As the pharmaceutical outsourcing industry grows in complexity, sponsor companies are reevaluating their contract-manufacturing choices and in some cases, asking contract organizations to provide different or additional services. For their part, contract manufacturing organizations (CMOs) are burdened with new requests—and new competition—and working to restrategize and restructure their offerings and performance. To gain perspectives on the metrics currently used to evaluate supplier performance and continuous-improvement methodologies as part of the outsourced relationship between sponsor companies and contract-service providers, *Pharmaceutical Technology* conducted a roundtable of leading CMOs engaged in this work.

Participants in the roundtable include: Scott Jenkins, business unit manager, manufacturing, global pharmaceutical operations, Abbott (Abbott Park, IL); Colleen Dixon, manager, Project Management Office, Baxter’s BioPharma Solutions business (Bloomington, Indiana); Michael Kosko, president, Pfizer CentreSource (Kalamazoo, MI); Jochen Alberstetter, vice-president, project management/supply-chain management, Vetter Pharma-Fertigung GmbH & Co. KG (Ravensburg, Germany).

**Outlining evaluations and expectations**

Criteria such as on-time delivery and making product in specification have historically been and continue to be important elements in evaluating supplier performance. What methodologies do you use to evaluate your company’s performance in this respect? How have sponsor companies’ expectations changed in terms of delivery points and how they measure those criteria?

**Jenkins (Abbott):** It is crucial to have a management-reporting process in place that drives a company to forecast, plan, execute and report on a daily, weekly, monthly, quarterly, and annual basis. This process may involve key meetings and reports and address performance indicators that drive the business. Having a set process in place allows for transparency of information and ensures...
Performance Metrics

Roundtable participants, from left to right: Scott Jenkins, business unit manager, manufacturing global pharmaceutical operations, Abbott; Colleen Dixon, manager, Project Management Office, Baxter’s BioPharma Solutions business; Michael Kosko, president, Pfizer CentreSource; Jochen Alberstetter, vice-president, project management/supply-chain management, Vetter Pharma-Fertigung GmbH & Co. KG.

that the operation is focused on the right factors: cost, compliance, customer service, and continuous improvement (what we call the “four Cs”).

Several years ago, Abbott set out to become best in class from an operational-excellence standpoint. As part of our certification process, we established a methodology to ensure we could meet customers’ demands within a specified window. Class-A performance means being able to achieve delivery success within a designated window of performance at least 95% of the time. As part of our process, if we step outside of this window—regardless of the reason—we perform a root-cause problem-solve (RCPS) analysis with cross-functional subject matter experts (SMEs) within our organization to understand exactly why we missed the delivery. We then implement a sustainable improvement to ensure that the cause of the misstep won’t reoccur.

»Dixon (Baxter): Performance-evaluation methods are a crucial element of achieving optimal results in contract manufacturing. A true partnership must serve the needs of both the supplier and the customer, so we make every effort to carefully evaluate and measure performance, striving to meet or exceed our collective goals. This approach begins with an upfront discussion at the kickoff of a project to establish key success factors and the associated metrics to be measured throughout the project, and agreement on how the metrics will be calculated and the frequency at which they will be reviewed.

In Baxter’s BioPharma Solutions business, we have designed working environments to ensure comprehensive integration of the staff, processes, and tools as part of our Process 360° customer experience. This environment enables client teams to monitor metrics for each project at each stage. By understanding the robust data and being aware of key process checkpoints, our client teams can take direct action and find improvement opportunities that can influence project outcomes.

We have spent a considerable amount of energy and resources on mapping the customer experience and learning and asking which data points and associated metrics are important to our clients as a project moves from start-up to product release. To support each client’s needs, our applications are designed to tailor metrics. We recognize that there are differences in how clients want metrics calculated and how they will use the data. Another component of our customer-experience strategy has been to harmonize the way we calculate and use metrics across our global facilities to ensure a common understanding of the data and how to apply the data. In addition, we use detailed, customized training programs for our project teams to make sure they understand the importance of data integrity, monitoring, tracking, and reporting. By providing clear definitions and technology investment, the client and project team together gain a heightened sense of transparency and control.

Fundamentally, our client expectations for evaluating supplier performance have not changed. A few of the common key performance indicators (KPIs) requested by clients include on-time delivery, salable yield, exceptions, incident rates, and schedule accuracy. Other metrics such as measures of client satisfaction and mutual financial accountability, are also important to ensure a holistic approach to the partnership.

We have noticed a heightened interest in maintaining control over projects as well as a clearer understanding of potential variables and anticipated challenges. Because many clients use a combination of in-house manufacturing and outsourcing strategies, a major driver for customized metrics has become the comparison of internal manufacturing versus outsourced performance and, ultimately, long-term value. In the upfront evaluation process, clients are interested in understanding our approach to project management, data comparisons, qualification of teams, and metrics tracking as a means of supplier research and assessment. Thanks to our integrated systems, we can share the seamless approach we have to data during every step of the process.

»Kosko (Pfizer): A number of Pfizer CentreSource (PCS) customers use scorecards that are reviewed on a quarterly, semi-annual, or annual basis. Many of these components are based on the Assurance of Supply/Regulatory Compliance, Quality, Service, Cost and Innovation (AQSCI) Pyramid for rating suppliers.

The base of the pyramid and its most important component is assurance of supply and regulatory compliance. This component reflects the minimum requirement for any company that supplies the pharmaceutical industry. While consistently meeting the specifications of a client is a prerequisite, companies can differentiate themselves by the services that they extend to their clients, including:

• Product-delivery timing
• Customer service
• Technical service
• Regulatory support
• Business development.
Although cost is always a factor, it is typically not the most crucial factor in a supply relationship. A producer’s ability to be innovative is always valued by customers, but that ability needs to be closely coordinated due to the potential impact on regulatory filings.

»Alberstetter (Vetter): Vetter manufactures based on customer demand. We measure our deliveries using the KPI Customer Service Level (CSL) with respect to “on-time-in-full.” This measurement is performed monthly and shared within the company as well as with the customers. To achieve the preset targets, we make use of SAP (an enterprise-resource planning system) and respective operational excellence procedures [Oliver Wright is an international business improvement specialist] that have been in place at Vetter for five years.

Identifying key performance indicators

PharmTech ›› What other KPIs or balanced scorecards do contract-service providers and sponsor companies use to set measurements for accountability and product supply?

››Jenkins (Abbott): It is important to work with suppliers to ensure you have what you need when you need it and to produce and deliver customer products on time. The backbone of our relationship with partners is a high degree of communication and transparency. In addition, we use various tools to help us drive accountability.

For example, we have a Supplier Excellence program in place to measure our suppliers’ ability to deliver on our needs. This ensures transparency. As part of our Management Control and Reporting system, we track weekly metrics such as schedule adherence and monthly metrics such as supply-plan achievement. We use monthly metrics to measure delivery performance and to conduct RCPS sessions and put corrective actions in place.

››Dixon (Baxter): In addition to on-time delivery, quality, and meeting product specifications, we evaluate our success by analyzing a number of other performance indicators through client scorecards. These scorecards serve as a measurement of the ultimate value for both Baxter and our customers and are reviewed by both parties on a regular basis. For example, saleable yield is one KPI that helps us outline our end result. Other scorecard factors focus on process quality, including monitoring cycle times throughout the batch life cycle and conforming to schedules.

In addition to strictly quantitative factors, we focus heavily on customer-service measurements by using a robust customer feedback program that is matched with an internal assessment and health scorecard. Ultimately, we look for comprehensive and real-time evaluations to help demonstrate mutual accountability and partnership value.

»Alberstetter (Vetter): Depending on the relationship with the customer (i.e., multiple products/projects) we usually share and discuss KPIs along the entire supply chain. This supply chain begins with the “inspection of incoming goods to setpoint” and follows the preset material flow. Other shared KPIs include: lead time, yield, stock coverage, right-first-time-rate, and master production-schedule stability. During the precommercial phase in project work, we use the methods outlined by the International Project Management Association (IPMA) Baseline 3.0. (IPMA is a nonprofit standard-setting body based in The Netherlands.) A respective certification program has therefore been established. Vetter’s projects are released and steered by an operational and strategic steering committee.

Tracking performance results

PharmTech ›› How does your company evaluate internal performance? For example, is performance benchmarked against other projects? Do you employ a Six-Sigma approach or other total quality management approach?

››Jenkins (Abbott): At the core of our relationships is a strong focus on the four Cs previously mentioned (cost, compliance, customer service, and continuous improvement). We aim to provide high compliance and customer service at a market competitive cost. A sustainable continuous-improvement program helps the provider company continue to improve existing operations with long-term results and can lead to decreased cost for both companies. RCPS, Kaizen (this approach involves subject-matter experts mapping out a process and looking for improvement opportunities), and Six-Sigma approaches are integral to our overall business-partnership plan.

As part of our management-reporting process, Abbott holds regular meetings to review performance metrics and to discuss whether we are on track to meet the overall schedule and deliver according to customers’ needs. If any KPIs are off track, we conduct an RCPS session.

We also seek feedback from our customers. For example, we ask, “What would make it easier for you when you’re in our facility?” Based on feedback to this question, we installed a Customer Conference Room with a table, chairs, phone, overhead-projector screen, white boards, and wireless Internet access so that customers have a comfortable place to work while visiting our facility.

››Dixon (Baxter): Setting internal goals and metrics, in addition to the metrics we strive for with clients, and measuring those metrics is a crucial element of our work. We are not satisfied with merely meeting targets, but always strive for continuous improvement. This philosophy is based on Baxter’s implementation of Lean manufacturing. We apply Lean methodologies to monitor
and improve day-to-day performance at every level. We apply techniques from Lean, Six Sigma, and total quality disciplines to drive broader improvement efforts. Through these disciplines, we use standard review points or stage gates for our process-improvement efforts to ensure that individual projects are integrated into the overall company strategy.

In addition to internal scorecards, we use a tiered management-review system, which includes regular assessments of functional performance using visual display boards that help ensure productivity and identify outliers. These display boards showcase real-time data and outcomes for each team member and each process. On a less frequent basis, high-level meetings are held to review major projects and KPIs to ensure we are meeting customer needs as well as short- and long-term strategies.

Kosko (Pfizer): As a sales/marketing organization, Pfizer-CentreSource does not have manufacturing assets but rather uses the Pfizer Global Manufacturing (PGM) network of sites. Within PGM, the Network Performance Organization focuses on the evaluation of internal performance. The Operational Excellence team within the Network Performance Organization is charged with building our Six-Sigma and Lean-improvement capability across the network and its functional groups to deliver high performance. By organizing this function centrally and focusing on effective knowledge management, sites can readily adopt best practices.

Alberstetter (Vetter): Performance of processes is measured using SAP. After the data are graphed, project performance is presented and discussed at the operational steering committee meetings. Supply-chain performance evaluation is part of the sales and operations process.

Vetter has implemented—and is continuously improving—a company-wide program called Vetter Optimization System (VOS). It consists of three pillars, one of which is to maintain focus on statistics and to fully implement Six-Sigma methods. The other two pillars cover business process management and Kaizen.

Considering new challenges
PharmTech: Given recent industry concerns in supply-chain integrity, can you explain what additional criteria you may use to evaluate suppliers of raw materials or other ingredients (e.g., increased audits, additional testing)?

Jenkins (Abbott): We have an extensive program to evaluate raw-material suppliers. We gather information from supplier questionnaires and conduct on-site facility audits. Suppliers are automatically a part of our Supplier Excellence program, which involves monthly evaluations. If there are any issues or concerns, an RCPS session is held.

Dixon (Baxter): Baxter takes a strong position and stance in ensuring that quality raw materials are used in production processes. The quality-by-design (QbD) approach emphasizes a more careful examination of the quality of our raw materials and raw-material suppliers. This industry trend will only continue as we see more companies involved in the complex pharmaceutical supply chain. Specifically, we use a variety of measures and analytical techniques to assess raw materials received at our facility. Raw materials go through rigorous, predefined testing procedures, including appropriate compendial testing to ensure consistency in raw-material performance.

Based on our preemptive actions on quality standards for our external vendors, we have been able to further improve a strong supplier-quality process. Baxter recently implemented a Global Supplier Quality Plan to ensure that suppliers meet rigorous global quality criteria. The plan is supported by supplier audits and quality agreements between the supplier and Baxter, which enable Baxter to determine and maintain the quality of goods. This global system also enables Baxter to share knowledge across the entire organization as it relates to raw materials and vendor-supplied goods.

The improvements to our supplier-quality plan have led to continuous improvement and better customer service. By using the mentioned techniques previously described, we are able to better understand the cycle time and throughput capability of our planning processes, which enables us to accommodate unanticipated client requests.

Kosko (Pfizer): Pfizer remains extremely active in the area of supply-chain integrity. Even before the most recent concerns about economically motivated adulteration, Pfizer had an aggressive process in place to effectively evaluate and select suppliers, raw materials, and packaging. That process includes assessments of supplier technology and capabilities, operational and manufacturing capacities, and investments. We also evaluate quality processes, systems, procedures, and compliance to current good manufacturing practice as well as supply-chain practices that include supplier selection and quality management.

Alberstetter (Vetter): Vetter’s quality system includes regular supplier audits and a thorough incoming inspection process. API-related raw materials often are supplied by our customers. Methods are selected or developed separately depending on the product.

We respond to customers’ demands by applying security measures such as defined and documented interfaces within the process. Vetter Solutions develops packaging components that support anticounterfeiting measures, including tamper-evident closure (Vetter-OVS). We also apply other available solutions based on customer needs.

Growing continuous improvement goals
PharmTech: Continuous improvement is of benefit to the sponsor company and contractor. Are there certain methodologies (e.g., organizational or operational structures and communication vehi-
Performance Metrics

...that you would recommend to identify and facilitate continuous improvement? What approaches might be used to recognize those improvements in the context of the working relationship?

»Jenkins (Abbott): We have a Business Excellence/Continuous Improvement team that focuses on driving continuous-improvement efforts across the organization. RCPS, Kaizen, and Six-Sigma approaches play a role in operational improvements and drive sustainable results that can improve cost, compliance, and customer service—all of which benefit the customer.

Developing a collaborative relationship in which both parties work together for the most optimal success is key. This collaboration involves treating the client’s product as if it were our own and recommending improvement opportunities that will benefit both parties. Building trust in the working relationship opens the door for other opportunities with the partner in the future.

For example, we were struggling with one partner. We held a joint Kaizen event, which gave us a chance to walk through the current situation (i.e., discuss expectations/concerns among both parties), break down communication barriers, identify areas for improvement, and map out a new process specifying tangible steps and expectations. The event further developed a foundation of trust and strengthened the relationship, ultimately improving our ability to meet the customer’s needs.

»Dixon (Baxter): Continuous improvement remains a major opportunity for advantage. Most importantly, we believe that thorough understanding of both leading and lagging process indicators can help create an environment conducive to continuous improvement. We rely on robust data analyses to determine statistical significance of process efficiency and consistency measurements. This approach helps to target the most promising and correct continuous-improvement opportunities to ensure the desired outcome. We use rigorous analysis to select, drive, and confirm our improvements.

Furthermore, Lean-manufacturing methodology enables us to identify and implement improvements in an efficient manner. Our culture emphasizes—with every employee in every facility—the importance of owning one’s specific role and areas for improvement. When encouraging staff to identify small ways to improve, the effect is multiplied throughout the company, creating combined improvements and reinforcing a culture of change. As a result, we are able to provide better services to our clients to help them better serve their patients.

We also rely on identifying and sharing best practices within our facilities and with our clients to optimize the effectiveness of our client teams. We work in an ever-changing industry environment and see mutual benefit from working collaboratively to identify and implement techniques that can improve our service.

One of our latest initiatives focuses on improving methods to manage historical knowledge and to ensure that it is appropriately leveraged to improve future programs. By using more sophisticated technology such as an internal collaborative portal or central knowledge base and past experience, we can more effectively assess risks and opportunities associated with new projects. In addition, we are able to demonstrate improved capability to clients by showcasing our history of innovation, problem solving, product delivery, and support.

»Alberstetter (Vetter): Our approaches depend on the type and depth of the business relationship. We do use an agreed governance structure that includes frequent business and quality review meetings, joint project steering-committee meetings, and sales and operations meetings. We also engage in Six-Sigma projects together with our customers and suppliers.

Planning for evolving partnerships

PharmTech › Looking ahead five years, how do you see the relationship between contract-service providers and sponsor companies evolving? Has quality by design, for example, affected sponsor expectations?

»Jenkins (Abbott): I definitely see more collaborative planning efforts with more integrated systems. Expectations for companies to have strategic, system-based approaches (e.g., project management, new product introductions, and new business development) are going to be even higher. Additionally, I believe service providers will be expected to have the expertise and ability to handle more specifics (e.g., product development, project management, product planning, and supply-chain logistics) as sponsor companies downsize and rely on the service provider to handle greater responsibility.

»Dixon (Baxter): In an ever-evolving industry where regulations and standards change regularly, we expect that contract-service relationships will continue to evolve. In particular, we have seen a trend toward tighter, more integrated partnership approaches between clients and their partners. As industry focuses more on core competencies, outsourcing continues to grow as a viable, productive option to mitigate risk, produce cost savings, and explore life-cycle management strategies. Some recent examples demonstrate that service providers are beginning to participate in regular interactions and planning meetings previously reserved for internal staff only. This type of integration helps reduce communication errors, improves understanding, and aligns processes more effectively, which can translate into significantly improved long-term outcomes.

Several pharmaceutical customers are undertaking QbD approaches with their internal manufacturing, and we recognize that aligning our own processes accordingly is a smart approach. We believe QbD will improve our offerings because it dramatically changes the way we approach specifications and the way we moni-

There is a trend toward preventive development approaches in the pharmaceutical industry,” —Jochen Alberstetter, Vetter Pharma-Fertigung GmbH & Co. KG
tor product quality. In summation, with the help of technologies and an ever-continually increasing attention to the metrics and quality of our work, we can develop ever-improved partnerships that can lead to great solutions for the healthcare industry.

»Kosko (Pfizer): I envision that the working relationship between suppliers and their customers will continue to grow closer. The opportunity to employ QbD principals during development will enhance process knowledge and process understanding. Experiments and risk-management tools can be used to ensure product quality and further enforce a science and risk-based approach to product and process development. Suppliers are likely to more broadly use process analytical technology (PAT) to control key aspects of their manufacturing process.

When a contract manufacturer applies QbD, it’s not unrealistic to consider that real-time release testing approval might also be pursued. Such an approach is a great example of a contractor bringing tremendous value to customers.

»Alberstetter (Vetter): There is a trend toward preventive development approaches in the pharmaceutical industry. From our perspective, customers that have fully implemented QbD are still setting the benchmark at the present time. By the same token, we have noticed an ongoing consolidation process around this topic, and this will presumably lead to the industry adapting to QbD. PT

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