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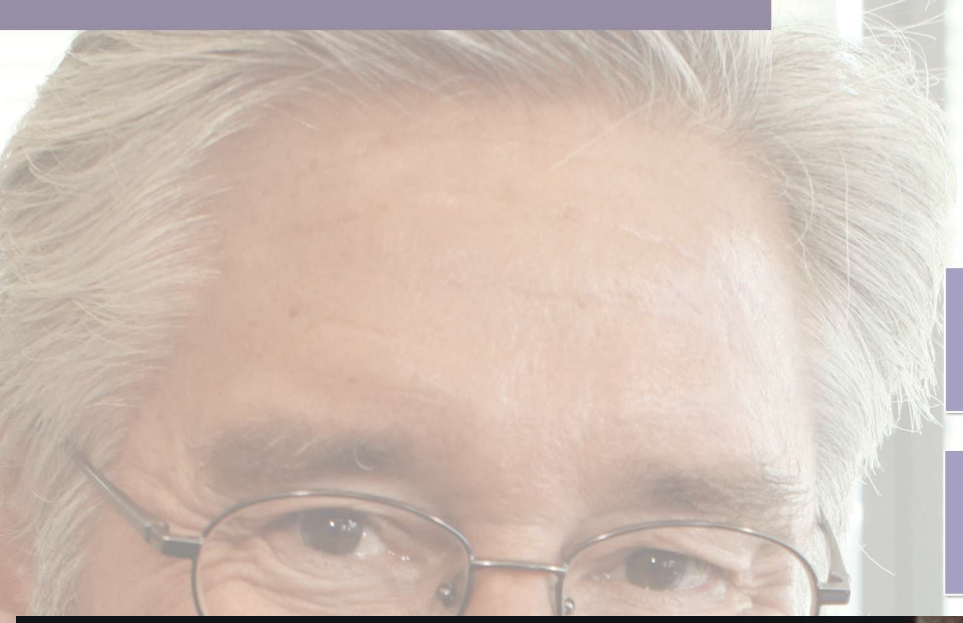

Merck BioVentures

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"The biosimilar market was attractive to us both financially and from a business perspective."

Michael Kamarck, Ph.D,
president,
Merck BioVentures

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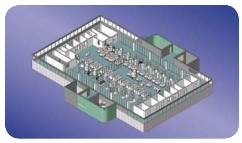

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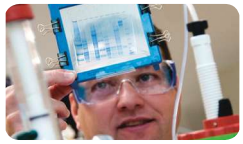

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14 FEATURE: MERCK BIOVENTURES

"At least for now, we don't anticipate that biosimilars represent a serious threat to branded innovator biotechnology products," says Michael Kamarck, Ph.D., president, Merck BioVentures.

November 2011

Welcome to *Life Science Leader*

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Life Science Leader

DEPARTMENTS

Correction: In the October issue on page 8 under Jeff Evans' answer, it should have said "Wisconsin ... is now emerging as a biotech player via a $400 million state-administered venture fund."

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Talking Turkey And Giving Thanks

I realize *Life Science Leader* magazine is global, but here in the states, the month of November is significant, as it represents a time for giving thanks. Thanksgiving is always held on the fourth Thursday of the month and is one of my favorite holidays. To me, it represents everything that is good. Friends and family get together, break bread, watch American football, and reflect upon that for which they are thankful.

Last year at this time, I was just beginning my new career as chief editor for *Life Science Leader* magazine after having been laid off from a 17-year pharmaceutical industry career. I am thankful for the opportunity this past year to have been able to work with so many talented people within our organization, as well as making some lifelong relationships while traveling on the road. This year I have had the chance to "talk turkey" with CEOs, bestselling authors, top industry consultants, sales representatives, scientists, engineers, and more. I learned something from every interaction, and I would like to express my thanks to all of you. I am especially thankful for the support and understanding I received from my family while I have been on the road.

Speaking of on the road, I just got back from two shows — the Emerson Exchange in Nashville and AAPS in Washington, D.C. Both occurred the same week, so I ended up trying to catch a bit of each. If you are not familiar with the Emerson Exchange, it is really an interesting concept. Years ago, Emerson (NYSE: EMR), a diversified global manufacturing and technology company with approximately 127,000 employees, began inviting its customers to the company to ask for some very transparent feedback on how they could improve — essentially, an idea exchange. From these humble beginnings, the event now offers more than 351 workshops and is attended by thousands of people desiring to exchange ideas and create solutions.

The 2011 AAPS Annual Meeting and Exposition took place at the Walter E. Washington Convention Center. The keynote speaker, Janet Woodcock, director of the Center for Drug Evaluation (CDER) at the FDA, just so happened to be on the cover of our October 2011 issue. Other speakers of note included John Lechleiter, Ph.D., CEO for Lilly; Francis Collins, M.D., Ph.D., director of the NIH; and Sir Michael Rawlins, M.D., chairman of the National Institute of Health & Clinical Experience (NICE). Perhaps someone from AAPS will soon be featured on the cover of *Life Science Leader.* Stay tuned.

Thankfully yours,

Rob Wright
rob.wright@lifescienceconnect.com
@RFWrightLSL

Exactly what's in these boxes?

Find out in just a few seconds.

China is soon expected to become the world's third-largest prescription drug market, with a domestic product mix that includes synthetic chemicals and drugs, biopharmaceuticals, herbal remedies and Traditional Chinese Medicines.

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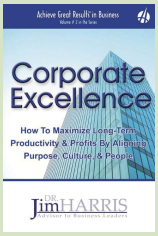

Ask the Board wants to hear from you. Have a question that you would like to pose to our editorial advisory board of experts? Send it to atb@lifescienceconnect.com.

If we select your question for publication, we will provide you with a complimentary copy of a business book, such as Jim Harris' *Corporate Excellence*. Dr. Harris is an internationally acclaimed leadership expert and author who teaches leaders how to take themselves, their businesses, and their people to a higher level of success and significance.

ASK THE BOARD

Have a response to our experts' answers? Send us an email to atb@lifescienceconnect.com.

Q: For a start-up, what are some initial approaches to raise money?

If the company is spun out of an academic laboratory, the university may provide a small amount of money to get started. If the founder is independent of a research institution, then oftentimes the founder's own resources are used (this may include money raised from friends and family, such as through a convertible debt offering). Many states offer "greenhouse" grants or loans to small businesses through programs financed through the federal government, such as the Small Business Administration (SBA). The federal Small Business Innovation Research (SBIR) grant program is another way to obtain funding. Private foundations can be a source of funding if the topic agrees with the foundation's goals. Once the project is ready to move towards the clinic or commercialization, angel investors and venture capitalists can provide larger amounts of funding in return for an equity stake in the company.

Laura Hales, Ph.D.
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.

Q: What is the biggest factor for a sponsor when selecting a CRO?

The team the CRO provides is the biggest factor. As a sponsor, you are going to work with these individuals. Do you want to? Is the CRO providing a team that will execute? The successful conduct of a clinical trial is a complex orchestration of people, skills, knowledge, good clinical practice, and risk mitigation over time. Teamwork is the most underrated factor in success, and by outsourcing, your challenge is to form a well-functioning team across two companies, two cultures, and teammates with multiple agendas. That desired team is one that is execution-driven and will put the team goals ahead of their own. Will you be able to create a team that proactively mitigates risk because, despite your careful planning, the clinical trial will not go as planned? Will your team still execute in the face of obstacles? If not, therapeutic expertise, geographic reach, costs, and any other factors you might consider will not be relevant.

Tim Krupa
Tim Krupa is president of TSK Clinical Development, LLC, a consulting firm providing leadership and solutions in clinical planning, project management, clinical operations, and outsourcing. He began his career with Eli Lilly and most recently served as executive director, project management with Quintiles.

Q: How can you ensure the safety and integrity of products during cold chain transportation?

You must first understand your product and the environment through which that product must pass. The more comprehensive your understanding of the metrics of a distribution or transportation system, the more precise your communication to your service providers can be. Communications, particularly for products requiring special handling, should always be in the form of a quality agreement or service contract between and among supply chain stakeholders and followed through with regular, healthy, and open dialog.

For the unaware, quality agreements are negotiated, documented processes between the customer and service provider that define common understandings about materials or services, quality specifications, responsibilities, guarantees, and communication mechanisms. Their scope often outlines minimum requirements, performance monitoring and reporting, problem management, escalation procedures, compensation information, and remedial action.

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.

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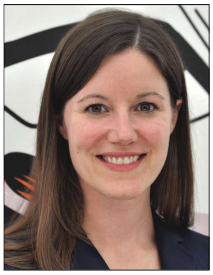


OUTSOURCING INSIGHTS

Is A CMO With A Global Supply Chain Always The Best Option?

By Kate Hammeke, research manager, Nice Insight

Between the 1970s and 1980s, the American automobile industry learned a lesson from the Japanese in the form of a leaner manufacturing model. Rather than follow Henry Ford's concept of a vertically integrated production facility where raw materials from company-owned mines and plantations were transformed into cars, their idea was to focus on the core competency of building cars and buy the steel from someone else. The structure of the Japanese plant ultimately contributed to Japan's ability to produce cheaper, better cars.

In the past decade, the pharmaceutical industry has looked to supply chain inefficiencies in order to improve operations and streamline costs. Much like the American car manufacturers realized they could reduce expenses and increase production by not doing everything from scratch, pharmaceutical companies have learned that partnering with third parties — contract research and contract manufacturing organizations — for certain services increases efficiency and flexibility. Outsourcing specific steps in the manufacturing process has become so commonplace that approximately 80% of drug substances are now manufactured outside the United States.

THE IMPORTANCE OF LOGISTICS & DISTRIBUTION SERVICES

Globalization of the pharmaceutical supply chain has brought benefits to the industry, such as reduced operating costs and the ability to better allocate resources to core competencies; yet it also carries significant risks. A current challenge faced in protecting the integrity of the global pharmaceutical supply chain is counterfeiting. The World Health Organization has identified the international trade of pharmaceutical ingredients through free trade zones where regulatory oversight is lax or absent as a factor contributing to an increase in counterfeit drugs. With this consideration, Nice Insight looked at its data to see if there were differences in customer perception scores for quality, reliability, affordability, and regulatory compliance among global CMOs who offer logistics and distribution services and global CMOs who do not provide this service.

Survey results indicate that global CMOs providing logistics and distribution services have a small advantage (+2%) over CMOs that do not offer support in this area with respect to affordability and regulatory. However, global CMOs without this service offering scored 2% higher on reliability and eked out 1% ahead with respect to quality. Knowing that some of the challenges in streamlining the supply chain come from global businesses trying to meet varying regulatory standards and shipping materials through localities without sufficient oversight to completely prevent tampering, Nice Insight investigated to see how the top 10 CMOs that solely operate in the United States fared against the top 10 global CMOs that provide logistics and distribution.

Across the two groups offering logistics and distribution services, both had near equal ratings for quality, affordability, and regulatory scores. On the other hand, the U.S.-based CMOs scored 2% higher on reliability than their global counterparts. Interestingly, reliability was the lowest scoring measure across each subset of CMOs analyzed, yet survey respondents rank it as the second most important driver in outsourcing. When it comes to the global supply chain, outside factors that cannot be controlled by a CMO itself — such as transit and border delays, regulatory oversights, and political pressures — impact supply chain logistics and often influence reliability perceptions. These marginal differences are not strong enough to indicate that using a U.S.-based CMO is a better all-around option, but it will likely reduce some concerns associated with partners in emerging markets.

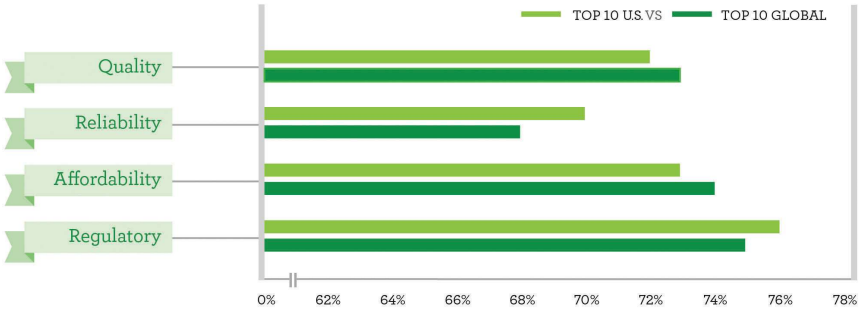
Ultimately, there was not a clear indication whether or not outsourcing companies should opt for a global CMO with logistics and distribution support when using an overseas provider, as the averaged customer perception scores were very close. However, when looking to reduce expenses by restructuring the supply chain, it makes sense to start the search with global CMOs that do offer logistics and distribution services because these businesses are the most likely to innovate technologies (or use innovative technologies) to protect the supply chain's integrity.

NI: CUSTOMER PERCEPTION MEASURES

Q3 N=3,021

based on Q3 survey results	QUALITY	RELIABILITY	AFFORDABILITY	REGULATORY
Global CMOs without Logistics & Distribution Services	73%	69%	73%	74%
Global CMOs with Logistics & Distribution Services	72%	67%	75%	76%

based on Q3 survey results	QUALITY	RELIABILITY	AFFORDABILITY	REGULATORY
Top 10 U.S. Logistics & Distribution CMOs	72%	70%	73%	76%
Top 10 Global Logistics & Distribution CMOs	73%	68%	74%	75%



Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to 40,000 outsourcing-facing pharmaceutical and biotechnology executives on a quarterly basis/four times per year [Q3 2011 sample size 3021]. The survey is composed of 1,200+ questions and randomly presents ~30 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perceptions on 406 companies that service the drug development cycle. Over 1,600 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, Accessibility, Regulatory Compliance, Pricing, Productivity, and Reliability, which are ranked by our respondents to determine the weighting applied to the overall score.

If you want to learn more about the report or how to participate, please contact Victor Coker, director of business intelligence, at Nice Insight by sending an email to niceinsight.survey@thatsnice.com.

BIO DATA POINTS

Demand For New Downstream Technologies Is Driving Vendors' R&D

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

Vendors are investing heavily in new technologies and products for downstream purification. In our 8th Annual Report and Survey of Biopharmaceutical Manufacturing, we asked 180 suppliers to the biopharmaceutical industry to identify the top new technology areas currently in development at their company. The results, not surprisingly, correlated well with the survey's 352 biopharmaceutical drug manufacturers' demands for better technologies.

New disposable single-use devices, including those for downstream applications, are what the largest percentage of vendors in this industry are working on. The same percentage of vendor respondents noted bioprocess development services (indicated by 40.5% of vendors). Disposable chromatography is the third hottest R&D area, with 34.2% of vendors.

Increasing use of disposable products and the demand for new downstream purification technologies are driving investment and directing vendors' R&D in these areas. Today, both developers and CMOs are expecting that physical capacity of downstream purification equipment will continue to constrain facility capacity in the near term. So, we are seeing research and improvements in purification technologies that will likely move this industry bottleneck forward.

BIOMANUFACTURERS' DEMANDS

Among biomanufacturers, our results show that the downstream technologies in demand in 2010 continue to be sought after this year, but by an even larger percentage of respondents. This suggests that the problems from previous years have not been adequately resolved: cost of chromatography materials, cost of membranes, and the time for operations. This year there was also strong interest among biomanufacturers for high-capacity resins and in-line buffer dilution systems. The most rapid growth has been in single-use prepacked columns, which jumped from single digits last year to 32% this year. We asked our respondents about new downstream processing technologies that they are actively considering to address bottlenecks and problems. Areas of opportunity for addressing these issues include:

- High-capacity resins
- In-line buffer dilution systems
- Single-use filters
- Single-use disposable TFF (tangential flow filtration) membranes
- Buffer dilution systems/skid
- Membrane technology
- Moving bed technologies
- mAb (monoclonal antibodies) fragments

PROBLEM AREAS IN DOWNSTREAM OPERATIONS

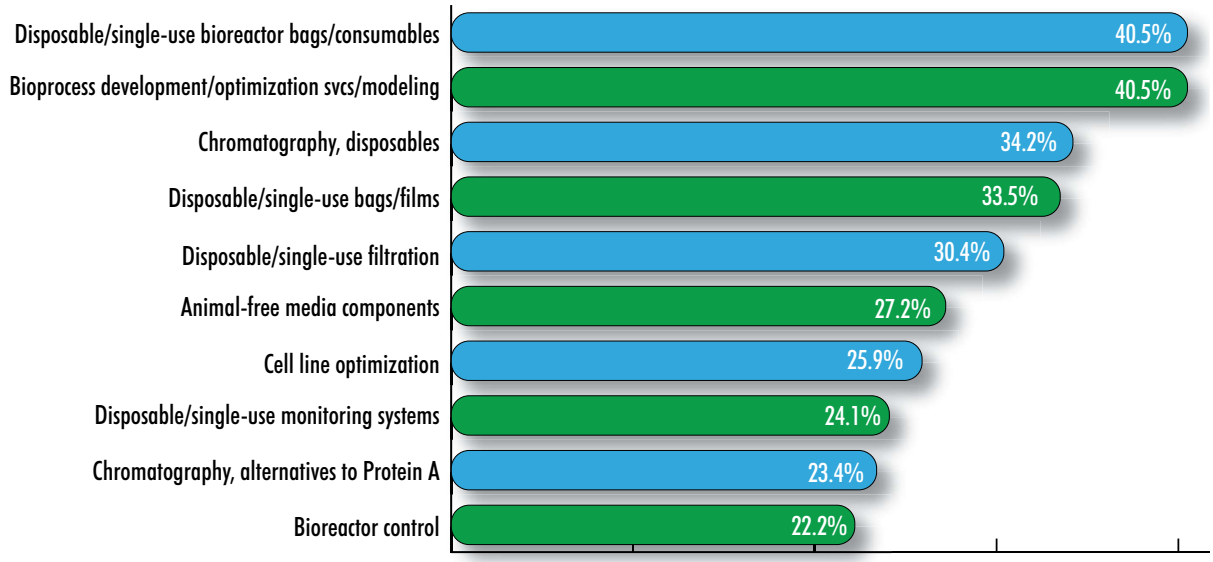
Column chromatography remains the major concern in downstream operations. Of all the unit operations performed during downstream processing of bulk drug substance, chromatography is the most challenging and has the gravest consequences when things go wrong. Areas where biomanufacturers see room for improvement include: faster-flow resins, greater binding capacity resins, better membrane separation technologies, and better UF (ultrafiltration)-membranes.

According to Scott Wheelwright, Ph.D., president at Strategic Manufacturing Worldwide, Inc., "The relative ranking of each of the [downstream] issues rarely varies by more than one position; that is, the issues induce more or less the same relative level of anxiety year after year." So far, although incremental improvements have emerged, we have yet to see groundbreaking alternatives to current filtration and chromatography methods. Even when new technologies are introduced, the rigid regulatory nature of biomanufacturing will likely result in gradual adoption of any new approaches.

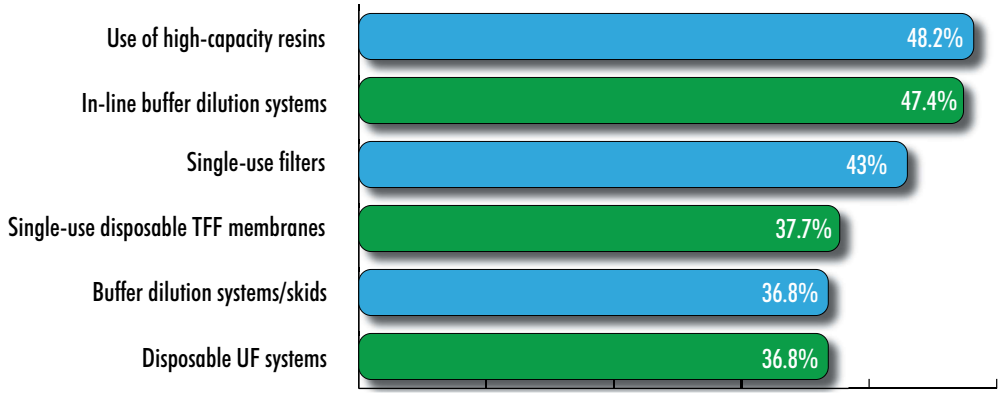
Survey Methodology: This eighth in the series of annual evaluations by BioPlan Associates, Inc. yields a composite view and trend analysis from 352 individuals at biopharmaceutical manufacturers and CMOs from 31 countries. The methodology also encompassed an additional 186 direct suppliers (vendors) of materials, services, and equipment to this industry. This year's survey covers such issues as: current capacity, future capacity constraints, expansions, use of disposables, trends and budgets in disposables, trends in downstream purification, quality management and control, hiring, employment, and training. The quantitative trend analysis provides details and comparisons by both biotherapeutic developers and CMOs. It also evaluates trends over time and assesses differences in the world's major markets.

Selected Areas Of Vendor Investment In R&D For New Technologies

(As indicated in BioPlan Associates' 2011 Eighth Annual Report and Survey of Biopharmaceutical Manufacturing, April 2011)



Downstream Purification (DSP) Technologies Being Considered in 2011



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

"At least for now, we don't anticipate that biosimilars represent a serious threat to branded innovator biotechnology products," says says Michael Kamarck, Ph.D., president, Merck BioVentures.

Biosimilars:

What To Expect From Merck BioVentures

By Cliff Mintz, Ph.D., contributing editor

In 2009, sales of branded biopharmaceutical products exceeded $125 billion and accounted for 17% of the worldwide pharmaceutical and biotechnology markets. There is little doubt among industry analysts that the biopharmaceutical market will continue to experience explosive growth over the next few years and that a larger percentage of drug pipelines will be composed of biologics and biotechnology products.

However, during the next 5 to 10 years, patents for blockbuster biopharmaceuticals such as Epogen (Amgen), Enbrel (Amgen), Avastin (Roche/Genentech), and others will expire. This has created a business opportunity for companies that develop noninnovator versions of biopharmaceuticals called biosimilars. At present, only the EU, Canada, Australia, and Japan have legal regulatory approval pathways in place for biosimilars. Since 2005, 13 new biosimilar products have been approved and are being sold in the EU. Despite their lower cost, the uptake of these molecules has been poor, and in 2009, sales of biosimilars was only around $89 million.

At present, there is no regulatory approval pathway for biosimilars in the United States. Although legislation has been introduced in the U.S. Congress, it is not clear when or if it will be adopted. Given the regulatory uncertainty of biosimilars in the United States, it was a surprise when in 2008 New Jersey-based Merck & Co formed a new division called Merck BioVentures (MBV) to compete in the biosimilar marketplace.

The person charged with running and divining a business strategy for MBV is its president, Michael Kamarck, Ph.D. He has cross-divisional responsibility for commercialization, manufacturing, and nonclinical late-stage development of Merck's biosimilars pipeline and manufacturing responsibility for all of Merck's vaccines and biologics. Prior to joining Merck, Kamarck served as president, technical operations and product supply for Wyeth Pharmaceuticals, where he was responsible for an organization of more than 16,000 employees in 25 countries. He received his undergraduate degree from Oberlin College and his Ph.D. in biochemistry from the Massachusetts Institute of Technology. Kamarck is the author of more than 20 issued patents and 50 peer-reviewed publications.

> "From the regulatory, clinical, and business perspectives, I think the EU and the United States are the best-prepared markets to drive the uptake of biosimilar products."
>
> Michael Kamarck, Ph.D., president, Merck BioVentures

While the commercial success of biosimilars is still uncertain, Kamarck believes that MBV can develop and deliver safe, effective, and lower-cost biologics to patients who need them. In this interview, he shared his insights into developing and commercializing biosimilar products and focused on some of the hurdles that must be overcome to garner regulatory approval of these products in the United States and elsewhere.

WHY DID MERCK DECIDE TO GET INTO THE BIOSIMILAR BUSINESS?

KAMARCK: We viewed the biosimilar market as a unique new opportunity in healthcare that is markedly different from traditional branded and generic products. The biosimilar market was attractive to us both financially and from a business perspective. And, it is our goal to develop a global portfolio of these new molecules. But, most importantly, we entered the biosimilar market because we believe it will improve patient accessibility to potentially lifesaving lower-cost drugs.

In the early days, we were moving back and forth between developing biosimilars and so-called biobetter or biosuperior products. In fact, we created a second-generation version of Epogen but decided against its commercialization because of the clinical and regulatory issues that subsequently arose about the safe use of recombinant erythropoetin EPO and related products. Ironically, the legislative uncertainty of the 2009 Biologic Price Competition and Innovation Act — legislation that defines a regulatory approval pathway for biosimilars in the United States — actually helped us to more clearly assess business opportunities in the biosimilar space. This is because the debate over the legislation provided us with insights into the likely clinical, technical, and regulatory requirements for approval of these products. After some discussion, we decided to exclusively focus on biosimilars rather than biobetter molecules.

Although MBV focuses only on biosimilars, there are other divisions within Merck that are charged with developing new biotechnology products as well as biobetters. In other words, Merck has not jettisoned its efforts in the biobetter space; biobetters are no longer part of the MBV mission.

WHAT PRODUCTS ARE BEING DEVELOPED BY MBV, AND WHEN WILL THEY REACH THE MARKET?

KAMARCK: Early on, so-called replacement products like EPO were the clear winners and darlings of the biopharmaceutical industry. However, it is becoming increasingly evident that mono-

there hasn't been a fleet vehicle like this since, well, today.

The Prius Plug-in is the most advanced member of the Prius Family, combining an extended all-electric mode[1,2] with proven hybrid technology. You also get the convenience of plug-in charging with rapid recharge times: 3 hours with a standard 120V household outlet or 1.5 hours with a 240V outlet. The ability to choose between electric and hybrid gives people the freedom to drive more, see more and do more. It's a new kind of Prius. And it's just the right vehicle for your fleet. Call 1-800-732-2798 or visit fleet.toyota.com

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clonal antibodies (mAbs) and related antibody fusion proteins are going to be a bigger and more tactical part of MBV's business going forward.

As far as specific products are concerned, we have publicly announced that MBV is currently developing three biosimilar products: GCSF (granulocyte colony-stimulating factor), PEG-GCSF (pegylated-GCSF), and a biosimilar version of Enbrel. Generally speaking, I think that the greatest commercial opportunities for molecules in the biosimilar space are ones that modulate immunity or treat various cancer indications.

While there is still no certainty about the launch of our products, we expect them to be on the market by mid-decade — right around the time patents expire, and we have "freedom to operate." I think there will be an explosion of biosimilar products on the market by mid-decade, and that the trend will likely continue at a brisk pace into the 2020s.

WHICH REGIONS OF THE WORLD REPRESENT THE GREATEST BUSINESS OPPORTUNITIES FOR BIOSIMILAR PRODUCTS?

KAMARCK: The lack of regulatory guidelines in the United States is somewhat problematic. And, while there are well-established and clearly defined guidelines for approval of replacement biosimilar products in the EU, EMA (European Medicines Agency) has not yet issued guidance on the development of biosimilar mAbs and related products. Interestingly, in recent months, both the FDA and EMA have signaled their intentions on what the guidelines will likely be for biosimilar mAbs. Further, the FDA and EMA are working closely with one another to develop clinical safety guidelines and technical guidelines for biosimilar mAb molecules and other new biosimilar products.

MBV has been meeting regularly with the FDA and EMA about our products, and after 10 or more meetings with both agencies we are starting to get specific guidance from them in response to specific questions for specific products. Because of this, I firmly believe they are signaling to us — and more than likely our competitors — where they feel the final regulatory guidelines are going to end up. Obviously, we are not waiting for the guidelines to be issued to move forward with our products. But, we think we have a good idea of where the regulations will land because of those meetings. This has been extremely useful from a new product development perspective.

From the regulatory, clinical, and business perspectives, I think the EU and the United States are the best-prepared markets to drive the uptake of biosimilar products. Geographically speaking, rollout of our products will likely first occur in the EU and United States, followed by introduction into emerging markets. Interestingly, emerging markets like India and China are becoming increasingly more regulated. And, I think the regulatory requirements for biosimilars in emerging markets may ultimately not be that much different from those already adopted in regulated markets.

One of the tougher issues that needs to be addressed is the cost model or pricing of these new products. At present, we don't know how these products will be priced. But, biosimilar sales in Europe provide us with some idea of how the products must be priced to be competitive.

WHAT ARE YOUR THOUGHTS ON SUBSTITUTION AND INTERCHANGEABILITY OF BRANDED PRODUCTS WITH BIOSIMILARS?

KAMARCK: From a regulatory point of view, substitution and interchangeability have been dealt with differently in Europe and the United States. In Europe, extant biosimilar guidelines do not mention substitutability nor do the regulations provide a technical path forward for it. Consequently, substitution or interchangeability of biosimilars for branded products is not possible or permitted in Europe.

In contrast, the possibility of interchangeability has been raised in the proposed U.S. regulatory guidelines for biosimilar products. Not surprisingly, the criteria to prove interchangeability are much higher than those required to show biosimilarity. Consequently, it may not be worth it for biosimilar developers to even attempt to prove interchangeability between their products and innovator molecules. For example, proving interchangeability would invariably require overly large clinical trials that are expensive and probably not practical in today's economic climate. Nevertheless, the debate surrounding substitutability and interchangeability is likely to continue in both the United States and Europe.

In our view, we do not think that interchangeability or substitution is necessary for biosimilars to be successful. We believe MBV will be successful by developing and winning regulatory approval

> "I think there will be an explosion of biosimilar products on the market by mid-decade, and that the trend will likely continue at a brisk pace into the 2020s."
>
> Michael Kamarck, Ph.D., president, Merck BioVentures

of high-quality, branded biosimilars that are proved to be as safe and effective as original innovator products.

The slow uptake of biosimilars in Europe is likely the result of a failure of the companies that introduced them to recognize that physician and patient education about the products would be necessary to ensure their use and ultimate financial success. Because biosimilars are so different from traditional generic medicines, European physicians didn't understand them or their potential benefits and eschewed their use in favor of innovator products. The experience in Europe has helped us to better shape our biosimilar strategy, and hopefully, we will be able to avoid the same mistakes and pitfalls.

DO YOU THINK THAT BIOSIMILARS REPRESENT A THREAT TO THEIR BRANDED INNOVATOR COUNTERPARTS OR CAN THEY COEXIST?

KAMARCK: At least for now, we don't anticipate that biosimilars represent a serious threat to branded innovator biotechnology products. This is because, at least for the foreseeable future, biosimilars will likely not be deemed to be interchangeable or substitutable for innovator molecules. Unless that changes, I think that biosimilars and innovator products can coexist in both established and emerging markets.

WHAT WILL THE BIOSIMILARS MARKET LOOK LIKE IN 10 YEARS?

KAMARCK: The biosimilars marketplace is currently in its infancy, and many potential players are eyeing the opportunity. As the market matures, we will likely see some of the early participants drop out.

In my view, those that do succeed will deliver greater value to customers in addition to offering price reductions relative to the originator. For patients and caregivers, these value-added services include improved delivery devices, training and education, and patient support services. For physicians, this includes clinical data to support evidence-based decision making regarding biologic options for their patients, improved delivery options, physician education tools, patient support, and when appropriate, reimbursement and third-party payer support.

So You Want To Be A Life Sciences Industry Consultant?

BY ROB WRIGHT

With the vast number of layoffs which have been the recent plague of the pharmaceutical industry, many management-level folks find that their industry knowledge and insider access positions them well for consulting. And why not? When CNNMoney asked what the best jobs in America are, management consulting ranks in the top three — behind software architect and physician assistant. The money is not bad either. Salaries for consulting vary, depending upon experience and industry. A typical range is from 50K to more than 200K, ranking it as one of the top 20 highest-paying jobs. And thus, the allure of consulting — good money, great job satisfaction, and the barrier to entry is limited only by your past experience. But do you really have what it takes? — because consulting has its downside as well. For example, one of the U.S.-based consultants with whom I spoke was calling me from overseas. The grueling travel, late hours, and punishing deadlines can put a tremendous strain on those with family commitments. Another downside seems to be that just about anybody can claim the title of consultant, thereby diminishing the credibility of the profession.

I reached out to a variety of consultants with varied levels of experience (i.e. from as little as 18 months to more than 20 years). My goal in interviewing these people — to provide our readers with insight into the

"You have to be willing to say things you know could conceivably lead to their terminating your contract."

Leslie Kossoff

profession, pitfalls to avoid, necessary skills and attributes, as well as resources on getting started should becoming a consultant be something you are pondering. Some of their clients include 3M, Baxter, Bristol-Myers Squibb, Deloitte, Fidelity Investments, GM, Hitachi, Kraft, Medtronics, Pfizer, Sony, and UCLA. None of the consultants interviewed work for the large consulting groups such as PricewaterhouseCoopers, though interestingly enough, they have served as consultants to these consultants. Heeding their words of wisdom may prevent you from having to learn the field of consulting via the school of hard knocks.

HOW THEY GOT THEIR START

Leslie Kossoff has been a speaker, writer, entrepreneur, and confidential advisor to executives for 23 years. "I became a consultant because of my frustrations with my previous job," she says. As a director with a major aerospace and defense contractor, Kossoff was responsible for a quality and change initiative inside a division of 20,000 people. Executives were interested in understanding how people from inside the organization were doing things, generating ideas, and implementing innovations. A system was created to capture this information, and a presentation of recommendations was conducted with senior executives. "The last straw for me," says Kossoff, "was when the executive team with which I was working brought in a group of consultants that made the exact same recommendations which we had made internally." The executive team paid the consultants several hundred thousand dollars for the same recommendations which had been generated internally. This was an eye-opening experience for Kossoff because she felt, that in order for her to get executive management to listen to the ideas being generated within a company, you have to be from the outside. "If I want to be able to achieve what I want for an organization, I have to be a consultant. I have to be outside the company. The system demands it," she states.

Unlike Kossoff, Jacquie Mardell, director Anhvita Biopharma Consulting; Peter Calcott, president and CEO at Calcott Consulting; and John Farris, president and CEO of SafeBridge, all got into consulting because the corporations they worked for underwent restructuring. Both Calcott and Mardell have the same regrets — wishing they had grabbed the opportunity to become consultants sooner. For Farris, the story of how he and his colleagues started SafeBridge (a life sciences industry safety, health, and environmental services firm) is a little different.

In 1995, Farris worked for Syntex Corp., a Palo Alto, CA, pharmaceutical company which was being acquired by Roche for $5.3 billion. A new management representative from Roche visited the Syntex facility in April 1995 to announce that all Syntex management would be gone by the end of the year. Just one problem — Farris and his team of environmental and toxic experts were in the process of being mobilized to attack a court-ordered cleanup project of 26 sites, including Times Beach, MO, — a small town

What To Do During An Economic Downturn

During an economic downturn, consultants are often the first things to be cut. Kossoff hates the financial impact of economic downturns but also sees a positive side to the situation. "In a downturn, everything is up for grabs," she says. It gives you time to reflect, analyze, assess, plan, and prepare. Use the time to start putting the pieces into place for when the cycle reverses.

Farris says that if you have developed your war chest as advised, then you can focus your efforts on increased marketing efforts. Take the time to update your website, write papers for journals, author a book, seek out speaking opportunities at professional forums, and contact prospective clients with ideas on how you can help. Calcott also advises adjusting your strategy. For example, before he moved into industry he had taught in university. He approached a school about some of their current offerings. Through the conversation he uncovered the administration's desire to develop a new offering. He ended up consulting with the school to develop the curricula for a new postgraduate certificate program in the areas of quality and compliance, regulatory affairs, process development, and manufacturing as these pertain to the pharmaceutical and biotech industries. He was invited to teach one of the courses, which kept him front and center in the industry and garnered him other consulting opportunities. "If you are really serious about being a consultant, be on the lookout for other opportunities, including academia," Calcott espouses. In other words, don't throw in the towel on your consulting career during an economic downturn.

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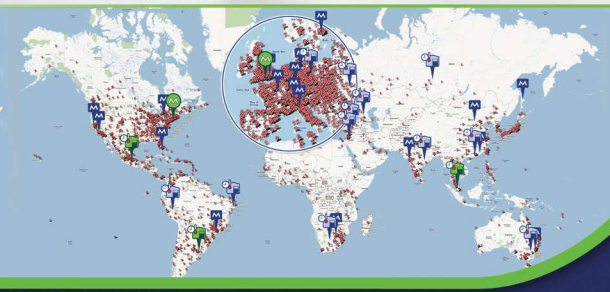

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southwest of St. Louis, which, by order of the federal government, had been evacuated of all of its 2,240 residents in what was the largest civilian exposure to dioxin in the United States. Dioxin is deadly to animals and causes chloracne — an eruption of pimples, cysts, and pustules — and is suspected of causing cancer in humans. After being told he was going to be let go, Farris asked Roche management who was going to be doing the cleanup. Roche quickly realized it needed Farris and his team, but now he and his crew no longer trusted Roche. Farris negotiated an agreement that would keep him and his team in place through the completion of the Times Beach project, and when that was completed, they would launch SafeBridge, with Roche being its first client. When SafeBridge opened its doors the following year, it had a $500,000 contract from Roche. Farris hadn't intended on becoming a consultant. He confided that when he was working for Sytnex, he had aspirations of retiring at 55, an age he passed over eight years ago. That being said, he enjoys having had the opportunity to build a company which is recognized as an industry leader in its field, from the ground up. He still puts in 60-hour work weeks and has three offices around the world. He advises, "Unless you are passionate about it, don't do it. Be responsive, and go the extra mile to help clients and prospective clients. Surprise them with your commitment regarding turnaround time and not charging for every little thing," he states. Most importantly, Farris advises consultants to focus on building long-term relationships with clients. Mardell, Calcott, and Farris all entered the consulting world unexpectedly. Nonetheless, they did have some sort of business plan. Their advice — if you are seriously thinking about becoming a consultant, don't make the mistake of entering into the business without a formalized business plan with cash flow projections, a SWOT analysis, and so on.

PITFALLS TO AVOID

If you were in a large corporation, you may be tempted to set up your business with a loose structure in an attempt to avoid bureaucracy. Moving completely away from a corporate structure of having written goals, objectives, and firm budgets is not wise and can be a struggle to implement later. "Thinking that because you are self-employed means freedom from bureaucracy results in *seat-of-the-pants* management," say Farris. He advises getting advice and support from outside professionals such as accountants, insurance agents, and lawyers and starting with a structure for your business. Further, if you are trying to set up a consulting firm with several team members, avoid making the mistake of attempting to do so without administrative support. This is one mistake Farris was thankful to have avoided. "I told the group I was not willing to start the business without an experienced office manager to mind the business while the technical professionals found and completed the work," he states.

For Mardell, her mistake was undervaluing her services when she was first getting started. "I sort of doubted my ability and lacked the confidence I needed, so I settled for a lower rate of pay than I should have," she says. She learned from this, and says she will never do it again. According to Kossoff, a 23-year consulting veteran, this is a very common pitfall for new consultants. "Never adjust your fees," she advises. "Adjust your services. If the client says they aren't willing to pay your fee, find out what they are willing to pay and adjust your services accordingly," she recommends. Consultants typically have a daily rate. Kossoff believes structuring fees based on the type and length of engagement is better for you and the client. "You need to be honest with yourself as to how much time you think a project is going to take," says Kossoff. Once you have done this you can develop your fees based on your hourly or daily rate for a big or small project. Then you can present the client with a price. Avoid presenting clients with a daily or hourly rate for a project because this seems too open-ended, and according to Kossoff, "They get scared about what you're going to be doing to their budget, because they know how much they want

5 Things A Consultant Should Do When Getting Started

Build your war chest — Make sure you have two years of living expenses. If you tap into it, put the money back in during the good times once successfully established. Not having to worry about money will prevent you from becoming desperate (i.e. choosing work which is not the best fit, lowering your fees, or giving up).

Define your consulting focus — This will help you establish who your potential customers are as well as your competition.

Build a realistic business plan — Be sure to set up a business system and utilize outside sources for professional assistance (e.g. bankers, lawyers, accountants, HR). With a realistic budget and appropriate funding you can focus on building your clientele. There are plenty of free resources to get started, such as the U.S. Small Business Administration (www.sba.gov).

Develop a marketing strategy so you can best tell your story — Decide which conferences to attend. Volunteer to moderate sessions, serve on a panel as a speaker and develop editorial which can be submitted to different journals and trade publications. Social media should also be a component of the marketing plan and is a great inexpensive means of building a reputation. Set up profiles on LinkedIn, Facebook, Twitter, YouTube, etc. Set up a website and a blog, and be sure to keep them up to date. Not sure how to start? Dan Zarrella has plenty of good advice at danzarrella.com.

Network — Talk to as many people as you can. For example, if you get a request to connect via LinkedIn, don't just accept it; request that they call. Perhaps there is more to be gained than just getting access to each other's connections. Word-of-mouth still remains one of the most powerful marketing tools at your disposal and is best achieved through excellent service and effective networking.

"I sort of doubted my ability and lacked the confidence I needed, so I settled for a lower rate of pay than I should have."

Jacquie Mardell, Anhvita Biopharma Consulting

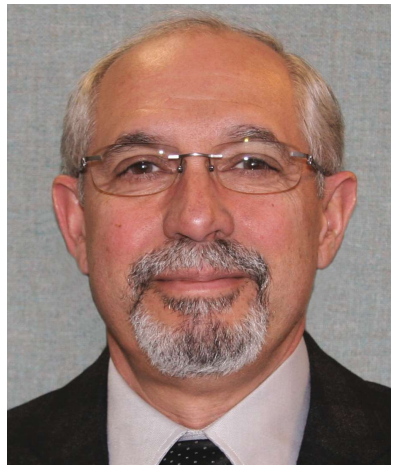
to spend." For a new consultant, it is important to take the time up front to analyze your value in terms of time. Doing so will allow you to build menus of services and their fees. This will allow you to more easily adjust your fees for clients who experience sticker shock by being able to remove items from the menu and lowering the price. Kossoff also advises getting a percentage payment up front for two reasons. First, it helps with the mortgage payment. Second, it makes the client feel committed to the project. "Until they put that money out, they don't have 'skin in the game,'" states Kossoff.

Another common mistake for a new consultant is becoming too closely aligned with the client, behaving as if you are an internal employee. Never ask for an office on-site at a client location. If you need an office, Mardell and Kossoff suggest you just ask for a job, because you will find it very difficult to break away once you have embedded yourself into the company. Good consultants have planned obsolescence so that when the job is done, the client is free to implement the recommendations without being dependent on the consultant. No on-site office makes this much easier.

Another mistake Calcott sees rookies making is taking on work just to pay the bills when there might be someone more qualified either internally or externally. Remember, demonstrating a willingness to recommend someone else for a project builds trust, return business, and referrals. For example, Calcott once had a client who

"Be responsive, and go the extra mile to help clients and prospective clients. Surprise them with your commitment regarding turnaround time and not charging for every little thing."

John Farris, president and CEO, SafeBridge



wanted him to write some standard operating procedures (SOPs). Instead of taking the job, he suggested the client have someone internally produce these documents, because it would create a sense of ownership for that individual, and the SOPs would be written in the company's own "language." A project like this is also more likely to be successfully implemented because someone inside the organization has a vested interest in seeing it succeed. Not doing this is what Calcott refers to as *consultant overfishing* — the willingness to do everything for a client and bill for it as well. If you really want the client to be successful, be willing to recommend other consultants who may be a better fit for a project or internal processes/resources that will save the client money.

SKILLS VERSUS ATTRIBUTES

Skills, such as technical competence in an area of expertise, aptitude for oral and written communication, a knack for running a business, marketing, and selling are all things which can and should be learned if you are going to be a successful consultant. Attributes, though, differ from skills. Successful consultants need the attributes of honesty, integrity, trust, strong interpersonal qualities, the ability to quickly assess a situation, and most importantly, courage. The consultants I interviewed caution you from entering the profession if you do not possess these attributes, or else find a business partner who does.

Consultants often have to deliver messages that make clients a bit uncomfortable, especially if it has to do with change management. Consultants need to have the courage and conviction to be able to deliver tough messages in a tactful way without their being watered down. According to Kossoff, "You have to be brave. Skills can be developed, but you have to have a comfort with risk that goes beyond anything else. You have to be courageous for yourself, and you have to be courageous for your clients." Consultants are usually brought in because the client has a problem which can't be fixed internally. "You have to be willing to say things you know could conceivably lead to their terminating your contract," she states. "They're spending money that, no matter how much they have, they don't have to spend on you, unless you're going to do something that's radically different from what they would get from keeping it inside anyway," concludes Kossoff.

GETTING STARTED

Calcott suggests using the Internet to begin your research. One site he found helpful was the Small Business Administration. "They have an incredible amount of information which, if you go through it, can help you set yourself up, whether it be as a sole proprietorship, LLC, or corporation," he affirms. Farris recommends taking the time to read books on consulting and talking to experienced consultants and business advisors. Doing this helped his team develop a set of founding principles which still guide them today and include: Think long term, always have the best interests of the client at heart, accept the client's problem or challenge as your own, write good proposals and ask the client to manage to those commitments, focus on quality in everything you do, stay within your boundaries of technical knowhow, underpromise and overdeliver, and finally — earn more money than you spend.

Kossoff recommends seeking out a mentor. For her it was Dr. W. Edwards Deming, most well-known for his role in turning around Japan's manufacturing industry after WWII and considered by many to be the father of quality. Kossoff sought the opportunity to become one of his assistants while attending one of his seminars. She had the opportunity to briefly meet with Deming and inform him of how meaningful she found his theories. He asked her if she would like to travel with him as an assistant. She jumped at the opportunity and was able to see firsthand how he implemented his consulting model. Kossoff describes working with Deming for three years as an eye-opening experience. "It really taught me what is wasted inside an organization in terms of human potential, capability, product service, and innovation. The waste is just horrific," she exclaims. Of course, your mentor does not have to be someone world-famous. Have the courage to seek out someone, perhaps within your organization, whom you admire and would enjoy learning from. Following the wisdom provided by your mentor and these consultants will serve you well should you ever decide to take the plunge into the challenging and rewarding field of consulting.

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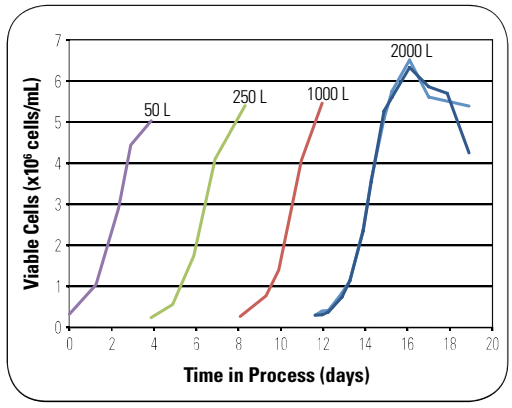

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A New Model For Life Sciences Collaboration

By Fred Olds, contributing editor

Getting things done. How does a business get things done with invasive regulations, bureaucracy, and uncertain taxes and personnel costs? These are significant barriers. Yet, three world-class research institutes on the West Coast have risked a move east to form a biotech cluster with a local hospital in the Traditions Center in Port St. Lucie, FL. The site's principals are confident of success and argue that their collaborative style may be a model for business and government synergy in similar ventures.

A business-friendly climate and incentives convinced the Torrey Pines Institute for Molecular Studies, the Vaccine and Genetic Therapy Institute, and the Mann Research Center to open operations in the Traditions Center for Innovation (TCI) in Port St. Lucie. Martin Memorial Health Systems (MMHS), a six-time winner of the Thompson Reuters top 100 hospitals, decided to join the venture to provide a community hospital campus designed for clinical research. The principals say success lies in their independence, entrepreneurial spirit, acceleration of business, and, perhaps most importantly, collaboration.

"This is a new model," says Larry Pelton, president of the Economic Development Council of St. Lucie County. "The TCI development is a purposeful build." The decisions of what to build and whom to recruit are the result of collaboration among the scientists and the community. It is an ongoing process among the health science tenants and the community, designing growth they agree will attract others and result in spin-offs and marketable therapeutics.

A BRIEF HISTORY

Early in the past decade, then Governor Jeb Bush set Florida on a path toward an education-based economy. Traditional industries regularly proved their susceptibility to economic and meteorological events. So, the legislatures authorized funds and resources to attract technology to the state. One of the first attracted to Florida was Richard Lerner, M.D., president, Scripps Research Institute, who opened a Scripps campus in Jupiter, FL. Lerner was taken with the opportunity. So, he contacted Richard Houghten, Ph.D., CEO, founder, and president of Torrey Pines, and recommended that Houghten take a look at Florida.

Houghten did so with the expectation that he'd take a vacation and return to work relaxed. Instead, he says, "I fell in love with Florida by itself." What he found, says Houghten, was a business-political team with a clear plan for the future. "It's a place where they want things to happen, and it's a vibrant place that's not just interested in building a cluster, but building an entire community."

Andrew Favata, VP of Mann Research Center, says this is a dramatic advantage to Port St. Lucie and TCI. The government and developers planned carefully for near- and long-term growth. The traditional tech corridors merely evolved. This often left communities with labs and homes but few schools or shopping and little room for expansion. TCI is a 150-acre tech center in a 2,200-acre mixed-use development. Consideration was given to living there as well as working there.

Houghten found out plans can move quickly. He worked with the city of Port St. Lucie on construction of Torrey Pines' new 100,000-square-foot facility. Twenty acres were deeded by Core Communities, LLC, the construction was permitted, and the headquarters built in less than two years. Pelton says ground was being broken as the signatures landed on the permits. "In California," says Houghten, "permitting would have taken one to two years."

Jay Nelson, Ph.D., founder and executive director of Vaccine and Gene Therapy Institute (VGTI), says he was contacted by Houghten and encouraged to take a look. Nelson welcomed the atmosphere in Florida and saw opportunity. He wrote a business plan focused on translational research in human immunology based on the animal research the institute was doing in Oregon. He said VGTI hit the ground running. In space he borrowed from Torrey Pines until his building is completed in 2012, Nelson began research, including clinical trials at Martin Memorial.

Favata says Mann's search for expansion was similar. He adds that while Florida

offers incentives to business, it's very attractive to employees, as well. There is no income tax, the cost of living is low, and the real estate market is an inconceivable value for folks used to West Coast or Northeast prices. "Of, course there's a geographical advantage too; we don't have four months of gray skies, cold, and snow."

INDEPENDENCE AND SCIENTIFIC CAPITALISM

Independence is key. The tenants are not a division of governmental agencies or universities. "The mission of universities is to train," says Houghten. "Our mission is to do research and come up with new discoveries." At universities time is split among teaching, publishing, boards, and panels. Universities offer security. Research can become secondary. In a private institute, Houghten says, there is no time to lose focus. Things have to get done.

Houghten says the advantage, and the risk, of their independence is "scientific capitalism." He says every day is like standing on the edge trying to find a way to cross the abyss to another success. It's an atmosphere that forces efficiency and ingenuity. Survival depends on nonlinear thinking, long hours, and hard work. "So we can't do things in the traditional way," Houghten says. "If we did, we would fail because, individually, we don't have the resources."

ACCELERATING BUSINESS

Favata says one of the differences is leadership's commitment to accelerating business. TCI is a private operation, so red tape is limited. Likewise, local Port St. Lucie governmental agencies accelerate the process for development. It's not that there are shortcuts; it's that decisions are expedited, and there aren't 1,000 rules when 100 will do.

Mark Robitaille, president and CEO of Martin Memorial Health Systems, agrees. He says it's about results, not process. "There's no need to wait for quarterly committee meetings. One could wait four or five months for a decision from committees that actually only spend a matter of an hour on a topic." Robitaille says, "We can pull those committees together rapidly and walk information around the system.

"At MMHS, staff can pull everything together, do the contracting, and get a study under way in matter of weeks, not months or years." Robitaille says, "When the flu was here a couple years ago, VGTI wanted us to do a trial with one of their vaccines. Time was critical, and we were able to put the study together in a matter of a few weeks." Robitaille says MMHS physicians are engaged and savvy with research and actively recruit patients, so the study was done quickly.

COLLABORATION

All the partners agree that one of TCI's strongest assets is the collaborative nature of the entities. Tenants meet monthly under the umbrella of Florida Innovation Partners, LLC to discuss their individual and collective operations and plans. It's the venue where the partners explain what they are working on, what help they need, or provide to others.

Nelson points out that collaboration maximizes resources and prevents duplication of efforts. VGTI can go to Torrey Pines and search its library of more than three trillion compounds. Mann collaborates with Martin to build a center for research attached to the future home for Mann. VGTI and MMHS coordinate clinical trials.

Partners also monitor operations at the center and propose plans for future growth. Discussions focus on the physical plant, as well as marketing and recruiting. A continuing theme is what or who's next to recruit to TCI. They look for complementary or value-added entities to flush out the project. With a nucleus of a hospital, a research firm, and a medical devices company, the question is — what's next. Pharma is logical. All agree on the necessity to attract pharma to bring their discoveries to market, says Nelson. Robitaille adds that it's a perfect fit for a small high-tech boutique pharmaceutical company because many of those discoveries may be in niche markets with specialized expertise. Pelton says TCI would be an opportune situation for CROs or private for-profit companies in IT.

Externally, Pelton says that since Port St. Lucie had no established resources, and that the vision for TCI included neither university nor government affiliation, it was clear that the community and tenants had to collaborate. The community and TCI share representation on each others' boards and contribute to mutual objectives for growth and success. Pelton says, "At this point, it's not so much our telling TCI what we can do. Now that they have a team, they usually come to us and tell us what would make the project more successful. Then we work together to make it happen."

That requires the ability to compete for funding and intellectual capital in hard times. Many doubt the ability to attract talent to what some have considered a backwater of technology. Nelson says what impressed him about Florida's vision was the wisdom in courting the best institutes in the world. He admits, "I would not be here if it weren't for Richard Houghten, who probably wouldn't be here except for Lerner." And Nelson was able to draw Rafick Sekaly, Ph.D., scientific director for VGTI Florida, one of the world's leading HIV investigators, from Canada. He says the local government has impressive plans for the future and the energy to enact them. Robitaille says it simply, "You have to come here to believe it."

What may be most impressive about TCI and the Florida project in general is its speed. In less than 10 years a small coastal community remodeled its plans and developed a community to nurture a tech center. Through a business-friendly collaborative process, TCI has progressed along a coherent path of complementary research entities. Progress now focuses on recruiting private companies to bring that research to market.

Lessons From The Google Patent Acquisition For Pharma and Biotech Companies

By D'vorah Graeser

The term "patent thicket" relates to a patent portfolio that extensively covers a particular technological niche, effectively blocking any competitor's entry into the market. As the name suggests, the competitor becomes entangled in the "thicket" of patents and is unable to locate any clear path to avoid them. Effectively, the competitor loses "freedom to operate" or the ability to make, use, or sell inventions in that niche.

Of course, if the competitor is able to obtain a license to the patent portfolio, then the patent thicket no longer represents a barrier to entry. Instead, it is simply an added cost of doing business. The owner of the patent portfolio decides to whom to license these patents or even whether to license them to anyone at all, thereby controlling entry to the niche.

Such patent thickets frequently arise when a research leader obtains many early-stage patents in a particular technological niche. The earlier a leader enters or even creates such a niche, the broader the resulting patent protection. According to international requirements, inventions claimed in a patent must be novel and nonobvious, effectively different from everything which was known before the initial patent application was filed. Thus, early research leaders in a particular technology have the chance to obtain broader patent protection and to more effectively block others from entering.

The ultimate effect of a patent thicket, however, depends on the desired goal of the owner of the patent portfolio. For example, the much maligned "patent troll" or NPE (nonpracticing entity) only wants to make money by licensing or selling its patents. Sometimes a company (or a consortium of companies) may choose to purchase a patent portfolio simply to prevent it from being purchased by an NPE. Two recent examples of this are the purchase of the Nortel Networks patents by a consortium (including Apple, Microsoft, and others) and Google's purchase of Motorola Mobility (a company that was pared off from Motorola itself) in order to obtain ownership of its patents. In both cases, the patent portfolios were purchased, directly or indirectly, to allow these companies and their allies to enjoy freedom to operate in a particular technological area and to be able to assert the patents against their competitors.

ALNYLAM'S PATENT APPROACH

Another method to build a patent thicket is to license technology developed by others, such as universities, which would prefer not to commercialize the technology themselves. Alnylam Pharmaceuticals, for example, has adopted such an approach to obtain exclusive licenses to the most important broad patents in the area of siRNA (small interfering ribonucleic acid) molecules, which block production of proteins through interference with the corresponding mRNA (messenger RNA) molecule. Of the most fundamental patents in the siRNA technology area, Alnylam either owns or licenses all of them. Thus, Alnylam, an early research leader, has effectively become a patent giant in the technological area of siRNA.

Alnylam estimates that its most fundamental platform RNAi patents will expire between 2016 and 2025. The list of companies with which Alnylam has successfully concluded partnering deals is quite extensive and includes Takeda, Cubist, and others. All of these deals are based upon these fundamental platform patents.

Alnylam provides access to its patent portfolio through licensing agreements — at a price. Its 2010 revenue from its collaborations was estimated to be $100 million in its SEC annual filing. Therefore, Alnylam could pick winners and losers in the siRNA field, as without access to the Alnylam patent portfolio, it would be difficult for any company in

this area to make, use, and sell its siRNA product.

PROTECTING PATENTS

A recent court case, Tekmira vs. Alnylam (and the countersuit by Alnylam), indicates that Alnylam is aggressive in establishing patent positions in technological niches within the siRNA area, even at the expense of a so-called research "partner." Tekmira develops lipid-based delivery technologies for siRNA molecules. It accuses Alnylam of stealing trade secrets and attempting to patent its proprietary technology. In its 2010 SEC 10-K filing, Alnylam states it has an exclusive license to three Tekmira patents, which it believes is critical to the development of this lipid-based delivery technology.

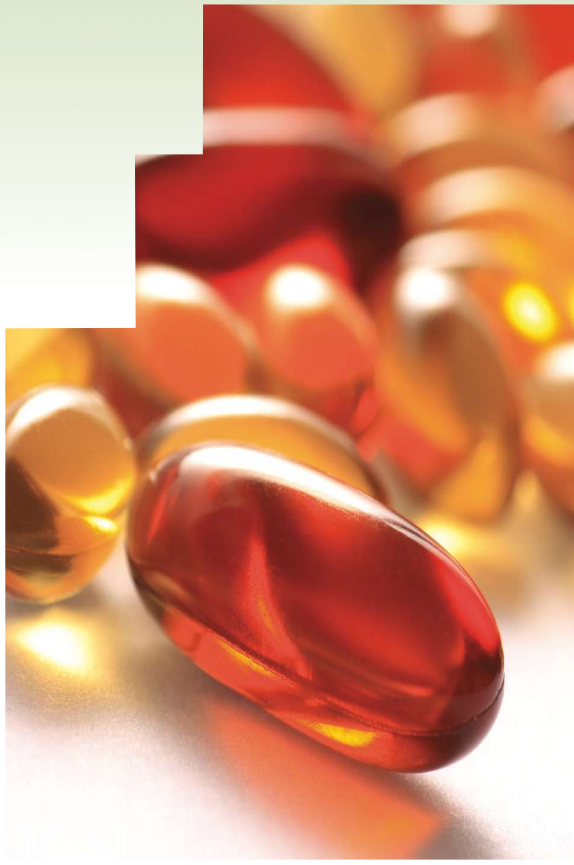
While some other companies do own significant siRNA IP, their holdings are limited in scope. For example, Silence Therapeutics holds certain important patents for specific siRNA delivery methods and for specific siRNA chemical modifications. It also holds an exclusive license to three Zamore patent families, which relate to siRNA stability. Silence Therapeutics also uses a differently structured siRNA, which it claims is not covered by the fundamental patents owned or licensed by Alnylam, a theory which has not yet been tested in court. Alnylam and others have joined to oppose the European grant of a Silence Therapeutics patent relating to siRNA stabilization; various re-examinations of U.S. Zamore family patents have also been requested and are on-going. Similarly, while Tekmira has significant siRNA delivery IP, Alnylam has its own delivery technology that it could use if prevented from accessing Tekmira's technology.

But, the early promise of siRNA therapeutics has given way to some disappointment and disillusionment. Merck (having made a large investment of over $1 billion in this field) earlier this year closed an RNAi research facility that it acquired when it bought siRNA. Novartis and Roche have both elected to stop partnership deals with Alnylam, with Roche pulling out of the field altogether. Problems in delivery remain a significant stumbling block, increasing the importance of the Tekmira/Alnylam battle. If Alnylam wins, it could seal its dominance in the siRNA technological space for years to come.

About the Author

Dr. D'vorah Graeser is the founder and CEO of Graeser Associates International (GAI), an international intellectual property firm specializing in the preparation, filing, and prosecution of medical device, biotechnology, pharmaceutical, bioinformatics, and medical software patents.

Securing Supply In Single-Use Systems — The Second-Source Decision



By Wayne Koberstein, contributing editor

The use of disposable systems for bioprocessing manufacturing has become a viable and cost-effective way for many pharmaceutical manufacturers to handle bioproduction requirements during clinical trials of drug candidates. The impact of single-use systems on cost reduction in manufacturing has been well-documented elsewhere. However, a company's reliance on such systems also comes with a stronger tie to the suppliers of single-use systems and components, because only products qualified for use and validated in the process can be used in production. What happens if the supplier cannot deliver?

Recently, geographic and environmental events, such as the Japan earthquake and tsunami, have disrupted many resin suppliers, which is the basis of all of the films used in single-use systems. Qualifying a second source for supply of products is a logical solution and can reduce the risk of manufacturing supply gaps, but qualifying each supplier is costly. And so, how does a manufacturing executive balance the risk against the reward of the second supplier?

Here we describe the context, challenges, and consequences of single-use supply disruption — looking at available solutions; focusing on the benefits, costs, and criteria for choosing a second-source solution; and examining the current and long-term implications for single-use technology and supply. In practice, the term "second source" may actually refer to multiple sources for different sets of single-use components.

VULNERABLE STATES

Supply-chain management in traditional biopharmaceutical production technology mainly concerns raw materials such as medium and column resins. Single-use technology requires a wider management strategy.

"By working with single-use technology, producers massively extend the supply chain to include all single-use components on top of the raw materials," says Alain Pralong, former VP of process development at Crucell and now head of Pharma-Consulting ENABLE. "Hence, procurement, storage, and QC need to be set up to match the new requirements."

Generally, procurement should ensure the manufacturer has enough stock of single-use components to maintain operations for four to six months, depending on how long it would take to replenish them. Because most single-use components can be sterilized by gamma radiation and used up to five years thereafter, the risk of maintaining larger stocks is low.

Beyond stockpiling, the only other way to reduce vulnerability to supply interruptions is to secure and validate second sources, compatible with the first. All suppliers must be fully qualified, including QC release (conformance with use specifications) and validation of the process as well as leachables and extractables.

"It comes down to excellence in supply chain management that includes qualification of suppliers, keeping the leachables and extractables validation up to date, and using well-planned QC-release procedures," Pralong says. In short, the manufacturer must have a system that allows release of disposables based on the qualifying certificates supplied with the single-use components. Lack of efficient, advance supplier qualification puts the production line at risk, he says. "In general, the risk of supply disruption is biggest when the organization is immature with regard to activity planning, demand forecast, and procurement."

TRUTH & CONSEQUENCES

Even with the best planning, stocks may not outlast a disruption in supplies. The worst case scenario is that the company must stop production until a new supplier

has passed qualification and validation — a complete regulatory review of all batch manufacturing and packaging records for correctness, completeness, and compliance to GMP standards. (See http://www.cgmp.com/qcRelease.htm.)

The obvious but still challenging solution is to already have a second qualified supplier in place. Additional suppliers may be necessary to cover all components, except for integrated systems that offer bags equipped with tubing, connectors, and filter cartridges. For example, the ready-to-use bag assemblies in Xcellerex systems can be supplied by Advanced Scientifics or Charter Medical, among others.

Among all single-use system components, bioreactors and mixer systems are the most critical because they are used together with specific hardware. For customized parts, second supply can only be assured if the integrated-system supplier grants licenses to other suppliers of bag assemblies. Nonlicensing suppliers usually have manufacturing sites at multiple locations to mitigate disruption risk, but global corporate procurement and warehousing guidelines could threaten that strategy.

For example, special components are used in bioreactors and mixers to enable engine drives with magnetic couplings which are supplier-specific. With such components, a second-source approach might be difficult due to technical complexity and IP considerations. Thus, warehousing and stringent quality control mitigate the manufacturer's risk.

Pralong cites a real-life experience with supply disruption at Crucell in the form of delivery delays with key components, which "required quite some management to keep the programs on track." A complicating factor was that suppliers do not offer standard bag manifolds "without further customization, as a baseline product for purchase on short notice."

Films — the basic material of bags used for storage of media, buffers, and process intermediates, as well as in mixer and bioreactor vessels — represent the most problematic supply issue, as the Japanese situation attests. For all other items, alternate suppliers are readily available. Film suppliers are not only few in number, but each one is also unique; there are no common film standards.

"When complete and extruded films are the base of the supply issue, then manufacturers are stuck," says Pralong. "Hence, having enough film-based material in stock, or better, owning the technology to do film extrusion from raw materials is critical."

RESPONSE STEPS

Manufacturers' immediate response to a supply disruption should include the following: Notify customers, and thereafter keep them informed; keep the supply repartition between two suppliers equal, thereby lowering the risk of a supply gap before the second supplier ramps up; and turn to noncustomized components that can be adapted by adding filter cartridges and other components in-house, which requires much more work than using ready-to-use assemblies but can prevent a production halt. It is possible to validate entirely new single-use components (other than bioreactors and mixers) but that might take more time than is feasible, according to Pralong. Similarly, he believes having a backup, stainless-steel system is impractical because "the maintenance, qualification, and validation effort is too big."

Ideally, manufacturers should prepare before disruptions occur by working with customers on risk-mitigation strategies in the design of customized components and leachables/extractables validation. Specifically, they must qualify several connector, tubing, and filter producers to build and supply customized single-use components. That stage must be managed in concert with customers to ensure they take the possibilities for second-supply into consideration for process validation.

Several major steps are involved in engaging a second source:

1) audit of the supplier and assessment of the quality system in place, continuous oversight, and quality control

2) leachables/extractables studies to complete validation requirements

3) validation of connections, gamma irradiation, etc.

Pralong estimates completing the steps will typically take from five to nine months, depending on the component. Securing the second source will also require an assurance of "significant business" for the backup supplier, he says: "Ninety percent for supplier A vs. 10% for supplier B does not work."

How does a biomanufacturing executive balance the risk and reward of having a second supplier to decide whether one is appropriate? A second supplier takes more effort, but mitigates the risk of losing supply — only, that is, if the first and second suppliers are fully integrated into the risk-mitigation approach, including full process validation, on the customer side.

The current lack of standard product specifications among single-use suppliers becomes even more problematic when a major supply source is interrupted. All suppliers provide validation guides showing data on leachables and extractables gathered according to U.S. Pharmacopeia and European Pharmacopeia guidelines (USP 661 and EP 3.1.5). But, to perform a process-specific, leachables/extractables validation would require full testing and analysis of reactions, including toxic byproducts, among all materials and components from all suppliers. "Clear common guidelines should be established to take away most of this burden from manufacturers using single-use systems," Pralong says. "This would require a major collaboration initiative of the different suppliers of single-use components to match chemistries so that potential cross-reactions are prevented."

Standardization will also have to occur in other forms: consistency of single-use technology adoption, supply, and regulation among world regions. Although most of the new single-use technology originates in the United States, Asia may lead in actual adoption by the pharma industry and its regulators. Thus, a crisis in Asia can affect supply in the United States and Europe.

SUPPLY & DEMAND

Alain Pralong, former head of process development at Crucell, believes the only remedy for the dependence of U.S. and European companies on Asian suppliers is greater overall acceptance and adoption of single-use technology: "Dependence on non-U.S. suppliers for single-use components can be mitigated by creating a basis for business in this field within the United States and Europe. To do that, decision makers have to change their ways of thinking. U.S. and European suppliers have to wake up before they lose biomanufacturing to Asian and emergent countries, which are much more open to new technologies offering them major cost benefits."

Pralong sees a bright future for single-use as the technology further develops: "The increase in productivity and the development of high-capacity membrane chromatography (e.g. Natrix Separations) in downstream bioprocessing allows manufacturing of biopharmaceuticals, such as antibodies, at much smaller scales that are today already within the range of what can be done with single-use components (up to 2000L). There are, however, processes (especially microbial) that will continue to rely on traditional, stainless-steel technology due to size and physical/chemical constraints for which single-use components are not designed. Hence, both technologies will coexist. But using traditional technology for antibodies will prove too expensive in the future."

SINGULAR AFFIRMATION

Could supply disruption be the Achilles' heel for single-use technology? Among traditionalists, even the potential for such cutoffs strengthens the case for stainless-steel versus single-use technology. But Pralong draws the opposite lesson.

"At first glance, traditional technology seems safer from the supply point of view. But, its dependence on huge amounts of water and utilities — as well as the whole control, monitoring, and validation process — makes it more vulnerable to poor output than single-use components," he concludes. "The risks of single-use sourcing can be mitigated through a mature and holistic approach to demand planning, procurement, warehousing, QA oversight, and QC release. It is also important that the single-use suppliers be aware of their impact on their customers' process validation and drug-product supply."

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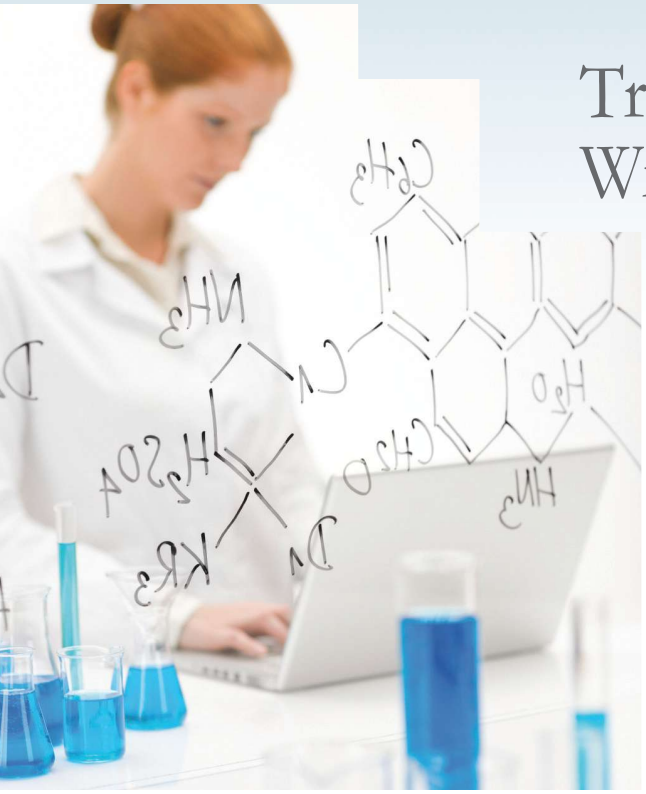


Trimming Technology Transfer With Automated Solutions

By Michalle Adkins & Robert Dvorak, Ph.D.

Taking a potential molecular or biological entity from research and development to market can be challenging for even the most experienced life sciences companies. In addition to the product development work, it requires collecting, organizing, and transferring the masses of information required to define a product, produce sufficient quantities, satisfy regulatory agencies, and obtain the necessary licenses. Simply satisfying the basic requirements is very costly and time-consuming.

The sheer volume of information can be daunting. Moving an ever-increasing amount of data from R&D through the various stages of testing, licensing, and commercialization is a huge responsibility where problems can derail even the most promising products. Frequently, this transfer is accomplished by means of written protocols, aggregated data, and reports that leave room for misinterpretation. However, by employing high-level knowledge management techniques and a common set of communication tools, transfers of technology can be accurate, effective, and efficient, thus reducing product development costs and shortening the time to market. According to a study by Tufts University Center for the Study of Drug Development (summarized in the Standard and Poor's Industry Surveys Biotechnology, Aug. 13, 2009), it can take as long as 15 years and as much as $1.2 billion to move a drug from preclinical development to biopharmaceutical product market launch. Even excluding the financial drain of drug development failures and associated time expended, the cost remains at $559 million per biologic.

Obviously, any viable method of efficiently pushing potential products through the maze of requirements, hastening the elimination of unacceptable candidates, and shortening elapsed time before a product is commercialized will have a dramatic impact on a company's R&D costs and bottom-line profitability.

CHALLENGES OF TECHNOLOGY TRANSFER

Technology transfer is an iterative process of moving information from development to manufacturing. This involves disseminating known information about the product and the anticipated process, collecting and analyzing test results, defining and executing experimental batches and campaigns, gathering process data, and providing summaries. Inputs consist of what is known about the product and the process at the time — data from prior similar products, research data from lab notebooks, characterization studies, batch instructions, set points, experimental data, and a campaign plan. Outputs consist of executed batch records, processing data, and test results, generally in the form of written reports — often hundreds of pages long. These huge, often repetitive, documents must be reviewed and understood in total.

Without a common vocabulary and a shared set of tools, technology transfer can be particularly frustrating. Extra effort is required to deal with variations across the enterprise and contracted sites, inconsistent terminology between groups, and disconnected sets of information needed to support licensing a marketable product. This can create costly delays due to inconsistencies, errors, and poor translation of data introduced by each successive group.

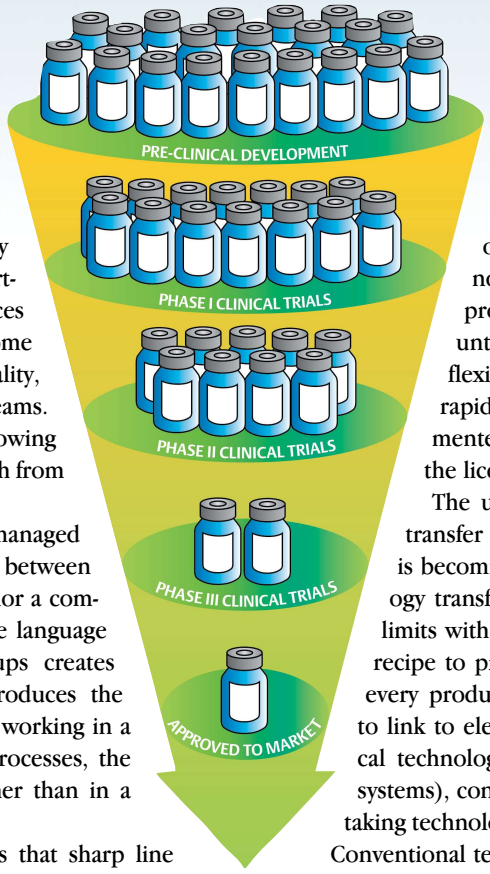
Each site often has unique methods for managing similar business and production processes, even for the same product manufactured at two commercial sites within the same company. Additionally, there are differences between equipment at the sites engaged in technology transfer through the development life cycle. This can be particularly trying when equipment characteristics, piping, valves, instrumentation, and automation algorithms differ at each step along the way.

Equipment differences may be overcome with appropriate engineering and scale-

up techniques. Piping, valves, and instrumentation differences as well as business process differences are handled with batch records and standard operating procedures specific to a site. Automation is generally developed for a specific site, sometimes starting with a library of objects. So, differences from site to site may eventually be overcome with a lot of hard work by the project, quality, technology, engineering, and automation teams. Of course, this contributes to the ever-growing volume of information moving along the path from development to commercialization.

Whether technology transfer efforts are managed within a site or between sites, these efforts between groups share neither a common language nor a common set of tools. The need to translate the language and associated knowledge between groups creates an inefficient process that inherently introduces the opportunity for error. Since each group is working in a somewhat isolated domain with its own processes, the knowledge is situated in that domain rather than in a common expression.

The lack of shared tools only reinforces that sharp line between groups and emphasizes the need for data migration and the development of automated structures from scratch. In addition, due to these differences, a nonvalue-added review loop is required for the experts on each side to verify the accuracy of the knowledge transfer.



Business process efficiencies are needed to reduce overall drug development costs.

SOLUTIONS FOR REDUCING DEVELOPMENT AND APPROVAL TIMES

According to an economic study sponsored by the National Institute of Standards and Technology and reported in Standard and Poor's Industry Surveys Biotechnology, Aug. 13, 2009, between 25% and 48% of R&D expenses can be saved through improvements in technology infrastructure, standardization of data collection, and quality control for postmarket surveillance. Similarly, a significant reduction in development and approval time of biopharmaceuticals is also possible.

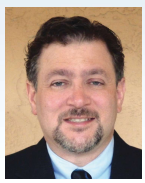
A shared set of tools can help break down those barriers by allowing the various groups to exist in a common authoring environment and, more importantly, provides the means to hand off knowledge, data, and design without the need to translate or transcribe. In addition, shared tools enable an organization to focus on the five or six things that are really important to a particular process. The end product can be measured against truly critical process parameters. This focus on critical parameters is fundamental to PAT (process analytical technology).

When a production process is under development, the scientists and engineers may not know exactly how they want a particular process to run (down to all the parameters) until they are actually underway. They need the flexibility to make changes through start-up and rapidly modify production records with a documented, understandable rationale that supports the licensing application.

The use of information technology to aid in the transfer of appropriate data, information, and recipes is becoming an essential factor in support of technology transfer. The ability to narrowly focus on control limits with parameterized recipes in order to transfer a recipe to production is becoming more important with every product moving through the channel. The ability to link to electronic lab notebooks, PAT (process analytical technology) systems, MES (manufacturing execution systems), control layers, and business systems is crucial to taking technology transfers into a new and improved reality. Conventional technology transfer procedures are challenged by errors and site-to-site inconsistencies as large volumes of information are transferred manually in paper or electronic document format. These problems can be reduced or, in some cases, eliminated because advanced technologies and tools are now available to improve these practices. Companies that embrace these capabilities will be able to bring products to market more quickly with consistent, well-characterized, quality processes.

About the Authors

Michalle Adkins, a senior industry consultant at Emerson Process Management, has 20 years of pharmaceutical industry-related experience, including 13 years with Merck. In her consulting engagements, Michalle uses her varied experiences including project management, planning, manufacturing, automation, and engineering.



Robert Dvorak, Ph.D., is director, Syncade/Data Integration Management at Emerson Process Management and has more than 25 years in the life sciences industry with a focus in electronic systems and data analysis. He has worked as a preclinical researcher, information systems consultant, MES consultant, IT Director, and MES Project Director.

Making The Most Of Industry/Academic Partnerships

By Gail Dutton

Industry/academic partnerships are changing from the traditional hands-off approach to true collaborative efforts that better utilize the expertise and resources of each group. By teaming best-in-class academic researchers with scientists skilled in drug development, life sciences companies expect to make advances that enhance their understanding of a drug candidate, streamline drug development, and quickly translate into the clinic.

"A decade ago, the term collaboration was a misnomer in discussions of industry/academic partnerships," recalls Erik Halvorsen, director of the technology and innovation office at Children's Hospital Boston. "Industry/academic research agreements were very hands-off for pharmaceutical companies, and the results weren't as good as they could have been because neither side leveraged the expertise of the other. Neither party got enough out of the relationship."

FUNDING DRIVER

As funding for biotech dried up, "Genentech and others decided to build richer relationships with universities to create ideas around targets that can be developed," notes James Sabry, M.D., Ph.D., VP of Genentech Partnering. "Universities themselves aren't interested in drug development, but as their supplementary funding from grants decreases, they are becoming increasingly interested in work that allows them to apply their knowledge in a practical setting. Often, professors have identified novel targets involved in particular processes or have implicated a process in disease. Academics are good at identifying patterns we rely on, and we are good at identifying therapies to treat disease," Dr. Sabry says.

To remedy this situation, several of the most forward-thinking life sciences companies are changing the traditional collaboration model. Here's a look at how Bayer, Pfizer, and Genentech are creating a new era in industry/academic partnerships.

BAYER

"We're taking a much more collaborative approach to working with scientists at research institutions," says Christopher Haskell, Ph.D., head, U.S. Science Hub, Bayer Healthcare U.S. Innovation Center. Last January, Bayer opened its U.S. Innovation Center adjacent to the Mission Bay campus of University of California – San Francisco (UCSF) to expand its collaborative relationships. "Our goal is for each organization to bring its bench strengths to a project that advances scientific knowledge and that leads us toward therapeutic breakthroughs. Both organizations share the risks and benefits, creating a balanced partnership as opposed to the more 'purchased' research format popular in the past few decades," Dr. Haskell says.

The key to Bayer's new Science Hub collaborative structure is a master research agreement between it and UCSF. As Dr. Haskell explains, the master agreement streamlines the legal process of establishing these types of working collaborations, allowing the industry and academic scientists with great ideas to begin their work more quickly.

"These collaborations are day-to-day research partnerships that bring scientists at both organizations together to work on a clearly defined project," Haskell explains. Partners share the risks, costs, and benefits, leveraging the expertise and resources of each. Therefore, they must be committed to working together. And, he adds, "The collaborations work best when project objectives align with the missions of the organizations."

To help ensure the projects are productive, the partners establish clear objectives as well as the roles and responsibilities of each organization. Additionally, lead scientists from each organization establish the project plan and meet regularly to ensure it stays on track. Haskell says, "Quick attention to any challenges also is vital to the project's success."

PFIZER

"About one year ago, we established the Centers for Therapeutic Innovation (CTI) to provide a different source of innovation," notes Anthony Coyle, Ph.D., VP and chief science officer of Pfizer's CTI. Pfizer sees the CTI as an opportunity to work not only

with researchers who have pondered a specific scientific question in depth for many years, but also to work in translational medicine with university faculty who have strong ties to the clinic. "The CTI model doesn't work for everybody," Coyle notes. "It attracts individuals who want to ask questions in a clinical study, not just in a mouse model. Therefore, we build unique teams composed of basic researchers, clinicians, and Pfizer scientists."

According to Coyle, the CTI is unique because of the breadth of expertise accessed. With CTI facilities in San Francisco, New York, and Boston, Pfizer is positioned to tap the expertise of some of the world's foremost scientists. "This network brings together 19 institutions and thousands of investigators throughout the United States — all working off the same basic partnership agreement — to identify candidate drugs and move them into the clinic," he notes.

CTI's focus is on translational medicine, rather than upon animal models or upon evaluating therapies in clinical populations. "There's no predetermined disease focus. Research projects are based upon the opportunity to translate an idea into the clinic," he says. The CTI does focus, however, on biologics. "That allows us to build more intimate relationships without the need to also involve large teams of medicinal chemists," he explains.

The scope of collaboration ranges from discovery to Phase 1, helping Pfizer streamline development. For example, by populating a research team with individuals who have spent decades unlocking the scientific mysteries of a particular niche as well as with Pfizer's own experts in toxicology and pharmaceutical science, the company may benefit by addressing issues as early as possible in the candidate selection and drug development cycles.

About 250 proposals for research have been submitted to the CTI this year, and about 10% of those will be funded by year's end. "Some are very early stage — some have one paper in Cell — and the individuals have an idea that could become a therapeutic," Coyle says. Thanks to this collaborative research model, "In less than a year and a half, we've been able to achieve what would have taken five to six years to build."


Pfizer's Centers for Therapeutic Innovation (CTI) in New York

Proximity to the researchers is so important that Pfizer has leased space across the street from UCSF's Mission Bay campus, at New York's Alexandria Center for Life Science near New York City University, and in the same building that houses many of the researchers from Children's Hospital Boston, Deaconess Beth Israel Hospital, and Dana Farber Cancer Center. The principal investigators (PIs) and post-docs have a Pfizer badge for easy access to the Pfizer facilities, and Pfizer researchers have access to theirs.

All relationships with the institution are for five years, although funding commitments for individual projects will be shorter. The funding mechanism is very venture capital-like. Funding depends on scientific advances, and according to Coyle, a significant number will terminate in two years' time.

"At the end of a project, if we don't exercise our option (to advance it), whatever we've generated returns to the academic institution to do with as they desire," he explains. That includes developing the project with another partner. "If it's a therapy that's potentially viable, we don't want it held up," Coyle emphasizes.

GENENTECH

Genentech has an omnibus agreement with the University of California at San Francisco and at Davis to allow materials to be exchanged without tech transfer agreements for each project. Genentech has signed deals for several partnerships all based upon this master agreement. For instance, its agreement with USCF's Small Molecule Discovery Center is designed to develop a drug candidate against neurodegenerative disease. Under that agreement, the university has the potential to receive more than $13 million — plus royalties — when certain development and commercial milestones are met.

Genentech and other companies engaged in these more collaborative agreements tend to manage the projects through joint project teams — at least for the larger projects — to drive the work toward a common goal. Aside from good science, "An appreciation of the other person's point of view is one of the key elements in determining the success of the collaboration," Sabry says. "It's easy to forget the other partner has different goals. Ours, for example, is to develop great medicines to help patients, while universities' goals are to educate, advance knowledge, and conduct clinical work. Where they overlap, we can work together."

BIOTECH EFFECT

The emergence of more collaborative industry/academic partnerships isn't expected to adversely affect the small biotechs that have traditionally engaged in many of these collaborations. "This will have no real effect on small biotechs," Sabry says, simply because "there are fewer small biotechs than there were." In today's economic climate, researchers considering spinning off research to form their own companies may be daunted by lack of start-up funding.

Pfizer and Bayer both stress the possibilities for similar collaborations with small biotechs. As Coyle says, "We're looking for opportunities to participate with small biotechs and even venture capital groups to find more creative ways to partner." Bayer's Haskell notes, "This collaborative model also is used for other types of partners, in addition to traditional licensing and codevelopment/comarketing partnerships."

Refinement Of Industry Guidance Promotes Harmonization Of Good Distribution Practices ... But Gaps Remain

By Chris Fore

It is an exciting time for those with an interest in the pharma cold chain. While change may cause uncertainty, for those engaged in the heavily regulated healthcare industry, the ongoing refinement of guidance further clarifies the regulatory requirements for the storage and distribution of temperature-sensitive products.

In 2005, there were seven carriers that had a branded cold chain service. Often the focus was on fresh foods, while healthcare products were hardly mentioned in IATA (International Air Transport Association) perishable cargo regulations. Now, more than 20 carriers have branded cold chain product services, and next year IATA will require the labeling of healthcare shipments.

3 KEY DOCUMENTS TO UNDERSTAND

A lot has happened in just seven years. The most influential event during this period was the 2007 release of the Parental Drug Association *Technical Report #39: Revised Guidance for Temperature Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment,* commonly referred to as TR39. This report was coauthored by the U.S.-based Pharmaceutical Cold Chain Discussion Group and the European-based Cold Chain Committee. Because the majority of pharmaceutical traffic flows between Europe and the United States, TR39, to a large extent, harmonized the qualification of packaging and transportation process. It also defined the obligations of both the shipper and transportation provider with respect to quality and training. TR39 has become a common reference for regulators, WHO, United States Pharmacopeia (USP), and IATA.

IATA Perishable Cargo Regulations Chapter 17 should prove to be just as important to the industry as TR39 because it is a regulation for the 230 IATA member airlines that comprise 93% of air traffic. However, if Chapter 17 is to achieve the same status as that of TR39, it must become more available to manufacturers and forwarders who must then require their selected carriers to comply because, regrettably, IATA is not enforcing it.

Finally, this year the long-awaited publication of *Model Guidance for Storage and Transport of Time- and Temperature-Sensitive Pharmaceutical Products* as Annex 9 to the WHO Technical Report Series, No.961, 2011 has created a global standard for good distribution practices (GDPs). All three of these documents align, given the cooperation of the WHO, USP, IATA, and PDA (Packaging and Design Association) and the fact that many of the authors were involved in more than one organization.

THERE IS STILL WORK TO BE DONE

Manufacturers continue to refine their requirements and speak of the "end mile" and a holistic approach to quality in the face of increased regulatory focus on distribution and processes down the supply chain. Several new industry guidance documents have or will be published this year, and a rewrite of TR39 is

planned. Chapter 17 is ambitious enough in scope, and, with all this activity, there will continue to be gaps between the shipper's requirements and operational capabilities of the transport service providers.

For the forwarders, the challenge has been to maintain training and service quality at similar levels throughout their networks. For the carriers, they must finish implementing Chapter 17 and face similar training challenges as forwarders. Carriers have made tremendous progress, but it has created even more disparity between carrier service levels. And, many need to further develop their training programs, align their procedures to Chapter 17, and implement other elements of an ISO-based quality system such as corrective and preventative action plans and assessments or audits.

Other gaps appear with subcontractor training requirements. According to TR39, it is the obligation of the carrier or forwarder to ensure subcontractors (agents) meet their level of training and quality. Unfortunately, current GDP requirements for training and quality may not be clearly defined in contracts or service-level agreements. Often, demonstration-based training is ad hoc and undocumented. The instruction may be limited, the content dated, or cold chain training is secondary to dangerous/hazardous goods and security.

Tremendous progress has been made through the harmonization of cold chain guidance. The regulatory oversight and industry requirements continue to increase, and the development of the cold chain ultimately serves us all.

About the Author

Chris Fore is the compliance manager at Envirotainer and is responsible for the Qualified Envirotainer Provider Training and Quality Program (QEP). He was a principal author of IATA Perishable Cargo Regulations Chapter 17 and serves on the Time and Temperature Task Force.

9 Crucial Steps Toward Making The Business Case For Quality

By K.R. Karu

Today's life sciences manufacturers face enormous challenges in managing their quality and compliance initiatives. Market trends point to even greater scrutiny on these efforts as pressure mounts from both consumers and the FDA for manufacturers to deliver safer products and services. To meet these important regulatory challenges, many manufacturers have identified the need to implement a quality management system across the enterprise, automating processes and providing efficient, effective, and timely access to relevant data.

But the task of actually implementing an enterprise quality management system (EQMS) at a life sciences company can often be easier said than done. Cost pressures stemming from the global economic downturn and other factors have created difficulties in making a significant business case for quality management at both large and small companies. And, though no executive will deny that quality is an imperative for their organization, this usually comes with the caveat that implementing an EQMS must result in a tangible ROI for the business.

The following are nine simple steps on how to not only determine the scope and size of your EQMS implementation, but also how to convince the necessary stakeholders that quality management is a business imperative essential to driving bottom-line performance and long-term competitive advantage.

STEP 1: UNDERSTAND THE APPROVAL PROCESS

Understanding the process your company uses to evaluate potential capital investments is the critical first step in your project. Meet with your immediate supervisor, someone in the finance department, or a person who has shepherded a similar project through the approval process to find out how your company handles it. Discuss the specific steps that will need to be taken and identify key stakeholders whose support will be needed. Make sure you walk away with a clear understanding on how the process works, who is involved, and what their roles are.

STEP 2: IDENTIFY YOUR CHAMPION

Every organization has a hierarchy of decision makers with different degrees of influence in the approvals process. To make the case for EQMS, it's important to find a partner with both the organizational leverage and the willingness to move the proposal up the hierarchy. In some cases, the right person may be somebody high up in the quality department. In other cases, they may be a senior manager in IT or someone in finance. It all depends on who at your company is involved in financial decision making about major new projects.

STEP 3: DETERMINE YOUR CHAMPION'S PRIORITIES

Once you know who your EQMS champion will be, invest some time to identify specific priorities. For example, if your champion is in IT, you may find that their top concerns are all about reducing support costs by consolidating infrastructure and reducing the number of systems the IT department needs to manage. If your champion is in quality, you may find that training, documentation, auditing, or a new regulation is a principal challenge. Do a little digging, and find out if there has been a recent issue that dominates decision making in your champion's department or if there is a relevant industry challenge that has been highlighted in their area.

STEP 4: GET RESOURCES ALLOCATED FOR FURTHER INVESTIGATION

Most enterprisewide projects require their champion to build a business case to justify the capital spend. Your next step will be to convince your champion and/or your direct supervisor to approve the allocation of resources for further fact-finding. In building a business case, the champion needs to

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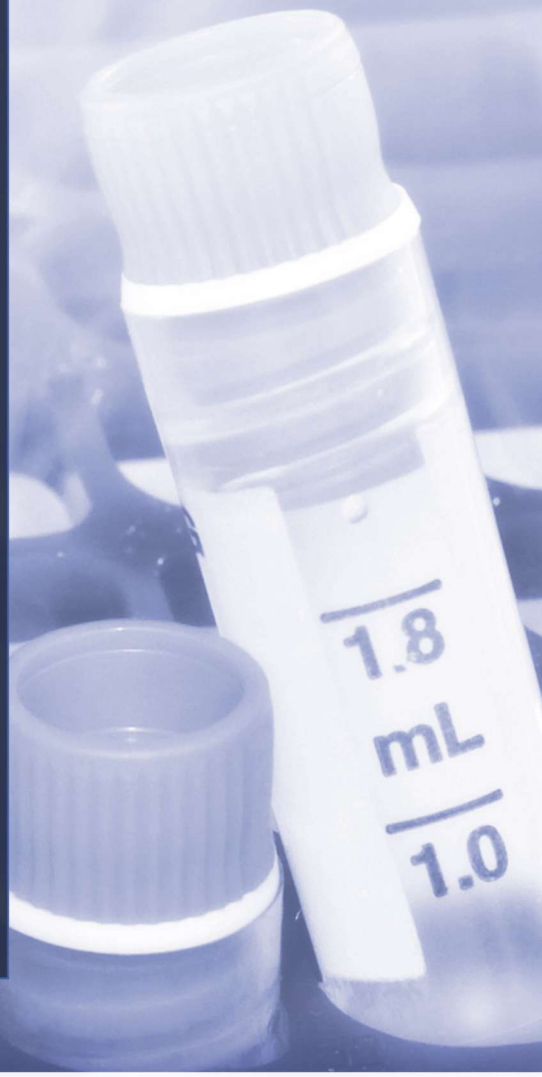

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capture all tangible benefits that the company would obtain from implementing the EQMS and then place a defensible monetary value on these benefits in terms of annual savings to the organization. The goal of the business case is to ensure that the project delivers value greater than the corporate hurdle rate for capital investments. The following steps are required to develop the financial business case to ensure the resources are allocated for this endeavor:

- Identify quantifiable business benefits.
- Capture the state of the current scenario and collect baseline metrics.
- Develop a future state scenario.
- Model future state metrics.
- Populate ROI data and quantify the benefits.
- Communicate value

STEP 5: WIN SUPPORT OF YOUR STAKEHOLDERS

It's vital to get key internal stakeholders involved and invested in the project and to avoid conveying the impression that you are out to change the way their world works. Even if the change is an improvement, stakeholders might be resentful if it is forced upon them.

This is the time to have thoughtful conversations with stakeholders across the various business processes that will be impacted by EQMS. Ask them what they think needs to be improved and what they would like to see changed. Your willingness to listen, discuss, adjust, and make them part of the change process will help to build their support and provide momentum for your ideas at the middle and lower levels of your company. It will also help you gauge the extent of your organization's openness to change.

STEP 6: GATHER SUPPORTING DATA

At this point you will need to get the information needed for a cost/benefit analysis outlining gains, risks, and resources required to implement a solution, with a focus on the key concerns of your stakeholders. To get the right information, you must engage with the people who are on the front lines of each process and who have the direct experience to help you understand the scope and components of each process. Make sure these people understand your goals and engage with them to develop detailed process maps of both the current and the future states you envision for each process. Be sure to include every process step no matter how trivial.

STEP 7: REENGAGE WITH VENDORS

If you haven't already done so, this is the time to engage software solution vendors so you can understand the order of magnitude of your implementation costs. If you've already spoken to vendors, this is the time to reengage with them. If you're proposing a centralized EQMS for the first time, the exact scope and details of the project can come later, but you want a solid ballpark figure that takes into account both installation and ongoing maintenance costs. If there is already support for enterprise quality management in the organization, now is the time to get more detailed numbers. Remember that you may want to consider not only the costs involved with your initial adoption of enterprise quality management, but also any expansion plans if they will be implemented in the near-term future.

STEP 8: CREATE YOUR BUSINESS CASE PRESENTATION

Next you'll want to use the information you've gathered from stakeholders and their teams as well as outside vendors to build your business case presentation. It should include the following quantifiable elements:

- current state
- current state metrics
- future state
- future state metrics
- benefits/value of future state
- cost of an EQMS
- justification — ROI/TCO (total cost of ownership).

STEP 9: WORK WITH YOUR CHAMPION TO TAKE THE PROPOSAL THROUGH THE APPROVAL PROCESS

By this time your champion and key stakeholders should be in support of your proposal. Present your findings and metrics to your champion, and arm them with the information needed to present the investment. Then allow your champion, with your help, to use them political leverage to take the EQMS proposal through the approval process.

About the Author

K.R. Karu is the industry principal for Sparta Systems product management group. He has worked to provide technology solutions to the global life sciences industry for 25 years.

Pharmacovigilance Isn't a Walk in the Clouds... *Or Is It?*

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Scientific Articles: The Engine Inside Pharma

As a pharmaceutical company seeks to guide a new product from concept to commercial success, it must effectively harness an important tool: the scholarly research paper. A clear understanding of the roles an article can play and the challenges of maximizing its effectiveness are valuable knowledge for any pharma executive. Let's first review the multiple roles a paper can play and then assess the challenges.

During the preclinical study phase, your company's researchers will be navigating through the millions of articles that exist in support of the scientific process. After preclinical work, clinical trials are conducted and the publication-planning process accelerates, culminating in scholarly articles that will be submitted to peer-reviewed academic journals. Once published, they become a major part of your investigational new drug application (INDA) submitted to the FDA. If the FDA approves your product, the articles take on a new role as your marketing efforts begin. As witnessed by the growing importance of evidence-based promotions, there is no greater weapon in your sales representatives' arsenal than research studies that can be effectively presented along with prescribing guidelines to the healthcare professionals (HCPs) with whom they meet. Being able to back up one's claims for a medication with science — in addition to the promotional materials prepared by your marketing firm — is not only a good idea; it has become the chief method by which you can distinguish yourself from rival companies with competing drugs. It has also become one of the few ethical methods remaining to communicate with HCPs in light of the highly restricted code of interactions adopted within recent years.

Naturally, there are challenges linked to these uses of scientific articles, which are related to issues of compliance and business process. First, it is well known that an IND submitted to the FDA can easily run 10 or more volumes, largely consisting of reviews and copies of published studies of the drug in question. Assembling, transmitting, and managing this volume of materials is a major task for any pharmaceutical company, particularly with the new electronic common technical document (eCTD) format. It is vital for your bottom line that this task be completed in as economical a manner as possible and in a way that avoids unnecessary duplication of materials. Similar care must be taken when distributing key articles proactively through your sales force or digital marketing initiatives or reactively in response to medical information inquiries. Additionally, regulatory issues pertaining to good reprint practices (GRP) and copyright issues must be adhered to when articles are acquired and distributed.

THE VALUE OF CONTENT REPURPOSING

The good news is that your company need not go it alone in navigating these challenges; a company specializing in content repurposing can oversee much of this process. For example, with regard to the eCTD submission process, the content repurposer can process orders for articles either singly or in batches and procure them, ensure that the retrieved documents are digitally formatted to specifications, and oversee quality control and assurance processing. The service can also be tasked to report on the details of usage for every article requested by your company and assign a dedicated project manager to oversee the entire process.

Also, the content specialist can provide a streamlined method for obtaining reprints, ePrints, and single articles in a copyright-compliant manner. It can offer tools that make it easy to obtain and legally share these articles from secure online environments, via your customer relationship management (CRM) or inventory system, and a variety of other ways. Having access to single document delivery, for example, can provide your company's scientists and researchers with copies of most articles you need in as little as a few minutes to a few hours—a significant advantage considering the costs for every day a new product is delayed in getting to market.

As we have seen, research papers are becoming the lifeline of life sciences. When written, published, compiled, and disseminated in effective ways, they can make the difference between successful or unsuccessful development and marketing efforts for your company's new drug. Partnering with the appropriate content repurposing company can go far toward accomplishing these goals.

Peter Derycz

Peter Derycz is chairman and CEO of Derycz Scientific, whose wholly owned subsidiaries like Reprints Desk develop enterprise content management, workflow, and compliance solutions for Fortune 500 companies in the life sciences and other industries.

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[1] Survey Details: *Q4 2011 figure is an estimate based on previous quarters.

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How To Get The Most From Your Existing Resources

In today's operating environment, biopharmaceutical and medical device companies are under increased pressure to be as efficient and cost-effective as possible. Establishing effective resource planning can go a long way toward helping companies achieve these goals by ensuring management has up-to-date, accurate insight into their resource obligations for a clinical study, now and in the future.

A good resource-planning process gives companies the tools they need to make insightful, strategic business decisions — enabling them to match the right level and mix of resources to a clinical project and across the project portfolio.

The result? Effective resource planning in clinical development delivers significant benefits:

- reduces study risk by ensuring adequate resources are available and assigned when needed
- lowers operating costs by utilizing resources more efficiently
- improves long-range planning by enabling earlier hiring/outsourcing decision making
- increases employee morale and productivity through consistent utilization and advance notice of project timelines and duties.

THE FOUR PILLARS OF EFFECTIVE RESOURCE MANAGEMENT

The most important aspect of resource management is to recognize that it is a continuous process involving multiple components. There are four key components, which I refer to as the "Four Pillars of Effective Resource Management": resource planning, portfolio management, tracking project progress, and reforecasting.

RESOURCE PLANNING

The process of determining a resource demand projection for an individual project.

The life sciences industry is moving away from a reliance on spreadsheets and educated guesses to a methodology widely used in other industries for accurate resource planning — activity-based planning. Activity-based planning begins by deriving the level of effort for a specific resource to perform a given activity and when the activity is to be performed. Resource planning in this manner is sufficiently detailed to account for estimates on not only how many resources are needed (by role), but also when and where they are needed.

PORTFOLIO MANAGEMENT

The process of rolling up individual projects to allow for global assessment across multiple projects.

Portfolio management is critical to resource management because an organization typically has multiple projects going on within a single resource pool. Portfolio management allows for the global assessment of all projects from many perspectives. From a resource management perspective, an organization will be able to determine resource utilization and thus make more informed staffing/outsourcing decisions. In addition, portfolio management also gives a company the global perspective of what the organization is trying to accomplish, thus empowering strategic decisions as well.

TRACKING PROJECT PROGRESS

The process of acquiring real-world data in order to gain the insight needed to assess the project's progress and make informed business decisions.

Tracking a project's progress over time can be accomplished in many different ways. However, it is important to limit the information being tracked to actionable data. Limiting the information gathered on a regular basis to actionable data, as opposed to informational data, helps focus attention on what really matters to the success of the project while also helping avoid the pitfall of data overload.

A best practice in this regard is the use of earned value management. Earned value management is a proven project management technique for measuring project performance and progress in an objective manner, providing visibility to a project's current scope, schedule, and cost.

REFORECASTING

The process of updating project projections (timelines, budget, resource demand, etc.) to account for actual progress and/or project changes.

Reforecasting should be done on a regular basis based on the pace of change in the project and the organization's standard business processes. While frequency of reforecasting will vary, it is critical in keeping resource demand current especially in long-term, fast-paced clinical studies. When in doubt, it is recommended to reforecast more often than not; quarterly or semiannually is recommended.

Todd Reul

Todd Reul is a director of clinical services for ClearTrial, a provider of clinical trial operations software. Reul has more than 18 years' experience in the pharmaceutical industry, including 13 years in clinical research.

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One Question That Drives Accountability

Here is a simple yet powerful way to drive accountability ... even when you are not the boss!

Dr. Jim Harris

A few years ago, when I asked an executive with a global Fortune 500 firm, "What's your greatest leadership challenge that keeps your firm from reaching the next level?" my client and friend replied, "accountability — how to hold others accountable across divisions, locations, and positions even when I'm not their boss."

In today's decentralized, team-focused, and multilocation work world, one of the greatest challenges facing any leader is how to effectively drive individual and team accountability for results. Over the years, I've advised leadership teams on how to launch a culture of greater accountability by beginning, ending, or focusing meetings and even casual conversations around one powerful question: "What two things are you going to accomplish this week?" The impact of this nonthreatening, results-focused question is amazing.

Focus

This question helps people focus in three significant ways. First, it focuses the individual contributor on what they are to get done (results) — not just what they are doing (activities). It reinforces to them that productivity is paramount, not how busy or how hard-working they claim to be. Second, it helps the leader focus on how best to align available resources to help accomplish the goals. Additionally, it helps bust through potential silos to focus everyone on how best to collectively reach the goals with no excuses.

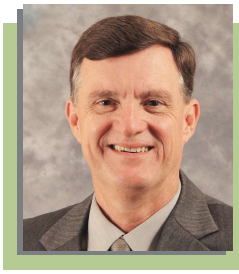
Peer Pressure

It is still true — peer pressure is more powerful than position pressure! Any real professional desires to "look good" in front of their bosses and colleagues. They need to be seen as a vital contributor to the overall success of the organization. This question quickly places the employee in control of their output with a proper amount of peer pressure. It's pointed enough to be direct without being painful (unless they don't have an answer).

Line Of Sight And Progress

Today's top talent, realizing low probabilities for significant pay increases or bonuses, are looking for two keys to inspire their continued commitment to excellence. First, they demand what I call "line of sight," that their work has direct and positive impact on the overall company goals. Second, they demand the company is making real progress toward those goals. Without line of sight or progress, they will likely leave. Through initiating a systematic focus on what the entire team is to accomplish in real time, top talent is more likely to stay and remain highly productive.

Whether you are a boss or a colleague, asking "What are you going to accomplish this week?" is a great way to drive a culture of accountability.



Dr. Jim Harris is an internationally acclaimed leadership expert and author who teaches leaders how to take themselves, their business, and their people to a higher level of success and significance.

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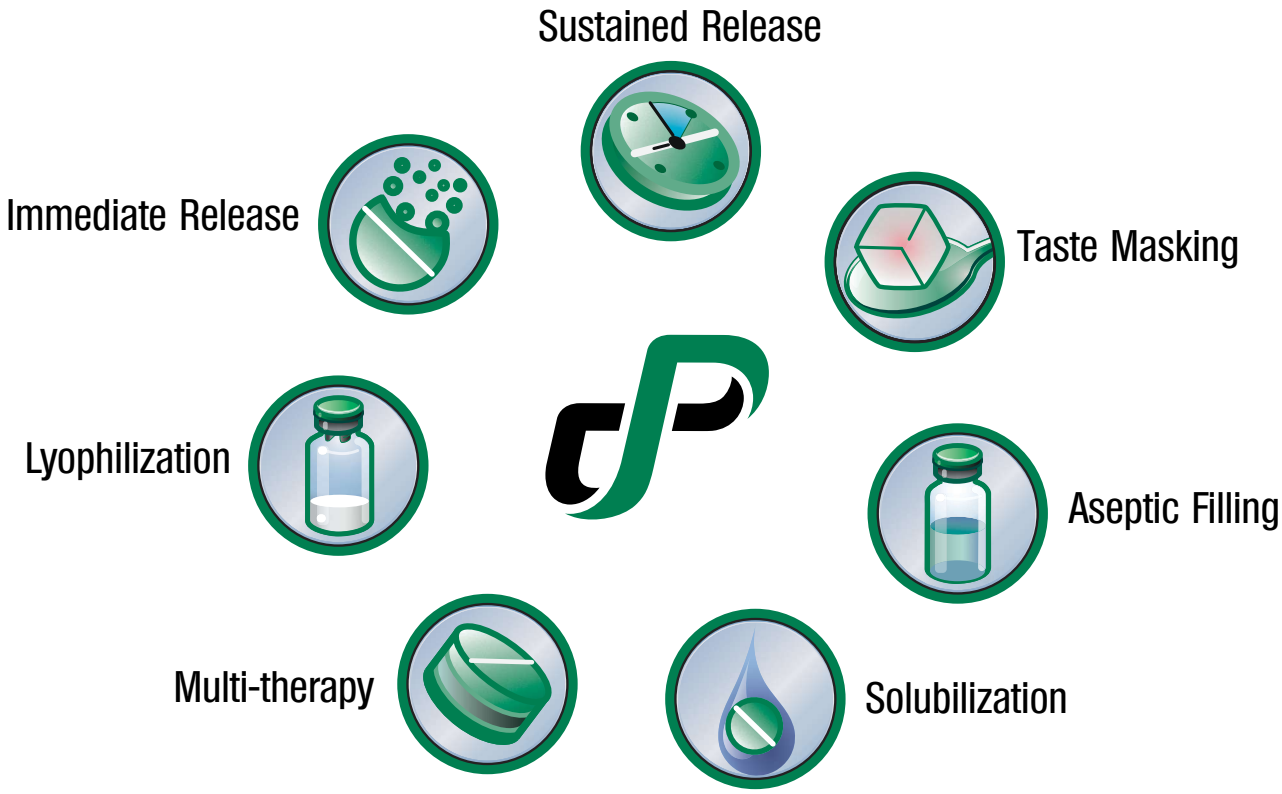

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