A Supplement to

Life Science Leader

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JULY 2014

DEVELOPMENT & MANUFACTURING OUTSOURCING INSIGHTS

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Life Science Leader

JULY 2014 CMO SUPPLEMENT VOL. 6 NO. 7

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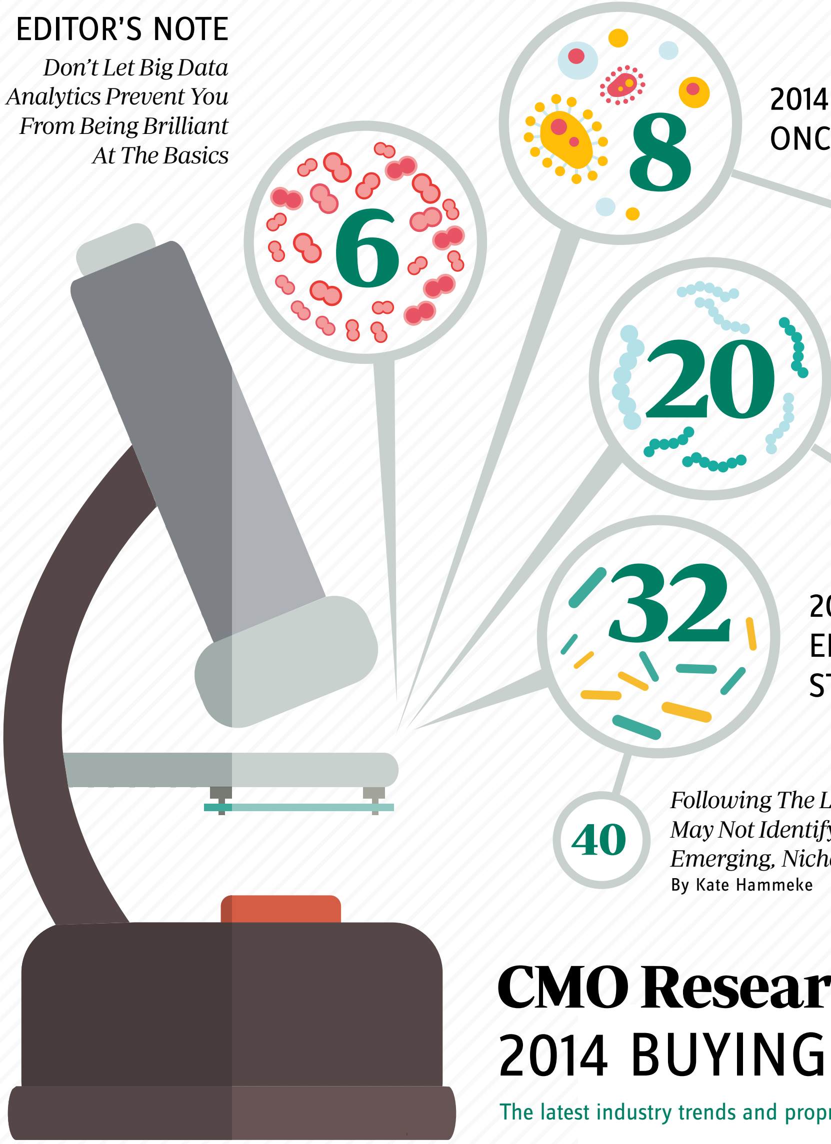

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Don't Let Big Data Analytics Prevent You From Being Brilliant At The Basics

ROB WRIGHT Chief Editor

When I think of the potential Big Data presents for the field of life sciences, it reminds me of *The Rime of the Ancient Mariner* — "Water, water, everywhere, nor any drop to drink." Like the salt water ocean surrounding a thirsty sailor adrift, we are seemingly surrounded by Big Data yet struggle to tap its potential. Worse yet, from my perspective, most of those in our industry are only viewing the tip of the iceberg when it comes to looking at how to use Big Data — ignoring the massive amounts residing below the water's surface. The McKinsey Global Institute estimates the application of Big Data strategies *could* generate up to $100 billion in value annually across the U.S. healthcare system by optimizing innovation, improving the efficiency of R&D and clinical trials, and providing new tools for physicians, consumers, insurers, and regulators. Like a majority of the research and discussions surrounding the application of Big Data in the pharmaceutical and biopharmaceutical industries, the focus seems to be on that which garners the most attention (e.g., skyrocketing drug discovery and development costs or rising healthcare costs). It seems little attention is paid to the potential value that could be created in the U.S. healthcare system by being brilliant at the basics, such as manufacturing or shipping. Who cares how stylish a car is if it doesn't start?

A December 2013 *Harvard Business Review* article noted that most companies investing in data scientists, data warehouses, and data analytics software have little to show for their efforts. Why? Most companies don't do a good job of managing Big Data. Further, they don't know how to analyze it in ways that enhance understanding and then make changes in response to new insights. Jeanne Ross (MIT Sloan Center For Information Systems Research), Cynthia Beath (University of Texas at Austin), and Anne Quaadgras (MIT Sloan Center for Information Systems Research) say that until a company learns how to use data and analysis to support its *operating decisions,* it will not be in a position to benefit from Big Data. In other words, what is your core business and how can you apply Big Data to make evidenced-based decisions? UPS is an interesting example. The shipping company tracks data on more than 16 million packages per day for nearly 9 million customers from telematics sensors in over 46,000 vehicles. Why? To be able to determine trends (drop-offs and pickups) in real time and reconfigure the most efficient route of navigation. What kind of impact can this have? In 2011 UPS reported saving more than 8.4 million gallons of fuel by cutting 85 million miles off of daily routes. Not only does this improved efficiency make UPS "greener" and more sustainable, but it also translates into significant savings. UPS estimates saving just one daily mile driven per driver saves the company $30 million.

In order to help you improve your efficiencies in selecting a strategic partner for your drug development and manufacturing needs, we decided to put together some Big Data trends of our own via this special supplement. However, please don't let this data-driven research and analysis by Nice Insight prevent you from being brilliant at the basics. For example, when you are on a site tour, don't let a presentation on how a CMO is using Big Data analytics to improve manufacturing efficiencies prevent you from asking — " So, when was the roof last replaced/inspected?" Big Data, without application of intellect, doesn't make a good business decision model. L

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ONCOLOGY TRENDS IN 2014

The latest industry trends and proprietary data from Nice Insight survey results

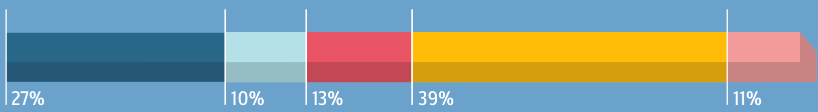
Outsourcing has proven to be valuable to biopharmaceutical companies of all sizes. And different types of drug makers, from virtual biotechs to Big Pharma, have implemented outsourcing programs for a variety of reasons. There are commonalities in both outsourcing motivations and practices across the various buyer groups, as well as differences. Knowing which services are outsourced by your peers, as well as which factors are most relevant to their outsourcing strategy, may add value to your organization's 2014 planning and future outsourcing initiatives.

RESPONDENT **PROFILE** INFORMATION

Research conducted by Nice Insight [n=886]

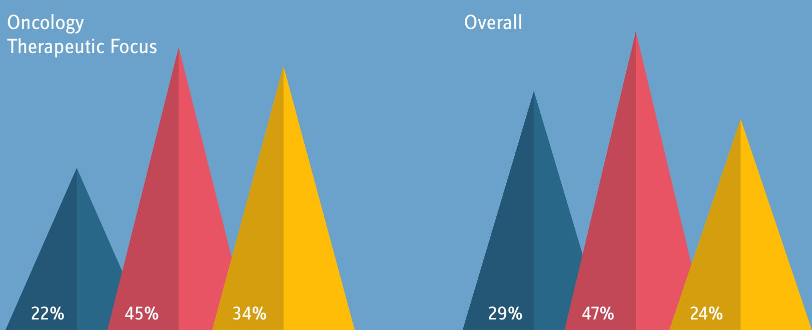
BY **COMPANY TYPE**

■ Biotech ■ Emerging Biotech ■ Specialty Pharma ■ Big Pharma ■ Emerging Pharma

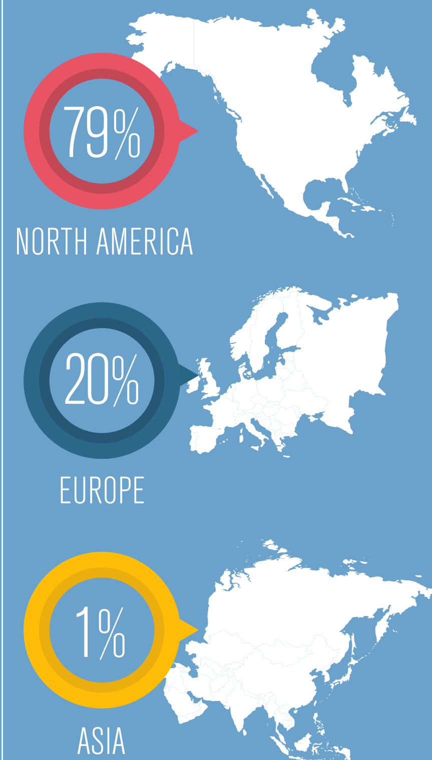


BY **ANNUAL OUTSOURCING EXPENDITURE**

■ Less than 10M USD per year ■ 10 to 50M USD per year ■ 50M+ USD per year



BY **REGION**



3.5 DIFFERENT THERAPEUTIC AREAS

Oncology drug developers will average 3.5 different therapeutic areas of focus for outsourced projects in the next 12 to 18 months

8.5 DIFFERENT SERVICES

Oncology drug developers are looking to outsource an average of 8.5 different services in the next 12 to 18 months

METHODS USED TO IDENTIFY **OUTSOURCING PARTNERS**

3.1 AVERAGE # OF METHODS USED TO SELECT AN OUTSOURCING PARTNER

OUTSOURCING **ONCOLOGY PROJECTS** TO **EMERGING MARKETS**

75% of respondents will consider CMOs in emerging markets for manufacturing projects

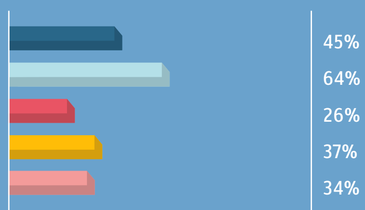
Biotech · Emerging Biotech · Big Pharma · Specialty Pharma · Emerging Pharma

Respondents Who Outsource Oncology Projects and Consider CMOs in Emerging Markets by Buyer Group

37% of respondents are already working with CMOs in emerging markets on manufacturing projects

Biotech · Emerging Biotech · Big Pharma · Specialty Pharma · Emerging Pharma

The Percentage by Buyer Group Who Are Already Working With CMOs in Emerging Markets on Oncology Projects



14% of respondents say the quality level is too risky to offshore manufacturing projects

Biotech · Emerging Biotech · Big Pharma · Specialty Pharma · Emerging Pharma

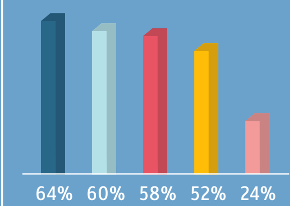
The Percentage by Buyer Group Who Believe the Quality Level Is Too Risky to Offshore Oncology Projects

MANUFACTURING SERVICES ENGAGED BY **ONCOLOGY OUTSOURCERS**

Development Services

26%

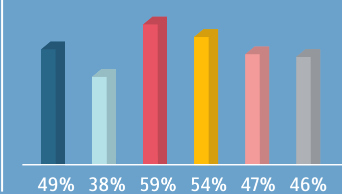
- Large Molecule API / Biologics
- Small Molecule API
- Injectables Product Development
- Solid Dose, Semi-Solids, & Liquid Development
- Other Delivery Forms (Inhalable / Transdermal)



Manufacturing Services

31%

- Large Molecule API / Biologics
- Small Molecule API & Advanced Intermediates
- Solid Dosage Forms
- Injectables
- Semi-Solids & Liquids
- Specialty Dosage Forms



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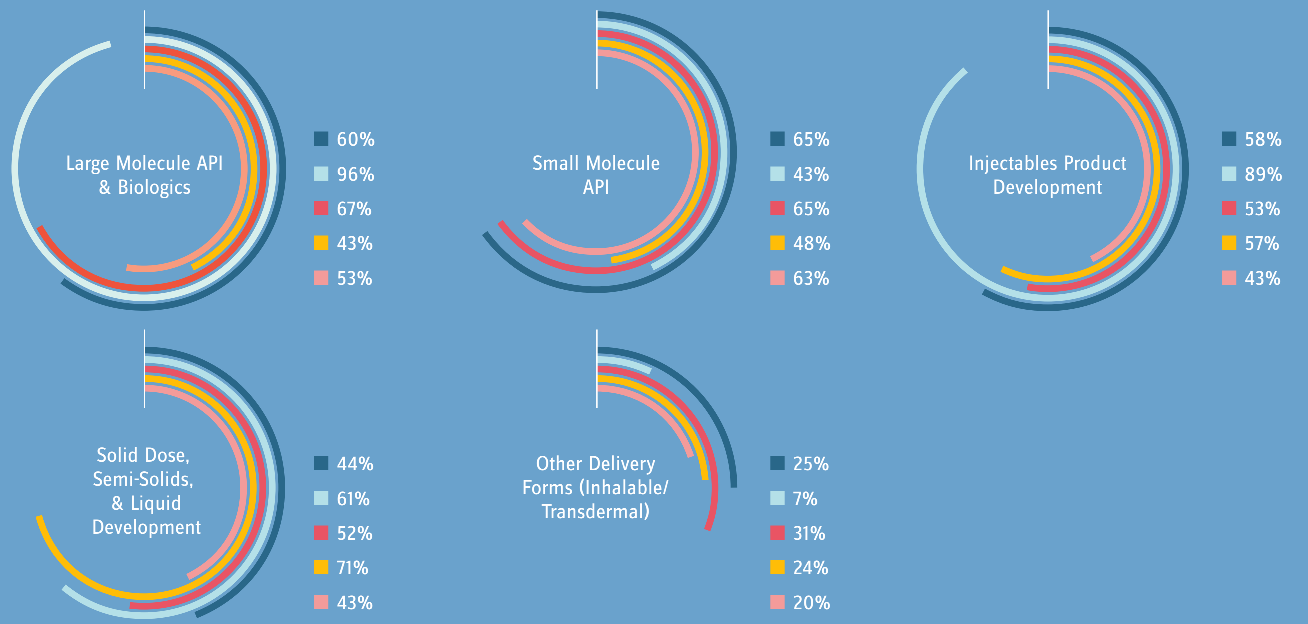
MANUFACTURING SERVICES ENGAGED BY **ONCOLOGY OUTSOURCERS**

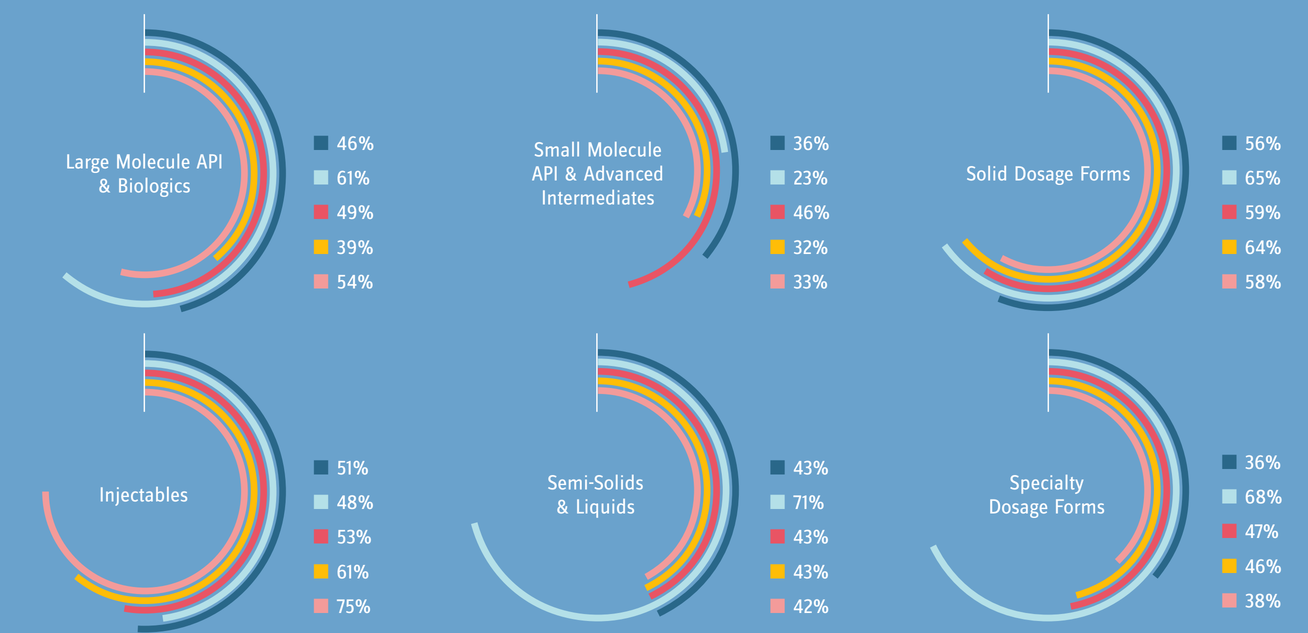
DEVELOPMENT SERVICES BY BUYER GROUP

■ Biotech ■ Emerging Biotech ■ Big Pharma ■ Specialty Pharma ■ Emerging Pharma



COMMERCIAL SCALE MANUFACTURING BY BUYER GROUP

■ Biotech ■ Emerging Biotech ■ Big Pharma ■ Specialty Pharma ■ Emerging Pharma



OUTSOURCING PREFERENCES & PRACTICES **ONCOLOGY PROJECTS**

OUTSOURCING **RELATIONSHIPS**

% of projects contracted to each type of outsourcing relationship

28% 39% 34%

- Tactical Service Provider
- Preferred Provider
- Strategic Partnership

INTEREST LEVEL IN A **STRATEGIC PARTNERSHIP**

49% 36% 15%

- Interested
- Neither interested nor uninterested
- Not interested

LEVEL OF INFLUENCE ON **CMO SELECTION**

HARD TRAITS

- Track record & History of success — 80%
- Experience — 80%
- Adaptability & flexibility with project needs — 76%
- Financial stability of the organization — 75%
- Range of services & service offering — 67%
- Risk-sharing opportunities — 54%
- Size & structure of the organization — 46%
- Geographic convenience & location — 46%
- Use of contractors in emerging markets to save costs — 45%

SOFT TRAITS

- Good communication & transparency — 81%
- Responsiveness — 81%
- Industry reputation for doing quality work — 80%
- Understanding of the customer's requirements — 80%
- Willingness to go the extra mile — 75%
- Adaptability to sponsor's desired methodology — 71%
- Rapport between teams — 70%
- References from colleagues or coworkers — 60%
- Cultural fit — 48%

An Update On The Buzz Around Oncology

KATE HAMMEKE Contributing Editor

The heightened interest in developing cancer treatments, combined with the R&D efforts put forth over the past decade, contributed to the emergence of a class of "smart bombs" first reported as one of their most hopeful developments at the American Society of Clinical Oncology's annual meeting in June of 2012. These medicines use antibodies that bond to specific cancer cells to deliver a very toxic drug directly to the cancerous cell, leaving healthy tissue alone.

In February of 2013, the FDA approved the first "smart bombs" to treat breast cancer, commercially known as Kadcyla and developed by Roche's Genentech.

The second major development reported at the time was some degree of success in using the body's own immune system to fight cancer, an idea that has been around for a century, but training the immune system to recognize the cancer cells as an "enemy" to attack had previously met with limited success. At present, there are still no FDA-approved drugs on the market that work using immunotherapy, but evidence from clinical trials testing PD-1 (a protein) blocking drugs have shown a "quantum leap" of progress. These potentially new kinds of therapies, combined with progress in diagnostic tests that help predict which medicines will work for which patients, are important tools in reducing cancer deaths and carry huge potential for the developers who bring them to market.

Eighteen oncology drugs were approved in 2012 (of 50 new drug approvals, including new molecular entities [NMEs] and biologic license applications [BLAs]), 12 in 2013 (of 41) and one so far in 2014. This success rate has remained steady for the past few years, where oncology drugs comprise roughly one-third of the new drugs approved, with 36 percent in 2012 and 29 percent in 2013. The large number of medicines being developed for oncology is no surprise, as cancer is still a leading cause of death in the United States, second only to heart disease. The vast market for cancer medicines has secured its position as a therapeutic area of focus for the drug development pipelines of 38 percent of all pharmaceutical and biotechnology businesses — up five percentage points in the past three years.

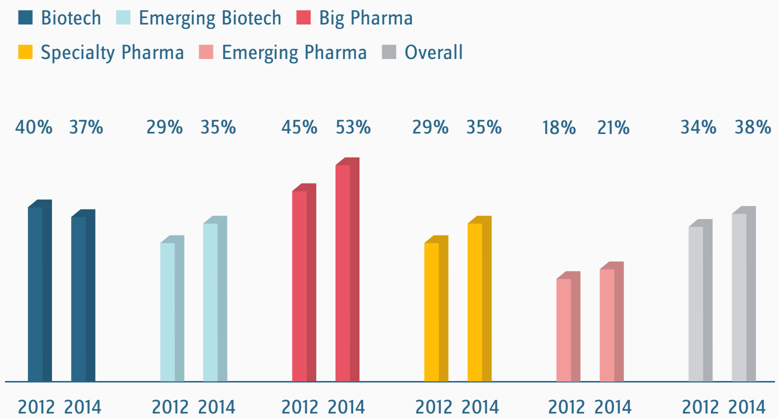
In looking at the various sponsor segments, the data shows that 53 percent of Big Pharma companies have oncology drugs in their development pipeline, up from 45 percent in 2012. Biotech follows with 37 percent, a slight drop from 40 percent in 2012. Specialty pharma and emerging biotechs have ramped up oncology drug development, with a six-percentage-point increase over 2012, both rising from 29 percent to 35 percent. Emerging Pharma companies had the smallest increase in developing oncology drugs, with a three-percentage-point increase from 18 to 21 percent.

SIGNIFICANT EXPENDITURE AND HEAVY OUTSOURCING MEAN MARKET INFLUENCE

The results from the Nice Insight pharmaceutical and biotechnology outsourcing survey show that sponsors whose pipeline includes oncology medicines have broadened the base and are looking to outsource projects across an average of 3.5 different therapeutic areas of focus, up from 2.25 in 2012. These respondents were identified as heavy outsourcers in 2012, averaging 6.9 different services, as compared to the overall average of 5.3. This continues to be true and has shown solid gains, with an average of 8.5 different services outsourced as compared to the overall average of 6.4.

This heavy outsourcing is still accompanied by substantial outsourcing expenditure; however, spending is not quite as high as it was in 2012 when 41% of businesses whose therapeutic area of focus is oncology diseases indicated they would spend more than $50M, as compared to 26 percent of the overall

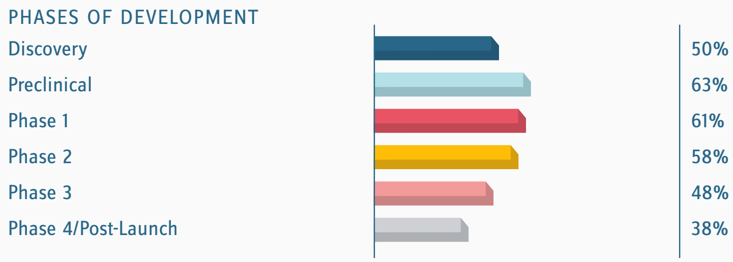
Oncology as a Therapeutic Area of Focus Among Each Buyer Group



Outsourcing Drivers as Prioritized by Oncology Outsourcers

OUTSOURCING DRIVERS	2012	2014
Quality	1	1
Reliability	2	2
Regulatory	3	3
Productive	4	4
Affordability	5	5
Innovative	6	6

The Percentage of Oncology Outsourcers That Engage Outsourcing Partners by Phase



Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to outsourcing-facing pharmaceutical and biotechnology executives on an annual basis. The 2013-2014 report includes responses from 2,337 participants. The survey comprises more than 240 questions and randomly presents ~35 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perceptions of the top 100+ CMOs and top 50+ CROs servicing the drug development cycle. Five levels of awareness, from "I've never heard of them" to "I've worked with them," factor into the overall customer awareness score. The customer perception score is based on six drivers in outsourcing: Quality, Innovation, Regulatory Track Record, Affordability, Productivity and Reliability. In addition to measuring customer awareness and perception information on specific companies, the survey collects data on general outsourcing practices and preferences as well as barriers to strategic partnerships among buyers of outsourced services.

respondent group. In 2013, this number decreased to 34 percent, as compared to 24 percent of the overall respondent group. In 2014, 45 percent indicated their expenditure would be between $10M and $50M, as compared to two years ago when 36 percent fell into this category. The percentage of respondents in the lowest-spending category remained the same — at 22 percent — from 2012 to 2014.

These traits — significant expenditure and heavy outsourcing — give the group considerable influence over the market size of the services they outsource. For this reason, among others, it pays to gain some traction in this therapeutic area. Four out of every five respondents prioritized a CMO's "Track record/History of success" with the highest level of importance when considering an outsourcing partner. Further, therapeutic experience adds appeal to a CMO's position as a strategic partner. L

Kate is the director of marketing intelligence for Nice Insight, the research division of That's Nice. Kate runs all custom market research for the company, and she designed the first industrywide study on selecting outsourcing partners during the drug development cycle for the pharmaceutical and biotechnology sector. Kate continues to update the Nice Insight CRO/CMO research according to evolving industry trends, and she works on the development of Nice Insight's new subscription product on the excipients market. Kate has developed and coordinated custom research projects for more than 30 major brands in the Fortune 500. Using her industry knowledge, Kate has written dozens of articles related to pharmaceutical outsourcing for five industry magazines. She is a monthly contributor to *Life Science Leader* magazine, authoring the column "Outsourcing Insights."

BIOMANUFACTURING TRENDS IN 2014

The latest industry trends and proprietary data from Nice Insight survey results

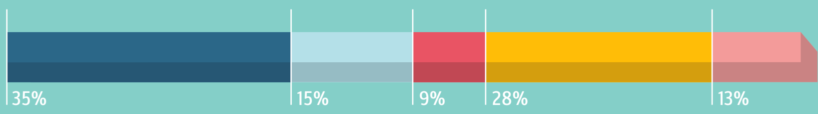
The drug development industry is motivated to invest in developing biopharmaceuticals as a form of pipeline security because these products have demonstrated profitability. The practice of partnering with or acquiring biopharmaceutical companies is mirrored in the results of the Nice Insight Pharmaceutical and Biotechnology Outsourcing survey, where 73 percent of respondents stated the company they work for engages in the development of biologics-based therapeutics. These respondents will spend more than half of their outsourcing budget on the development of biologics – 57 percent compared to 43 percent of the outsourcing budget spent on conventional therapeutics.

RESPONDENT **PROFILE** INFORMATION

Research conducted by Nice Insight [n=643]

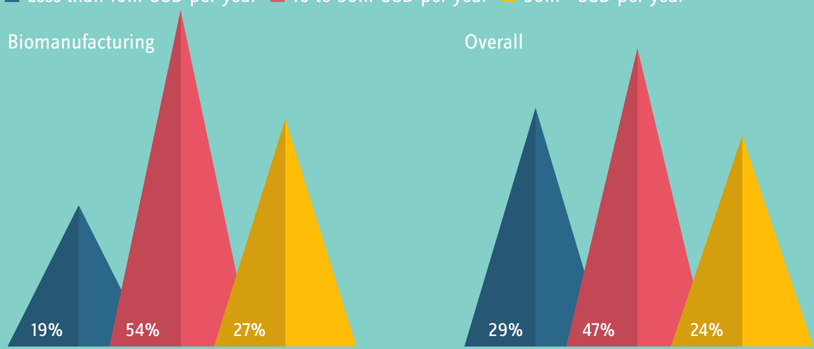
BY **COMPANY TYPE**

■ Biotech ■ Emerging Biotech ■ Specialty Pharma ■ Big Pharma ■ Emerging Pharma

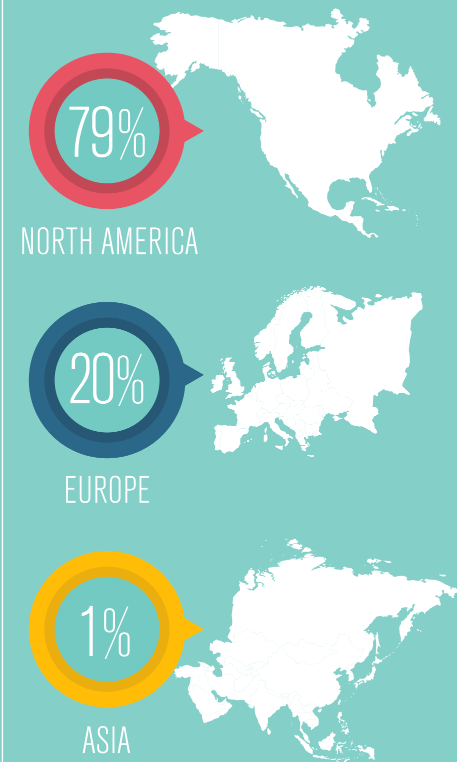


BY **ANNUAL OUTSOURCING EXPENDITURE**

■ Less than 10M USD per year ■ 10 to 50M USD per year ■ 50M+ USD per year



BY **REGION**



3.1 DIFFERENT THERAPEUTIC AREAS

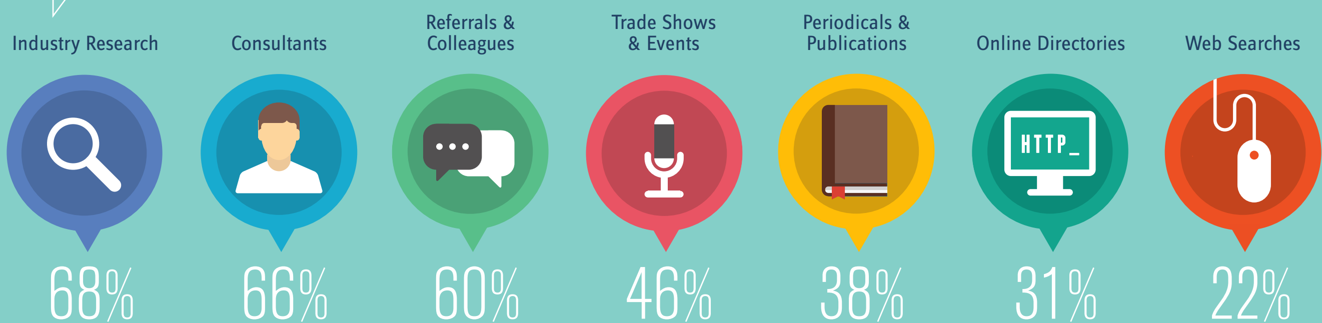
Biomanufacturing outsourcers average 3.1 different therapeutic areas of focus for outsourced projects in the next 12 to 18 months

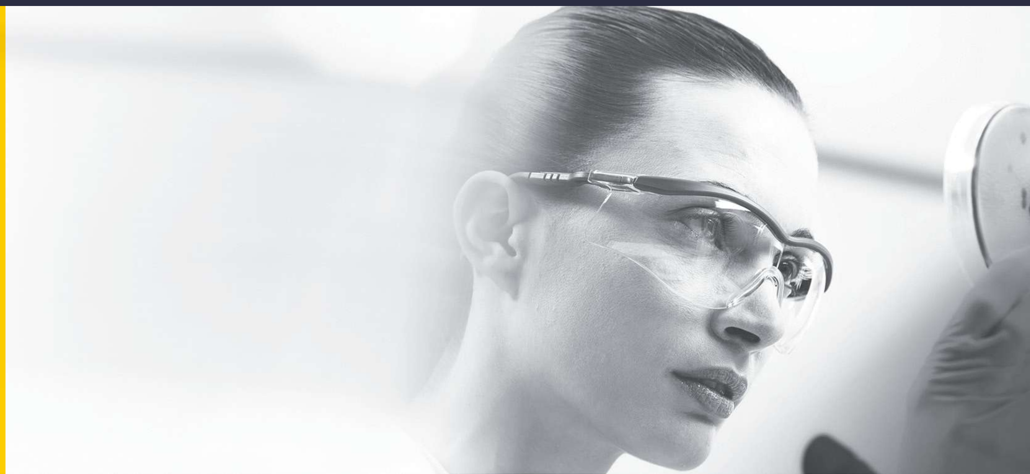
10.1 DIFFERENT SERVICES

Biomanufacturing outsourcers are looking to outsource an average of 10.1 different services in the next 12 to 18 months

METHODS USED TO IDENTIFY **OUTSOURCING PARTNERS**

3.3 AVERAGE # OF METHODS USED TO SELECT AN OUTSOURCING PARTNER





OUTSOURCING **BIOMANUFACTURING** TO **EMERGING MARKETS**

85% of respondents will consider CMOs in emerging markets for manufacturing projects

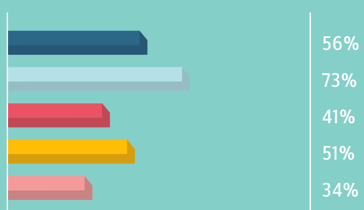
Biotech | Emerging Biotech | Big Pharma | Specialty Pharma | Emerging Pharma

The Percentage by Buyer Group Who Would Consider Outsourcing to CMOs in Emerging Markets

51% of respondents are already working with CMOs in emerging markets on manufacturing projects

Biotech | Emerging Biotech | Big Pharma | Specialty Pharma | Emerging Pharma

The Percentage by Buyer Group Who Are Already Working with CMOs in Emerging Markets on Biomanufacturing



9% of respondents say the quality level is too risky to offshore manufacturing projects

Biotech | Emerging Biotech | Big Pharma | Specialty Pharma | Emerging Pharma

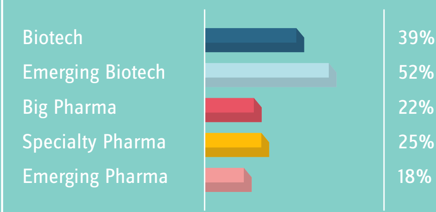
The Percentage by Buyer Group Who Believe the Quality Level Is Too Risky to Offshore Biomanufacturing Projects

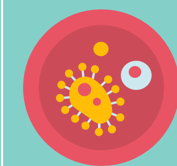
BIOMANUFACTURING SERVICES OUTSOURCED

Mammalian Cell Culture

53%

The Percentage of Respondents Who Outsource Mammalian Cell Culture Services to Emerging Market CMOs by Buyer Group

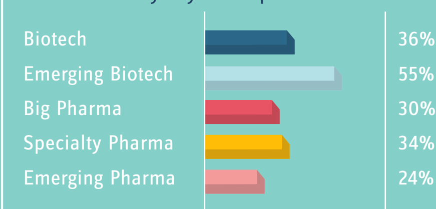




Microbial Manufacturing

65%

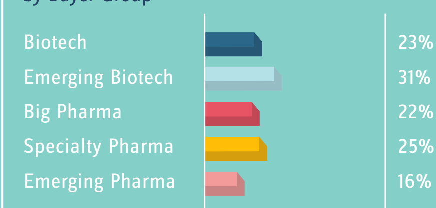
The Percentage of Respondents Who Outsource Microbial Manufacturing Services to Emerging Market CMOs by Buyer Group



Vaccines

40%

The Percentage of Respondents Who Outsource Vaccine production to Emerging Market CMOs by Buyer Group



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Email: diezzi@therapurebio.com

OUTSOURCING PREFERENCES & PRACTICES **BIOMANUFACTURING PROJECTS**

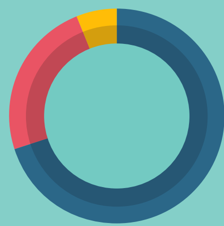
OUTSOURCING **RELATIONSHIPS**

% of projects contracted to each type of outsourcing relationship

32% 36% 32%

- Tactical Service Provider
- Preferred Provider
- Strategic Partnership

INTEREST LEVEL IN A **STRATEGIC PARTNERSHIP**



70% 24% 6%

- Interested
- Neither interested nor uninterested
- Not interested

LEVEL OF INFLUENCE ON **CMO SELECTION**

HARD TRAITS

- Track record & history of success 77%
- Experience 77%
- Financial stability of the organization 77%
- Adaptability & flexibility with project needs 72%
- Range of services & service offering 68%
- Risk sharing opportunities 57%
- Use of contractors in emerging markets to save costs 55%
- Geographic convenience & location 53%
- Size & structure of the organization 51%

SOFT TRAITS

- Good communication & transparency 79%
- Responsiveness 78%
- Industry reputation for doing quality work 77%
- Understanding of the customer's requirements 77%
- Willingness to go the extra mile 73%
- Adaptability to sponsor's desired methodology 72%
- Rapport between teams 69%
- References from colleagues or coworkers 61%
- Cultural fit 50%

Outsourcing Biomanufacturing Continues To Grow In Frequency

KATE HAMMEKE Contributing Editor

Nice Insight has learned from its strategic partnering surveys that the long-term strategies of many businesses in the pharmaceutical industry for maintaining a strong drug development pipeline include integration of biopharmaceuticals.

This integration can take several different forms, from partnerships with large biopharmas (56 percent), purchase of a small biopharma company (51 percent), partnering with a small biopharma (37 percent), or simply purchasing a biopharma's compounds (22 percent). These activities are motivated by the demonstrated profitability of biopharmaceuticals. The practice of partnering with or acquiring biopharmaceutical companies is mirrored in the results of Nice Insight's annual survey, where the percentage of respondents whose businesses are engaged in the development of biologic-based therapeutics continues to increase — up two percentage points from 71 percent in 2012 to 73 percent in 2014.

Spend on biologics development now consumes a slightly larger portion of these businesses' annual expenditure as well: 57 percent in 2014 as compared to 54 percent in 2012. Such expenditure continues to show promise for contract service providers both in winning outsourced biomanufacturing projects and in manufacturing biosimilars/bioequivalents for the biologics that come off patent in the coming decade. Now is a good time to start considering CMOs for these projects.

OVERALL EXCELLENCE IN CUSTOMER PERCEPTION PLAYS A STRONG ROLE IN CMO SELECTION

Interest in identifying quality suppliers for biomanufacturing services prompted the expansion of Nice Insight's research to include specific questions about buyers' habits when outsourcing mammalian and microbial manufacturing, as well as their supplier preferences. According to the 2014 study, 53 percent of respondents who will outsource biomanufacturing would engage a CMO for mammalian cell culture. In reviewing the companies that were most likely to be considered for this type of project, it was clear that overall excellence in customer perception played a strong role. In fact, these companies averaged excellent ratings (between 80 and 100 percent) from respondents who outsource mammalian cell culture in four out of five categories. Quality was the single category where scores fell slightly below the excellent range (by 2 percentage points). The top companies considered for mammalian cell culture projects were GSK Contract Manufacturing, Boehringer Ingelheim, CMC Biologics, Lonza, and KBI Biopharma.

Microbial manufacturing was reported to be outsourced with greater frequency than mammalian cell culture, with nearly two-thirds of respondents who will outsource biomanufacturing reporting they would outsource microbial manufacturing (65 percent). Three of the companies that were most likely to be considered for mammalian cell culture also made the top five for microbial manufacturing: GSK Contract Manufacturing, Boehringer Ingelheim, and Lonza. Pfizer CentreSource and Althea rounded out the top five companies most likely to be considered for a microbial manufacturing project. While the highest scores among the top five companies were in reliability and regulatory, these companies averaged excellent scores in all five categories.

Nice Insight also reviewed the scores from a broader group of CMOs for both mammalian cell culture and microbial manufacturing to see where these companies received their highest scores.

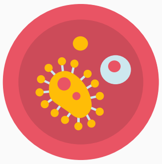
OUTSOURCING BIOMANUFACTURING CONTINUES TO GROW IN FREQUENCY

By K. Hammeke

Among Respondents Who Will Outsource Biomanufacturing

Mammalian Cell Culture

53%



Microbial Manufacturing

65%

Top Five Companies Considered for Mammalian Cell Culture Projects

PERCENTILE RANK	
GlaxoSmithKline Biopharmaceuticals	97%
Boehringer Ingelheim GmbH	97%
CMC Biologics	94%
Lonza	91%
KBI Biopharma	88%

AVERAGE SCORE AMONG TOP 5	
Quality	78%
Reliability	81%
Innovation	81%
Productivity	81%
Regulatory	81%
Overall Customer Perception (CP) Score	80%

Top Five Companies Considered for Microbial Manufacturing Projects

PERCENTILE RANK	
GlaxoSmithKline Biopharmaceuticals	99%
Boehringer Ingelheim GmbH	95%
Pfizer CentreSource	94%
Althea	74%
Lonza	68%

AVERAGE SCORE AMONG TOP 5	
Quality	80%
Reliability	83%
Innovation	81%
Productivity	81%
Regulatory	83%
Overall CP Score	82%

The data showed that among microbial manufacturing CMOs, the companies received their best scores in Reliability and Regulatory. For mammalian cell culture CMOs, the best scores across the group were in Reliability and Innovation. It will be interesting to see from future research if CMOs increase the chances of being considered for a project if they improve on these outsourcing measures.

The percentage of new drugs to market that are biologic based continues to rise — from 26 percent of new approvals in 2011 to 29 percent in 2013 — which means it's a good time to identify prospective outsourcing partners and begin to develop relationships. Consideration of the companies mentioned above is a good start, but doing so may end up costing more than joining forces with a smaller, lesser-known CMO. In which case, outsourcers of microbial manufacturing can start by looking for contract manufacturers with strong Reliability and Regulatory scores. Those looking to engage a CMO for mammalian cell culture should look for companies with strong Reliability and Innovation scores, or select one of the most frequently considered companies that showed excellence across four categories. L

Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to outsourcing-facing pharmaceutical and biotechnology executives on an annual basis. The 2013-2014 report includes responses from 2,337 participants. The survey is comprised of 240+ questions and randomly presents ~35 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perceptions of the top 100+ CMOs and top 50+ CROs servicing the drug development cycle. Five levels of awareness from "I've never heard of them" to "I've worked with them" factor into the overall customer awareness score. The customer perception score is based on six drivers in outsourcing: Quality, Innovation, Regulatory, Affordability, Productivity and Reliability. In addition to measuring customer awareness and perception information on specific companies, the survey collects data on general outsourcing practices and preferences as well as barriers to strategic partnerships among buyers of outsourced services.

REPORT | EXCLUSIVE LIFE SCIENCE FEATURE

2014 TRENDS AMONG EMERGING / NICHE & START-UP BUYERS

The latest industry trends and proprietary data from Nice Insight survey results

Research from Nice Insight's pharmaceutical and biotechnology outsourcing survey has shown that buyers of outsourced services have differing viewpoints when it comes to strategic partnerships. The research explores how phase of development or the services outsourced factor into a buyer's desire to form a strategic partnership. The data has also shown that company type, such as Big Pharma vs Biotech, and company size play an important role in identifying the right CMO for a project or partnership.

RESPONDENT **PROFILE** INFORMATION

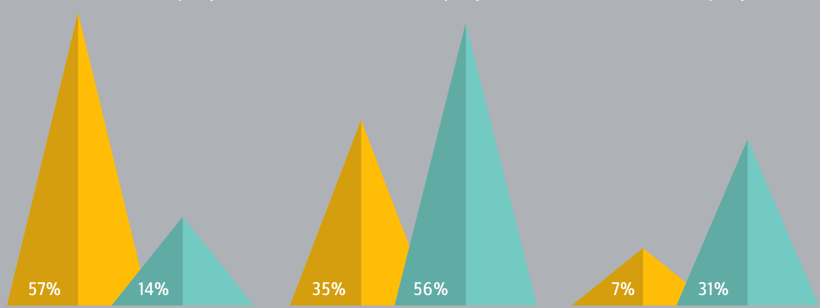
Research conducted by Nice Insight [n=713]

BY **COMPANY TYPE**

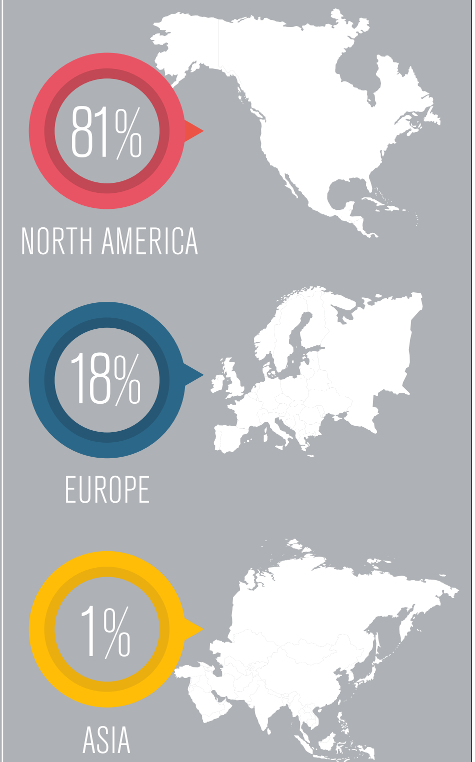
■ Emerging Pharma ■ Emerging Biotech

BY **ANNUAL OUTSOURCING EXPENDITURE**

■ Emerging Pharma ■ Emerging Biotech



BY **REGION**



Average # of different therapeutic areas of focus for outsourced projects in the next 12 to 18 months

1.8 Emerging Pharma

2.7 Emerging Biotech

Average # of different services companies will outsource in the next 12 to 18 months

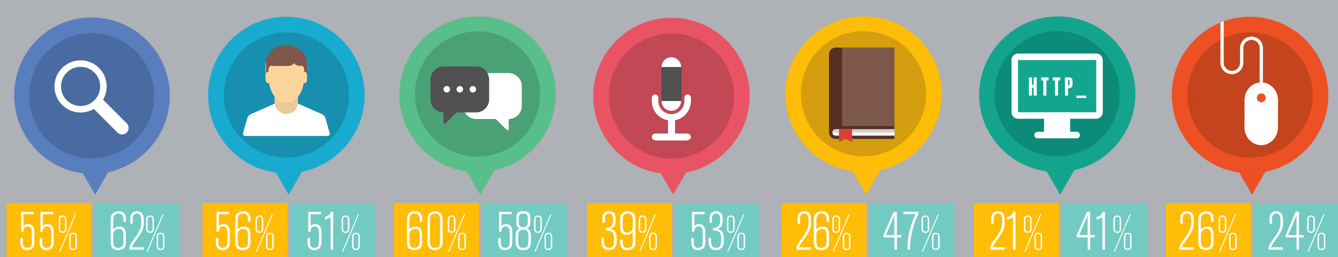
5.5 Emerging Pharma

7.6 Emerging Biotech

METHODS USED TO IDENTIFY **OUTSOURCING PARTNERS**

3.4 AVERAGE # OF METHODS USED TO SELECT AN OUTSOURCING PARTNER

■ Emerging Pharma ■ Emerging Biotech



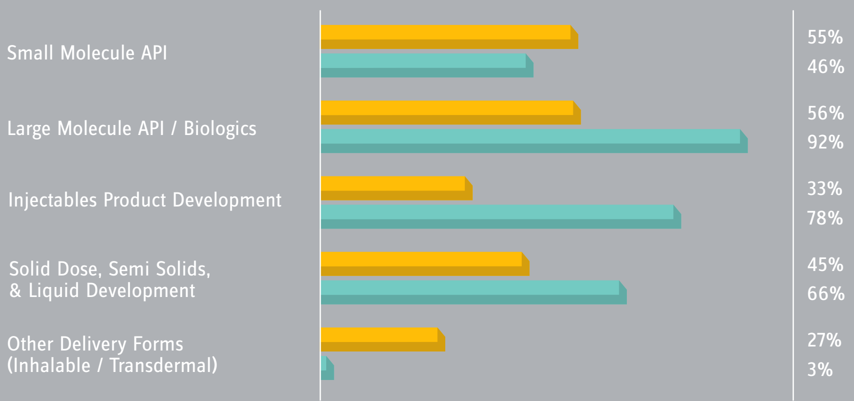
MANUFACTURING SERVICES ENGAGED BY **EMERGING/ NICHE & START-UP BUYERS**

Development & Phase I/II Clinical Trial Material Services

17% Emerging Pharma **24%** Emerging Biotech

Development Services by Buyer Group

Emerging Pharma Emerging Biotech

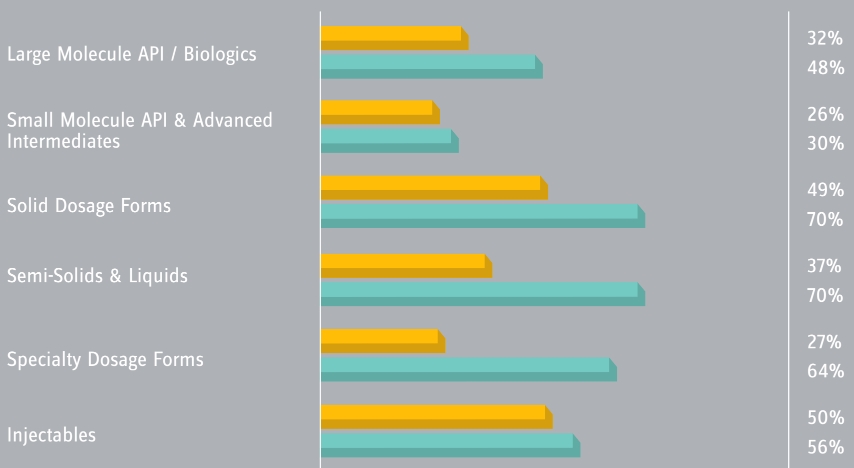


Commercial Scale Manufacturing Services

22% Emerging Pharma **25%** Emerging Biotech

Manufacturing Services by Buyer Group

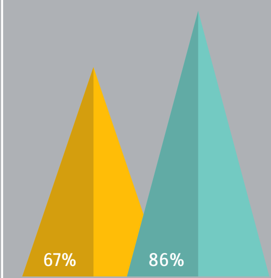
Emerging Pharma Emerging Biotech



OUTSOURCING TO EMERGING MARKETS AMONG **EMERGING/ NICHE AND START-UP BUYERS**

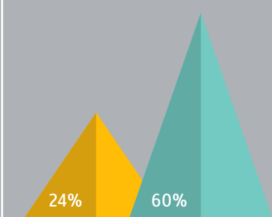
Emerging/Niche & Start-up Buyers Who Would Consider CMOs in Emerging Makets

Emerging Pharma Emerging Biotech



The Percentage Who Are Already Working With CMOs in Emerging Markets

Emerging Pharma Emerging Biotech



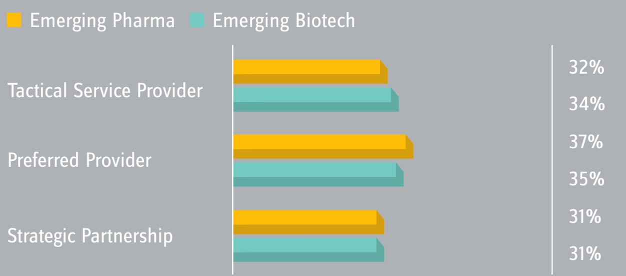
The Percentage Who Believe the Quality Level Is Too Risky

Emerging Pharma Emerging Biotech

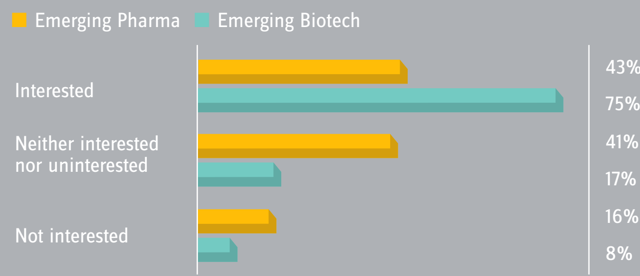
OUTSOURCING PREFERENCES & PRACTICES AMONG **EMERGING/ NICHE AND START-UP BUYERS**

OUTSOURCING **RELATIONSHIPS**

% of projects contracted to each type of outsourcing relationship



INTEREST LEVEL IN A **STRATEGIC PARTNERSHIP**



LEVEL OF INFLUENCE ON **CMO SELECTION**

Emerging Pharma / Emerging Biotech

HARD TRAITS

Trait	Emerging Pharma	Emerging Biotech
Track record & History of success	77%	64%
Risk sharing opportunities	49%	56%
Experience	70%	72%
Use of contractors in emerging markets to save costs	43%	58%
Adaptability & Flexibility with project needs	72%	69%
Geographic convenience & location	47%	52%
Financial stability of the organization	69%	71%
Size & structure of the organization	39%	53%
Range of services & Service offering	61%	61%

SOFT TRAITS

Trait	Emerging Pharma	Emerging Biotech
Good communication & transparency	78%	70%
Rapport between teams	64%	64%
Understanding of the customer's requirements	76%	68%
Adaptability to sponsor's desired methodology	59%	68%
Responsiveness	75%	67%
References from colleagues or coworkers	57%	64%
Industry reputation for doing quality work	73%	66%
Cultural fit	41%	54%
Willingness to go the extra mile	70%	68%

Following The Lead From Big Pharma Or Biotech May Not Identify The Right Supplier For Emerging/Niche Or Start-Up Companies

KATE HAMMEKE Contributing Editor

A couple of years ago, Nice Insight explored how the essential qualities for outsourcing relationships varied between large and midsized companies, in addition to traditional pharma companies versus biotechs. As one would imagine, these essentials differ quite a bit from emerging or start-up companies, as their needs when it comes to outsourcing are different from larger companies.

Oftentimes the company is too new to the industry to have a well-established process for selecting providers or a track record of what has worked well in the past. To further complicate matters, it is not uncommon for senior leadership at start-up companies to have a history at a Big Pharma or biotech and to be brought on for their expertise — which is a strong positive in many aspects of running a successful business but not necessarily in finding the right type of outsourcing partner.

Folks in the biopharmaceutical industry know that identifying which qualities make the greatest contribution to a positive relationship with an outsourcing partner is an ongoing and ever-changing process. The fluid nature of the drug development industry – one that is constantly adapting to new health challenges, technologies, and regulations – is part of what makes it so difficult to outline which attributes in a contract manufacturer should be prioritized so that the relationship functions like a strategic partnership in which both the buyer and CMO benefit. The continual transformation of drug development reiterates the importance of keeping an open mind and learning from the successes of one's industry peers. That way, the pressure to find the right business for a project diminishes and is replaced by confidence in finding a company with the right mix of attributes that will make for a successful long-term partnership.

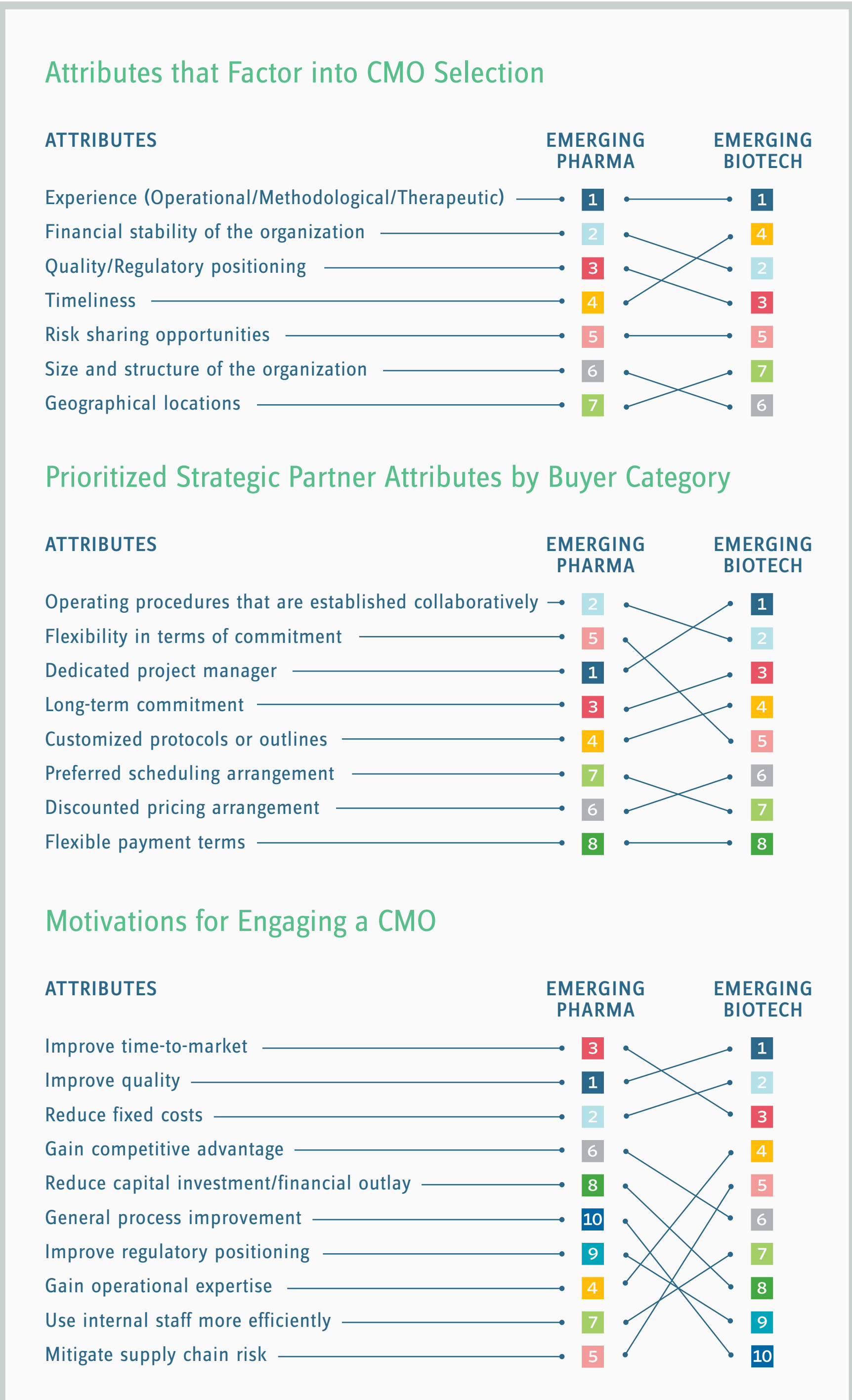
PRACTICES OF EMERGING PHARMA AND EMERGING BIOTECH COMPANIES DIFFER

Nice Insight reviewed the outsourcing behaviors and strategic partnering preferences of respondents who work at emerging / niche or start-up pharmaceutical companies and those who work at emerging or virtual biotechs to see how these smaller businesses identify CMOs and develop mutually beneficial relationships. Starting with the methods used to identify potential outsourcing partners, Nice Insight found that the practices of emerging pharma companies and emerging biotechs differ. Emerging pharma relies on referrals from colleagues as their main resource (60 percent), whereas emerging biotechs use industry research to identify potential CMOs (62 percent). Emerging pharma companies are more likely to seek advice from consultants on outsourcing (56 percent as compared to 51 percent of emerging biotechs), while emerging biotechs are more likely to seek out suppliers at trade shows than emerging pharma companies (53 percent vs. 39 percent).

The primary reason for engaging contract manufacturers — improving quality — was consistent between emerging pharma, Big Pharma, and Biotech companies; however, among emerging biotech respondents, this trait came in second after improving time to market. It is no surprise that cost savings are a key factor in outsourcing. Whether it is decreasing fixed costs or capital investment, reducing financial outlay proved important among established and emerging companies and for both traditional pharma and biotechs.

An interesting area where outsourcing motivations diverged between emerging companies is the desire to gain operational expertise: prioritized fourth among emerging pharma companies but ranked eighth among emerging biotech companies. Mitigating supply

By K. Hammeke



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chain risk carried greater importance among emerging pharma companies than among emerging biotechs (5th position vs. 10th). Conversely, emerging biotech companies ranked general process improvement much higher than emerging pharma (6th position vs. 10th).

When it comes to selecting a CMO, the number one factor for both emerging pharma companies and emerging biotechs is experience. Experience is one of two common rankings between these two buyer groups, the other being "risk sharing opportunities" in fifth position. Emerging pharma placed the CMO's financial stability over quality and timeliness (3rd and 4th, respectively), whereas emerging biotechs ranked financial stability after those merits, identifying quality/regulatory positioning as their second priority, followed by timeliness. Neither emerging pharmas nor emerging biotechs placed much importance on the size and structure of the CMO or its geographical location.

As a contract manufacturer, you should apply this knowledge to pitch the right company strengths to the relevant audience in key sales communications, which will more strategically position your business. Emerging companies that understand how other buyers identify and prioritize CMO qualities before engaging a provider can eliminate some of the trial and error elements of vendor selection and serve as an advantage with respect to strategic decision making in outsourcing. L

N. WALKER S.FAZZOLARI

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