PharmTech.com
ESSENTIAL INSIGHTS FOR PHARMA MANUFACTURING

February 1, 2011

Strategies for Becoming a Preferred Provider

By Angie Drakulich

A contract-service provider roundtable, featuring Albemarle, Baxter, DPT, Pfizer CentreSource, Dr. Reddy's, SAFC, and Vetter

This article is part of a special issue [http://special issue |~pharmtech.findpharma.com/pharmtech/issue /issuedetail.jsp?id=19830] on Preferred Providers.

This special supplement to *Pharmaceutical Technology* acknowledges the growing emphasis throughout the pharmaceutical outsourcing arena on being a strategic, or preferred, provider. We gathered input from leading contract-service providers to understand the drivers behind this trend and how it's affecting outsourcing. Participants include: David DeCuir, director of fine chemistry R&D at Albemarle; Brik Eyre, general manager of Baxter's BioPharma Solutions business; Paul Josephs, vice-president of sales and marketing at DPT; Hans Engels, president of DSM Pharmaceuticals; Michael J. Kosko, president of Pfizer CentreSource (PCS); R. Ananthanarayanan, president of Pharmaceutical Services and Active Ingredients (PSAI) at Dr. Reddy's; Mark Cassidy, vice-president of SAFC Contract Manufacturing Services; and Peter Soelkner, managing director of Vetter Pharma International GmbH.

Drivers behind supplier consolidation

PharmTech: There seems to be an overall trend in recent years by pharmaceutical companies to consolidate their supplier base (i.e., to work with fewer and more strategic suppliers). Have you observed this trend, and if so, what factors are driving the change? Are large pharmaceutical companies primarily pursuing this business model or is it prevalent among smaller drug companies as well?


David DeCuir, director of fine chemistry R&D at Albemarle

DeCuir (Albemarle): Yes, we have observed this trend, or at least have heard major pharma companies talk about this. I believe it has to do with difficulty of cultivating working relationships with multiple suppliers. In addition, there is always a learning curve when working with new suppliers and some pharma companies are on a very tight production schedule. We see it mostly from larger pharma, although many smaller companies continue to work with just a few suppliers because occasionally, they lack the staffing to find and develop new suppliers and may be unwilling to devote extra resources if their needs are being met.


Brik Eyre, general manager of Baxter's BioPharma Solutions business

Eyre (Baxter): We're in the midst of a great deal of change in the global economy. Pharmaceutical companies are assessing the effectiveness of their strategies with limited resources, while still achieving the commercialization objectives for their pipeline. Regardless of the company size, use of external resources has long been embraced as an effective strategy to gain efficiency and flexibility, but we have seen a shift from the utilization of service providers to the integration of service providers. In the past, utilization of external vendors was driven by the perception that service providers were essentially interchangeable. This perception is why so many pharmaceutical companies maintained ties with a large number of service providers for long periods of time. Coupling the economic crisis with the increased scrutiny on oversight of partners, managing multiple suppliers proves to be a costly and complex task that is no longer viable. Therefore, the adoption of supplier management standards and increased need of a broader set of services from a consolidated set of strategic partners is occurring.

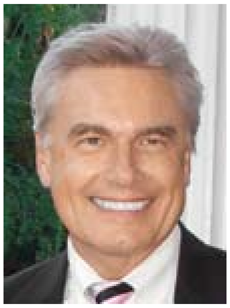
Within the sterile drug-manufacturing marketplace, in particular, manufacturing is capital intensive. As a result, many companies have chosen to access this competency by partnering with a supplier that has a demonstrated track record within the specialized manufacturing process to avoid investments in this aspect of commercialization. This is especially true of certain types of molecules, such as cytotoxics or highly potent compounds, which have considerable containment and safety standards. In addition, by selectively partnering with a supplier with a broad portfolio of solutions, companies gain access to a range of options across a product's life cycle.

In our experience, there continues to be an understanding that external partnerships provide the most value when objectives are clearly understood and aligned. This allows the service provider to elucidate the objectives of the partner and provide tailored and applicable solutions. This mindset dictates a closer working relationship so that the most value is provided to each party. Because of this increased commitment, the logical extension of this philosophy has been a reduction in the number of relationships maintained among pharmaceutical companies and their partners.

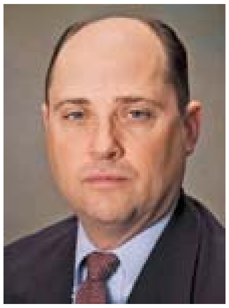

Paul Josephs, vice-president of sales and marketing at DPT

Josephs (DPT): We have observed the trend of pharmaceutical companies consolidating their supplier base, primarily due to mergers among major pharmaceutical companies. In many cases, the mergers led to an initial growth of the supplier base. Since that situation is unsustainable, there is a conscious effort to reduce the supplier base down to a manageable level and use preferred suppliers. Increased pressure in the industry to reduce costs and lower overhead has also factored into consolidation.

Although the true preferred-provider relationship concept has been talked about for several years, it's really taken off in the past one to two years. I would say large pharmaceutical companies are driving the trend because they have more products to leverage. Smaller companies are more concerned with finding an expert with regard to a certain technology.


Hans Engels, president of DSM Pharmaceuticals

Engels (DSM): Consolidation of vendors is a definite Big Pharma trend and the reasons behind it are the drive for efficiency and more leverage for the big pharmaceutical firms to get things done in a way that they desire (e.g., approach to quality and compliance and additional cost leverage). The typical approach is to reduce the number of suppliers by 50% or more. An unsolved challenge of this consolidation goal as a result of mergers and acquisitions is how to handle new products with an established manufacturing base.


Michael J. Kosko, president of Pfizer CentreSource (PCS)

Kosko (PCS): Pfizer CentreSource has seen a strong trend during the past few years toward pharmaceutical companies reducing their number of vendors, and our business development colleagues have seen this trend apply to both large and small pharmaceutical companies with locations in the US, Europe, and Asia. One factor driving the approach is industry consolidation. Acquisitions have brought together companies with different sourcing philosophies and supply chains. Efficiently managing these merged organizations going forward requires that this issue be addressed. Additional drivers for vendor consolidation include the pursuit of improved performance in the areas of supply, quality, and service as well as cost.


R. Ananthanarayanan, president of Pharmaceutical Services and Active Ingredients (PSAI) at Dr. Reddy's Laboratories

Ananthanarayanan (Dr. Reddy's): We have observed a strong trend, particularly among mid- to large-sized pharmaceutical companies to consolidate their supplier base and to work with more strategic suppliers. From our interaction with customers and with the industry, one of the significant reasons for the consolidation is to incorporate an outsourcing strategy that creates a more intimate relationship with the supplier. This allows the pharmaceutical company to understand the suppliers' operations in a more detailed way, influence how the operations are being run, and enhance cost effectiveness along the way. Other organizations that are less strategic in their outsourcing efforts are reducing the number of suppliers that they work with as a mean of controlling their own internal resources, such as staff to manage suppliers and tighter control of their spend. While this is not a new concept, over the past couple of years, the effectiveness of the pharma organizations to execute against this kind of strategy has evolved.


Mark Cassidy, vice-president of SAFC Contract Manufacturing Services

Cassidy (SAFC): In recent years, SAFC has definitely observed a trend for medium and large pharmaceutical companies to consolidate their supplier base and move toward identifying and selecting strategic vendors. There are certainly cost savings in managing and working with fewer suppliers. Also, the trend for many companies is to take more of a partnership approach with suppliers, as opposed to basic outsourcing of activities. To achieve better results and efficiencies, selecting vendors that will fit into the strategic partnership model is an important factor in the overall program. For example, when outsourcing GMP active pharmaceutical ingredient manufacturing, it becomes much more efficient to have two or three strategic contract manufacturing organizations (CMOs) already identified, with master service agreements, clearer expectations, communication standards, and relationships in place to complete the work more quickly and efficiently.


Peter Soelkner, managing director of Vetter Pharma International GmbH

Soelkner (Vetter): We have noticed that strategic partnerships have become even more important for pharmaceutical and biotech companies. They are increasingly interested in working with partners in long-term and strategic projects and have begun setting up programs to assess and choose preferred suppliers. In the process, manufacturers are continuously screening suppliers, creating databases, and using electronic bidding with the goal of creating a base of two or three qualified service providers. They also evaluate existing suppliers with scorecards and key performance indicators, such as adherence to cycle time, supply-plan adherence, or compliant-closure adherence.

Several factors have led to this development. First, a number of product patents will be expiring in the coming years. This is exacerbated by the fact that the pipelines of many companies are simply unable to compensate for this loss. They are trying to find a solution by acquiring or merging with other companies. Competitive pressure is increasing as well, leading many companies to look for growth in the emerging pharmaceutical markets. For the established markets of the US, Europe, and Japan, growth is expected to continue. Therefore, to take advantage of opportunities and savings potential, manufacturers are banking on preferred suppliers. Even the smaller biotech firms and start-ups are increasingly recognizing the advantages of strategic partnerships. For them, what's more important are CMOs that are able to support them in the development of new products. This level of cooperation and partnering allows a more seamless transfer to commercial manufacturing after products have passed clinical studies.

Preferred provider–sponsor company relationships

PharmTech: From a contract-service provider perspective, how has supplier consolidation affected the pharmaceutical contract environment, including the expectations and nature of the outsourced relationship? When a contract service provider becomes a so-called preferred provider, how might its relationship with the sponsor change?

DeCuir (Albemarle): In this case, the service supplier has more opportunities, but occasionally this means that the sponsor's need is outside the supplier's core expertise. Frequent communication is key and must be combined with a positive working relationship, including among technical staff. It is important to stay abreast of future trends and products. Having a larger presence with a customer, however, can be a double-edged sword. On the one hand, your customer becomes more valuable to you, but on the other hand, your importance to the customer increases and that changes the balance of power somewhat in your favor.

Eyre (Baxter): A strategic relationship requires an increased level of commitment from both parties. In our view, this needs to be considered as an investment by both parties with the goal of establishing a relationship that provides both organizations with additional value. These types of relationships are not simple and require a high degree of experience and knowledge, as well as clear communication practices to ensure proper alignment of goals.

What hasn't changed despite the trend is the fact that pharmaceutical companies still have clear commercialization objectives and are focused on results. Therefore, delivering on commitments—whether development milestones or commercial-scale manufacturing targets—is crucial for creating mutual reliability in such a collaborative relationship. We see pharmaceutical companies seeking more assurance that their projects will be managed diligently, and service providers providing support to maintain budgets, timelines, and quality. As the partnership evolves, it becomes increasingly synergistic and both parties realize increased benefits by periodically revisiting alignment of strategies and goals.

For the preferred-provider model to be successful, increased attention must be paid to metrics. New metrics may be needed to assess the effectiveness of the partnership and provide data that can be used to drive mutual continuous improvement.

Josephs (DPT): The practice has provided significant opportunity for a contract provider like DPT. The preferred-provider environment forces both the contract provider and the client to look at the relationship in a different paradigm. You go from looking tactically at one or two different opportunities, where you manage them in a specific way, to managing a relationship or partnership on a strategic level. There is more transparency on both sides with regards to future volumes and commitments. On the provider side, there's more transparency and commitment with regard to capacity, resources, and so forth.

In addition, a preferred provider tends to complement the customer rather than being a general supplier. This level of integration drives inefficiencies out of the system. Where it was once a transactional, buy–sell relationship, it becomes an integrated relationship with access and visibility in the customer supply chain.... For example, with an integrated supply chain, we have access and visibility into our customer's network and are working as a complement to our customer. From a development perspective, we also have dedicated resources proactively working on development projects for our customers, so we are not working on an opportunity-by-opportunity basis but actually have staff working on multiple projects for our partners.

Engels (DSM): One major impact on the industry from supplier consolidation is a more aggressive pricing structure. The governance structure between suppliers and sponsors also becomes more sophisticated (e.g., annual relationship, trend assessment meetings) and supply-chain planning becomes more integrated.

Kosko (PCS): When a supplier enters into a preferred-provider partnership, it is crucial that each party have a clear understanding of the arrangement. In our experience, having agreed-upon metrics to evaluate performance is key. In addition to developing metrics (e.g., delivery performance), the performance evaluation should contain a dialogue on the customer pipeline that addresses how both companies can increase the span of their relationship with new opportunities. In our more developed partnerships, for example, PCS regularly schedules sessions involving key executive leadership from both organizations.

Ananthanarayanan (Dr. Reddy's): In our experience, once a service provider has been invited into the fold of strategic suppliers, the relationship evolves rapidly. Access to senior management on both sides is much more evident, and the information flow between the parties is more free-flowing. This information goes beyond the technology needs, and by revealing more sensitive information, parties can align to ensure success on both sides. The desire for both parties to succeed tends to have a far greater priority than what we normally observe in a more tactical relationship. More objectives are set between the parties to define what success means as well. Even the language we use and the titles we assign to each other are different. For the very tactical projects, we could be referred to as a "vendor." For something bigger we are usually a "supplier." When we get involved on a strategic level, we become "outsourcing partners." Language says a lot in our experience. If you are being called a supplier, you probably are one.

Cassidy (SAFC): The expectations are high regardless of whether a strategic relationship is in place. However, most service providers desire a more strategic relationship with their key customers and an expectation that comes along with these relationships includes longer range planning, more transparent communication, preferred capacity utilization, and well-defined plans for escalating issues that affect product quality or team cohesion.

Crucial success factors

PharmTech: What does it take to be a preferred provider? What would you identify as the critical success factors?

DeCuir (Albemarle): First, and foremost, one must have a positive track record with the customer. Then, the contract-service provider must be able to provide a variety of technology options. It may difficult for niche technology players to become key suppliers.

Eyre (Baxter): A contract service provider has to demonstrate a proven track record in three key areas: delivery (i.e., the expertise and ability to deliver on commitments); service (i.e., a robust customer-centric philosophy and committed, engaged project teams); and integrity (i.e., a culture of "doing the right thing" that fosters confidence in the partnership). Trust and reliability are the foundation of any partnership. And in the most effective partnerships, each party contributes unique services, expertise and technology.

Within Baxter's BioPharma Solutions business, we have a systematic approach to partnerships that starts from project initiation through the mature phase of a project through conclusion. All aspects require diligent alignment of expectations and monitoring of critical success factors. We have increased our investment in customer-service training and certification programs for our project managers, built communication-sharing tools, and developed improved metrics-tracking programs to better enable our teams to meet the needs of our clients and produce optimal results.

Josephs (DPT): Transparency is critical, as is trust. And, goals that are mutually beneficial are vital because there has to be incentive for both the sponsor and the contract provider. When I talk about transparency, I mean transparency not only through today but three years down the line.

Critical and fundamental success factors in today's environment are financial stability, a solid quality track record, and proof of capability. A customer is not going to take a risk in this environment with somebody who doesn't have a quality track record. That's your ticket into the game. Proof of capability comes from your ability to execute.

At DPT, we have implemented these things with all of our partners so that there is an ongoing scorecard. We are measuring month by month, quarter by quarter, so we are on track, and if we are not on track, we identify how we are going to get back on track.

Engels (DSM): Good reputation (primarily through common history), flexibility (i.e., delivery of products and services, contract design, and pricing), and sound financial sustainability.

Kosko (PCS): Critical success factors required to take a vendor from a status of "supplier" to "partner" include supply assurance, regulatory compliance, product quality, service, and cost. A supplier's ability to innovate will also set it apart from the competition. A strong focus on relationship development is essential to building strong, enduring and collaborative relationships. Expanding the relationship to include marketing, technical service, regulatory affairs, finance, customer service, and leadership can deepen the partnership and promote ongoing collaboration.

Ananthanarayanan (Dr. Reddy's): Attaining a preferred-supplier status usually involves a fairly significant journey over a period of time. Typically, there are a series of information exchanges that occur in the beginning to ensure that the two parties are compatible with respect to service offerings and strategic needs. Once the determination is made that the two organizations are indeed compatible, then function-to-function and person-to-person relationships are evaluated. Both parties need to know that they are able to not just meet each others' needs, but are able to work together harmoniously. Mutual respect must be achieved or the trust needed to evolve a strategic relationship will never come to fruition. Trust must be earned through proven execution. Most often, smaller projects are awarded to the supplier to test performance, and if successful, more projects to prove performance are awarded. Typically, it is when a dependable track record established, that a discussion about being a preferred supplier occurs.

Cassidy (SAFC): Critical factors would include having the appropriate capabilities to match the sponsor's needs; trust and communication; excellent service, quality, compliance, and safety record; experience and/or expertise in the specified service area; an understanding of the sponsors' expectations; excellent project management and competitive pricing

Soelkner (Vetter): The demands made on CMO partners are clear: quality, reliability, flexibility, and punctuality are among others the most important factors necessary to achieve a successful partnership. At Vetter, for example, we invest in high-quality materials and aim to achieve the highest possible safety and cGMP standards. We implement a highly structured project-management approach. This, combined with ongoing direct communication, serves to reinforce mutual trust.

Most important, a CMO has to know and understand the needs of its clients, and meet them accordingly. For Vetter, it is important to know what a client needs today, but it is also crucial for us to understand what support they will need in the future.

Evolving business models

PharmTech: Has your business model evolved in response to changing market conditions? For example, to fit a preferred-provider model, has your company changed its range or type of capabilities?

DeCuir (Albemarle): Albemarle has always been a quality, reliable supplier with a large toolbox of technologies in which we are proficient, so our business model and offerings have not changed much.

Eyre(Baxter): We continuously monitor market data and other intelligence to better understand changing market conditions for our clients, but we also gather feedback from our current clients. This allows us to identify ways for us to provide new solutions, and presents opportunities for us to be a better partner.

For example, the development of a new sterile injectable product comes with specific challenges that a contract service provider can help solve, including formulation optimization, lyophilization development, and clinical-scale manufacturing. The needs and potential solutions change as the molecule moves through the development phases toward regulatory submission, manufacturing scale up, launch, and patent expiry. As the product nears the end of its maturity, the potential for enhanced delivery systems may offer a means to achieve life-cycle management objectives. This range of potential solutions within a single service provider reduces complexity for the pharmaceutical company and has increasingly become a factor in their decision-making process.

Josephs (DPT): DPT's business model is evolving, and we are responding now to this growing trend. We have benefitted because we have been a proven provider in this market for 20 years. While our service offerings continue to evolve, we would not change the type of capabilities we offer exclusively in response to the preferred-provider model. We are going to continue to add capabilities that complement what we do best.

Engels (DSM): We continue to focus on our core competencies and technologies, and to bring these offerings into the partnership. In other words, we do not try to be somebody we are not.

Kosko (PCS): With 40-plus years in the contract-manufacturing arena, PCS has a strong history of building excellent customer partnerships. From our perspective, the preferred supplier relationship allows us to more fully understand the challenges that our customers face across various aspects of their businesses, and how we may be positioned to assist. This focused and ongoing dialogue has enriched and expanded our existing customer relationships and brought new business opportunities while at the same time enabling our customers' to achieve specific business goals. Our response to the growing market trend toward contract manufacturing of highly potent drug products speaks to the preferred-provider model. Our customers' pipelines contain a greater percentage of potent compounds, and based on their feedback, and the strength of this growing market trend, PCS is focusing on high-potent drug-product contract manufacturing out of three European facilities. Our ability to develop and produce clinical supply quantities along with small and large-scale commercial quantities is a strong selling proposition for our current and future customers.

Ananthanarayanan (Dr. Reddy's): It is not enough to be able to offer general service any longer. To achieve "preferred" status, some kind of differentiation must exist for the supplier to offer added value to the outsourcing organization. That differentiation may come in the form of novel or expert technical abilities, in specific service abilities, in unique intellectual property offerings, in superior cost positions, and so forth, but the bottom line is that if a service provider is not adding value in a differentiated way, the opportunity to become preferred is reduced substantially.

Our particular business model does offer substantial differentiation because we have multiple in-depth technical areas, such as high potency facilities, activated PEG offerings, chiral-chemistry solutions and formulation-technology platforms. Being able to offer a wide portfolio of generic assets for use in innovative ways opens the door to strategic opportunities.

Cassidy (SAFC): A key approach at SAFC has been to find ways to differentiate our capabilities and expand capacity where needed to support customers' needs. The company has invested more than $70 million in recent years to meet market demand and customer expectations for API process development and GMP manufacturing, for example, including for high potency and viral manufacturing, and to provide both small and large molecules.

Soelkner (Vetter): As a strategic partner to pharmaceutical and biotech companies for many years, we have already implemented many measures required of a preferred supplier. We will continue to evolve and innovate and foresee great opportunities for our company in this process. An investment in our new US facility, which performs aseptic filling of clinical batches from preclinical to Phase II, is an example of our early response to customer needs. Other examples include our investments in capacities for secondary packaging, where we can meet higher demands on cosmetic integrity for final assembly and secondary packaging, the construction of a new logistics center, and the extension of our visual inspection facilities.

Future of outsourcing

PharmTech: Looking ahead five years from now, how do you see the model for outsourcing evolving?

Eyre (Baxter): We anticipate an ongoing trend toward increased integration of service providers into pharmaceutical companies' commercialization strategies. Pharmaceutical and biotech companies of all sizes are searching for effective ways to increase sales and control costs. In many cases, these goals can be maximized by partnering to access resources and expertise that exist outside of their own organizations. To make the most effective use of these external services, companies should partner with service providers that are organizationally skilled in managing collaborations and have proven to be reliable. Service providers that are able to effectively assess, harness and maximize relevant resources within both organizations will be in a position to provide superior value for their partners and will likely see growth. On the other hand, this is a difficult paradigm shift and it's not likely that all providers will be able to withstand the change. Those partners that are able to consistently deliver on their commitments, while at the same time providing access to relevant services and capabilities over a range of product life-cycle needs, will survive and thrive.

Josephs (DPT): The preferred-provider relationship will continue to grow and manifest itself as mergers and acquisitions by Big Pharma continue. We need to respond to that in an even greater capacity in the future. At the same time, I think we are going to come across smaller pharmaceutical companies who aren't looking for a major partnership, but that need our assistance. So, we need to be flexible in how we manage our business and the relationships we enter into—whether it's with Big Pharma or the emerging biotech and virtual organizations.

Engels (DSM): We will see more consolidation in the CMO industry to meet pharma's needs regarding financial stability, breadth of service, and overall professionalism. More internationalization (emerging markets) and price pressure (e.g., volume discount, commitment to continuous efficiency improvements) are likely as is the reduction of capital employed. Demand may lead to further reduction of in-house capacities among pharma companies, and more and smaller stock keeping units or SKUs (i.e., decline of blockbuster products, focus on serving smaller and regional markets) will drive up complexity.

Kosko (PCS): In the near term, we fully expect to see the high level of competition and consolidation trend across the global manufacturing industry continue. At the 2010 CPhI Worldwide conference, for example, I noted the number of companies undergoing consolidation via sale or acquisition, in addition to those companies that are reducing their service offerings. These signs support the continued growth in outsourcing over the next 5 to 10 years—and the CMOs that bring the strongest value proposition to their customers will be the clear winners. Key value drivers include technology, innovation, supply assurance, service, and cost.

Ananthanarayanan (Dr. Reddy's): The future of the outsourcing model is that outsourcing will only grow from here. It will not make sense for pharma companies to overly invest in small-molecule production facilities when they have the ability to partner with organizations that can help them produce safe and effective medicines. I believe that the relationships between organizations will continue to deepen, and that the service provider will become so ensconced in the supply chain, that the outsourcing party will consider the service provider a virtual in-house plant. The service provider will have to embrace the pure customization of their operation to perform to their customers' needs, but remain flexible enough to take on multiple deep relationships with the customer base. Some of the factors involved in this will be the ongoing pressure that pharma organizations face with respect to getting new products innovated and produced. Gone will be the days where manufacturing will be as necessary to control with internal assets compared to the need to launch new products consistently.

Cassidy (SAFC): Our largest clients are going through structural changes whereby they are continuously looking at their asset base and the best way to use that base, potentially to a point of exiting from manufacturing as a core activity. The outsourcing model has been proven to work, but the outsourcing 'winners' will be those companies that match up in a range of technologies, have a global footprint, possess preclinical through commercial capabilities, and have experience in working with the different governing regulatory bodies.

Soelkner (Vetter): We believe that developments such as the expansion of emerging pharma markets will continue. Additionally, companies will become more local in their approach to the market. And, of course, established markets like the US and Europe will continue to play a significant role.

David DeCuir, director of fine chemistry R&D at Albemarle
Brik Eyre, general manager of Baxter's BioPharma Solutions business
Paul Josephs, vice-president of sales and marketing at DPT
Hans Engels, president of DSM Pharmaceuticals
Michael J. Kosko, president of Pfizer CentreSource (PCS)
R. Ananthanarayanan, president of Pharmaceutical Services and Active Ingredients (PSAI) at Dr. Reddy's Laboratories
Mark Cassidy, vice-president of SAFC Contract Manufacturing Services
Peter Soelkner, managing director of Vetter Pharma International GmbH