Leveraging Quality by Design and lean and green principles in their contract partnerships, drug manufacturers can gain a competitive advantage.

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OPERATIONAL EXCELLENCE IN PHARMACEUTICAL OUTSOURCING

LEVERAGING QUALITY BY DESIGN AND LEAN AND GREEN PRINCIPLES IN THEIR CONTRACT PARTNERSHIPS, DRUG MANUFACTURERS CAN GAIN A COMPETITIVE ADVANTAGE.

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Cultivating Partner Relationships: Leveraging Quality by Design

CALL IT QUALITY BY DESIGN, CALL IT GOOD DEVELOPMENT, IT HAS TO BE LEVERAGED IN PUTTING TOGETHER A SOURCING STRATEGY.

BY RUSS SOMMA, PHD, SOMMATECH, LLC

WE NEED to be clear about scope. The present climate looks upon Quality by Design as an approach or option for the filing of NDA’s. But QbD can also be looked at as a business practices manual, and many fail to leverage the opportunity to use aspects of QbD to focus business and development plans.

Within those plans are contract agreements with various product and service providers. QbD does not become the driving factor of partnerships, but it becomes the philosophy against which one sets up strong partnerships.

Just as Quality by Design is best defined in ICH guidances Q8 through Q10, so, too, can partnerships (Figure 1):

ICH Q8 (Pharmaceutical Development): Collecting the knowledge needed to cast a partnership.

ICH Q9 (Quality Risk Management): Application to our sourcing needs using the knowledge.

Q10 (Quality Systems—i.e., “The Enablers”): The maintenance of our product, process, and the partnership through the lifecycle of the product, and the fostering of understanding between the two organizations in an outsourcing situation.

THE SOURCING-QBD CONNECTION
Manufacturers have always questioned whether there is significant payback in Quality by Design. They might say, “I don’t see the flexibility, I see a lot of data being shared, no clear pathway is provided for filing, and it’s expensive.” Those are all true statements, but what we’re talking about here are the precepts of Quality by Design—the way you think about putting things together and how you leverage them when you go to procurement, when you go to setting up partnerships. Let’s not focus on the regulatory aspects, but on what Quality by Design tells us to do.

QbD affords us the opportunity to rethink and enable our sourcing initiatives. The following items can be looked at as an inventory of information:

- Drug substance specifications which include physicochemical properties
- Drug product specifications as well as basic knowledge of excipient interactions and process understanding
- Raw material characteristics and variability
- The envisioned sourcing partner and its related facility design, and capacity through the product lifecycle
- Target product profile, “desired state”

Figure 1. How QbD Supports Partnerships
• Stability of clinical forms/prototype as well as drug substance
If we forget buzzwords like Quality Analysis and Design Space and look at drug substance aspects or product requirements, we start to see that we have a blueprint to understand better our product expectations and how we move forward.

The target product profile should be emphasized—it is absolutely imperative but some companies fail to do it. Yet it provides documented proof of what we expect the product to be, and what we expect the capacity to be. And this is looking forward. It is the lifecycle. This is the flag under which everybody marches, internally and subsequently externally to the outsourcing partner.

LEVERAGING QBD, CRAFTING A STRATEGY
Components which are needed to address a conventional regulatory review are fundamentally those needed to craft a sourcing strategy. We call it Quality by Design, we may just as well call it good development. Whatever it is, these things all have to be leveraged in putting together a sourcing strategy:
• An understanding of the product and process in terms of fundamental, mechanistic properties as opposed to empirical
• Utilization of prior knowledge in defining product, process and facility—your own or your partner’s
• Partnerships to accommodate the product’s lifecycle.
Lifecycle is the key word. That’s the business driver. If we apply this to partnerships we have, we’re going to reduce costs and shorten time to market. We’re not going to have the inevitable accidents. Quality by Design enables the inventory of information and how to think about the data objectively.

Many industries, from biotech to medical devices, have used the precepts of QbD effectively in a range of situations. They all share a similar vision speed to market, cost reduction and flexibility:
• A small biotech firm conducting a knowledge inventory/design space as it approaches submission of a novel delivery system for a vaccine.
• A start-up molecular design/discovery firm looking to develop an early stage CMC package with the required “curb appeal” for potential partners.
• A large-scale device manufacturer looking toward seamless process introduction and cost reduction as it enters the combination product market place.
These are examples of Quality by Design to enable a business plan, and from that business plan to foster outsourcing or whatever partnerships are necessary.

How do we get to the Desired State, which is outlined in the target product profile? Increase our mutual organizational knowledge. Ask ourselves some broad-based questions and begin to put together inventories and constructs around them:
• What is needed in a submission?
• What will the partner provide in terms of flexibility?
• What is needed to release a product?
• What is needed to manufacture a product?
• What will be our capacity needs over the product lifecycle?
• What is needed to control a product?
• What would be needed to manage post-approval submissions?
Taking a simplistic approach, I always suggest going with a three-step process:
Step 1: What knowledge do we have to shape these areas?
Step 2: Refine the knowledge so we can make a product.
Step 3: Control the product and process to deliver consistent results.
Looking at these three steps, we start to get three shopping baskets full and we start to understand what we need to do when we look for assistance externally.

ASSESSING CRITICALITY AND RISK
My frequent admonition to clients is not to get into a debate about what is critical. Criticality is a function of risk. We have to look at it against a backdrop of what risk is necessary, and that risk is
Quality by Design

often dependent upon patient safety. But it is also dependent upon manufacturability—what is the risk of batches not meeting requirements, of not maintaining a lifecycle or maintaining a market presence?

One aspect which must be made clear to all the players is the need defined by ICH Q9 (Risk Management) concerning risk. A sponsor must work toward a system which is based on Risk Knowledge or “What If” aspects. This has two components: Risk Assessment and Risk Control. The path to this goal must be to leverage product and process knowledge.

This task, knowledge management, must be seen as an enabler of all the functions and may best be dealt with in a well-defined and agreed to “Mutual Quality System” between the sponsor and the partner. In my experience, there can be a disconnect between what we feel is acceptable or unacceptable and what the partner feels is or is not. These things have to be agreed upon because, if not, they can create delays just as much as a bad formulation or faulty process.

Risk should be assessed based on cause and effect and relative to the following criteria: probability—the likelihood of a consequence; severity—the magnitude of the impact of a consequence; detectability—the level or ability at which a consequence can be measured; and sensitivity—the attenuation of interactions between multivariate dimensions.

This is how we whittle down criticality and get a concrete sense of the things that need to get done. These are things that have to get looked at, and our partner has to look at as well. If a partner does not, we have to provide it with a package to help it assess risk. One of the things we do is a risk analysis. This is a living document, and this becomes very important when you provide it to a partner as a living document.

Consider these questions we should be asking internally. If answered upfront they have a significant effect on the sourcing strategy and position us for success—so that we and partners can be a unified team:

• What properties of the drug substance affect product performance?
• What is the formulation intended to do?
• What are the special requirements of the drug substance and drug product?
• How do we define the critical process steps?
• What are the process parameters for each step and how are they monitored and controlled?
• What must we design into the facility in order to assure we meet critical quality attributes of the product?

These things have to be communicated. The manner in which we answer these questions and allocate risk greatly affects our business plan and the cost of the process and/or the product supplied by our partner.

SUMMARY

The development aspects needed to do QbD are those needed to form a sound relationship. They are complicated and challenging to be implemented, using our internal resources as well as our external partnerships’ expertise. They are complicated not in terms of doing experiments and technical work but in terms of inventorying and putting together a library of knowledge.

About the Author

Russ Somma, Ph.D., is President of SommaTech, LLC. Dr. Somma has more than 30 years of pharmaceutical industry experience, specifically in the areas of production troubleshooting, dosage form development, manufacturing scale-up, technology transfer and project management.
Cultivating Supplier Excellence: Driving Value at Wyeth

Supply-chain excellence is about metrics, and people and relationships as well.

By Ron Perry, Wyeth Consumer Healthcare (Pfizer)

A FEW years ago, Wyeth Consumer Healthcare (now part of Pfizer) had a number of supplier quality issues that affected key business metrics and compromised our customer service. Inconsistency and unreliability of supply were costing us money, causing us downtime, and affecting our ability to meet customer demands.

These issues were varied and for the most part unpredictable. They ranged from discolored or contaminated materials to malfunctioning components. What’s most important is that the potential for mis-orders was lowering our customer feedback ratings, and we were concerned about the impact this might have upon brand reputation as well as organizational credibility.

Our senior management said something needed to be done. So we established an effort to address these needs and prevent future supply quality concerns—the Supplier Quality Excellence (SQE) program.

FOUNDATION FOR SUCCESS
Our program success factors include an executive-endorsed vision, a very organized program, processes and approaches that are standardized, and metrics with meaning. We accentuate the right people, and we partner with the right providers (Figure 1).

The Supplier Quality Excellence program works to improve suppliers who may be delivering poor and inconsistent quality. It works to increase existing supplier performance, whether it is poor, at par, or above par. And ultimately it works to try to drive greater overall value.

We’ve established partnerships with suppliers at each and every one of our manufacturing sites. We have carefully defined projects per each supplier and we try to employ standardized Lean, Six Sigma, and even Total Production System approaches to ultimately be the best. We aspire that one day people will point to Wyeth the way they do Toyota and say, “That’s the Wyeth Way.”

We have top-down executive management endorsement, and we believe it has been critical to our success. This program is a key strategic initiative within Wyeth Consumer Healthcare. It’s governed by a senior-level steering team which importantly includes representation from all our manufacturing sites. This is not just a corporate-run initiative. The engine of this program is embedded in each and every one of our sites that interact with suppliers and materials on a daily basis.

Our strategic initiative is defined beyond its vision. It has a specific mission: Reduce the risk of product supply interruptions due to raw material and packaging component issues. Develop a mutually beneficial relationship with key, selected suppliers to proactively prevent these occurrences.

And we have established goals, priorities, and key metrics. Our top-line metrics are very simple. They are about expanding our program
and having a greater impact on our suppliers. It's about reducing the potential for unwanted events and controlling a lower level of events. And it's also about reducing the potential for a supplier event to occur. We expect the metrics of our program over the next few years to include more measures on total value, and more clear connections to budget reduction and operational efficiency, and whether we're using our resources the best way we can.

The program started about two years ago with concepts. We had many non-standardized approaches, but we had people working within our North American and European sites that had great ideas, and they were trying things on. Our team members frequently shared their approaches and best practices. They decided to replicate what they felt worked best. And they ended up putting together standard practices that we use today and try to improve upon.

I’d like to note, citing author Jeffrey Liker, that standard doesn’t mean permanent or unchangeable. It does mean consistent and improvable.

FOCUS
Critical to our process is making sure that each and every team that is working with a supplier on a particular project has focus. We have focus by using project charter documents to know what it is that we’re aiming for—the clear endpoints and success measures (Figure 2). We have the ability to monitor progress on our agreed-upon targets, and when they’re achieved. And we capture that history and manage that knowledge.

Our experienced green and black belts quickly apply the DMAIC approach (Figure 3). This is a standardized process we use in every single one of our programs. We have quality training, development, and experience, all of which has proven essential to the success of each SQE initiative.

Within the programs, we employ failure mode and effects analysis (FMEA), and this has become a tool which each supplier uses outside the program, even with their own supply chains and with other customers. This has been an excellent and comprehensive measure for assessing where the potential or likelihood of risk may occur. It’s fostering a Mutual Quality System and helps us to estimate the probability of issues.

Additionally, there is a softer side to the program. Stealing from the Toyota way, Genchi genbutsu, or “Go and see for yourself,” includes our engagement with all levels of suppliers—even shop-floor level. It’s personal. It’s high touch-point. You can apply it anywhere. The value here comes from observation and from learning about how each company can improve, recommend changes to one another, and improve the overall value chain.

KEEPING SCORE
The SQE program isn’t just one-directional. The program includes a reverse scorecard which helps assess a supplier’s perspective on us. The feedback is essential, to be used as a mirror so we know how to change, where to focus, and what to prioritize. We use this with our own customers, called “Voice of the Customer,” so why not do it with our own supply channel?

Measures and metrics are important, but we have different kinds. We have what we call what metrics, which are the specific, outcome-based results of each program that we put in place.

But equally, if not more importantly, we have how metrics, which are relationship-based and

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<thead>
<tr>
<th>Milestones</th>
<th>Status</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>I – Gather available data (specs, scorecards) from each site</td>
<td>Feb 08</td>
<td></td>
</tr>
<tr>
<td>II – Kick off team meeting; Establish priorities, quick hits</td>
<td>Feb – April 08</td>
<td></td>
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<tr>
<td>III – Reduce risk &amp; vulnerability using FMEA approach</td>
<td>April – Nov 08</td>
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<td>IV – Implement actions</td>
<td>Nov – Dec 08</td>
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<tr>
<td>V – Process control &amp; monitoring</td>
<td>Dec 2008</td>
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Figure 2. Example of SQE Progress Monitoring
about how we work. They’re about the behaviors that are being exemplified and how we’re changing behaviors and attitudes, and the way we work to construct relationships that are sustainable to drive greater value with suppliers. We believe it’s the behaviors that count and that become standard practices in the way we work.

**IT’S ABOUT PEOPLE**

We have a multitude of project-level metrics, but ultimately many of them are focused on quality issue reduction, performance improvement, and the prospect of quality assurance.

But it’s not just about the suppliers, the processes, the tools, the governments. It’s about the people. We created a special role at each of our manufacturing locations called the Supply Base Manager. The role of this person is to focus on the activities that we’re describing, ensuring that suppliers and their performance are managed effectively and working deeply with all functions within sites, above-sites [corporate], and certainly throughout a supply chain to serve in a preventative way to ensure quality, as well as in a restorative way.

A Supply Base Manager:
- Ensures suppliers and their performance are managed effectively enabling site operational excellence
- Assures site commodity and category needs addressed through effective sourcing
- Supports Corporate and provides support for site-based supplier strategy & plans
- Evaluate current & select new suppliers and materials
- Serves as critical site-team player as new sources and materials are being introduced

**SELECTING PARTNERS**

Regarding partners, we have a selection process to understand where we should focus first. Our partnership and program selection are carefully planned and managed. We decide around purpose, we decide around value for both parties. We look at suppliers input as well as our own input.

We use several criteria to screen and select suppliers and projects (Figure 4). Ultimately, approvals are gained internal to the company and externally with our suppliers.

**RESULTS**

Results are looked at in several ways: recognition, reduction, relationship, and replication.

**Recognition:** This program was recognized by *Pharmaceutical Manufacturing* for its 2008 Team of the Year for large companies. Internal to Wyeth, we’ve been recognized by the president of Consumer Healthcare with his Global Pride award. We’ve also recently been recognized throughout our Wyeth network, across all divisions, as a best practice program with a

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**Figure 3. The DMAIC Approach**

**Figure 4. Supplier Focus Areas**
Network excellence award. You can see the results that partially justify the recognition:

- 68% Reduction in Supplier Investigations
- 53% Reduction in potential supplier issue occurrences (RPN)
- 90% Supplier Scorecard use common performance scorecards.
- 80% of suppliers with Kaizen programs
- Structured communications with 80% of participating suppliers
- 60% Go-See “genchi genbutsu” visits

The rest of the justification comes from the hows and acknowledgement of the way we work. These are significant mile markers and progress towards being the best. Finally, recognition is also how our suppliers notice changes in their own facilities.

Reduction to us means measures to reduce cost, waste, cycle time, resources, inefficiencies, and transport. We have quantifiable reductions in all those areas, including energy use. Reduction in total costs and non-quality costs continues to be an area of focus for us because it goes far beyond just reducing quality incidents. It's about operational excellence and efficiency in our organization. This is what is essential to us, not only to have a strong program today, but to have a sustainable program that brings value back to our bottom line tomorrow.

Replication is the core. This isn’t an isolated program. It has been picked up and stolen shamelessly across several biopharmaceutical, pharmaceutical and nutritional plants that we have across the Wyeth network. We’re very proud of this because people are pointing to us and trying new practices and techniques, and feeding back to us what is working so we can improve our program as well.

Relationship: Importantly, it does relate to customer service. Figure 5 shows one example of how our customer service measures have increased out of one location from 75% to 90% throughout 2008. How does it relate to our brand image? Customers are telling us they’re more satisfied. With greater confidence and better feedback, can you see how marketing can now make greater plans and commitments with new and existing products and markets? We can see that, and it gives us greater confidence and greater predictability to figure out how our top line will be affected.

This program for us is structured, is Lean-focused, and it’s driving efficiency, waste-reduction, and cost improvement. We have greater assurance of the customer needs that we serve, and also know that we can go to sleep at night not being fearful of inconsistent, unreliable, unpredictable quality, which are the concerns that I shared in the beginning.

We know that we can increase our confidence and business continuity, and our compliance. We’ve limited our liability. But we also recognize that there is always much room for improvement. Using the right people, partnering with the right suppliers, and working in the right ways in new and existing relationships are all critical to our success.

About the Author

Ron Perry is Senior Director, Global Manufacturing Procurement Leader, Established Products & Emerging Markets, at Pfizer. He has been co-champion of Wyeth Consumer Healthcare’s Supplier Quality Excellence program. He has an MBA with emphasis in Finance & Operations from Penn State University, and earned his B.S. from Michigan State University.
Our dosage form services are supported by a compelling facility in Greenville, North Carolina, where personnel expertise reflects four decades of experience. Beyond exceptional capabilities for pharma and biotech companies today, our market insight and flexibility also make DSM a logical, sustainable partner.

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- More than 90% of pre-approval inspections [PAIs] waived since 2007
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- Clinical Trial Materials
- Scheduled Drug Dosage Forms (Solids & Steriles)
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Making Outsourcing Work For You and Your Employees

How managers can ensure seamless relationships with contract partners, while also empowering their most valued employees.

By Rakesh Kishan, President/CEO, UMS Advisory

**COMPANIES WHO** outsource significantly often get the reputation of caring only about the bottom line and not about their core workers. It doesn’t have to be this way. There are companies who outsource and use the opportunity to empower their core employee base, or make the outsourcing a chance to transition good workers to meaningful employment with the partner company. This article looks at best practices in outsourcing pharmaceutical manufacturing operations, consults industry experts, and focuses on the role that plant management can take in ensuring a seamless relationship with the contract partner while also empowering key workers.

Outsourcing has gained growth and acceptance as an effective management strategy for a broad range of processes and products. The primary reasons cited for outsourcing include cost reduction, time to market, and greater ability to focus on the core brand of the company. Recently, bellwether companies such as Pfizer and GSK have both outsourced portions of their manufacturing operations and signaled their intent to do more. In parallel, suppliers have become stronger with increased chemist capability and have maintained growth even as regulatory pressure continues to mount. But despite its growth and successes, outsourcing causes anxiety and uncertainty for many affected employees. This article will discuss steps the leadership team can take to make outsourcing an empowering experience for those employees.

Outsourcing represents a discontinuous change for employees that creates significant levels of uncertainty. Consequently, employees take a different point of view on outsourcing for a number of reasons. Concerns about continued employment persist as employees worry whether or not they will have a job after the business process or operation is outsourced. In addition to continuity of employment, employees worry about whether their compensation (income and benefits) will be affected. Employees also face a shift in identity when they transfer to an outsourcing services provider. They move from a pharmaceutical company, whose mission is typically centered on creating healthy human lives, to something else. Finally, employees worry about their future growth prospects at a supplier. Perhaps the highest anxiety is due to the fact that employees face unclear outcomes regarding their new employer and employment over an extended period of time. This is because outsourcing is not a rapid process but can take months and in some cases, years.

So what can managers do to empower their employees over the course of an outsourcing initiative? For management teams contemplating implementing outsourcing, there are several steps for ensuring that employees are productively engaged in the process. It is important to note that these steps are inter-related and that a comprehensive approach needs to be taken to effectively engage and empower employees over the course of an outsourcing initiative.

**THE CORE COMPETENCY CASE**

The first step to consider in formulating an outsourcing decision is to determine the core competencies for the function or operation under outsourcing consideration. Core competencies represent critical skills and roles required for performance advantage. Core competencies are the activities in which the corporation will
continue to invest in training, technology and advancement. The non-core activities are the ones that can be considered for outsourcing. In essence, the strategy here is to take commodity, non-core activities and transfer them to a supplier. Managers need to conduct their due diligence and develop a clear business case and strategy for outsourcing non-core facets of the business to highly qualified suppliers. Most importantly, they also need to ensure that there is broad alignment within the company with key stakeholders.

In developing the clear business strategy, performance improvement objectives, managers should pursue due diligence, market intelligence and use objective decision-frameworks to do what is right for the patient, employees, and shareholders. Objective, data driven decision-frameworks for outsourcing will be far less polarizing than opaque decisions made for reasons unclear to employees. We find the following framework helpful in framing the outsourcing decision.

ORGANIZATIONAL READINESS
The second important step is to ensure that the corporation is ready to accept outsourcing. Readiness includes both cultural and operational readiness. Cultural readiness refers to ensuring that the broader organization (stakeholders, customers, community, etc.) has been communicated with and is aligned with the outsourcing strategy. As mentioned earlier, developing alignment is essential and the required effort should not be underestimated. Education, fact-based supplier market intelligence, and an ability to understand why previous outsourcing efforts may have failed or under-performed are all necessary for developing cultural awareness and readiness for the need for outsourcing.

Lack of alignment or indecisiveness within leadership teams is a major inhibitor of outsourcing success and is frequently a cause of delay, scope change, or business case dilution. Delay in schedule extends the period of uncertainty for employees means greater loss of productivity and higher anxiety. But let’s face it, developing alignment over a strategy that may represent a departure from legacy operating practices does not happen overnight. It is likely to take some time as the organization prepares itself. What can be done in these situations is to move forward to the extent you can by structuring the outsourcing initiative in phases. Employees are likely to be more engaged with a clear, phased-in approach that is solidly supported by an aligned management team and where there is flexibility to calibrate the outsourcing effort to the cultural readiness of the organization.

A second reason to phase in the initiative may be due to the operational readiness of the organization. If processes are poorly defined and service levels, financials, quality, and measures are not well quantified, the ability to effectively manage a third party relationship may be compromised. Employees are likely to feel more empowered if they feel they are part of a contract relationship with clear service levels, quality, financials, and processes and hence a fair chance of attaining contract success. In common parlance, “fix and shift” versus “lift and shift”.

TIMELY AND EFFECTIVE COMMUNICATIONS
One of the most important aspects of communications is the timing of communications regarding outsourcing intent. Communications that are timed prematurely or those that are provided too late in the process are both likely to demoralize employees. Effective communications are those that are consistent no matter which leader you talk to, are backed up with a solid business rationale, and are expressed in “plain-speak” on key issues – why is this happening, what will happen, when will it happen, how will I be affected, what are my choices, and how can I prepare.

THE RIGHT SUPPLIER & FIT
The selection of the right supplier creates a powerful motivation for employees. Our observation is that more and more, selection decisions are emphasizing cultural value fit
criteria. Not only should the supplier bring the right capability set, but also cultural values that offer the right fit with your company values. What this means is that business development or procurement and operations must work together closely and effectively to design due-diligence processes for supplier that reveal the broader set of values and cultures at a plant level. You should have appreciation of how the supplier’s intent, strategy, approach to problem solving, decision-making style, professional and collegial treatment of their employees, how they frame trade-offs, view towards operating risk, etc. – the important intangibles that affect your ability to build and implement an effective supplier relationship that is flexible and performs well over time. A strong supplier partner selected by the appropriate due-diligence process is likely to empower employees and engage them as they will feel that they are transitioning to the right supplier, selected after careful consideration, that gives them the most career growth potential and best “fit”.

**EFFECTIVE HR TERMS AND POLICY**

HR provisions, key part of the outsourcing contract agreement, form the backbone of governing how employees will be treated at separation, transfer, and also at contract term. In Europe, the HR provisions are labor law driven (for example, TUPE in the U.K.) and require formal processes for notification and provide protections for employee compensation (income, health care, pensions). In the U.S., not all of these protections are provided.

At the outset of the outsourcing relationship, key issues the HR terms address include the policy for how the supplier should approach employing the affected employees, compensation, recognition of years of service, vacation, and treatment of key employees over the contract term. Terms affecting pay rate management are an issue. If there is a large spread between wages earned by employees and the going market rate for employees, the HR terms will determine to what extent the employees have a “soft landing” on wages. Pay rate management may also mean ensuring that the supplier effectively manages compensation fairness and market parity over the course of the outsourcing agreement to ensure good treatment of employees and reduce the risk of turnover or loss of critical skills.

HR terms mitigate against risk of loss of key employees and loss of knowledge. Staff turnover in outsourcing always represents a source of risk to companies and HR terms are strong determinants of how best to balance and manage that risk against competing objectives (such as cost reduction).

**AN “A TEAM” MENTALITY**

Leaders need to think not only about how to manage outsourced employees at the start of an outsourcing agreement, but more importantly, how they should lead and manage the supplier after transition. The key point here is ensuring that the supplier (and transferred employees) is treated and managed effectively. If your SRM process positions the supplier as a “B team” operation, or manages with an “us vs. them” mentality, then employees will feel disempowered. To empower them, ensure that your supplier management team expects the supplier take the highest level of ownership for quality, cost, integrity, and your (customer’s) success. This is likely to be achieved if you manage the supplier with an “A Team” mentality.
SUSTAINABLE MANUFACTURING

Going Green as a Competitive Advantage

DSM Pharmaceutical Products has found that “going green” in its processes is easy to justify from a cost standpoint and gives it a competitive advantage.

EARLIER THIS year, DSM Pharmaceutical Products (Parsippany, N.J.) received a Profiles in Sustainability award from United Business Media and ICIS Chemical Business, based upon its use of microreactor technology to intensify processes and its “green chemistry toolbox” to make production more sustainable and cost-effective.

We directed questions about the efforts behind these achievements to four of DSM’s green leaders: David Ager, PhD, Principal Scientist; Peter Poechlauer, PhD, Principal Scientist; Oliver May, PhD, Corporate Scientist; and Ronald Gebhard, PhD, Director, DSM Innovative Synthesis.

PhM: To what extent do DSM’s “green chemistry toolbox”, and its sustainable mission in general, provide a strategic advantage over competitors?

DSM: The sustainable mission of DSM has many positive consequences that result in a competitive advantage. The use of a renewable feedstock can quickly pay off, as more traditional sources become scarce and raw material prices increase. A reduction in waste decreases waste treatment and disposal costs. The use of a more efficient process not only reduces waste but can also increase throughput and provide a lower cost product.

PhM: What about catalysis? Can you provide details of some of your improvements?

DSM: We continue to move towards catalytic processes both with chemo- and biocatalysts. The use of a catalyst alleviates the use of a stoichiometric reagent. This can have cost benefits through the need to buy less catalyst than the reagent. In addition, waste handling and disposal can be easier and cheaper. Even with transition metal catalysts, cost benefits can be seen, as the methods to recycle the metals are well established. For biocatalysts, enzymes can be overproduced making them readily available. An example is PharmaPLE—pig liver esterase that can be used in pharmaceutical applications as it is produced by microorganisms rather than a pig.

PhM: What have been the hardest challenges in implementing microreactor technology, and have your advances in this area been driven by client mandates?

DSM: Every project is different and has not really been driven by client mandates. The
sustainable Manufacturing

safety factor has played a large role in the implementation of microreactor technology. In addition, the ability to control reactions in a more precise manner can lead to significant cost savings, as by-product formation can be reduced and isolation becomes simpler. Once the technology had been accepted in the plant, there have been few challenges, other than the usual technical ones. In fact, many customers want to use microreactor technology when it is not necessary.

PhM: What sustainability-related metrics do you have for your processes? Can you share some of the more interesting data from these metrics?

DSM: The metrics employed are energy consumption, resource consumption, area usage, emissions, toxicity potential, and risk potential. The 12 principles of green chemistry provide other metrics that result in cost reductions, such as solvent choice and process mass intensity. The use of a single solvent in a process allows for “telescoping”. Solvent recovery is also simplified.

PhM: Is there a regulatory aspect to your green commitment? That is, does sustainable production facilitate your interaction with FDA, OSHA, and other authorities?

DSM: Although the majority of our production facilities are outside of the USA, the regulatory authorities respond in a similar fashion. The reduction in waste, “cleaner” and safer reagents, which reduce worker health concerns, are all seen in a positive light. We always work closely with the FDA and this has allowed us to use microreactors under cGMP.

PhM: What do you do in situations where a client brings a process to you that is clearly not aligned with your sustainable mission, or could be aligned better?

DSM: We would not run an unsafe process. For larger-scale production, “green” approaches will be cheaper than one that uses obnoxious reagents or produces large amounts of waste. Some of the discussions have revolved around solvent choice and usage, process mass intensity (or atom economy) and life cycle analysis (the process will not be feasible at large scale, for example, a starting material may not be available at the required volume.) As a consequence, it is usually a simple matter to convince the customer to go with a greener approach, as this will save money!