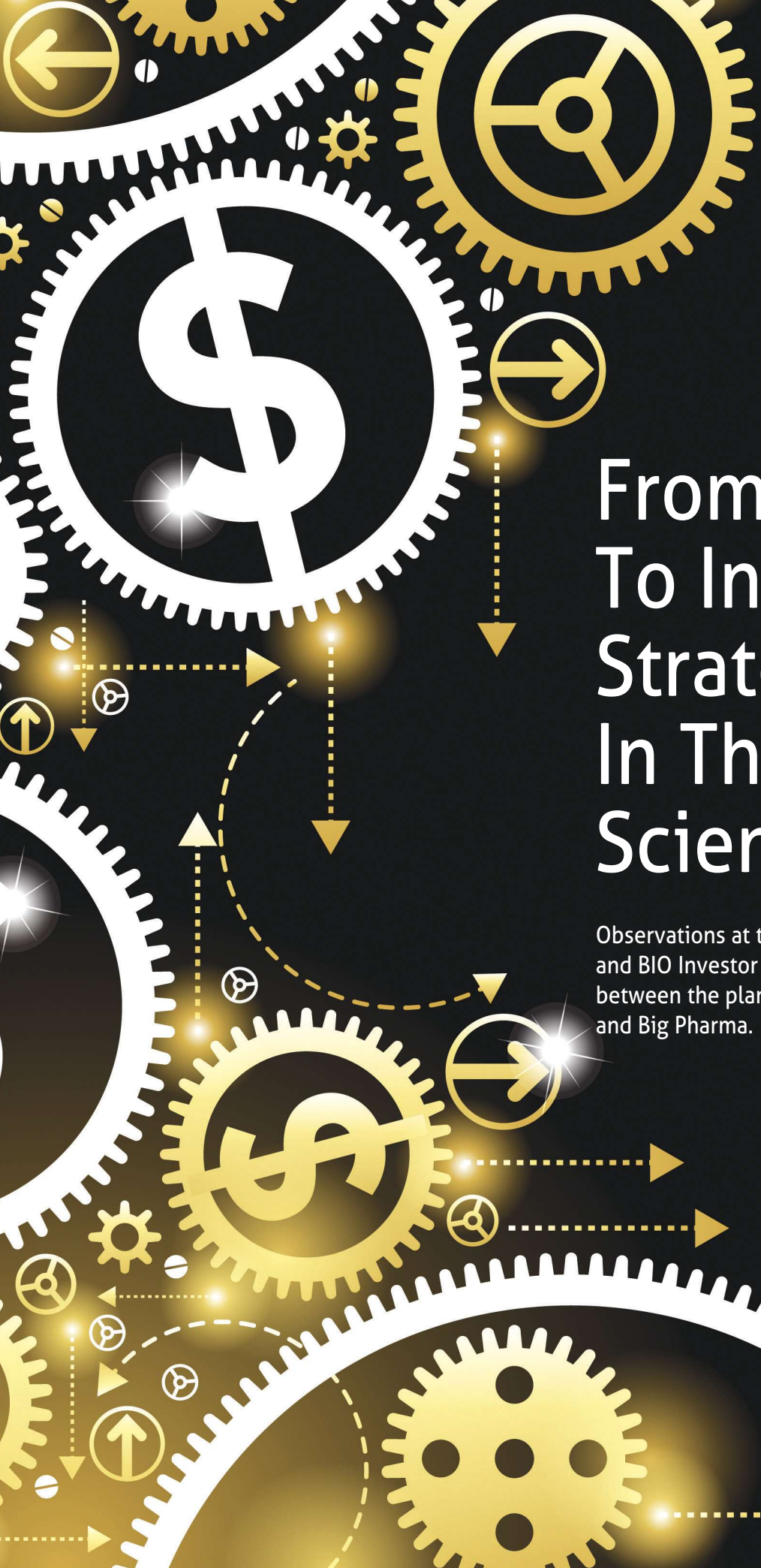


From Industrial To Investment Strategies In The Life Science Sector

Observations at the Emerson Global Exchange and BIO Investor Forum illustrate the great gulf between the plant floor and C-suites of biotech and Big Pharma.

By Wayne Koberstein
Contributing Editor

If you could start today, building a big company from the ground up with nothing to hold you back, you might succeed in constructing a fully integrated, uniform, company-wide manufacturing operation equipped with all of the most advanced technology available. Your production facilities would all look and act the same, organized as a common quality-by-design (QbD) system, optimized by process analytical technology (PAT), updated regularly, and constantly calibrated with automation to achieve reliable and predictable output for all of your products.

But you can't. And consequently not a single company on earth fits the preceding description. Big Pharma companies, nearly every one an amalgam of acquisitions and legacy systems, continue to resist sweeping changes in manufacturing, and life science investors share their avoidance of the manufacturing challenge and opportunity. That was the big lesson that returned to me over and over again at two quite different industry events I recently attended: The Emerson Global Exchange and the BIO Investor Forum, both held the same week in early October.

Emerson Global Exchange does not fit into the usual categories of industry conferences or exhibitions; Emerson is a huge industrial supply company serving many sectors, notably oil and gas and mining, with life sciences a relatively small but quickly growing slice of its business. The Exchange hosts the company's clients, and almost all presentations and exhibits address its products and services, with some room given to industry overviews and partner suppliers. But I found the life sciences sessions quite useful, especially for seeing how biotech and pharma manufacturing appear at the plant and unit management levels.

BIO Investor Forum focuses primarily on venture capital, stocks, partnering, and licensing for biotech and pharma. With the large companies, investors, and analysts in the background, small companies present their dog-and-pony shows in 15 to 30 minute rounds along four simultaneous tracks over three days. I attended the last day, seeing seven presentations, and meeting with several companies privately. A plenary session at the end featured a panel of VCs giving their forecast for 2013. It was the proverbial 30,000-foot view of people who configure the industry — and its lowly functions, such as manufacturing — only in financial terms.

NEW INDUSTRIAL VISION FOR BIO & PHARMA

Few companies, like Emerson, encompass the manufacturing side of so many different industries, and, thus, the Exchange put biotech and pharmaceutical production in a much larger context than we are accustomed to seeing. To walk the floor of the exhibition was to cross the bridge of time from artifacts of the 19th century — huge cast valves standing tall over the crowd — to working models of the latest automated systems for real-time monitoring and control of complex processes. It was easy to recognize pharma/biopharma manufacturing in the former but not in the latter.

At quiet moments, at a table or lounge isolated from the throng of attendees, heads around me nodded when I voiced the thesis that C-level executives in bio and pharma rarely poke their noses into manufacturing. One person related: "When I became head of a large pharma company's production unit, the CEO called me in, introduced himself, and then told me to make sure he didn't see my face again. He said that to see me would mean there was a problem — and he didn't like problems."

A life sciences forum echoed that theme, if more delicately. Dubbed "Process Robustness. From Molecules to Medicine," the forum began with some wise words from John Berra, retired chairman of Emerson Process Management, who stressed the potential of automation to boost manufacturing quality in the life sciences, where productivity, efficiency, and safety of pharma and biotech plants can have life-and-death consequences — and affect their exposure to regulatory and legal complications.

Automation in pharmaceuticals and biotech has succeeded in a vertical sense, he said; engineers have used traditional sensing, feedback, and control mechanisms effectively at various points along the production line. But such solutions tend to be unique to each factory and without linkages between the different production stages, from process development to clinical and commercial manufacturing. Horizontal discontinuities slow product development because they interrupt a potentially valuable flow of information and knowledge from the bench up to full-scale production and back again.

Scott Broadley of Broadley-James followed with a demonstration of how horizontal automation propels such information flow by creating "better tech-transfer packages" for process development, scale-up, and production. He described a project that teamed banks of small-scale bioreactors, networked and controlled by advanced industrial automation systems, and used to generate data for multivariate analysis predictive of large-scale process and output.

Immediate advantages of the automated banks over traditional scale-up modeling systems included more runs and greater throughput, more successful runs, operator efficiency, and the ability of the set-up to integrate with process-control technology. Such automated banks mimic process control strategies used at pilot and production and minimize data variance between bioreactors, batches, and facilities. Ideally, the scaled-up production system would follow not only the key process parameters produced by the small-scale model, but also — horizontally — its overall automation and bioprocess control approach.

FROM PROCESS TO PRODUCTION, TECHNOLOGY TO CULTURE

With visions of teamed bioreactors still dancing in the

BMS CREATES A MODEL PLANT

At a dinner event during the Emerson Global Exchange, where Bristol-Myers Squibb (BMS) received Emerson's Innovative Application Award, BMS Executives Chris Stevens and Dave Gleeson spoke on the topic "Manufacturing for the 21st Century" and described the Devens plant in more detail.

The plant produces the biologic drug Orencia (abatacept) for treating rheumatoid arthritis symptoms and slowing joint damage. The facility is recipe-driven and designed to meet ISA88 and ISA95 standards, employing operations management software and a digital automation system for paperless manufacturing. It is integrated with enterprise and plant-level systems, including SAP, LIMS (lab information management system), scheduling and computerized maintenance management systems, process information historians, and off-line instruments.

One specific goal for the company was for all CCPs (critical control parameters) and CQAs (critical quality attributes) to be electronic; automatic control charting was another. BMS also wanted alarm and event notification to comply with Western Electric Rules selected in its hierarchies, generating daily runs to automatically report any WER (Western Electric Rules) violations to the appropriate people, thus avoiding having to search for and report such items individually. The notification system uses the principle of "review by exception," looking only for variations beyond standard parameters.

Devens is the biologics site, but Francis Sidnam, director of biologics manufacturing and process development, said its model can be applied to pharmaceuticals as well. "In tablet presses, with our dry granulation, we try to have consistent product hierarchies so we can easily deploy them to other sites." Despite some data connectivity issues, depending on the data source from individual machines in a given site, the company is moving quickly forward with deployment. It is pragmatically adapting off-the-shelf components — hardware and information technology already widely employed in many industries — to existing facilities, rather than building some uniform, proprietary system from scratch.

To make the needed meta-analysis, decisions, and predictions based on all the discrete batch data, the company built the model around its MES system, automatically pulling "contextual data" from its LIMS, ERP, and historian systems. It created "universes" within its product "hierarchies," which, once developed for the first product in a product type, can be reused for subsequent products of the same type.

Building such a model requires starting with clear analytical goals, such as trending, based on batch-to-batch comparison, Sidnam said. He emphasized that the system's data structure must be something an engineer, not just an IT person, can understand. "Process engineers must be familiar with the process and also have the statistical training to look at the hierarchy and understand the data."

(Thanks to Healthcare Packaging for sharing its reporting on the dinner presentation.)

audience's heads, the remaining panelists brought a mixture of cold water and qualified support to the idea of horizontal automation in their industry. Lars Petersen, head of automation at Roche/Genentech, spoke of his company's Tech Transfer and Process Platform Initiative, which aims for more robustness in technology transfer in scale-up, the use of standard process platforms, and other new approaches to speeding drug development.

"Horizontal is the way of the future," Petersen said. "But the culture of how people are thinking is so significant that it could be a bigger issue than technology in the adoption of horizontal automation." He explained that the sequential manufacturing functions at most companies — laboratory, clinical, and large-scale production — still exist in separate silos and typically resist talking with each other. For instance, the process development (PD) lab may consider compliance issues so important to clinical manufacturing as outside its responsibility and thus reject the inclusion of compliance modules in its own work. Similarly, clinical manufacturing may react negatively when the company introduces SAP systems into its area.

Big Pharma companies, nearly every one an amalgam of acquisitions and legacy systems, continue to resist sweeping changes in manufacturing.

"We want to know the set-up of the process end to end," Petersen said. "Problem is, the PD lab would typically develop a single step in the process, then hand it over to clinical before it began work on the next step. It all happened incrementally. But we had our PD group develop the process platform, a process-development format, which creates a framework around every molecule."

Petersen observed that in most companies no single person oversees the development of a product and process from the lab, through clinical, and into operations. Typically, those functions are headed separately by managers who report high up in the organization. "So the process development head is focused on 'How can I get my process development done first?' and that is often at the expense of how fast you can get it into clinical. It is an issue that affects the entire industry," he said. "No one has solved it."

Ian Allan of Infinity Automation showed one way a process platform can speed process development. "You cannot increase yield, throughput, and so on without truly understanding the process. It's a simple loop: understand the variation, start to manage the variation, and then build your control limits around it." But such improvements depend on a continuity of knowledge traditionally lacking in many companies, he said. "Companies lost process understanding when they lost the process engineers who created it."

Allan elaborated on the technology needed to "understand the variation," describing a case of real-time monitoring leading to process improvement. Engineers were instructed to use new instrumentation to record pH levels continuously for 50 minutes in a particular phase of the operation. Not only did the method increase operators' focus — letting them see the data and respond to control rather than depend on alarms — but it also allowed them to conduct "real-time deviation management" and create a template for ideal initial conditions in the selected phase by matching one batch to another.

Francis Sidnam, director of biologics manufacturing & process development IT and global manufacturing & supply IT at Bristol-Myers Squibb, leads his company's "process robustness" initiative for pharma and biotech manufacturing. He capped the previous presentations with a more detailed look at "process robustness" on the manufacturing side, as exemplified by the new BMS Biologics Drug Substance plant in Devens, MA.

Sidnam gave some background on the plant. Expanding on the company's Paperless Plant Systems initiative, originally designed to deploy a system of electronic batch records in production, the company is developing a comprehensive "paperless production" model at Devens to be used eventually at all of its plants, including API manufacturing and even non-automated sites. Besides GMP and regulatory compliance, he said the model's efficiencies will

prove just as beneficial in the long run.

DO CEOs & VCs CARE?

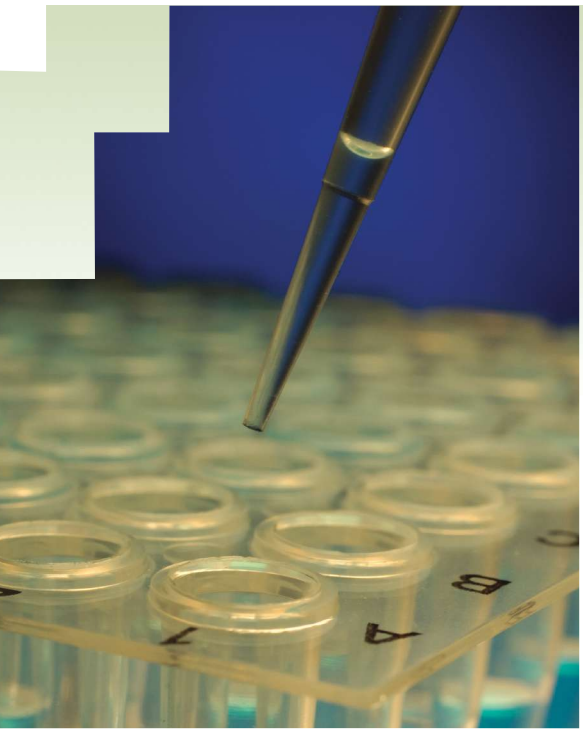
During the question and answer period, much of which was technical, I asked the panel in general to describe how the CEOs of life science companies typically view manufacturing issues. Are they normally interested and involved? Do they see manufacturing as an important strategic area, a competitive factor, a resource worthy of investment and optimization?

Responses from the panelists and the audience were naturally cautious. But it was easy to see a consensus that, at least historically and up to recent times, pharma and biopharma top management has not been known for its interest in manufacturing. The C-Level suites in many companies still prefer to keep manufacturing at arm's length, content to let plant managers run existing facilities along conventional lines in technology, process, and organizational structure. The same was said of how chief executives tend to regard their CMOs — distantly.

If CEOs pay too little attention to manufacturing, how do the primary investors in the most innovative part of the industry — small companies developing new drugs — treat the issue? The BIO Investor Forum helped me see at least part of the answer.

A roundtable of VCs gave a forecast for such companies in the coming year, most believing that the current burst of M&As will continue in 2013 as the total amount of venture capital investment dwindles. It was observed once again that most small companies fail in the transition from Phase 1 to Phase 2 and Phase 3 development, often because they run out of money paying for clinical trials. But they also acknowledged that clinical manufacturing, commonly perceived as a cost factor only to be minimized, can also play a role in development failures.

My take: Too few companies and investors value compound optimization and other supply chain components that can greatly affect drug potency, stability, and delivery — and thus safety and efficacy — in clinical trials. What are some ways all the players — top management, operations, investors, and others — could collaborate to solve a common problem like manufacturing, that sinks so many companies developing potential medical breakthroughs? The life science industry awaits new leadership that can make the critical connection between optimized manufacturing and competitive advantage, as a bridge from industrial to investment strategies.



A Biologics Road Map

By Gail Dutton

Biologics are among the most promising therapeutics for conditions that lack satisfactory treatments using conventional medicines. As a result of more specific targeting, biologics offer fewer side effects and, often, more potent payloads than would be feasible with traditional therapies. Biologics are also enabling the transition to personalized medicine.

"Biologics offer great opportunities for growth by addressing unmet needs so therapeutics are more efficacious and more convenient for patients," emphasizes Bobby Sandage, Jr., Ph.D., president, CEO, and director of Coronado Biosciences. "Their success depends upon identifying the best pathway and ensuring there is a clear, unmet need for an improved form of a drug that otherwise may require injection," he says.

For the cancer-fighting antibody drug conjugate T-DM1 (trastuzumab emtansine), the need was clear. In November 2012, the FDA accepted its Biologics License Application (BLA) and granted it priority review status. T-DM1 is one of many biologics in development. Since 2009, there have been more than 150 biologics development deals signed each year, according to Thomson Reuters. Sandage explains that there are few disease areas in which biologics aren't being developed. However, oncology, autoimmune diseases, infections, inflammatory diseases, and traditional vaccines are likely to experience the highest growth. "There is always a need in diseases like Crohn's, ulcerative colitis, Type I diabetes. So, if a biologic shows efficacy, it will find a market," he adds. "TNF-alpha is a good example. It treats autoimmune diseases and has experienced double-digit growth for more than a year. If it continues to show efficacy as new indications are added, its use in treating autoimmune diseases will grow dramatically." To underscore his point, Sandage points to the TNF (tumor necrosis factor) inhibitors Embrel, Humira, and Remicade, which had combined sales for $26 billion last year. "They represent a tremendous advance for patients."

At Coronado Biosciences, Inc., the focus is upon developing therapeutics to treat autoimmune diseases. Crohn's disease, for example, has no known cure, and treatments are limited to managing symptoms, prolonging remission, and preventing relapse. Coronado's lead therapeutic compound is based upon the hygiene hypothesis, in which an inverse relationship exists between the prevalence of autoimmune diseases and the extent of colonization of the parasitic pathogen helminthes. Therefore, Coronado Bioscienses uses Trichuris suis ova to modulate the immune system for patients with Crohn's disease, ulcerative colitis, multiple sclerosis (MS), psoriasis, psoriatic arthritis, and type-1 diabetes. It has three programs currently in Phase 2 trials for Crohn's disease, ulcerative colitis, and MS using that strategy. It also has one Phase 1 trial underway using tumor-activated natural killer (NK) cells against acute myeloid leukemia.

PERSONALIZED MEDICINE: THE NEXT GENERATION OF BIOLOGICS

Industrywide, biologic drug development is segmented into three broad categories: monoclonal antibodies (MAb), therapeutic proteins, and vaccines, using multiple potential targets and approaches. "The nice thing is that you can find a small molecule that sits on a receptor or, alternatively, you can make an MAb that fits a pathway," Sandage says.

He predicts the next generation of biologics will be geared to personalized medicine, as the understanding of the genome and of the disease pathway helps researchers to identify more targets. Autologous therapies are a good example. His company's NK program extracts a patient's own cells, increases their activity, and returns them to the patient. "That's not how traditional pharmaceuticals are developed," he explains.

In addition to expanding targets and indications, researchers also are searching for more patient-friendly delivery strategies. The vast majority of biologics, as large molecules, must be injected. Academic researchers, therefore, are partnering with biopharmaceutical companies to exploit novel pathways and develop methods to deliver proteins and other biologic materials intranasally, topically, or orally.

THE CHALLENGE OF CONSISTENCY WITH BIOLOGICS

Because biologics are made using living organisms that react to variability in their environment, some degree of batch-to-batch variability is inevitable. Demonstrating consistency, therefore, has been one of the greatest challenges faced by biologics undergoing regulatory agency evaluation. For biologicals, consistency often entails agreeing upon a range for each parameter that, though variable, still delivers a safe, effica-

cious product and the desired clinical outcome. "When a new biologic is developed that doesn't fit a known criterion, the developer must work especially closely with regulators to develop relevant criteria related to safety, controls, and endpoints," Sandage says. That's true for biosimilars, too. The FDA's draft guidances issued February 2012 provided a pathway to ensure interchangeability between biosimilars and already-approved biologic products."The follow-on biologics market won't be like the generic pharmaceutical market," Sandage says. "When a drug like Lipitor goes off patent, 25 to 30 companies can make it easily. But only a few of the generic companies will be capable of making biosimilars."

PARTNERING IS THE TREND FOR BIOLOGICS

Because the barriers to entry are high, biosimilars companies are partnering with innovator companies in ways that allow the innovator to continue to recoup some profits from its work. Recently, biosimilars firms AET BioTech and BioXpress Therapeutics formed an alliance to develop a biosimilars version of adalimumab (Humira). In India, Dr. Reddy's is working with Merck KGaA to codevelop biosimilar oncologics for the U.S. market. In Korea, Samsung and partner Biogen Idec plan to commercialize several biosimilars in 2015 at half the current price of the original medications. Typically, biosimilars are expected to be priced at 60% to 80% of the purchase price of branded drugs. In contrast, traditional generics typically are priced at 10% to 20% of the price of the branded drug.

As biologics move into the clinic, companies are investing in manufacturing facilities. Novartis, for example, recently announced plans to begin construction in 2013 of a $500 million biologics manufacturing plant in Singapore. WuXi AppTec opened a biologics manufacturing facility in Shanghai in October 2012 to support its joint venture with AstraZeneca, and UCB Pharma completed a $84.8 million biologics plant in Braine-l'Alleud, Belgium.

With such a plethora of options, the global biologics market ranges between Thomson Reuters' estimate of $90 billion and the IMS Institute for Healthcare Informatics' figure of $176 billion. Despite their different estimates, both agree the growth rate for biologics surpasses that of traditional pharmaceuticals. Another analyst, the Freedonia Group, projects the annual growth rate for biologics at 6.5% until 2015, versus about 5% for the pharma industry as a whole. "There's almost unlimited growth potential," Sandage underscores.

Making Precompetitive Partnerships Work

By Nick Taylor, contributing editor

In May 2011 Johnson & Johnson executives sat down to figure out how to tackle a growing problem — inefficient clinical trials. Improved internal processes and new technologies were at the top of the agenda, but it quickly became apparent these measures were insufficient. In fact, J&J executives realized that any action they took alone would be insufficient to address some problems. To design the clinical trial processes of the future they would have to look outside their walls. Collaboration was needed.

Andreas Koester, MD, Ph.D., was at the J&J meeting. "We identified very quickly that some of the things that make clinical trials inefficient today can only be tackled when we work in concert with other companies," recalls Koester, head of clinical trial innovation and external alliances at Janssen Research & Development. Many others have reached the same conclusion, but putting those simple words into action is tough. Most Big Pharma firms have tried to do it by forming precompetitive collaborations with rivals and academia. But it is tough for two companies to even agree on what information is precompetitive. Successful precompetitive collaborations only occur when multiple companies put aside traditional rivalries and adopt new ways of thinking about drug development and their respective roles within the industry. It is a big challenge.

Koester and his colleagues have managed it, though. Janssen's parent company, J&J, is now sharing investigator training information with Eli Lilly and Merck. And Koester went from discussing the idea internally to presenting the initiative to the world within 18 months. How? "We focused on what you could call 'low-hanging fruit,'" he explains. By targeting easily achievable, uncontroversial goals — the 'low-hanging fruit' — Koester hoped to quickly advance the project. But in an industry resistant to change, even 'low-hanging fruit' can be difficult to pluck.

HOW TO GET COLLABORATORS ON BOARD QUICKLY

To understand how to make a precompetitive collaboration work, Koester looked at what had failed in the past. He soon found a common theme. Many of the projects that stalled had over-reached, either in scope or scale. The J&J team was determined to avoid these traps and worked on a concept they could push through quickly. This involved anticipating potential bottlenecks, the first and most fundamental of which was opposition to sharing information. To sidestep this early potential obstacle, J&J looked at sharing "items and data that are really noncontroversial; everybody can easily say, 'Yeah, that makes total sense,'" Koester explains. For example, trial investigator good clinical practice (GCP) training information fit the criteria. It would be hard to argue that keeping these records confidential offers any competitive advantage. And there is a clear case that such secrecy is detrimental to the industry as a whole. It is among the lowest of the low-hanging fruit referred to by Koester. Currently, investigators undergo basically the same training each time they begin working with a new company. So, if investigators work with five companies, they will have to do five separate training sessions. This duplicated workload is often cited as a reason why more than half of investigators drop out after running just a few clinical trials. "They are inundated with red tape and administrative burdens, just because we don't share what is really generic information that should only be captured once," Koester says. As well as duplicated GCP training programs, clinical investigators must undergo repeated therapeutic area education sessions and face administrative burdens associated with institutional review board meetings. If these burdens distract too much from treating patients, a physician is likely to stop running clinical trials.

Having formulated an initial plan, Koester and his colleagues got in touch with their contacts at other Big Pharma companies. "The response was very enthusiastic. But of course it can take time for an enthusiastic response to become a firm commitment," Koester recalls. Persistence and patience are needed to bring people on board with such a project. Merck and Lilly were at the head of the queue, and J&J selected them as its two partners. J&J could have waited for more partners to sign up, but Koester says that was never the plan. The decision to restrict initial membership was made after looking into the travails of earlier collaborations. Koester saw that initiatives with more members tend to become bogged down by an inability to make decisions. "You can only move for-

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ward once you have consensus, and consensus is naturally easier to get with three players than with 5, 10, or 20," he says. Once inertia sets in, it is tough to regain the early momentum and optimism. With more voices involved, every potential stumbling block and bottleneck, from agreeing on a central data warehouse to the drafting of privacy agreements, would have taken longer to navigate. The risk of delays is particularly pronounced for a project, such as the database, that is well outside the comfort zone of the industry. Sharing information is, for many good reasons, unnatural to pharma as an industry, and getting the green light from internal departments can be more challenging than finding common ground with external partners. A lot of determination is needed to overcome such internal resistance and drive through disruptive innovation projects.

Having played a central role in multiple partnerships, Eli Lilly's Jeffrey Kasher knows more than most about what it takes to make a precompetitive alliance work. Kasher, Lilly's VP of clinical trial transformation, is an advocate of precompetitive partnerships but admits they present "unique challenges." These challenges meant that the investigator database remained a nice, but seemingly unworkable, idea for years. The concept became a reality only when a few "committed partners who were willing to take the much needed first step" got together, Kasher explains.

WHAT J&J IS DOING TO EXPAND THE DATABASE

The end result has made the effort worthwhile, though. J&J talked to investigators throughout the development of the project and found overwhelming support. Some asked Koester, "Why have you not done this 5 or 10 years ago? That's what we were waiting for," he recalls. Yet, in its current form, the database has limited benefits for investigators. The shortcomings stem from the deliberately narrow scope of the project. Investigators who sign up to share their data will avoid duplicated training by the three partners but still have to jump through hoops for the rest of the drug industry. Repeated GCP training will still weigh heavily on their business.

> We identified very quickly that some of the things that make clinical trials inefficient today can only be tackled when we work in concert with other companies."
>
> Andreas Koester, MD, Ph.D., head of clinical trial innovation and external alliances, Janssen Research & Development

J&J foresaw these shortcomings but decided to sacrifice comprehensiveness for speed. With 10 voices vying for attention, it is highly unlikely J&J could have got the database going so quickly. Yet, while the project could only come into being by starting small, it could only fulfill its potential by thinking big. "It becomes really valuable to the investigators only once all major pharma companies — and in the future smaller and biotech companies — share their data," Koester says. In working toward the ambitious goal of getting all companies to sign up to the project, J&J has broken the task down into manageable steps.

The first step is getting the remaining eight members of the Big Pharma consortium, TransCelerate, on board. Talks are already underway, and for companies looking to join now, the risk-reward proposition is clearer. J&J, Lilly, and Merck have already cleared out the stumbling blocks involved in setting up the project, and data on its benefits should start coming in soon. "Our thinking was that once we set up the database and showed its benefits, it would be much easier for other companies to join," Koester explains. To further simplify the process for new sign ups, TransCelerate members automatically qualify for participation. TransCelerate will formalize its support for the initiative next year when it makes the investigator database one of its priority projects.

WHAT INFORMATION IS PRECOMPETITIVE?

As J&J planned from the start, few if any companies are likely to have strong objections to sharing investigator GCP training records. But with this project now well underway, Koester and his collaborators are becoming more ambitious. "The discussion 'what is precompetitive?' can be expanded. There may be other data fields in the future we may want to include," Koester says. Other training records, such as those related to specific therapeutic areas, could be next. For example, it is questionable whether investigators need multiple companies to train them on how to limit placebo response in CNS studies. Sharing these training records could reduce duplicated effort.

Opening peoples' eyes to the benefits of collaborating through an uncontroversial proposition improves the chances of gaining acceptance for more radical ideas. How radical remains to be seen. To illustrate the breadth of views on what can be classified as precompetitive, Koester notes that some people are calling for companies to share all information on a drug target until it is validated. It would take a major re-imagining of the pharma industry to reach this stage, but clearly there is a lot of scope for expanding precompetitive collaboration. More importantly, the pressures on drug development mean there is now an increased willingness from the industry's biggest players to consider new ways of working.

In the past year Lilly alone has formed several collaborations, with the investigator database and TransCelerate coming months after it allied with the NIH. Each partnership is an acknowledgement that it is no longer viable to operate in isolation. Many of the current drug discovery and development challenges are simply too big for any one company. "It is important that those involved in the drug discovery and development ecosystem complement and not compete against each other. Ultimately, we believe we can create value for patients and clinicians through improved transparency and ease of use, and by engaging all to contribute to the drug development process," Kasher says.

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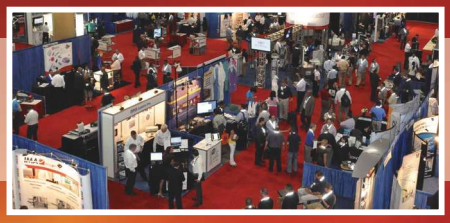

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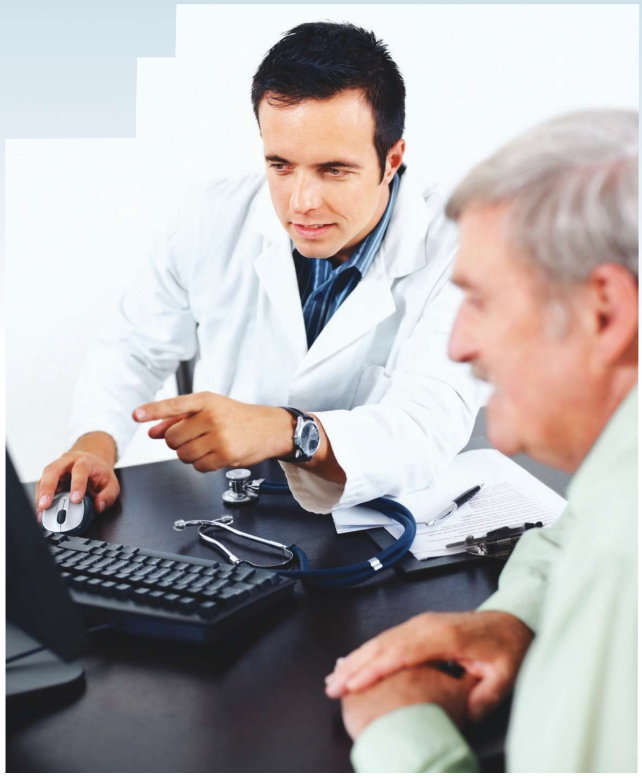
Continuous Patient Monitoring In Clinical Trials: Preparing For Prime Time



By Neil de Crescenzo

The clinical trial data capture process has made tremendous strides over the last 15 years. The age-old process of having clinical staff and investigators recording patient information from various inputs (medical instruments, laboratory reports, clinician notes, patient diaries, etc.) on paper-based case report forms, then manually entering this information into a database is fading into history. Electronic data capture (EDC) is rapidly becoming the new standard, yielding impressive productivity gains and helping to improve data accuracy.

Now that EDC has evolved from leading edge to the norm, we are already looking ahead to the next disruptive technology. The automated solutions that have emerged in the last decades have helped us to make great strides in improving the efficiency of clinical trial data capture and management. They have not yet, however, enabled us to enter a new era of more accurate and complete data and greater insight, as well as significantly faster clinical development processes.

Change may be coming, and quickly, with increased focus on machine-to-machine (M2M) technology that is beginning to make its mark in industries ranging from auto manufacturing to public utilities. The M2M model uses wired or wireless connectivity to exchange information and communications between Web-connected devices without human intervention. Healthcare and life sciences are very much in the mix, and we are beginning to see the emergence of wireless devices that enable continuous, remote patient monitoring. For example, in the summer of 2012, the industry was abuzz with news of FDA approval of the first ingestible event monitor (IEM) for medication adherence. The embedded monitor sends a signal through the skin, logging both the time the user took the pill and the unique identifier for that particular medication. A companion sensor worn on the skin receives and logs the signal from the IEM, as well as captures continuous readings of the patient's heart rate, temperature, activity, and rest patterns to collect as much context data as possible. The IEM can collect more than 5,000 data points per minute, which can be uploaded to a computer or mobile device at any time. The potential for M2M devices in the clinical trial process is exciting, compelling, and close to being within reach.

CONTINUOUS MONITORING — DEFINING THE POTENTIAL

WHO research from 2010 estimates that half of all patients fail to take medications properly. Adherence issues can have a dramatic impact on the effectiveness of any approved treatment. Protocol adherence is even more critical in a clinical trial in which a treatment's efficacy and safety are being studied.

It is easy, therefore, to see why the life sciences industry is interested in the potential of M2M technologies in clinical trials. Continuous monitoring can help researchers to confirm treatment adherence with certainty, which we cannot do today. As a result, study sponsors and managers can more accurately determine efficacy because non-adhering patients can be filtered out. In addition, it can help to facilitate subject recruitment and, ultimately, shorten the length of a trial. If participants are not adhering, trial managers can drop them quickly, yielding earlier insight into how many subjects will be required to complete the trial. Further, continuous monitoring can help to improve participant retention as recording critical data and adherence will be more convenient.

Continuous monitoring can further bolster clinical trial efficiency. Today, a clinician writes down information after a patient visit, which is then entered on-site into an EDC system. Later, the study sponsor or CRO sends a verifier to validate the process and data, adding layers, time, and costs. Continuous monitoring could eliminate these processes by automatically uploading the data to the clinical data management system. No source data verification would

be required, and trial sponsors and their development partners can benefit from continuous insight.

There is also a link between safety and continuous remote patient monitoring. The latter can enable trial sponsors to more readily and accurately identify potential events or side effects, such as changes to heart rate or rhythm, respiration, blood pressure, or sleeping patterns after taking a medication or undergoing a therapy.

CLEARING THE FINAL HURDLES

How can we expect the use of M2M technologies to evolve in the clinical space? For answers, we might look to the healthcare sector where we are seeing a growing number of pilots and small-scale initiatives, most frequently around cardiac monitoring and diabetic care. Widespread adoption, however, has yet to take off in healthcare due to some familiar barriers that also apply to the use of M2M devices in clinical trials. First, we see concerns about liability and security associated with new devices in the healthcare and life sciences sectors.

In addition, the technology supporting continuous remote patient monitoring is emerging quickly, and regulatory policies around its use are, at best, in their infancy. President Obama signed legislation in July that gave the FDA approval to continue to develop mHealth regulations while the Department of Health and Human Services continues to work on a "regulatory framework for health information technology, including mobile medical applications…." It remains unclear which applications and technologies will require FDA approval and what the approval process might entail. This uncertainty hinders adoption as well as device and software development.

The health sciences sector also continues to sort out standards that so far have not kept pace with technology evolution. While Internet protocol and telecommunications standards are widely used, they are not universal and, in some pilots, have led to issues with product development and rollout. In addition, there can be issues regarding changes in medical device transport protocols as well as device compatibility. The positive news is that standards such as those promoted by the Continua Alliance are gaining traction, as exemplified by Norway's adoption of them, with other countries starting to follow.

PREPARING TO PUT M2M TECHNOLOGY TO WORK

As government and industry lock down the remaining infrastructure, regulatory, and standards details, forward-looking life sciences organizations can begin to plot a foundation for adoption. The good news is that we have the core technologies — including data repositories, analytics, and the Internet — already at our disposal and can learn from other industries that are progressing rapidly through the adoption curve. The biggest challenge is likely to be the ability to deal with the exponential increase in data that M2M devices will capture and subsequently transmit to clinical development organizations.

Life sciences organizations are already facing a data deluge. C-level life sciences executives in a recent Oracle survey revealed their organizations are, on average, collecting and managing 78% more data than they did just two years ago. More important, nearly 30% of the life sciences execs gave their organization a "D" or "F" when asked about their company's preparedness to deal with the data pouring into their organizations.

If pharmas and CROs are not prepared, this data deluge can prevent researchers and clinicians from turning M2M data, as well as other clinical data, into useful insights about a therapy and its effectiveness. As such, life sciences organizations are wise to begin to take stock of their data infrastructure and analytical capabilities now, an exercise that can yield both immediate and longer-term benefits.

> The potential for M2M devices in the clinical trial process is exciting, compelling, and close to being within reach.

It is also important for organizations to review current analytics and reporting capabilities to see if they can handle data streams from a variety of sources and generate reports and dashboards within acceptable timeframes. Then, they must determine what legacy systems can be leveraged and what might be needed to enable the organization to make the most of its big data today and into the future.

To prepare to take advantage of continuous monitoring technology as it comes of age, health sciences organizations and their CRO partners are wise to address their data management challenges in the short term with infrastructures that can process, store, and, most importantly, analyze unprecedented amounts of information more rapidly than ever before. Those that move confidently forward and build out a system to support these requirements will be well prepared to begin the next clinical data capture transformation journey.

About the Author

Neil de Crescenzo is senior vice president and general manager for Oracle Health Sciences Global Business Unit.

Enhancing Your Ability To Innovate: An M&A Playbook

By Matthew Gurin

Blockbusters are dead? Not so fast. Bigger no longer is better? A definite maybe. Despite the fact that industry pundits have declared this to be a new day, the current reality seems to be that the more things change, the more they stay the same. This is not cynicism but rather an acknowledgment that the industry's (re)commitment to building drug pipelines, being more patient-centric and focusing on cost-effectiveness, is absolutely necessary, but insufficient to remove the stigma of "value play" from analysts' characterizations of many life sciences stocks. What that means is that historically successful strategies such as M&A deals are still on the docket. But before we dust off the old playbook, let's think about some revisions to make sure it's in sync with the new normal.

Our research has shown that only 9% of M&A deals fully achieve their objectives and that about 75% of business value from M&As can be linked to human capital-related intangible assets. In fact, 58% of companies in our research confess that overemphasizing systems integration resulted in insufficient focus on intangibles and cultural integration, while two-thirds believe an increased focus on these intangibles would improve merger success. Why is this important, and what steps can you take to ensure that the inevitable M&A activities are as successful as possible?

4 STRATEGIES FOR M&A SUCCESS

First and foremost, it is crucial to understand that, when done poorly, an M&A can actually undermine a firm's ability for future innovation by disrupting important networks, reconfiguring key project teams, and reorganizing key functions. In a Hay Group study of more than 800 R&D professionals in Big Pharma, 56% of scientists described their working environment as "demotivating" and another 15% as only "tolerable." These scores are worse than any other function in Big Pharma. In fact, Big Pharma R&D's working environment — what we call organizational climate — is lower than the R&D functions of any sector in our database.

We believe it is critical to change how life sciences companies conduct organizational transformations such as M&As in order to preserve their ability to innovate. We believe that adding the following four strategies to your M&A playbook will make the deal more successful while preserving or enhancing your firm's ability to innovate.

1. Evaluate human capital up front. Leaders must analyze their own ability to collaborate and put a value on their target's innovative capabilities during due diligence. They must understand the networks and matrices in their organizations — the very relationships that spur innovation — to determine what must be protected and what can be done away with. Cross-functional relationships are crucial, yet most change and M&A activity is conducted in silos — with (predictably) disappointing results.

For example, both Roche and Sanofi have recently acquired large, innovative biopharmaceutical companies. Instead of leaving them as stand-alones or fully integrating them into their existing structures, these companies took the time to understand both Genentech and Genzyme before taking action. As a result, Roche and Sanofi have both decided to leave the core of their newly acquired R&D-driven companies intact and instead to wrap their own R&D organizations around this new innovative core. In Roche's case, it is moving its R&D hub to San Francisco where Genentech was based, and Sanofi is building an important R&D hub in Boston where Genzyme is based.

2. Clear roles are essential. When mergers, acquisitions, and organizational transformations occur, people's jobs change: some get bigger, some get smaller, some change function. In times of change, people need, above all else, clarity about their role and an understanding of what excellence looks like. Leaders must manage these changes with confidence. All else can be in chaos, but if people know what is expected of them, success is far more likely.

In several recent client engagements related to M&A and organizational transformation, the Hay Group has worked with clients to go beyond structure, to dig into the detail of job designs to ensure they are aligned with the new organization and operating model. In one recent case where an acquired biopharmaceutical facility was being integrated by a European company, we worked with the parent company to understand its strategies and operating model for its global biopharmaceutical business. We then partnered with the facility to recraft all of the leadership and management job descriptions to ensure that capability requirements, accountabilities, and decision rights were aligned with the new model.

3. Focus on decision-making and governance. If leaders are not paying attention to relationships and role clarity, the quality and speed of their organization's decision-making suffers. Effective leaders pay as much attention to governance and decision-making as they do to cost synergies and structure. Most of us know this as the "operating model," which is the organizational/management system that controls 1) interfaces between groups; 2) allocation trade-offs related to distribution of resources; and 3) the rules of engagement and methods for resolving the inevitable conflicts.

> Our research has shown that only 9% of M&A deals fully achieve their objectives and that about 75% of business value from M&As can be linked to human capital-related intangible assets.

While most M&A due diligence and integration activity focuses on who is accountable for what activities, an effective operating model assessment strives also to understand how decisions get made. In a recent engagement with a Japanese pharmaceutical company expanding into the U.S. market, most of the prework had focused on establishing budgets and functional accountabilities. As a result, there was great confusion about how decisions were to be made regarding which drug development projects to advance and fund (e.g. decision criteria, decision rights, etc.). To speed up decision-making and defuse increasing tensions, we worked with this client to negotiate an agreement between the Japanese HQ and the new U.S. affiliate relative to how pipeline decisions would be made.

4. Conflict is necessary — and manageable. In the context of M&A or other organizational transformations, conflict is actually desirable to the extent it can be managed. To generate enterprise value, leaders must be prepared to rock the boat. Many leaders are uncomfortable with conflict, but they must be willing to show people that tough decisions and well-managed conflict are necessary and explain how they will make the organization healthier in the long run.

I will never forget a post-merger integration project in which I was advising a newly formed R&D leadership team. This was a team that had already established two unhealthy norms: 1) agreeing to new projects without agreeing which other projects would need to be put on hold, and 2) debating and challenging nearly every decision in a quasi-academic process. As a result, the head of R&D was frustrated that progress was not being made on the new strategy because resources were still being applied to legacy projects, and decision-making was painfully slow. We worked with the team to establish clear criteria and norms for how to identify and manage the inevitable conflicts between old and new projects.

At one critical point in the process, the R&D head slammed his fist on the table and exclaimed, "I've told you repeatedly what our priorities are, why aren't we making progress?" A lieutenant sheepishly raised his hand and replied, "Because anyone who has dared to disagree with you is no longer on the team." So, without clear norms and mechanisms for identifying and dealing with conflict and disagreement, the team had just learned to say "yes" and then continued to quietly pursue its own priorities. It wasn't until a year after the merger and multiple changes in the composition of the leadership team that we led the leadership team through a contracting process to determine how it would constructively manage conflict.

If we agree that M&A activity will remain a part of the industry game plan, then to reap the maximum financial benefit from M&As while also safeguarding the firm's ability to innovate, leaders need to integrate these strategies for dealing with the intangibles of human capital — which can account for the greatest potential for value creation and innovation.

About the Author

Matthew Gurin is VP of the U.S. Life Sciences practice at Hay Group.

Singapore Reduces Risks To Entering The Asian Market

By Fred Olds, contributing editor

While life sciences companies view Asia as a huge potential growth market, there are huge challenges. Opening operations 12 time zones away in a location without shared values, customs, or economic practices can be difficult for planners trying to estimate expenses and risks. Companies would rather look for a location where risks can be minimized. Kevin Lai, director of biomedical sciences, Singapore Economic Development Board (EDB), contends, "Singapore provides an environment for businesses to thrive and is the ideal and efficient market for businesses to access Asia."

A tiny country with no natural resources or markets, the government of Singapore placed its survival on international commerce when it was founded in 1965. It established practices that consistently rank it at the top of places to conduct business in the world in almost all categories.

At the millennium, the government enacted plans to attract the life sciences. "We started off by building Singapore as a key manufacturing center for pharmaceutical and medical technologies," says Lai. "At the same time we began to build capabilities for R&D." Singapore constructed Biopolis, a 3-million–square-foot innovation center. Biopolis provides adaptable space and shared equipment to industry to conduct research. Companies can contract for office space, state-of-the-art laboratories, and/or access to equipment like mass spectrometers, DNA analyzers, and advanced IT resources.

Coincident with the construction, the country focused on growing its intellectual capabilities to support R&D in the life sciences. Universities and research centers developed expertise in biomedical projects, bioinformatics, molecular biology, and immunology. Where gaps in knowledge or capabilities developed, Singapore recruited additional talent.

CONTROLLING OPERATING COSTS

"The broad variety of resources in Singapore allows a company to turn fixed costs into flexible costs. A company only has to pay for the resources it needs, and only for as long as it needs them," says Lai. To do this, Lai says, "The EDB enters into a deep engagement with a company to understand what drives their business, and from there we can propose collaboration models to meet their very specific needs."

The EDB can facilitate access to laboratories and equipment and make contacts with researchers, clinicians, or regulators. In some cases the collaborations can be elaborate without a major physical plant.

When Michael Schröter, Ph.D., head of global academic alliances, opened Roche's first Translational Medicine Research Hub in Singapore, he says, "We were looking for a new business model which would allow us to engage in tackling complex problems in a multidisciplinary approach across institutes, spanning preclinical as well as clinical." As science becomes more complex, he says, you need increased collaborative input from different areas of specialization. In Singapore the centers of knowledge are geographically concentrated, making this collaboration straightforward and easy.

"In Singapore, it's the nimbleness to build up value chains," says Schröter. He brought in a small cohort of Roche scientists, project managers, and clinicians. This group networked locally to find the expertise and science to conduct their research projects. "The network is very lean and flexible and requires no substantial physical presence," says Schröter. It now includes colleagues at 26 universities, hospitals, and research institutes. By leveraging the local talent, Roche reduced facility overhead costs while achieving its scientific goals.

"Singapore is run like a business, which makes it easy for companies to interact with the government; they speak the same language," says Schröter. Roche has a small staff on-site in Singapore to manage the partnership and the various collaborations. The umbrella agreement obviously took some time to negotiate, but once established and staffed, Roche was running several projects within one to two months.

INCENTIVES

Beyond access to the infrastructure of research facilities and intellectual capabilities, the government does not comment on specific incentives it can offer to a company.

Each partnership is individual. However, the government does structure its overall policies to support its long-term economic goals.

Taxes in Singapore are among the lowest in Asia, with a 7% consumption tax and 17% corporate tax. They are structured to incentivize investment and business activity that conforms to the country's long-term strategies. "Developing our knowledge base and R&D fit that strategy," says Lai. "Companies can enjoy incentives if they conduct research and development in Singapore. For example, they can earn 150% deduction for research expenses incurred in Singapore."

REGULATORY CONSISTENCY

In an interview with Pharma IQ, Jack Wong, director of regulatory medical affairs at Johnson & Johnson, points out two challenges for R&D in Asia. One is that even in countries where regulations have been established, like Japan and China, those regulations continue to change. The other is occurring in Asian countries without their own regulations. In the past, these countries accepted the registration approvals from proxies, such as the country in which a drug was developed. Inevitably, they will develop and enact laws of their own, introducing added uncertainties to companies trying to introduce therapies and protect their interests.

"There is no harmonized regulatory process in Asia," says Lai. "As a result, companies find it easier to conduct phase 1 and phase 2 trials in Singapore because of the infrastructure we've built and the regulatory environment." Lai says Phase 3 trials need to be conducted in the host country, but in the early stages of development when IP is being created, a company needs confidence that its IP will be respected and protected legally.

In much of Asia IP protection is inconsistent and evolving. Singapore ranks only behind Finland as having the world's best IP protection according to the *World Economic Forum Global Competitiveness Report 2011-2012*. Lai says, "In collaboration with local researchers, there have been no problems with conflicts or infringements. We have proven to companies that IP is respected, and that is a unique differentiating factor."

LOCATION — BOTH STRATEGIC AND CHALLENGING

Sitting as it does halfway around the world from the U.S., Singapore's location is both a challenge and a strategic advantage. Time differences can be a challenge when you have an international presence and have to collaborate across time zones, says Schröter.

Yet Singapore has grown into one of the world's busiest transportation hubs for shipping because of both its location and its commercial focus. Singapore representatives believe that, for the life sciences, the country offers two distinct advantages. "First," says Lai, "think of not only China and India, but also of Southeast Asia, Australia, Korea, Japan, and Indonesia. From Singapore you can quite efficiently access markets in China, India, and Southeast Asia."

"The second," he says, "is because of ethnicity and culture. The three largest ethnic groups in Singapore are Chinese, Malay, and Indian." This affords an understanding of cultural influences that may affect innovative advances, and it's an ideal population from which to draw sample groups for clinical studies.

CHALLENGES OF SUCCESS IN INTERNATIONAL COMMERCE

Singapore thrives when world economies thrive. Conversely, recent world downturns have led to slow growth in Singapore. In turn, this places pressure on the government to respond to complaints from its citizens that foreign nationals take jobs and property they could hold.

Historically, Singapore has had an open immigration policy. In attracting high-tech expertise, the country has become one of the wealthiest in the world. With that comes high costs. Expatriates and companies drawn to the country compete with native nationals for resources on a tiny piece of land. The government is now dealing with growing antiforeigner sentiment among nationals. In an effort to protect its citizens, the government has enacted laws to slow immigration and to protect the ability of nationals to have access to housing and jobs. This may increase the costs and restrict the ability of companies to expand.

ASIA OR NOT

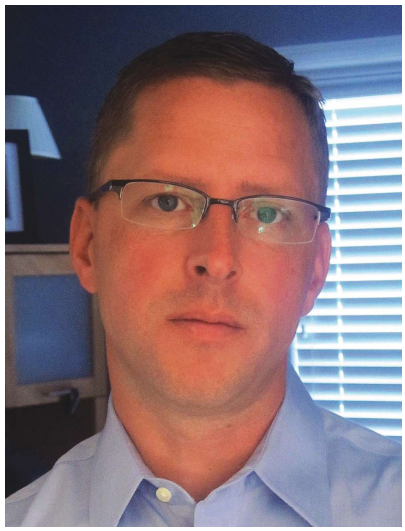
All of this begs the question of whether a company needs a physical presence in Asia to enter the market. Lai points out that a company needs to locate some functions in Asia. Sales need to be close to the customer. Distribution is more efficient from an Asian site. He also argues that R&D should be there. "Be in Asia to innovate for Asia."

Culture, ethnicity, infrastructure, geography, and economics are different in Asia and affect how therapies may be accepted and utilized. Practitioners might be in a small, isolated village with few amenities or a well-fitted hospital. Expense, complex administrations procedures, cultural reluctance to use medications, or biological variations may affect therapeutic efficacy.

Device companies like Greatbatch have opened R&D centers in Singapore. Thomas Hook, president and CEO of Greatbatch, says his company chose Singapore as the site for its active implantable medical device R&D center because of the nation's commitment to biomedical sciences and complementary research being conducted in the country's research centers.

The World Bank ranks Singapore as the world's easiest place to do business in its *Doing Business* report 2012. This makes Singapore an attractive option for any business. For life sciences, the added advantage is the government's active search and support for companies pursuing life sciences innovation.

How Cloud Computing Can Help Growing Pharma Companies



Jon Smith

Smith is director of industry development at Revitas. He advises clients on best practices in institutional and managed care contracts, transaction management, and government contracting.

Consider for a moment the diversity among emerging growth life sciences companies. Since the designation is not based on revenue alone, these midmarket companies vary in market potential, current size, and immediate needs. An emerging growth company might be public and have a large market cap and even be pre-revenue. It might have a small team of employees or be rapidly adding staff. It might be in the late stages of clinical trial approvals or have a small product portfolio. It might focus on generic, specialty, or branded pharmaceuticals, each of which has vastly different needs.

Still, every one of these companies faces the same challenges of compliance risk and operational inefficiency. These issues have always been thorny for pharmaceutical manufacturers, but they are even more so for emerging growth life sciences companies, which have limited resources to manage them. However, cloud computing brings new possibilities for effectively managing these challenges and helping midmarket companies rapidly scale into enterprises when sales take off.

OBSTACLES FACING MIDMARKET PHARMA COMPANIES

Few midmarket companies are equipped to handle blockbuster-like rapid growth. They need ways to scale and speed products to market.

When organizations aren't prepared, such growth correlates to an exponential increase in revenue leakage. A midmarket company with $250 million in revenue, for example, risks as much as $1.8 million (or just less than 1% of revenue) in a poorly managed pharmaceutical supply chain. However, if that company were suddenly to increase revenue to $1 billion — a not uncommon occurrence — the revenue loss could increase to $139 million or 13% of revenue, according to IDC Health Insights' *Business Strategy: Revenue Leakage—Pharma's $11 Billion Problem*. The manual systems these companies all too frequently use provide poor economies of scale when major, rapid growth occurs, translating to exponential rather than linear losses on margin.

Beyond managing contract revenue and associated obligations, emerging growth companies need infrastructure in place to adequately handle government pricing and prove compliance to avoid serious penalties. Between November 2010 and July 2012, 57% of pharmaceutical industry violations centered on overcharging government health programs, notes Public Citizen's *Pharmaceutical Industry Criminal and Civil Penalties: An Update*. During that same period, pharmaceutical manufacturers paid more than $2 billion in fines as a result.

What should be particularly worrisome to emerging growth companies is the trend toward greater scrutiny and oversight. The Public Citizen report also points out that the number of settlements in the past decade between pharmaceutical manufacturers and federal and state governments has increased more than 1,000%, as have the financial penalties. This is too big of a problem to just wing it with homegrown systems and spreadsheets.

LEVERAGING CAPABILITIES ONCE EXCLUSIVE TO BIG PHARMA

Cloud computing has leveled the playing field between the midmarket and the enterprise, allowing companies with fewer resources to gain enterprise computing capabilities without the capital expenditure. The cloud computing model also fully leverages the scalable hardware and software capabilities that benefit midmarket companies preparing for growth.

While cloud computing might go against the traditional IT thinking in life sciences organizations, the benefits are worth the effort to convince stakeholders. By virtualizing software, organizations will see an increase in computing efficiency that matches enterprise-scale infrastructure with no up-front capital expenditure.

At the same time, operating in the cloud provides scalability and fast provisioning that enables speedy, high-capacity, and reliable IT services. Cloud computing providers commoditize infrastructure, eliminating maintenance and upgrade costs, and leaving IT to focus on the more strategic aspects of its role.

Midmarket companies face the same challenges as their enterprise counterparts, but in the past have been at a disadvantage due to fewer resources. Now, if your emerging growth life sciences company needs a flexible solution to manage contracts, pricing, and compliance concerns, look to the cloud. Cloud-based solutions provide faster time to value, allowing users to add capabilities as needed, and, most importantly for midmarket companies, scale with a business as it grows.

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Overcoming Common Missteps In Clinical Trials

Maureen Lyden

Maureen Lyden, M.S., is president/CEO of BioStat International in Tampa, FL, with a background in biostatistical analysis in pharmaceutical, biotechnical, and medical device clinical research.

Throughout my years of work in biostatistics, there are certain problems I see recurring repeatedly in clinical trials. The most common problems are incorrect study designs and a lack of sufficient exploration into study conduct processes that could affect analyses and interpretation.

I have seen examples of companies that have reached the end of a study but have an unacceptable proportion of patients with missing data. They find that there are problems in analysis. Conclusions drawn from the data may be less precise and likely biased. Even if not biased, they may not have enough evaluable patients to meet statistical objectives and project goals.

The handling of missing data must be discussed in the statistical analysis plan of a study. To provide for accurate trial results, the missing data discussion should occur during the study planning stages, not after a study has veered out of control with gaps in key information. The statistician can plan the appropriate analyses for the most plausible missing data process that may occur.

When assumptions are being developed for sample size and analysis planning, information can also be inadequate or missing. While we cannot name any specific companies, we will use "Company XYZ" as an example.

Representatives of Company XYZ have data they believe is all they need to show that their product will be successful in a comparison pivotal study, but they do not have any comparator data. Against statistical advice to do a pilot study to obtain real data for study planning on sample size and endpoints, they use what they "believe" from this incomplete data instead of what they could have observed (evidence) in a pilot. Sample sizes are estimated based on this data. When the study starts, many issues arise, such as not being able to show statistical significance or clinical benefit.

No statistician likes to find out that data they have been asked to analyze cannot support research objectives. By nature, we like to investigate data to find answers to questions, not come back and say, "I just can't know from this data." Sometimes we find it is impossible to analyze objectives due to the information that was collected.

> Innovation is not always about reinventing the wheel, but instead, finding better solutions for the wheel.

Sometimes this happens due to how the data was collected — and in the worst-case scenario, not knowing why it was collected in the first place.

INNOVATION KEY TO BETTER CLINICAL TRIALS

The word innovation derives from the Latin word innovatus, which is the noun form of innovare, meaning "to renew or change." Our industry cannot fight innovation, so we must embrace technologies and tools that will improve our processes and renew our thinking when planning our clinical trials.

Innovation is not always about reinventing the wheel, but instead, finding better solutions for the wheel. An example of innovation improving the process of interpreting clinical trial data is the growing field of data standards for collection and regulatory submission. It is a human and technological effort. Technology creates tools that assist in the implementation of standards, yet it is the collaboration of experts and stakeholders such as clinicians, academics, regulators, and industry researchers that is essential for success. Furthermore, the specific skills and insights that statisticians have concerning the use of data for obtaining valid evidence of clinical benefit or safety should be considered when forming these collaborations. They can identify early pitfalls in substandard design and data collection, which could hinder the research project, and they can bring critical thinking and objectivity to any collaboration.

To quote an old adage, experience does not cost but it pays. Using an experienced team and avoiding missteps early on in your trial pays off in the end. The result: a clinical trial with the potential for success.


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Defining A Partnership Strategy For Personalized Medicine

Personalized medicine has the potential to revolutionize patient care and transform healthcare. But because this model is still in its infancy, companies will need to plan carefully and correct course quickly to address rapid market shifts.

For the near term, companion diagnostics, in its current "one test/one drug" form, will continue to propel advances in personalized medicine by providing validated biomarkers linked to approved therapies. Additionally, more holistic decision-support tests will emerge for multiple biomarkers (e.g. cancer panels), as well as more holistic decision-support solutions developed that consider a broader range of inputs that inform patient management such as lab test and imaging data, clinical trial activity, outcomes data, electronic medical records (EMRs), and reimbursement and coverage data.

While a comprehensive decision-support solution that considers all available data to support patient management is likely decades away, leaders in personalized medicine are beginning to pursue more holistic models and lay the groundwork for future participation.

NEW STAKEHOLDERS EMERGE IN PARTNERSHIP ACTIVITIES

The all-encompassing scope of personalized medicine is expected to drive new levels of partnership activity across the life sciences spectrum. To better understand the role of collaboration in this area, L.E.K. Consulting assessed publicly available personalized medicine partnership activity from 2009 to 2011 for approximately 150 leading organizations operating in the U.S., including academic medical research, biopharma, healthcare IT, imaging, *in vitro* diagnostics (IVD), personalized healthcare companies (PHCs), laboratories, tools vendors, and payers. The goal was to look at broader decision-support trends and track the emergence of more holistic solutions beyond just companion diagnostic tests. Specifically, the research included analysis of SEC filings, GenomeWeb, internal data, and other resources.

Across the sample, approximately 30% of the 189 publicly announced partnerships featured elements geared toward creating more holistic decision-support models. Partnerships that were categorized as holistic decision support were focused primarily on mining large patient data sets (e.g. from payers or providers), molecular profiling (e.g. deploying next-generation sequencing), creating the IT infrastructure needed to enable holistic decision-support models, and integrating various data sets to create richer solutions.

To illustrate this point, examples for each of the four decision-support-focused partnership categories follow:

- **Molecular Profiling**: Foundation Medicine and Novartis are deploying a cancer genomics analysis platform to support Novartis clinical research efforts.
- **Outcomes Data Mining**: Pfizer and Medco are leveraging patient genotype, phenotype, and outcome to assist in treatment decisions and target therapeutics.
- **Healthcare IT Infrastructure**: IBM and WellPoint are using IBM's Watson-based solution to support evidence-based healthcare decision making.
- **Data Integration**: Cernostics and Geisinger Health are integrating advanced tissue diagnostics, digital pathology, annotated biorepository, and EMR to create next-generation treatment decision-support solutions.

Notably, holistic decision-support partnerships often included stakeholders outside of biopharma and diagnostics and included organizations such as research tools companies, payers, healthcare IT providers, and PHCs (e.g. Knome, Foundation Medicine, 23andMe).

PARTNERSHIPS ARE THE BUILDING BLOCKS

The findings suggest that this emerging group of personalized medicine stakeholders will be increasingly important in influencing care decisions going forward. Holistic models will be powered by increasingly larger data sets, sophisticated decision-making algorithms, and intuitive reporting mechanisms. This will likely require the participation of an increasingly broad range of stakeholders to provide the science, technologies, infrastructure, and tools necessary for deployment.

Your partnership strategy may have a significant impact on the pace of your group's collaborative medical innovation, as well as your company's ability to capitalize on associated growth opportunities. Prudent companies will develop strategies that produce value by developing the building blocks of personalized medicine (e.g. companion diagnostics tied to therapies), but will also consider how these blocks might integrate into a more holistic decision-support capability in the future. Companies that don't define their role in the holistic decision-support ecosystem may find themselves at a significant disadvantage over the long term.

Alexander Vadas, Ph.D.

Dr. Vadas is a VP in L.E.K. Consulting's Biopharmaceuticals & Life Sciences practice where he focuses on diagnostics, research tools, and personalized medicine. L.E.K. Consulting VP Sue St. Sure and Manager Brian Baranick, Ph.D., also contributed to this article.

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7 Tips To Help You Speak Like A Leader

By Bob Garner

A short, pudgy man walked up to the microphone and, despite an obvious lisp, began to speak. By the end of his speech, he had won the minds, hearts, and eyes of his audience. This man, according to President John F. Kennedy, "mobilized the English language and sent it into battle." The man was Winston Churchill.

While the goal of your speech may be different from Churchill's, your battle to win the minds, hearts, and eyes of your audience is not. If you want your message to be heard, inspire people to action, or believe in your goal, you must win the battle for their minds through the words you choose. You must win their hearts through how you make them feel and win their eyes through how they perceive you as a communicator and leader. The best leaders are the most effective communicators and understand the importance of winning the aforementioned battle at the podium.

Here are a few tips to help you speak like a leader:

1. **Never "Wing" It**: By "winging" your speech, you risk boring your audience and being perceived as an ill-prepared, ineffective leader. There's not a single effective speaker who wings it.

2. **Write It Out**: Create an outline that focuses on a theme and three main points that support that theme. Write out your entire speech. Repeat your three main points throughout your presentation. The audience won't remember a point only said once.

3. **Cut**: Speak no more than 20 minutes. The longer you speak, the less impact your message and presence have on your audience.

4. **Stories And Quotes**: Stories are powerful speaking tools. A good story grabs and holds the imagination of the listener. Use a story at the beginning of your speech, and refer to it at the end. This helps cement your overall message. Use a few stories throughout your speech to accentuate points. Use quotes only from people your audience will recognize. Most importantly, all stories and quotes *must* tie back to a point.

5. **Rehearse**: Effective speakers thoroughly rehearse their speeches. Rehearse in front of a mirror, or film yourself and review for problems.

6. **On-Site**: Light the stage like it will be lit when you deliver your speech, and rehearse your speech on-site. Called "owning the room," this allows you to get familiar with your surroundings. Don't "walk through" your speech; do your whole speech. Know your entrance and exit points and what music, if any, will be played for your walk-on and walk-off.

7. **Connect**: Never read your speech. Connect with your audience by looking at them while you speak. If you rehearsed, you should be able to walk away from the podium, which aids in engaging the audience. If using a teleprompter, keep your written speech or notes on the podium.

A professional speaker with clients worldwide, Bob Garner knows how to engage, empower, and entertain an audience. His written works include a collaboration with Stephen Covey and Ken Blanchard. www.bobgarneronline.com

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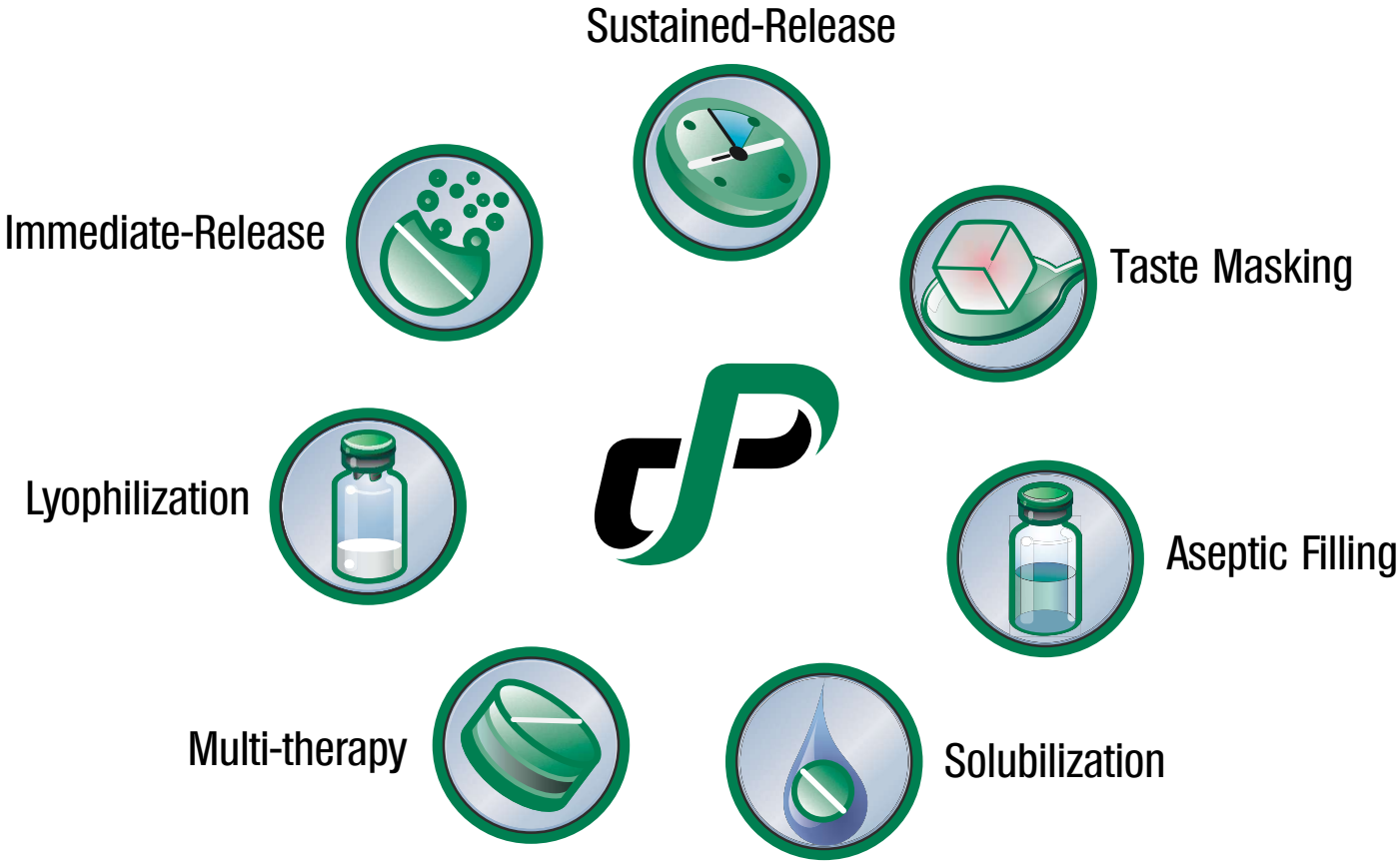

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