

# Improving Quality through Partnerships; Development of a Raw Material Supplier Relationship Management Program in the Biotech Industry

by

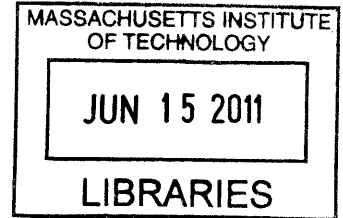
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Submitted to the MIT Sloan School of Management and the Engineering Systems Division in Partial Fulfillment of the Requirements for the Degrees of

**Master of Business Administration  
AND  
Master of Science in Engineering Systems**

In conjunction with the Leaders for Global Operations Program at the  
**Massachusetts Institute of Technology  
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## **ABSTRACT**

In biotechnology, much focus is put on the science behind proteins and cells; less attention has traditionally gone to the raw materials used to produce medicines. However, in the recent past, internal and external drivers have prompted a change in the way biotechnology companies manage raw material suppliers – the old focus was primarily around quality, cost and lead time; an additional focus is now around reliability and consistency.

Suppliers are an integral part of the supply chain for a biotechnology company. To be successful and competitive, biotechnology companies must work effectively with suppliers to understand raw material origins, compositions, interactions with processes and machinery, and to understand the causes of variability and quality defects. Such a partnership or collaborative approach can be executed under a robust supplier relationship management program.

This research study analyzes the early stages of a supplier relationship management program at a biotechnology company – it reviews the program and the results of two pilot activities with suppliers and combines that data with benchmarking and academic work to generate recommendations for improving the program and general recommendations around working collaboratively with raw material suppliers.

The findings of the research study include recommendations spanning a large breadth of activities including company culture, team formation and training, supplier selection, timelines and project management. Notably, the power of positive and proactive relationships was a tangible outcome of the pilot projects and that yields promise in the ability to improve quality and reduce variability through partnerships and collaborations with raw material suppliers.

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*The learnings from this thesis far surpass the duration of the internship and case study, the biotechnology industry, and supply chain management. Over the last year, the author has had the great privilege of learning from and working directly with Victor Yamauchi, a true practitioner of lean and the Toyota Production System (TPS); what she learned from him transcends the professional atmosphere and seeps into the character with which we approach our daily life. The author also thanks Amgen for their trust in her capability and assessment, for their willingness to share challenges and to open their resources in support of her work, and for their genuine desire in improving quality and operations in the name of the patients they serve all around the world.*

*Finally, on a more personal level, the author would like to thank her daughter, Miss Chassitty Saldana, for her resilience during the last 2 years of relocations and for her ability to mend challenges with an encouraging smile.*

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# **1 Introduction**

In biotechnology, incredible focus is placed on the bioscience behind proteins and cells and on the quality measures required to ensure sterility and protein/drug integrity throughout the manufacturing process. Less attention has traditionally gone to the raw materials used to manufacture and produce medicines. However, in the recent past, internal and external drivers have prompted a change in the way biotechnology companies manage raw material suppliers – the old focus was primarily around quality, cost and lead time; an additional focus is now around reliability and consistency.

## **1.1 Project Drivers**

Internal and external drivers have yielded an increased focus on raw material quality, reliability and consistency across a biotechnology company's supply chain. Internal drivers include disruptions to operations as a result of raw material variability previously unknown to matter, as well as newly discovered material properties and their negative interactions with processing equipment, in addition to other nuisances. External drivers include a regulatory focus on zero defects [10] and higher quality expectations from customers, particularly those in areas like Japan, where aesthetics are highly regarded.

Suppliers are an integral part of the manufacturing and delivery process of a biotechnology company. To be successful and competitive in light of the new drivers for quality, biotechnology companies must work effectively with suppliers to understand raw material origins, compositions, interactions with processes and machinery, and to understand the causes of variability and quality defects.

## **1.2 Problem Statement**

There is an opportunity for increased collaboration and partnership between biotechnology companies and suppliers in order to understand raw material origins, interactions with processes and machinery, and to understand the causes of variability and quality defects throughout the drug production process.

Such a partnership or collaborative approach reaches far beyond the typical supplier management that simply looks at metrics involving cost, lead time and quality-at-receipt attributes. The partnership can be executed under a robust supplier relationship management program and must involve improvements across the supply chain - in all aspects and perspectives. Once opportunities are created that help strengthen the overall supply chain, biotechnology companies and suppliers can, together, achieve highest quality, manage costs and shorten lead-time to better serve patients and customers around the world.

The project need serves the impetus described above; it involves the analysis and evolution of a pilot program aimed at executing an effective biotech and supplier partnership. It was believed that through improved supplier collaboration, visibility of product value-streams, structured problem solving and mutually beneficial process improvements, biotechnology would continue to deliver high quality products to patients worldwide.

### **1.3 Thesis Overview**

This document is organized in the following manner:

**Chapter 1** outlines the general motivation for the thesis and provides an overview of the thesis contents.

**Chapter 2** provides a brief discussion of the industry and company background, as well as a description of the evolution of supplier relationship management in the biotechnology/pharmaceutical industry and major improvements to date.

**Chapter 3** examines supplier relationship management at Amgen – the organizations involved, touch-points with suppliers, and the evolving SRM strategy.

**Chapter 4** presents the author’s hypothesis for the outcome of the case study.

**Chapter 5** outlines the methodology and approach used to execute the study.

**Chapter 6** explores relevant literature.

**Chapter 7** presents the development of the SRE program, including the initial state, the tools used during the case study, and the program's current state.

**Chapter 8** references the nuisances of implementing the SRE program.

**Chapter 9** provides the author's conclusions on the case study.

## **2 Background**

### **2.1 Biotechnology Industry**

The term biotechnology was originally coined in the year 1919. At that time, the term meant all the lines of work by which products are produced from raw materials with the aid of living organisms.[1] Nowadays, at its simplest, biotechnology is technology based on biology - biotechnology harnesses cellular and biomolecular processes to develop technologies and products that help improve our lives and the health of our planet. Modern biotechnology provides breakthrough products and technologies to combat debilitating and rare diseases, and also has applications in non-medicinal areas like reducing our environmental footprint, feeding the hungry, enabling the use of less and cleaner energy, and having safer, cleaner and more efficient industrial manufacturing processes.[4]

There are currently more than 250 biotechnology health care products and vaccines available to patients worldwide.[4] Many of these products treat previously untreatable diseases and therefore make a significant difference in the lives of patients and their families. Biotechnology companies can pick a sector of diseases/ailments, or choose to focus on several of them at the same time. Regardless of the type of disease being treated, biotechnology manufacturing is incredibly regulated and process-driven.

Because of the amount of sterility required to protect and to maintain a drug's integrity throughout the manufacturing process, quality plays an important role in the manufacturing lifecycle. Quality not only applies to performance against requirements in the final stages of manufacturing, but it also extends to the raw materials used in conjunction with the drug product, to interactions between raw materials, drug product and equipment, and to material handling throughout the supply chain.

### **2.2 Company Background**

Amgen, Inc. is a publicly-traded international biotechnology company headquartered in Thousand Oaks, CA. It discovers, develops, manufactures and markets medicines for grievous illnesses. In 2009, its

revenues were approximately \$14.4B, it invested about \$3B in research and development, and it ranked in as number 159 in the Fortune 500 list. Amgen employs 17,000 employees in several locations across the United States and in the Netherlands. Amgen's current products include Epogen®, Aranesp®, Enbrel®, Vectibix®, Neupogen®, Neulasta®, Nplate®, Sensipar®, Prolia®, and Xgeva®.[1]

Amgen, Inc. is a leader in the biopharmaceutical industry with more than 25 years of experience applying a science-based approach to drug development. After it was founded in 1980, Amgen pioneered the use of recombinant DNA and molecular biology to develop biologically derived therapeutic products. In the 1990's, the company introduced the biopharmaceutical industry's first blockbusters, Epogen® (Epoetin alfa) and Neupogen® (Filgrastim), which have since improved the lives of hundreds of thousands of patients. The company currently has ten products on the market that provide supportive cancer care and treat a variety of conditions from anemia to rheumatoid arthritis and other autoimmune diseases.[8]

Recently, Amgen has received the "Best Biotechnology Pipeline" ranking from *R&D Directions* in its January 2011 issue. The ranking is part of the magazine's annual review of the top 10 therapeutic pipelines in the biotech and pharmaceutical industries and the ranking highlighted the fact that Amgen has more than tripled the size of its pipeline since 2001.[3] As a leader in the biotechnology industry with a proven innovation and continuous improvement track record – in addition to the ranking noted above, Amgen has developed an Operational Excellence (OpEx) program that focuses on lean and continuous improvement – Amgen can offer valuable experience and results-based insight into the benefits of collaborative programs with suppliers and their resulting impact on product quality, cost and lead time.

### **3 Supplier Relationship Management at Amgen**

The management of suppliers is a crucial function at Amgen, Inc., just as is the case with any major manufacturer. Independent of sourcing strategy – vertical integration versus complete outsourcing, manufacturers and integrators alike are discovering the importance of understanding component manufacturing and interactions between components throughout the manufacturing process on overall product quality.

The procurement or sourcing function has traditionally held the most responsibility for supplier performance, although that role has evolved over the years to include dabbling in quality, engineering and continuous improvement. In the following sections, the author describes the role of Lean in supplier relationships, the different Amgen organizations that interface with suppliers, and Amgen’s evolved focus regarding supplier management.

#### **3.1 How Lean Plays a Role in Supplier Relationship Management**

Over the last three years, Amgen has experienced great momentum behind Operational Excellence (OpEx), a program that includes the basic principles of lean and continuous improvement, but caters specifically to the internal structure and processes of Amgen, Inc. The Operational Excellence group resides within corporate headquarters and is responsible for developing and appropriating continuous improvement frameworks and processes, and for systematically working with different organizations to implement them to improve processes and operations.

Employee engagement and a format of training trainers are both key in successfully proliferating the OpEx culture. With OpEx increasingly growing out of the corporate headquarters and permeating into each manufacturing facility, Amgen has found a great opportunity to tie in this corporate movement with collaborative improvement projects with suppliers.

#### **3.2 Evolved Supplier Relationship Management Strategy**

Internal and external drivers have prompted a change in the way Amgen manages raw material suppliers. The focus has evolved from the assurance of supply and quality to include an additional focus on value, reliability and consistency. OpEx, as described above, is an easy company tool to draw on for this purpose, as it incorporates a well-known internal program with a new [external] implementation model. Figure 1 below depicts how internal and external drivers create the need for an evolved supplier relationship management model that extends the OpEx framework to the supply base.

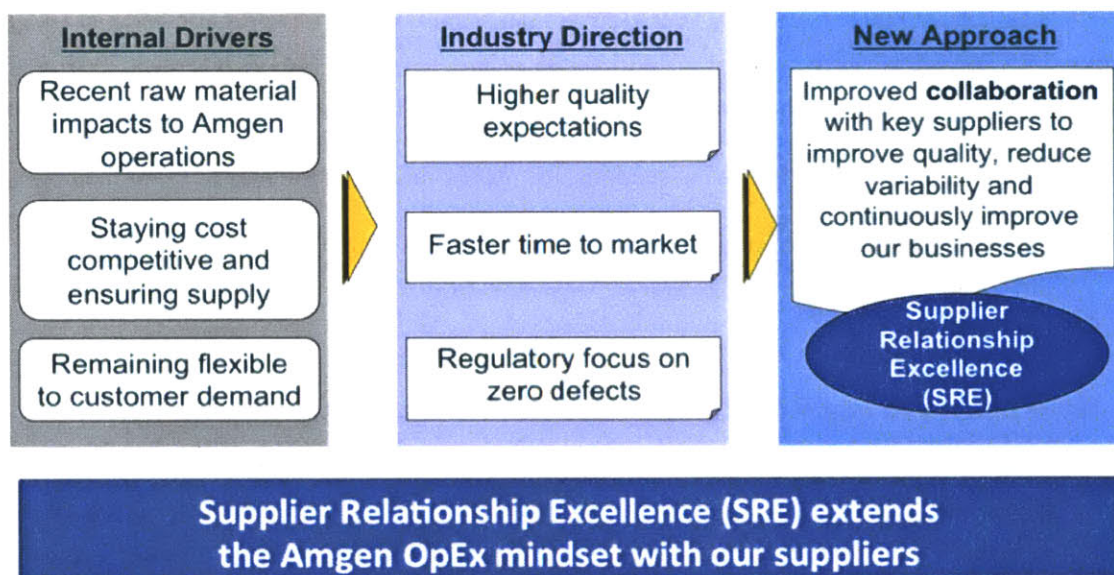
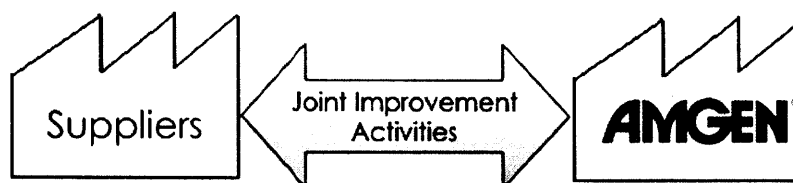


Figure 1. Internal and External Drivers for Change

As shown in Figure 1 above, internal drivers include recent raw material impacts to Amgen operations and increasingly stringent customer quality requirements. They also include more general and pervasive operations goals like remaining cost competitive, ensuring supply to patients, and remaining flexible to customer demand. The industry component is one that is expected to become more and more important with time based on current trends. It includes higher quality expectations globally, a faster product-to-market requirement, and a regulatory focus on zero defects.



These drivers have yielded a new supplier relationship management approach for Amgen. At the highest company levels, there is an acknowledgment that suppliers are an integral part of Amgen's supply chain; to be successful and competitive, Amgen must improve its supply chain from all aspects and perspectives.



**Figure 2. Joint Improvement Activities are Key to Improving the Supply Chain**

The evolved supplier relationship management approach is collaboration with key suppliers to improve quality, reduce variability and continuously improve both Amgen's and the Supplier's process. This collaboration is to be achieved under the Supplier Relationship Excellence (SRE) Program. The SRE Program is a comprehensive way to work proactively with key strategic suppliers. The foundational theme behind SRE is that it extends Amgen's Operational Excellence (OpEx) mindset with its suppliers.

### **3.3 Organizational Structure and Supplier Interfaces**

Amgen, Inc. is a large organization of about 17,000 staff members worldwide.[2] There are large groups that focus on engineering or process development, sourcing and quality. Along with executive teams and manufacturing representatives, these are the major players interfacing with suppliers. Some hold direct accountability for negotiating contracts or for maintaining metrics, while others provide oversight or focus on less tangible gains. Nevertheless, main organizations with a supplier interface are briefly described below and their interactions with each other are shown graphically.

The Amgen Supplier Governance Board (SGB) is a small strategy-focused group consisting of Vice Presidents in the areas of Global Strategic Sourcing (GSS), Supplier Quality Management (SQM), Corporate Manufacturing, Process Development (PD) and manufacturing site leads. The Board is

responsible for overseeing Amgen's raw material suppliers and for enacting strategic initiatives in an effort to reduce risk to Amgen operations. Supplier-related concerns arising from any area within the company can be elevated to this group. Additionally, it is this group that sets the tone and focus for working with suppliers at the company level. The SGB is therefore a key messaging vehicle for rolling out initiatives or refocusing efforts in any direction.

The Raw Material Risk Management team is a small action team dedicated to addressing risks involving raw material suppliers. The team is composed of Directors and Executive Directors in the same areas noted above. This group acts as the first responder to issues involving suppliers and as risks increase, this group can elevate to the SGB.

The Raw Material Operation Forum is a quality-personnel driven team composed of SQM and quality assurance (QA) employees across Amgen sites working together to ensure cross-site collaboration and process synchronization in handling raw material issues. This group is mainly concerned with effective and timely communication of raw material issues across sites and with standardization of tasks. However, their work also includes suppliers and supplier representatives in cases involving concerns with raw material receipts.

Supplier Relationship Management (SRM) is a process owned by Global Strategic Sourcing. SRM is a company-wide program that seeks to develop/foster relationships with all of Amgen's suppliers.

Organizations like product development and supplier quality management participate in the SRM process via surveys and specific feedback on the customer experience and on material quality and performance. A smaller subset of the SRM program deals specifically with Amgen operations and with the suppliers that support direct clinical or commercial work. The SRM-Operations team is the most relevant to this paper and the author's research project, as it serves as the umbrella organization for Supplier Relationship Excellence. SRE supports a specific "Joint Collaboration" effort of SRM-Operations. The joint collaboration component of SRM is depicted in Figure 3 below.

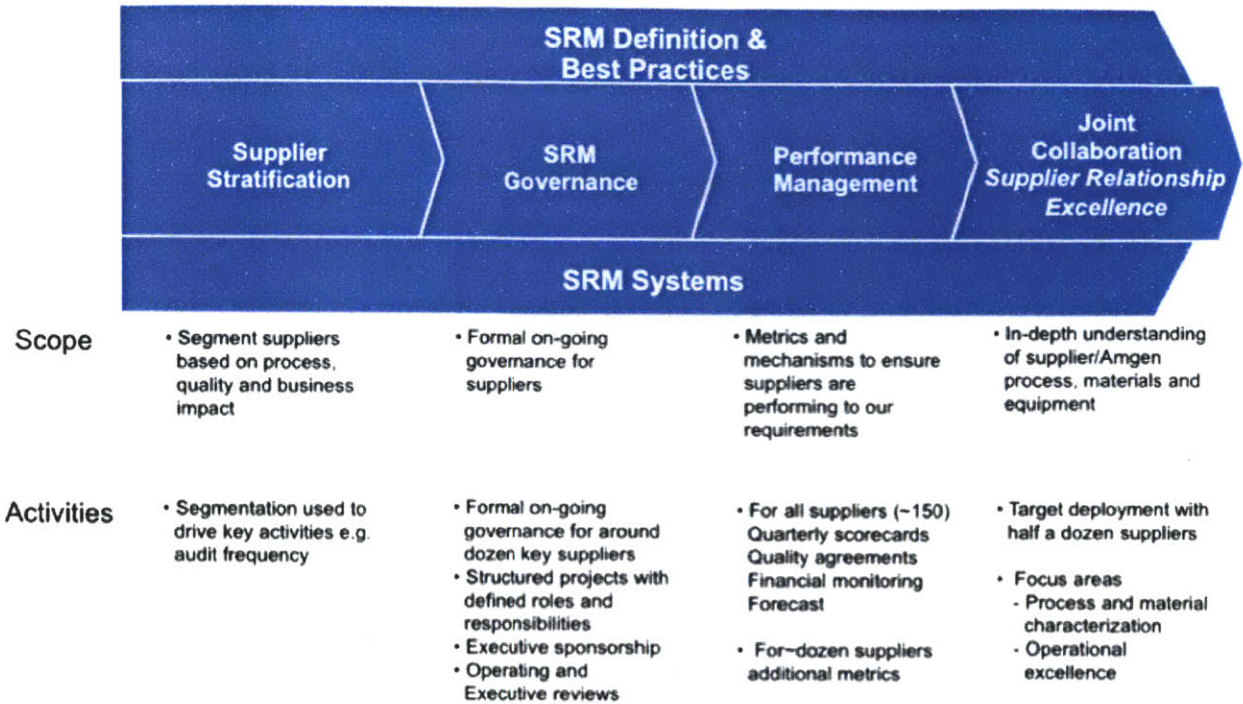
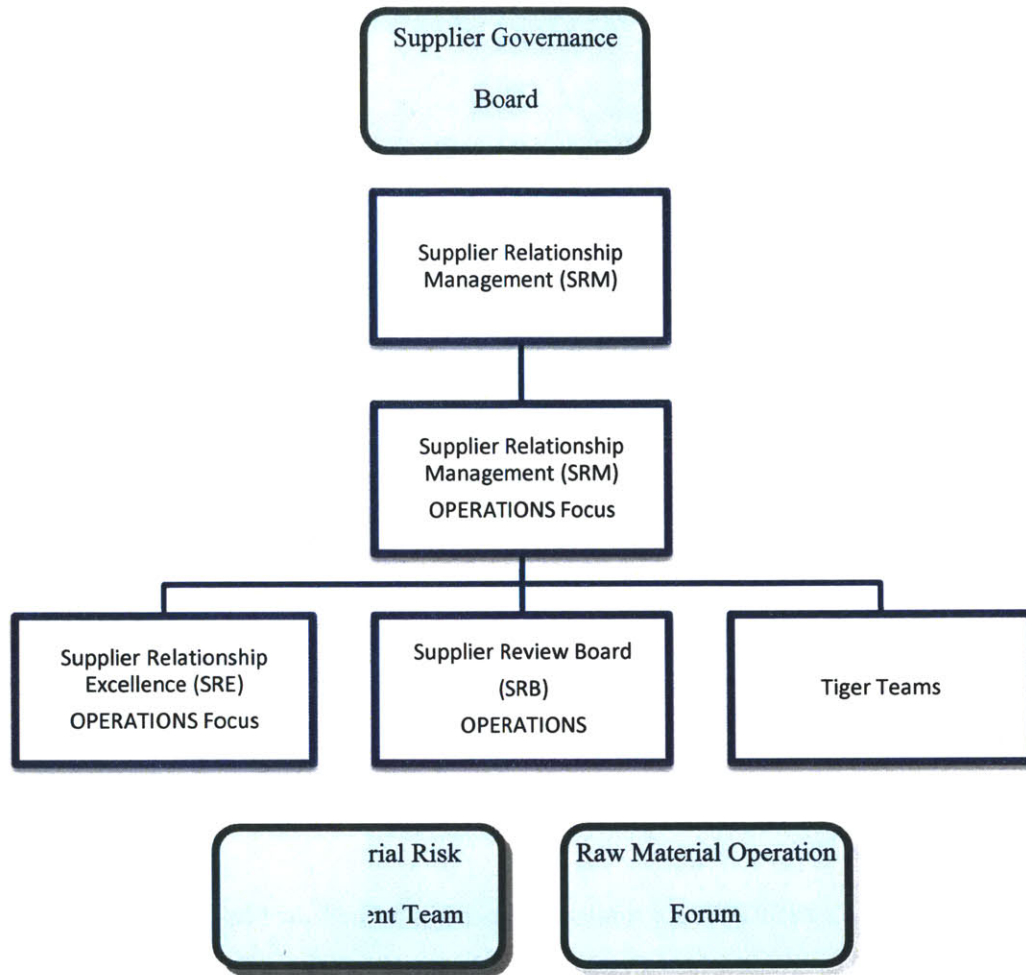


Figure 3. SRE Fits Into General SRM Structure

The Supplier Review Board (SRB) has a similar membership to the Raw Material Risk Management team described above. The SRB, however, not only responds to arising issues/concerns, but also develops strategic frameworks for thinking about supplier management and oversight. The SRB periodically compiles and reviews supplier scorecards and works collaboratively and cross-functionally to determine how to best proceed with any given supplier. The focus of the SRB is also on raw material suppliers and therefore, this team is very important to the research project carried out by the author and to SRE.

Lastly, Tiger Teams are identified below to acknowledge the myriad projects ongoing at any given time with a large number of Amgen and supplier teams. These projects begin to address specific needs and end once concerns are sufficiently solved or effectively mitigated.



**Figure 4. Overview of Organizations with Supplier Focus**

## 4 Hypothesis

The terms *collaboration* and *hypothesis* yield visions of classroom activities or projects in which the sum of parts is greater than the whole. As such, the hypothesis for the results of this case study included a vision in which raw material suppliers willingly partnered with biotechnology companies in pursuit of:

- Knowledge and training
- Humanitarian benefit of patients
- Competitive advantage

The hypothesis was therefore that collaboration and partnership would yield mutual tangible benefits around quality and processes, that the benefits would yield additional interest and resources, and that the program would quickly grow and gain popularity through the success of its early adopters. In addition, it was perceived that this model would soon permeate the industry as a business standard.

However, in business, and especially in high stakes businesses like biotechnology, there are intricacies involved with partnerships that the author discovered and uncovered through the progression of the pilot activities. These intricacies are discussed further in the Discussion section and are itemized below:

- Long-term versus short-term focus
- Relationship/performance improvement versus sustainment
- The role of ethics
- Phased implementation

## **5 Research Methodology**

Academic research has shown the importance and success of buyer and supplier collaboration efforts. In an academic study examining 56 buyer to supplier alliances, the author found that successful partnerships are significantly related to resource commitments, trust and coordination, information sharing, joint problem solving, and the existence of a formalized supplier selection process.[12] The framework for this case study was largely influenced by the results noted above and focused on specifically working to build trust, to share information, to jointly problem solve, and to institute a formal supplier selection process.

### **5.1 Data Collection and Analysis**

In support of this case study, data was collected through benchmarking research, one to one stakeholder interviews, and through direct participation in the pilot projects with suppliers. Existing metrics around supplier performance were also used to understand important measures of performance and current communication venues and frequency. All interviews, collection of data and subsequent analyses were performed at Amgen, Inc., primarily at the Thousand Oaks, CA site.

It is important to note that the themes of continuous improvement and lean are still maturing in the biotechnology industry. Consequently, while searching for benchmarking data, it was important to reach beyond the industry to look for successful supplier relationship management models and frameworks. In addition, while speaking with internal Amgen and external supplier stakeholders, it was necessary to first describe a vision of partnership and collaboration, and then ask questions based on such a relationship premise.

### **5.2 Framework and Approach**

The approach to the business case was largely influenced by the case study supervisor and then modified based on my experience. My supervisor's profound knowledge of continuous improvement and supplier relationship management enabled him to suggest an approach that included a go-and-see aspect in which I was able to tour internal and external manufacturing facilities.

Moreover, the framework ensured a systematic introduction to the challenges around raw material quality, consistency and reliability and also armed the author with explicit knowledge and data that aided in successfully executing each step of the approach. Figure 5 below depicts a Plan, Do, Check, Act framework, which was the basis of the approach to this case study.

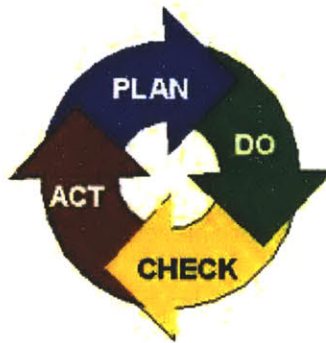


Figure 5. Plan-Do-Check-Act Cycle

The Plan, Do, Check, Act cycle is a four-step model for carrying out change. Just as a circle has no end, the PDCA cycle should be repeated again and again for continuous improvement.[4] The case study approach followed the PDCA framework as shown in Figure 6 below.

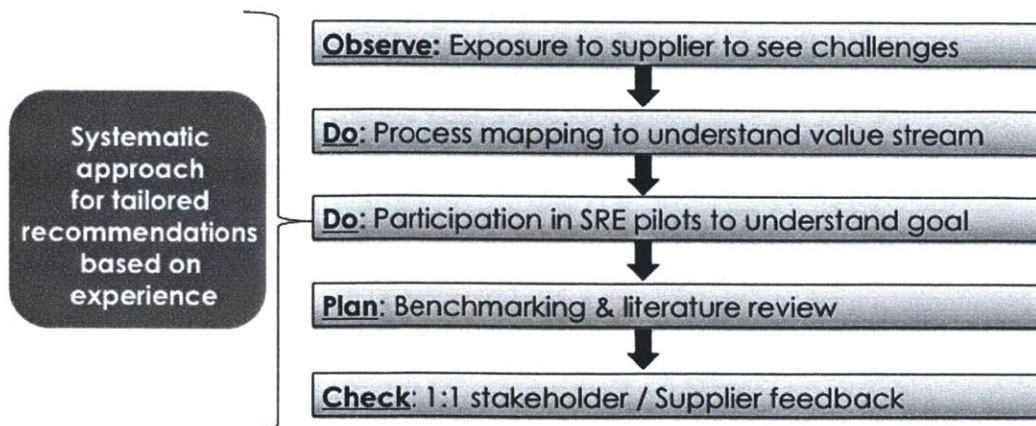


Figure 6. Systematic Approach to Case Study

1. Introduction & Observation: It was first important to obtain a general understanding of the biotechnology industry and to learn about Amgen's way of doing business. This included learning about Amgen's maturity in lean or Operational Excellence, and in continuous improvement. It was also of interest to learn about how different Amgen organizations work together to support suppliers and how many of them have an outward-facing relationship with suppliers. This introduction to the industry and to Amgen was accomplished via:
  - Process tours of the raw material receiving and inspection area
  - Shadowing of the upstream and downstream processes
  - Research and reading material, including the Amgen history book and website
  - One to one conversations with various organizations to understand their stake in SRM

The next observatory step involved visiting raw material suppliers to see first-hand what some of their manufacturing challenges were and what kind of resources they had available to expend on a partnership with Amgen. Overall, it was important to meet supplier personnel, to see their process, and to speak with their shop floor employees.

2. Value Stream Mapping: The next step involved using the access to suppliers to develop a concrete and physical value stream map following a primary device's value stream from raw material through the supplier and then through Amgen. Figure 7 below shows the value stream and then highlights the primary area of focus for this case study.



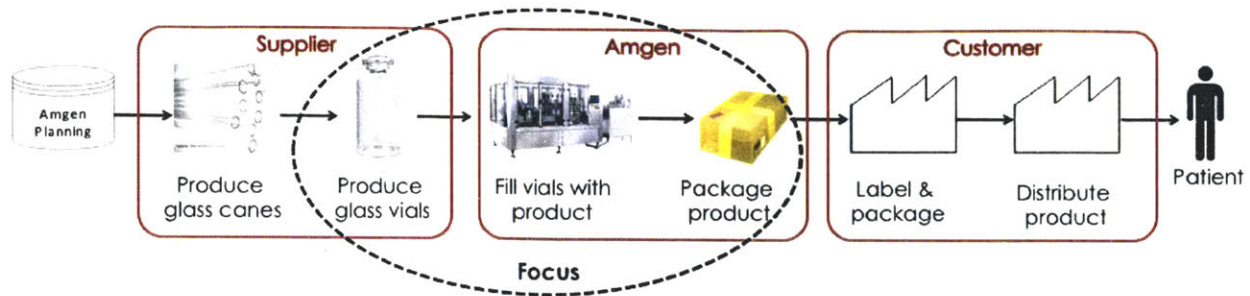


Figure 7. Glass Vial Value Stream

It was discovered that the suppliers visited did not have a robust way of capturing their manufacturing processes or their capacity and problem solving methodologies. Therefore, being able to do something **for** the supplier was key in building trust and inspiring credibility. Very often, companies visit suppliers and drain their time and resources by requesting information, tours, and data. The supplier provides a service and depends on the customer and is therefore obliged to assist with the requests. However, being able to both gather information and provide it during the same trip is key in setting the groundwork for an effective partnership and collaboration arrangement. The importance of this step was underestimated until much later – it empowered the author with critical and specific data that and also engaged the supplier in learning more about how they could benefit from Amgen’s expertise.

3. Participation in Program Pilots: With a high-level understanding of the industry, the process, and the supplier and Amgen challenges, it was then time to review the proposed supplier relationship management program and to deploy some pilots for evaluation.

Two suppliers were selected as pilots for the program based on their importance to Amgen operations, their perceived importance in the future, and their availability and willingness to collaborate among other factors. For each supplier engagement, an Amgen team traveled to the supplier, presented the program, met the supplier team, toured a production facility and jointly

identified workstreams, or target areas for further work. More discussion on the pilots is presented in Chapter 7.

4. Benchmarking and Literature Review: Literature review and benchmarking for best practices across varying industries was key in this case study due to the limited amount of data and experience around collaborative supplier partnerships in biotechnology. During this phase, the author relied on the expertise of her academic advisors and her supervisor, on the experiences of her peers across other sectors and companies, and on data found through the review of supply chain articles and journals.
  
5. One to one Stakeholder and Supplier Feedback: Another extension of first-hand exploration involved speaking one to one with both internal and external stakeholders. About three months after the pilots were kicked off, the author was able to conduct over two dozen interviews with those directly involved with the activities to understand the following:
  - Their motivation for participating – the need being addressed
  - Team makeup and whether it was comprehensive – on both sides
  - Project management effectiveness
  - Workstream effectiveness
  - Improvement suggestions
  - Evidence of improved supplier relationship
  - Resources expended

As noted earlier, the approach described above provided a strong framework from which the author could make tangible recommendations for the further evolution of the supplier relationship management program at Amgen. These recommendations were based on the results of the pilots, the feedback received from suppliers and internal Amgen stakeholders, and learnings from other companies. An analogous

approach is recommended to the reader for any type of case study work that involves collaboration between one company and its supply base.

## **6 Literature Review**

### **6.1 Suppliers as Part of a Company's Value Chain**

In a recent article, MIT Civil Engineering Professor David Simchi-Levi discusses emerging trends in value chain design.[11] He first defines value chain as a focus on who gets the value in the chain, who creates value, who captures value and where value is created. Whereas in a supply chain, the important topics are related to becoming more efficient or sustainable, in a value chain, the important topics are related to changing the competitive landscape and the competitive advantages through the design of an end-to-end value chain.

He presents two main models – modular and integral architectures. Integral value chains are defined as win-win models in which companies incentivize their suppliers to share innovation, because the attitude of the players is that they will benefit collectively from any value gained based on the long-term trust-based relationship that is developed. He then recommends the integral value chain architecture for mature industries or for companies ready to implement an end-to-end value chain design that yields a win-win benefit with suppliers.

### **6.2 Importance of Supplier Relationship Management**

Suppliers are contracted to provide goods according to set specifications for an agreed-to price and in support of an agreed-to schedule. Customers receive the goods and validate them against the specifications, yielding data on adherence to requirements. Metrics are also collected around annual spend on the supplier, on-time delivery performance, quality measures, and response to inquiries. In order to constantly improve and increase a company's bottom line (recall lean goals of highest quality, lowest cost and shortest lead time), relationships with suppliers must be managed by companies.

There is large variation in approaches to supplier relationship management. For providers of low cost goods, SRM has an emphasis on acquiring the lowest cost goods with quality being a less important

characteristic. For premium goods, quality is of much higher importance. For companies with short clockspeed, as described in MIT Professor Charlie Fine’s book Clockspeed[7], reliability is not necessarily a high priority.

Moreover, according to M. Bensaou, associate professor of technology management at INSEAD, “*Effective supply-chain management requires choosing a type of relationship appropriate to product and market conditions and adapting management practices to that relationship.*”[4] Professor Bensaou also notes the following management profile for a strategic partnership between buyers and suppliers:

<p><b>Captive Buyer</b></p> <p>Information-sharing mechanisms</p> <ul style="list-style-type: none"> <li>• “Broadband” and important exchange of detailed information on a continuous basis</li> <li>• Frequent and regular mutual visits</li> </ul> <p>Boundary spanners’ task characteristics</p> <ul style="list-style-type: none"> <li>• Structured task, highly predictable</li> <li>• Large amount of time spent by buyer’s purchasing agents and engineers with supplier</li> </ul> <p>Climate and process characteristics</p> <ul style="list-style-type: none"> <li>• Tense climate, lack of mutual trust</li> <li>• No early supplier involvement in design</li> <li>• Strong effort by buyer toward cooperation</li> <li>• Supplier does not necessarily have a good reputation</li> </ul>	<p><b>Strategic Partnership</b></p> <p>Information-sharing mechanisms</p> <ul style="list-style-type: none"> <li>• “Broadband,” frequent and “rich media” exchange</li> <li>• Regular mutual visits and practice of guest engineers</li> </ul> <p>Boundary spanners’ task characteristics</p> <ul style="list-style-type: none"> <li>• Highly ill defined, ill structured</li> <li>• Nonroutine, frequent unexpected events</li> <li>• Large amount of time spent with supplier’s staff, mostly on coordinating issues</li> </ul> <p>Climate and process characteristics</p> <ul style="list-style-type: none"> <li>• High mutual trust and commitment to relationship</li> <li>• Strong sense of buyer fairness</li> <li>• Early supplier involvement in design</li> <li>• Extensive joint action and cooperation</li> <li>• Supplier has excellent reputation</li> </ul>
<p><b>Market Exchange</b></p> <p>Information-sharing mechanisms</p> <ul style="list-style-type: none"> <li>• “Narrow-band” and limited information exchange, heavy at time of contract negotiation</li> <li>• Operational coordination and monitoring along structured routines</li> </ul> <p>Boundary spanners’ task characteristics</p> <ul style="list-style-type: none"> <li>• Limited time spent directly with supplier staff</li> <li>• Highly routine and structured task with little interdependence with supplier’s staff</li> </ul> <p>Climate and process characteristics</p> <ul style="list-style-type: none"> <li>• Positive social climate</li> <li>• No systematic joint effort and cooperation</li> <li>• No early supplier involvement in design</li> <li>• Supplier fairly treated by the buyer</li> <li>• Supplier has a good reputation and track record</li> </ul>	<p><b>Captive Supplier</b></p> <p>Information-sharing mechanisms</p> <ul style="list-style-type: none"> <li>• Little exchange of information</li> <li>• Few mutual visits, mostly from supplier to buyer</li> </ul> <p>Boundary spanners’ task characteristics</p> <ul style="list-style-type: none"> <li>• Limited time allocated by buyer’s staff to the supplier</li> <li>• Mostly complex, coordinating tasks</li> </ul> <p>Climate and process characteristics</p> <ul style="list-style-type: none"> <li>• High mutual trust, but limited direct joint action and cooperation</li> <li>• Greater burden put on the supplier</li> </ul>

**Figure 8. Management Profiles for Varying Buyer and Supplier Relationships**

Other academic articles have also lauded the importance of collaboration. In an article on strategic partnerships, USC Business School Professor Robert Spekman defines collaboration as the process by which partners adopt a high level of purposeful cooperation to maintain a trading relationship over

time.[13] He further notes that the relationship is bilateral; both parties have the power to share its architecture and future direction over time. Mutual commitment to a balanced relationship is also essential. It is under these academic umbrellas of value chains involving the customer and supplier relationships based on mutual commitment and collaboration that this case study is conducted.

### **6.3 Industry Philosophy for Supplier Relationship Management**

In biotechnology and the pharmaceutical industries, supplier relationship management plays an important role in ensuring the quality and integrity of medicines that help human beings treat diseases around the world. Traditionally, SRM in these industries has been intricate albeit focused predominantly on quality, cost and lead time.

### **6.4 Supplier Relationship Management Practices Across Other Industries**

In the two following sections, two approaches to supplier collaboration are highlighted. In the first example, we look at Toyota Motor Company as one of industry and academia's most well-known and most-cited examples of successful supplier partnerships. From Toyota, we gather tangible examples of how setting a vision from the company's highest executive levels is important in translating the value of supplier partnerships down to all levels of the organization. From Toyota, we also learn about the use of information technology and collaborative media tools to share information and to effectively communicate. In the second example, we look at United Technologies Corporation to understand how a supplier partner in a successful collaboration could be rewarded or recognized for their participation and contribution. Rewards and recognition are important tools in building trust and respect and in ensuring continued dedication and interest from suppliers. As such, it is important to not overlook these themes when designing a supplier relationship management program and to learn from a company that has a robust way of measuring and rewarding the suppliers it chooses to partner and collaborate with.

#### **6.4.1 Toyota Motor Company: Setting a Vision for Successful Partnerships**

When thinking about supplier relationship management and best practices in working with suppliers, it is inevitable to name the Toyota Motor Company as an example of a company successfully executing collaborative partnerships with its suppliers in the automotive industry. However, there are also many other companies in diverse industries executing beneficial partnerships and whose models have a lot to teach us in support of this case study.

To begin, we will briefly discuss the Toyota Motor Company model of working with suppliers.

Organizationally, Toyota has dedicated an entire division to proactive work with suppliers. Structurally, the company's vision and model support the partnerships from the highest of levels. In a recent speech to Toyota employees to present an updated global vision, President Akio Toyoda had important reminders for the Toyota family:

*"We conclude the vision with the reminder that we at Toyota are people "who believe there is always a better way." Every kaizen improvement is the beginning of other kaizen improvements. Kaizen is an unending process. All of us at Toyota share a commitment to that fundamental principle of the Toyota Way.*

*This is what the Toyota Precepts mean in reminding us to "be kind and generous" and to "create a warm, homelike atmosphere." The idea is to earn as many smiles as possible. It means building relationships of trust and mutual respect with customers and also with business partners, with members of the community at large, and with our fellow team members at Toyota."*[11]

It is of particular importance to see how principles of trust and mutual respect are so present throughout the speech. Recalling Professor Bensaou's management profile for strategic partnerships above, we can see consensus with climate and process characteristics of high mutual trust, a commitment to building the relationship, and overall fairness.

On a more practical and working level, Toyota has a website portal dedicated to working with its suppliers. Again, referring to Professor Bensaou's management profile for strategic partnerships, we see evidence of rich media exchange. The website has the following note regarding its purpose:

*“ToyotaSupplier.com is an extension of our commitment to long-term, mutually beneficial relationships with our North American suppliers. Toyota Motor Engineering & Manufacturing North America (TEMA) works side-by-side with hundreds of North American suppliers to build our top quality vehicles. Now current and potential suppliers can get information on our purchasing policies, newsworthy articles, and bio information through this home page. The login section takes existing suppliers to applications and documents they need to conduct business with Toyota online.”*

My corporate experience involving suppliers is mired with memories of the challenges of communicating expectations, updates, contact information and schedules between supplier and customer. Although the inner workings of the web portal can only be assumed, the structure and vision presented lead one to believe that the information boundary between Toyota and its suppliers is well integrated. Moving on to biotechnology, additional intricacies related with the industry have to do with good manufacturing practices (GMP), intellectual property, and potential raw material interaction with drug products.

#### **6.4.2 United Technologies Corporation: Recognizing and Rewarding Success**

Another supplier of interest when seeking buyer to supplier best practices is United Technologies Corporation (UTC), a diversified company whose products include Carrier heating and air conditioning, Hamilton Sundstrand aerospace systems and industrial products, Otis elevators and escalators, Pratt & Whitney aircraft engines, Sikorsky helicopters, UTC Fire & Security systems and UTC Power fuel cells.[17] UTC has a strong focus on developing its suppliers with a goal of reaching a world class integrated supply chain.

To accomplish supplier development, UTC uses resources like lean self-assessments and training courses, all available online and in a variety of languages. Just like Toyota, UTC also has a web portal suppliers use to access information essential to doing business with UTC, as well as tools and training to help develop the supplier’s capabilities.



To recognize suppliers who collaborate with UTC, the company has created the Supplier Gold Program, a program that facilitates and accelerates superior supplier performance and recognizes supplier excellence via four performance levels. The maximum level, gold, has the following criteria[18]:

- Zero escapes for the last 12 months
- 100% to requirements for the last 12 months
- Customer satisfaction score  $\geq 6$
- UTC Lean assessment score  $\geq 250$  in Manufacturing;  $\geq 350$  in Services/Distribution

Suppliers that reach the criteria noted above receive two main benefits: increased overall business performance enabling improved profitability, and rewards and recognition through physical awards, UTC leadership visibility and publication in industry journals. The following Figure shows the high level process for suppliers entering the UTC supplier gold program:

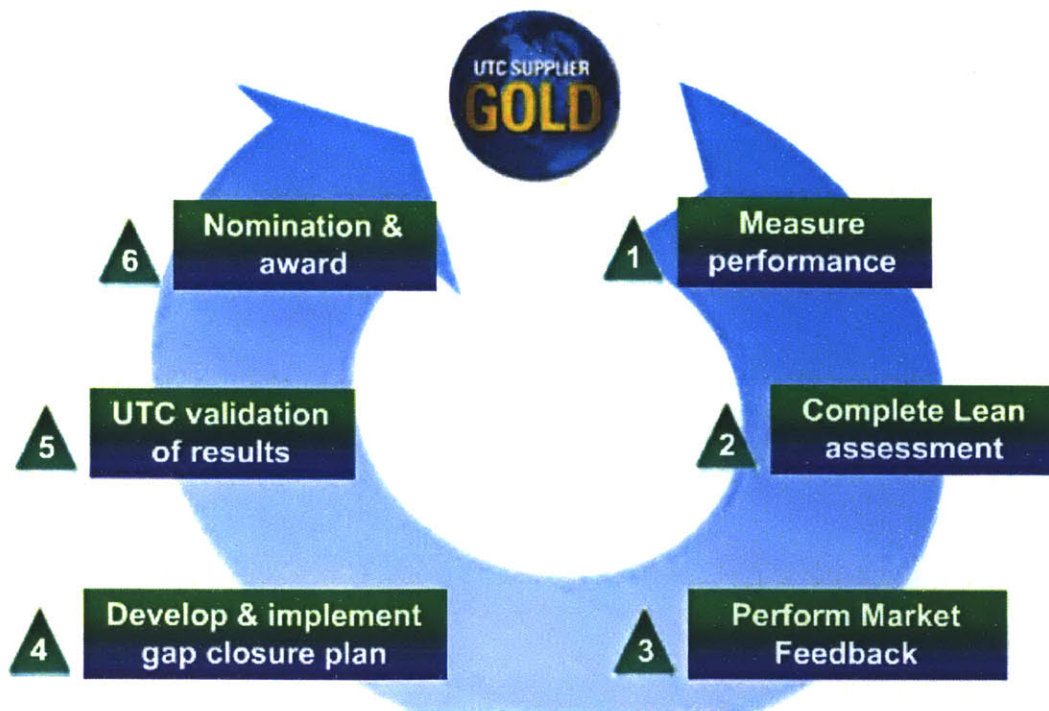


Figure 9. UTC Supplier Gold Program Process to Facilitate Performance

The UTC Supplier Gold program presents a great example of how to integrate supplier development and growth with recognition and rewards. With the Supplier Gold program, suppliers know exactly what it takes to reach and maintain gold status and they also know the benefits they can reap by reaching that level. Because buyer to supplier relationship building is still in its development stage in the biotechnology industries, companies like Amgen can use program's like this one as a way to gain buy-in from suppliers who want a first-player advantage at reaching industry-wide recognition.

# 7 Supplier Relationship Excellence Program Development

Armed with an understanding of operations challenges in biotechnology, and with knowledge of what other companies and industries are doing to improve quality along the value chain, the focus now turns to developing an appropriate supplier relationship management program.

## 7.1 SRE Initial State

The Supplier Relationship Excellence (SRE) Program was created as a comprehensive means by which to work proactively with strategic suppliers. The program’s name was coined by Amgen, Inc. in the first quarter of 2010 and was deliberately differentiated from the standard supplier relationship management activities that take place around the company for all suppliers as discussed in a previous section.

Prior to the internship that supports this case study, momentum around SRE existed. The figure below outlines the initial state of SRE at the time the case study began:



Figure 10. SRE Initial State

The SRE concept and initial definition was generated by Director-level employees in the sourcing, product development, and supplier quality organizations. In addition, this mini-steering team targeted suppliers for potential kick-off activities. The concept was presented to the Supplier Governance Board

(SGB). The board concurred with the concept and initial definition. Moreover, there was also some activity with a supplier that was managed under evolved partnership principles, although it wasn't explicitly referred to as an SRE project with the supplier.

## 7.2 Toolbox for Evolving SRE

To evolve the SRE program, several tools were used. These included following established processes and frameworks like the Plan-Do-Check-Act cycle and process mapping, as well as more soft tools like one to one stakeholder interviews and soliciting supplier feedback. Figure 11 below shows a more complete list (although not comprehensive) of the tools used to help evolve the SRE program at Amgen:

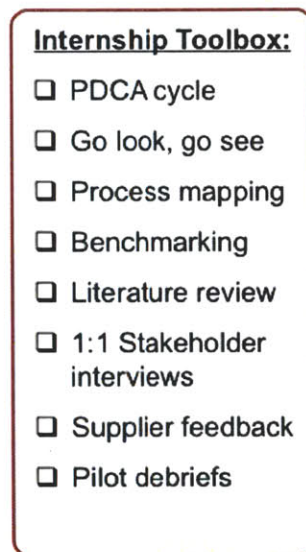


Figure 11. SRE Development Toolbox

The tools described in Figure 11 above were described in detail in Section 5.2, while discussing the framework of the case study and the approach taken.

### 7.2.1 The Importance of Go and See

Genchi Genbutsu is an important concept in Lean Manufacturing[11] and has to do with physically going to the source of concern to understand the problem from the eyes and perspective of those with first-hand

experience. When working on evolving supplier relationships it is therefore imperative to visit a supplier campus to understand the supplier culture, their vision and mission as evident in their marketing material and in the words of their employees, and their aptitude and capacity for resource allocation to a project like SRE. Another relevant go-and-see element to this case study involved visiting internal manufacturing campuses to hear first-hand what the challenges are with raw materials and how much they impact operations at Amgen.

As part of this case study, and with the impetus noted in the paragraph above, the author was able to travel to manufacturing sites of two raw material suppliers to Amgen. In addition, the author was able to travel to two Amgen commercial manufacturing sites to walk the production process, to speak with employees, and to understand how their experience and challenges could lend input to the evolution of the SRE program.

### **7.2.2 Building Credibility with Suppliers through Small Wins**

When attempting to work with a company in a proactive way for the first time, there are credibility hurdles to overcome. When a relationship culture has never previously involved proactive, non issue-driven visits or requests for information, a supplier can display distrust or general disbelief at the long-term nature of the approach or focus. To work to motivate the supplier, it is important to build credibility through offering something of value to the supplier.

For example, when the author visited the first supplier, it was noted that the supplier lacked a documented process flow of their manufacturing steps. The author recognized, with help from the project supervisor, that if developed, this could represent a good faith win with the supplier. A process flow clearly outlining the manufacturing process and identifying opportunities for improvement was then developed and shared with both supplier and Amgen teams. The process flow had tangible benefits of cataloguing a process, but it also had the intangible benefit of demonstrating the type of mutual benefits that could be gained from a program like SRE.

### **7.2.3 The Use of Pilot Projects**

The success of the Plan-Do-Check-Act (PDCA) problem solving cycle relies heavily on the “check” step.

Developing a program, albeit with the input of all stakeholders, remains an unproven vision until it is tested and evaluated. The initial state SRE program was piloted with two raw material suppliers in differing raw material categories. One supplier involved provides chemicals and the other provides primary devices – instruments like vials and syringes that hold the product and allow it to be administered to patients. This section gives a very general overview of the pilot projects.

Although the details of the pilot projects cannot be revealed for proprietary reasons, the reader should note that the learnings from the pilot projects have been incorporated into the evolved version of the SRE program, to be discussed in section 7.3. The following section provides an overview of the lessons learned from the pilots.

#### **7.2.3.1 Lessons Learned**

Lessons learned from the pilot engagements were collected using a variety of sources and tools, including one to one conversations, surveys and group meetings. Internally within Amgen, the author met with pilot participants to gather data. Externally with suppliers, the author spoke with pilot participants over the phone to gather data. Finally, during follow up meetings, the entire group was prompted for feedback on the value of the SRE program. The top six lessons learned are reproduced below:

1. Amgen team needs to be in agreement regarding the SRE program goals
2. Success criteria should be clearly identified
3. Executive sponsorship and presence should be balanced between Amgen and the Supplier during a kick-off activity
4. Effective project management is a critical success factor to cross-functional teams
5. Post kick-off, teams need to maintain momentum by meeting frequently
6. Training for pilot team members is crucial; in particular, training for communication tools like A3s and also VSMs

All top six lessons learned were addressed via direct improvements to the SRE program. The specific mitigation plans are noted in the table below.

<b>Lesson Learned</b>	<b>Mitigation Step; SRE Evolution</b>
Amgen team needs to be in agreement re the SRE program goals	Amgen team kickoff meeting and training details include a specific note regarding the alignment of expectations and the understanding of SRE elements prior to attending a kickoff with a supplier
Success criteria should be clearly identified	Success criteria has been identified at both the program level and at the element level
Executive sponsorship and presence should be balanced between Amgen and the Supplier during a kick-off activity	Amgen team kickoff meeting and training details include a specific note regarding the participation of an Amgen executive  Additionally, an Amgen executive sponsor is to be recommended by the SRB and is to be someone with consistent participation in the SRE engagement
Effective project management is a critical success factor to cross-functional teams	A project manager is listed as a key team member for an SRE engagement
Post kick-off, teams need to maintain momentum by meeting frequently	This guideline is included in the SRE program timeline
Training for pilot team members is crucial; in particular, training for communication tools like A3s and also VSMs	Amgen team kickoff meeting and training details include a specific note regarding training for specific communication tools like A3s and VSMs

**7.3 SRE Current State**

This section describes the state of SRE as of the end of December 2010. Figure 12 below recreates the current state and toolbox mentioned above, and adds a snapshot of the current state of SRE:

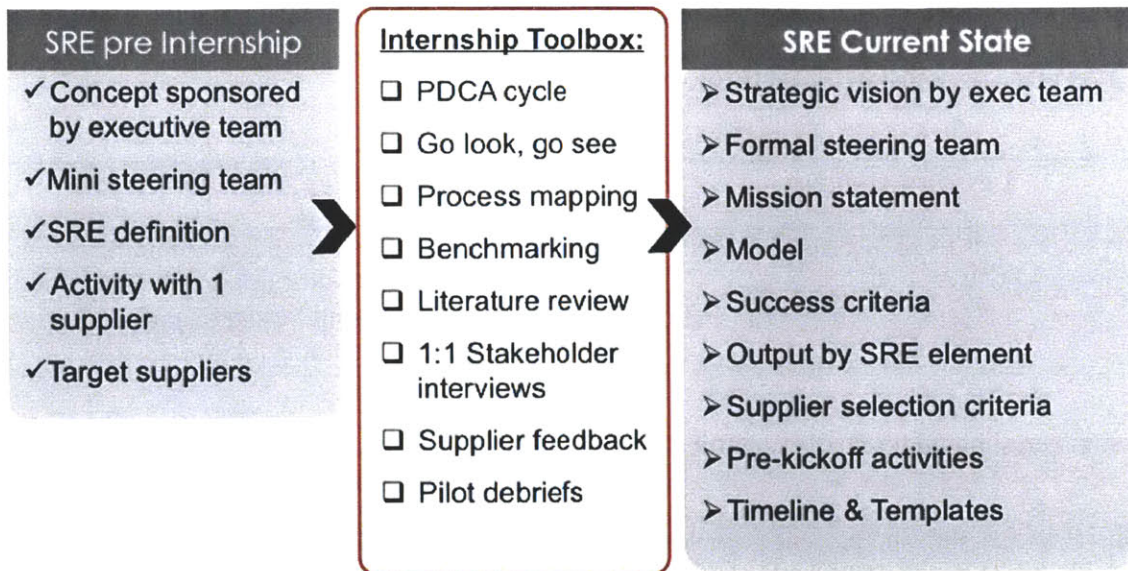


Figure 12. SRE Changes Through Internship

The next sections go into detail for some of the foundational items in the current state above.

### 7.3.1 SRE Mission

SRE has a distinct mission and model that differentiates the program from other cross-functional or Amgen and Supplier engagements or process teams. The mission is important because it ties SRE to the fundamental goals of lean – high quality, low cost and short lead time. In addition to tying in lean, the mission highlights what is perceived to be the biggest benefit of SRE – the potential identification and reduction of variability in materials, equipment, and processes.

The mission of SRE is to improve quality and reduce lead time, total cost, and operational risk by understanding and controlling variability in Manufacturing and along the supply chain. Manufacturing is denoted with a capital “M” because it is meant to include manufacturing of raw materials as well as manufacturing of the actual medicines within the Amgen, Inc. campuses.

### 7.3.2 SRE Model

The SRE operating model seeks to ensure that if and when SRE is deployed, it is done so in a systematic way to enable a high probability of success. Key features of the model are delineated below:



- Proactively partner with strategic suppliers: Initiate partnerships and collaborations under a non-issue driven scenario. This means that full attention and resources will be dedicated to working on identifying a methodology for continuous improvement without diverting resources and time toward solving preexisting issues.
  
- Collaborate intensely technically and operationally: One of Amgen's core values is to Collaborate, Communicate, and be Accountable. This aspect of the model ties in with that value and extends it to the supply base.
  
- Sustain executive sponsorship/focus: In any relationship or partnership, the ability to set a vision and to identify priorities is important. In the case of SRE, vision and priorities are set by the sponsoring executives at both Amgen and the suppliers. The support of these executives ensures that resources are being expended as required, and that all team members understand the scope and importance of the work being performed.
  
- Generate highly reliable cross-functional teams: To be successful, several Amgen organizations must work together to solve problems and to spur innovation. Similarly, supplier teams must also involve cross-functional teams in the collaborative process. These teams must include technically-savvy individuals, and must also include personnel from the shop floor who are able to speak to operations challenges.
  
- Maintain 1-5 active engagements per year: When a new program is initiated or rolled out, it is always important to generate and maintain momentum to keep teams engaged and to continue to generate results. Therefore, part of the SRE model includes the maintenance of 1-5 engagements each year. The exact number is to be determined by demand, operations requirements, and available resources.

Proactive engagements are important because they let the supplier know that Amgen is committed to learning about and improving processes without the pressure of an immediate operations problem. Collaborative and cross-functional teams are essential for problem solving, investigating and brainstorming. A sustained executive focus is also a key element of the SRE model. This means that it is necessary to have an executive sponsor of the Amgen and Supplier engagement at each company, and that the sponsor maintains the lines of communication open all the way down to the working team level. Priorities across the company should be set by this executive sponsor, as should ground rules and expectations. The note around active engagements is there to remind us that maintaining momentum is important and that we should always be working on a few SRE engagements, resources permitting.

### **7.3.3 Success Criteria**

Success criteria are critical in ensuring a program is moving forward and meeting expectations. In evolving SRE, success criteria were created both at the program level and at the element level. Below, the success criteria at the program level has been noted:

- Definition of Success
- Characterized raw materials, processes and equipment
- Transparent supply chains
- OpEx manufacturing practices
- Science-based problem resolution practices
- Collaborative and highly reliable cross-functional teams

At the element level, the success criteria are analogous to expected outcome of each workstream or process team. Those criteria will be presented later in this chapter.

### **7.3.4 SRE Elements**

The SRE program is includes three main elements, all fortified by strong Amgen and Supplier relationships:

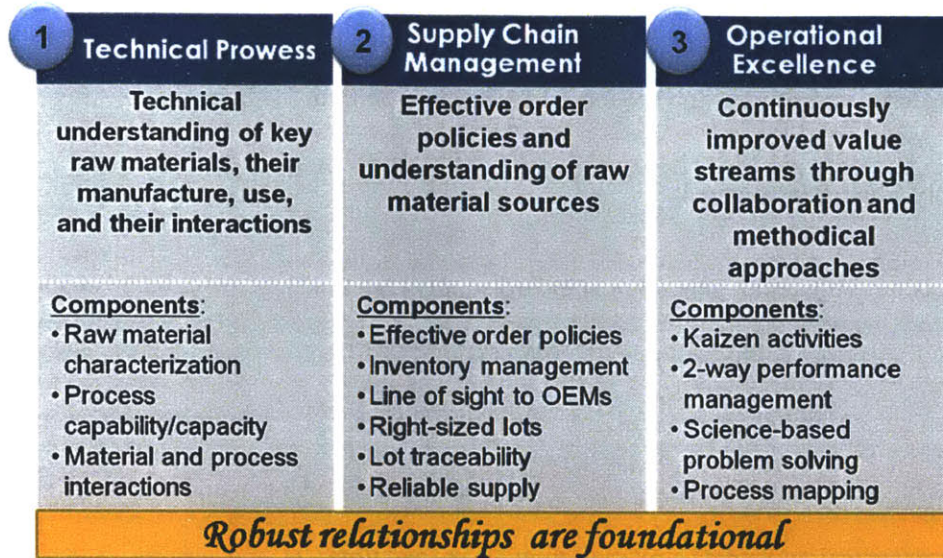


Figure 13. SRE Elements

Each element may warrant one or more teams. In Amgen terms, the teams are referred to as workstreams.

More detail on each element is provided below:

1. Technical Prowess

The first element is the most important to Amgen and conceivably, also to the supplier. It includes gaining a good understanding of the manufacture, use, and interaction of raw materials.

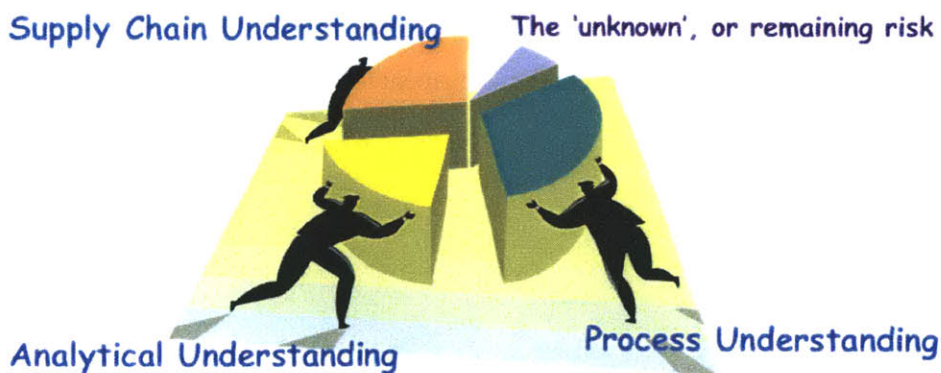


Figure 14. SRE Element: Technical Prowess

Components with this element include characterization, analyzing process capabilities and capacities and identifying material and process interactions at each touch-point in the Supplier → Amgen value chain.

## 2. Supply Chain Management

This element is not only about general or standard supply chain management, but also about establishing a line of sight to original equipment manufacturers (OEMs). Effective order policies are policies that ensure Amgen has a mutually beneficial order quantity, frequency, packaging requirement and inventory policy. It also has to do with reviewing metrics and ensuring that Amgen and the Supplier are aligned in the way they report/calculate/measure/track things like lead time.

An important component of Supply Chain Management includes lot definition and traceability. This implies Amgen understanding and documenting the Supplier's definition of a lot and, ultimately, being able to trace material back to that lot.

## 3. Operational Excellence

The third element is all about cross-sharing, cross-training, mutual process improvements and mutual continuous improvement. It includes bringing the "Be Science Based" Amgen value to suppliers by helping them define and institute a science-based problem solving approach, by bringing Lean/OpEx tools and training, and through other measures.

The image below shows Amgen's goal around this element – engaging shop floor staff to achieve continuous improvement:

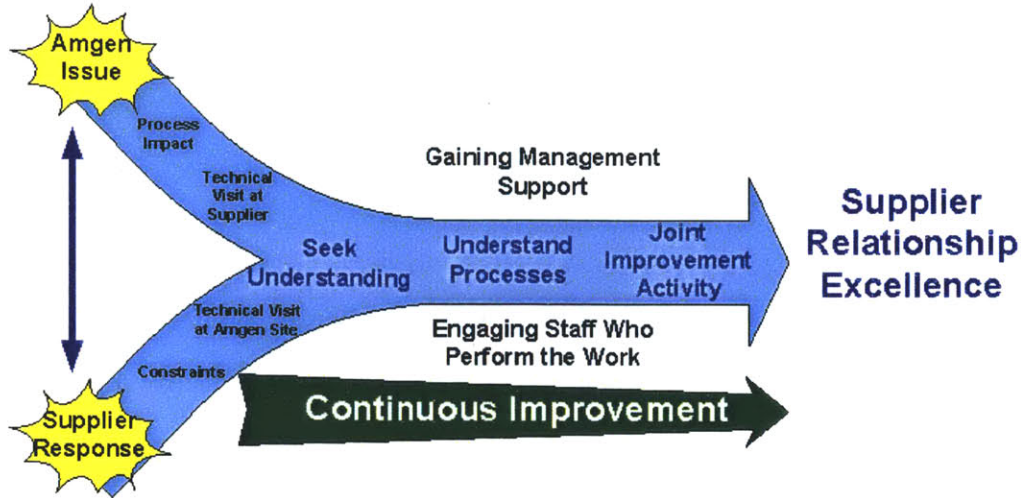


Figure 15. SRE Element: Operational Excellence

### 7.3.5 SRE Components, Benefits, Tools, and Expected Outcomes

The defined SRE mission, copied below, alludes to the long-term benefits of the program:

*Improve quality and reduce lead time, total cost and operations risk by understanding and controlling variability in Manufacturing and along the supply chain*

In addition to program-level benefits, there are also distinct benefits to each of the elements. These benefits, along with the why and the how, are noted below. The *WHY* includes benefits of the collaboration and the *HOW* includes tools and expected outcomes. Identifying these components of each of the three elements is an important evolution of the SRE program, because it adds structure and expectations to what otherwise could appear to be a very intangible goal of collaboration.

#### 7.3.5.1 Element #1: Technical Prowess

Components	Benefits
Raw material characterization	Visibility into Amgen/supplier processes →
Process capability/capacity	Understanding of raw material manufacturing

Material and process interactions	Improved information flow
	Reduced variability
	Replicable model

How/Tools	Scope to Define with Supplier	Expected Output
Shared risk management approach	Type and number of materials	Reduced variability
Data-driven	Engagement with 2nd/3rd tier suppliers	Well characterized materials, processes and equipment
Technical visits	Amgen and supplier sites / processes to visit and document	Process maps for key processes
Data mining		
Compositional analysis		
Statistical analysis		
MVDA		

### 7.3.5.2 Element #2: Supply Chain Management

Components	Benefits
Effective order policies	Validated order policies
Inventory management	Reduced lead times
Transparent supply chains	Transparent supply chains
Electronic COA	Increased material security
Right-sized lots	Replicable model
Lot definition and traceability	Efficient information flow
Integrated production planning	Visibility to Amgen forecasting

How/Tools	Scope to Define with Supplier	Expected Output
Capacity analysis	Supplier/Amgen sites to focus on	Line of sight to OEMs for key raw materials
Inventory management		

methodology	Materials to trace to OEMs	eCoA for key raw materials
Sharepoint site	Applicability of eCoA and to which material(s)	Validated order policy
Electronic CofA	Information Systems integration	Lot traceability
SAP, ERP		Process maps
Process maps, Value stream maps (VSMs)		

### 7.3.5.3 Element #3: Operational Excellence

Components	Benefits
Kaizen/shop floor activities	Reduced lead times
Two-way performance management	Transparent supply chains
Science-based problem solving	Increased material security
Process mapping	Replicable model
Site visits	Improved quality
	Reduced risk
	Clear expectations
	Defined Roles & Responsibilities

How/Tools	Scope to Define with Supplier	Expected Output
Problem solving process	Supplier/Amgen sites to focus on	Improved quality
Root cause analysis	Areas of Supplier need	Reduced cost, lead time, risk
Process mapping	Processes to map	Cross-training
A3s	Expected Workstream Output	
Lean/OpEx	Improved quality	
Kaizen	Reduced cost, lead time, risk	
Two-way performance feedback	Cross-training	

### 7.3.5.4 SRE Benefit Summary Across Three Elements

The picture below effectively summarizes the expected benefits to be reaped by both Amgen and suppliers in an SRE engagement. It lists both benefits at the element-level, and benefits at the SRE program-level. Based on experience and feedback, the benefits that are of utmost important to both Amgen and suppliers are highlighted in yellow.

	1 Technical Prowess	2 Supply Chain Management	3 Operational Excellence
<b>AMGEN</b>	<ul style="list-style-type: none"> <li>Understanding of raw material manufacturing</li> <li>Improved info flow</li> <li>Reduced variability</li> </ul>	<ul style="list-style-type: none"> <li>Validated order policies</li> <li>Reduced lead times</li> <li>Transparent supply chains</li> <li>Increased material security</li> </ul>	<ul style="list-style-type: none"> <li>Efficient processes; reduced flow</li> <li>Sharing of best practices</li> <li>Robust problem solving</li> </ul>
<b>SUPPLIER</b>	<ul style="list-style-type: none"> <li>Visibility into Amgen processes</li> <li>Reduced raw material variability</li> <li>Replicable model</li> </ul>	<ul style="list-style-type: none"> <li>Efficient planning</li> <li>Transparent supply chains</li> <li>Increased material security</li> </ul>	<ul style="list-style-type: none"> <li>Efficient processes</li> <li>Sharing of best practices</li> <li>Robust problem solving</li> </ul>
<p><b>Program-level benefits include:</b></p> <ul style="list-style-type: none"> <li>Visibility into Amgen’s manufacturing technology pipeline</li> <li>Mutual enhancement of technical skills and capabilities</li> <li>More efficient resource utilization at the company level</li> </ul>			

Figure 16. SRE Benefits: Program-Level and Element-Level



## 7.4 Stakeholders

At a very high level, every Amgen employee is a stakeholder in Supplier Relationship Excellence. As quality improves, and costs and risks reduce, the company becomes more robust and better able to deliver products and serve patients. With operational efficiency and performance comes profit and employment – gains benefitting all Amgen employees.

At a more tactical level, each of the following organizations has a more hands-on involvement in the execution of SRE. Unless otherwise noted, each organization below refers to the corporate entity.

- Supply Chain (S/C)
  - Mostly involved with element #2, but can also play a crucial role in element #3 by providing expertise around the order process and inventory holding policy
- Process Development (PD)
  - Almost exclusively involved with element #1
  - Can share what is known about the technical capabilities, capacities and process of the supplier and the gaps that exist
  - Should be the “owning” organization for all technical supplier knowledge; team members should be process experts and should know supplier manufacturing sites well
- Formulation & Analytical Research; Forensics (FAR)
  - Almost exclusively involved with element #1 and the technical expertise required to accurately characterize materials and equipment
  - Highly specialized and resource-limited group
- Supplier Quality Management (SQM)
  - Mostly involved with elements #2 and #3

- This group should be leveraged for process mapping and for training the supplier on the nonconformance (NC) process and any Federal Drug Administration (FDA) regulations that apply to either Amgen or the supplier or both
- Global Strategic Sourcing (GSS)
  - The current SRE engagements have involved GSS in the team leader role
  - Moving forward, GSS is to increase interaction with element #2 and the buying → receipt process at Amgen to understand the value chain and make more informed buying decision
- Manufacturing Representative
  - Each SRE engagement is to include a manufacturing representative from a commercial site relevant to the supplier and from a manufacturing area relevant to the raw material
  - The appropriate site, area, function and individual shall be investigated by the Site Representative on the Supplier Review Board and approved by the SRB
  - This individual is a crucial SRE team participant and must bring with him/her in-depth process knowledge as well as a history of any operations-related issues with the raw material or supplier
- Project Management Organization (PMO)
  - Each SRE team shall benefit from the partial appointment of a project manager
  - The project manager shall be well-versed in SRE and shall maintain an SRE program-level calendar, a project schedule, and all the A3s and data generated by the team

## 7.5 SRE Best Practices

Based on a long history of working with suppliers – under SRM, SRE, Tiger Teams and other engagements – a list of best practices has been generated. The table below outlines some best practices along technical, organizational and operational excellence parameters.

Technical	Organizational	Operational Excellence
Shared risk management approach for quality and supply continuity	Site to Site engagement via supplier visits  Going to supplier's shop and seeing/touching the process and vice versa	Kaizen events
Raw material characterization	Executive engagement  Clear definition of roles and responsibilities	IS infrastructure – creating an information pipeline
Compositional analysis of complex materials	Use of subject-matter-expert network  Database sharing, information and organizational knowledge, electronic certificate of arrival, raw material alerts, newsletter, discussion forum	Shared best practices and notes as to how to institutionalize SRE
Supplier process understanding and capability – multi-variate dimensional analysis	Use of supplier network	Internal training at Amgen to deploy SRE- learn and share from pilot activities
Alignment of supplier platform with Amgen process platform	Supply chain transparency	Lean and OpEx cross-training

## **8 Supplier Relationship Excellence Program Implementation**

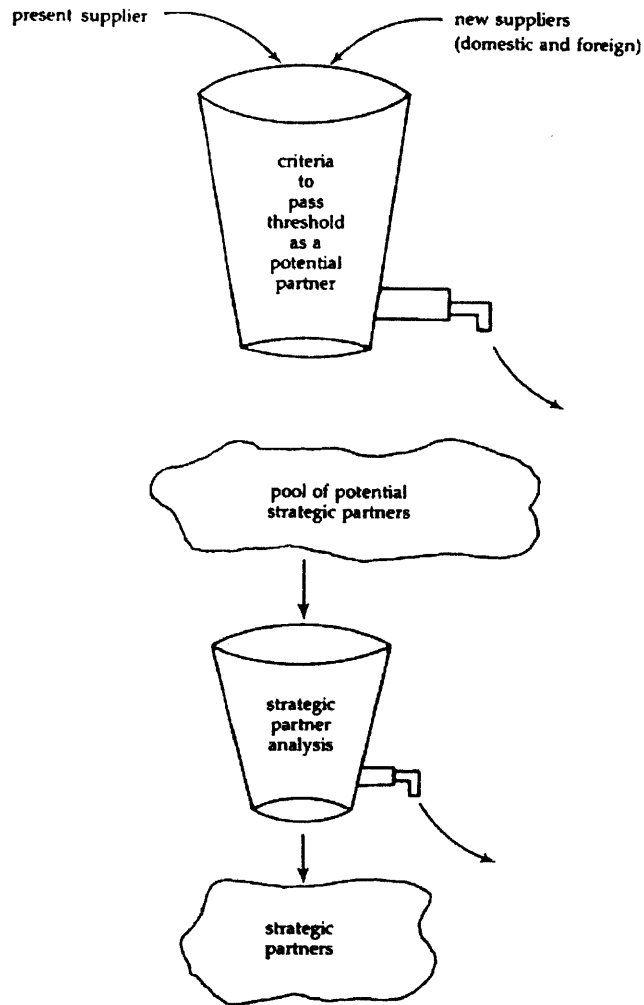
The preceding chapter talked about important structural elements of the Supplier Relationship Excellence program. In this chapter, more information regarding the implementation of the SRE program is provided. That includes selecting suppliers, a program timeline, and team composition, kickoff and training requirements. These guidelines help frame the culture and environment that will help enable the success of the SRE program.

### **8.1 Supplier Selection Criteria**

Although the Supplier Relationship Excellence future state involves SRE being a new way of doing business in general, at present, a supplier selection criteria for engaging in SRE is required to ensure that the company is working with key strategic suppliers that present an operations risk to the company.

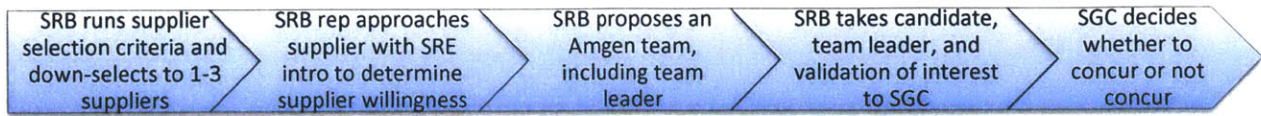
#### **8.1.1 Selection Process**

The supplier selection process for buyer to supplier partnerships should be an iterative and dynamic process. In his article on strategic supplier selection, Professor Robert Spekman[13] presents the following process, shown in Figure 17. He further notes that traditional approaches to vendor evaluation are seen as the first phase of the partner-selection process. While the process yields qualified vendors, it doesn't necessarily yield good partners because the focus tends to be around purchasing efficiency and quality, price and delivery. The second selection stage focus should focus on the need to select suppliers who. At the very least, are competent, reliable, and strong competitors.



**Figure 17. Model for Supplier Selection Criteria**

At Amgen, it is the responsibility of the Supplier Review Board, as the SRE steering team, to continuously monitor and manage the SRE program and to suggest new candidates for SRE engagement. At a very high level, the process should resemble the following:



**Figure 18. Supplier Selection Process**

The vetting process – represented by the last two steps above – is important. First, it is essential for the supplier to receive an introduction to SRE and to have the opportunity to consider the amount of time and resource that would be required in participating. The supplier should consider whether or not this is the appropriate time for such an endeavor – based on their business, their long-term strategy with Amgen, their resources, and the level of openness of their leadership team/company/culture.

Additionally, it is important for the Supplier Governance Council to continue providing strategic oversight by concurring with the suggestions of the Supplier Review Board to ensure operational alignment. This also helps validate the request for resources from each functional group.

Linking the Amgen process to the process suggested by Professor Spekman in Figure 17, it can be noted that the Supplier Review Board serves as the first filter for potential supplier partners, while the Supplier Governance Board serves as the second filter.

### **8.1.2 Supplier Selection Criteria**

In the first step above, there is mention of supplier selection criteria. The criteria were generated by a cross-functional team (including GSS, SQM and PD) with the goal of having a quantitative and repeatable way to identify candidates for SRE that are priorities at the company-level for Amgen.

The criteria was tested and validated with a set of approximately 20 suppliers. First, suppliers were selected according to the team's gut feeling. Next, the supplier selection criteria were applied. The results from both approaches matched.

The criteria itself is separated into three main categories – reach, criticality and performance. Reach has to do with how vested Amgen is with a particular supplier – how much money is spent on them per year, the number of products that are purchased and how many Amgen products and sites are impacted by the supplier. Criticality is based on recent events and on how close the raw material is to the drug product and to Amgen's patients. Suppliers of primary packaging or excipients are of particular interest for the latter concern. Likewise, when Amgen's Process Development organization feels like there is a lot to gain from collaborating with a supplier, then that supplier earns a high "technical benefits factor" score.

### **8.1.3 Excel Model**

The supplier selection data input and calculation is done via Microsoft Excel. The tool is pre-populated with formulas and will automatically highlight the 4 highest scoring suppliers. Below is a snapshot of a blank supplier selection criteria tool:

Supplier Candidate	Selection Criteria	Reach				Criticality			Performance	Supplier willingness	Total points
		1	2	3	4	5	6	7	8	9	
		Supplier spend (2011, \$M)	# of SKUs purchased from supplier	Amgen product impact (comm)	Amgen site impact	Excipients or primary packaging?	Technical benefits factor	Degree of single sourcing	Performance (2010 9 block)	Amgen spend as % of supplier's business	
	Criteria Scale	1=<\$5M 3=\$5M-10M 5=>\$10M	1=<20 3=20-100 5=>100	1=<3 3=3-7 5=>7	# of Amgen sites impacted (inc CM)	1=No 5=Yes	Scale of 1 Low to 5 High	1=Low 3=Med 5=High	1=Marginal 3=Standard 5=Preferred	TBD	
	Rating of Importance of Selection Criteria (1=low; 3=high)	2	2	3	2	2	3	1	1	1	
1											0
2											0
3											0
4											0
5											0
6											0
7											0
8											0
9											0
10											0
11											0
12											0
13											0
14											0
15											0
16											0
17											0
18											0
19											0
20											0

Key
Green highlights: Top 4 total scores

Figure 19. Supplier Selection Criteria

### 8.1.4 Discussion

The supplier selection criteria shown in Figure 19 supports a process in which the steering team for SRE understands not only the high level goals of the organization, but also understands long-term strategic partnerships and what it takes to make them successful. Three cautions in using the selection criteria include the need to select suppliers with mature processes, ensuring that the right questions are asked with suppliers to yield good partners, and maintaining high ethical standards when communicating with suppliers.

Selecting suppliers of mature raw material goods is an important factor to an effective SRE engagement. As noted in a recent article by Charles Fine, professor at the MIT Sloan School of Management and



David Simchi-Levi, professor in the MIT Civil Engineering Department, immature industries need to reach process stability before making commitments to long-term partnerships with suppliers. The article notes:

*“...take an immature industry like biotech for energy. There are still so many process and product questions. Is it going to be based on algae? Is it going to be based on ethanol and corn? ... We don't know yet. There's no dominant process or product technology. So, if you are in that business, how would you know who to have long-term trust-based relationships with if you don't have stability in the process and product architecture?”[11]*

The article suggests that suppliers of media or other raw materials with processes that are not fully stable or products not designated as industry standards might not be good candidates for long-term partnerships due to the potential for evolving industry trends.

In addition, when approaching suppliers, it is important to ask the right questions to ensure that the supplier understands the commitment and is as interested in the relationship as the buyer is. Professor Spekman suggests the following questions that can help determine the future of a partnership as well as the commitment to joint planning and problem solving:[13]

- How has the supplier signaled commitment? Has the supplier committed resources that cannot be used in other relationships?
- How early into the design stage is the supplier willing or able to participate? Is there a recognition that both companies contribute to competitive advantage? What does the supplier bring to the relationship that is unique?
- Does the supplier understand the level of commitment required to help achieve long-term quality gains? Does he have the resources to sustain such involvement over the long haul?
- As we grow and become more expert, is the supplier able to grow with us? Does he have the talent, resources, and expertise to offer added value in the future? Is the supplier committed to maintaining leading-edge capability at competitive prices?

- Does the supplier have adequate technical support? How capable is the supplier? Does he possess up-to-date technology and is he willing to contribute expertise as part of the total offering? Can he help us leapfrog existing technology and does he offer true innovation?
- Does the supplier present a team solution to purchasing, manufacturing or quality problems? Does he immediately revert to a negotiated stance or is there a mutual interest in joint problem solving? Does a win-win attitude exist?
- Is the supplier's senior management committed to the processes inherent in strategic partnerships? Is there an open and free exchange of information across functional areas between the two companies? Is there a tendency to do things through formal channels of communication within the suppliers' own organization? Does the supplier have the infrastructure to support such cross-functional interdependence?
- How much future planning is the supplier willing to share with us? Does he appear to play things very close to his vest? Is the need for confidential treatment of sensitive information taken seriously? How is proprietary information treated? What is the general level of comfort between the two companies?
- How well does the supplier know our business? What is his commitment to understanding our problems and concerns? Does the supplier appear to go to the source of the problem, or is there a tendency to focus only on the symptoms? Is prevention more important than remediation?
- What does the supplier demand of us? What kind of assurance does he look for as part of the partnership? Does he expect loyalty at any price?

Answering these questions as part of the supplier selection process will lead to a more educated and fitting match between buyer and supplier. While the list is not exhaustive, it presents a range of concerns the buyer should concern himself with when selecting a long-term strategic partner.

Finally, ethics also play a role in Supplier Relationship Excellence and in supplier selection. Balancing short term and long term company needs involves the need for leaders to remain open and honest with

suppliers. For example, short term operations needs might yield a need to work collaboratively with a supplier. The supplier might be in the process of being phased out or of having demand for their product reduced. In this scenario, while using SRE as an attractive collaborative media might be an option, it would not be ethical to do so because the supplier will not be around long enough or engaged deep enough, to really reap the benefits of a long-term partnership. While this has not been an issue at Amgen to date, it is important to maintain a commitment to using SRE as a tool for collaboration only in cases in which it makes the most logical and ethical sense.

In conclusion, the supplier selection process and criteria currently embedded in the SRE program is effective at yielding good supplier partner matches only when those involved understand high level company goals and ask the right questions of themselves and their potential partners. It is expected that continued SRE work and pilot activities will continue to improve the supplier selection process and the criteria.

## 8.2 SRE Program Timeline

A recommended timeline has been crafted to help project managers and team leads keep SRE engagements on track. Below is an overview of the SRE timeline from supplier selection through the first few Operating Reviews with the supplier:

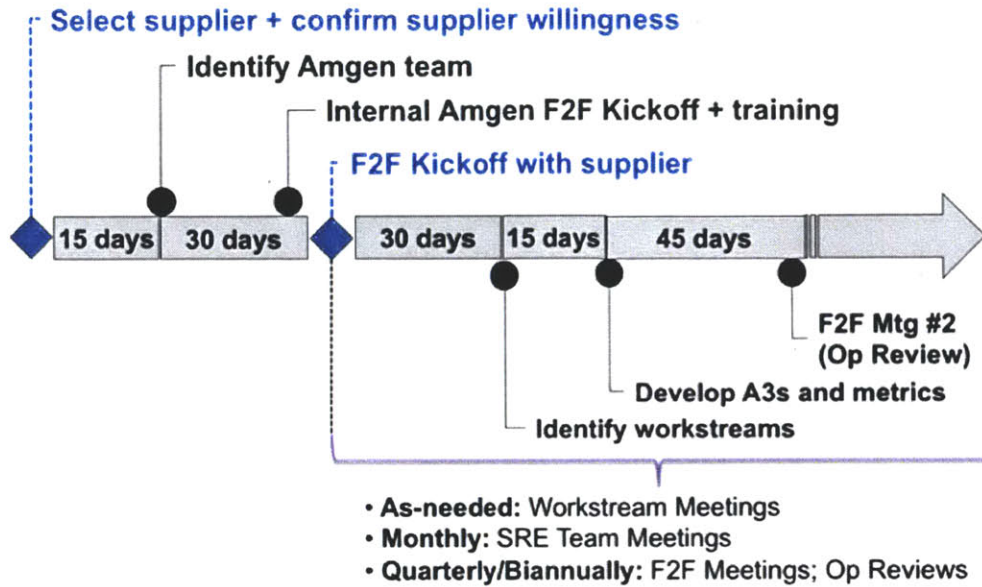


Figure 20. SRE Program Timeline

### 8.2.1 Pre Joint Kickoff Activities

SRE pilots and supplier feedback have yielded a requirement for internal pre-kickoff activities designed to align and train the Amgen team. Here is an overview of the activities that are suggested prior to the SRE kickoff with a supplier:



Figure 21. SRE Pre-Joint Kickoff Activities

We will explore each aspect, beginning with team identification.

### **8.2.2 Selecting an Amgen Team**

Selecting a cross-functional Amgen team to be supplier-facing and to work collaboratively across two businesses is a big and important task. Team make-up should be per the section in this document regarding SRE team members. The major steps are listed below

1. SRB determines team leader
2. SRB suggests Executive sponsor
3. Membership:
  - Sourcing, process development, supplier quality management, supply chain
  - Manufacturing Site Rep
  - Other functions as needed
4. Team is given Pre Internal Kickoff Survey to complete prior to internal kickoff

Particular attention should be paid to focusing on deploying SRE teams that:

- Are skilled in lean/OpEx
- Are able to build/foster positive supplier relationships
- Can focus on operations issues, not just technical/business/etc

In addition, existing relationships with suppliers (especially when positive) should be leveraged to minimize the amount of time/effort it takes to earn trust and respect and to fully engage those that already have supplier knowledge. Manufacturing sites should be engaged as well via a manufacturing representative relevant to the engagement.

The kickoff survey mentioned in Step 4 is meant as a baseline indicator of the relationship with the supplier. It will be used as a baseline metric when seeking to evaluate the positive effects of the SRE program.

### **8.2.3 Internal Kickoff and Training**

The internal kickoff is intended to be a two-day event held at an Amgen commercial manufacturing facility. The site selected should have relevance to the supplier and the raw material selected.

#### **8.2.3.1 Day 1**

Day 1 focuses on sharing information and aligning expectations. The major activities are listed below:

1. Team members to meet face to face and exchange data
  - Supplier history, performance
  - List of materials procured and their use
  - Recent quality issues
2. Align team member expectations
  - Jointly define targeted scope of SRE
  - Jointly identify materials to target
  - Supplier site for kickoff
3. Review survey responses

##### **8.2.3.1.1 Data Package**

The data referred to in step 1 includes the following packages, to be compiled by the team members themselves:

- Business (GSS)
  - Overview of supplier and supplier strategy
  - Overview and evolution of Amgen business with supplier
  - Role of supplier in Amgen's strategy for that category
- Quality (SQM)
  - Historical review of non-conformances, change notifications
  - Audit findings

- Quality agreements
- Review of scorecards
- Manufacturing Site Rep
  - Raw material/supplier quality/performance/issues
- Supply Chain (CRM)
  - List of specifications bought from supplier by site
  - Overview of how we use the materials and where
  - Inventory policy (safety stock, order policy)
  - On-time delivery performance
- Process/Technical (PD)
  - Description of supplier processes, relevant technical reports, concerns

### **8.2.3.2 Day 2**

Day 2 focuses on providing tools and training for the team. The tools and training are being provided to:

- Improve effectiveness of touch-time with Supplier
- Leverage our time spent on the shop floor
- Speak in a common language
- Lead by example

#### **8.2.3.2.1 Training**

The training to be provided can be tailored to the specific needs of the team or of the engagement, but will generally consist of two types – soft skills and tools/processes.

##### **1. Soft skills training**

- Leading by example
- How to observe a shop floor
- Change management

- How to gain trust and respect
2. Tool/process training
- Opex/Lean
  - A3 & A4 communication
  - Value stream mapping / process mapping
  - Problem solving methods (science-based)
  - Root cause analysis
  - Two way performance scorecards

In addition, case studies of previous engagements, scope, benefits, and lessons learned should be shared with the internal team so they can internalize the engagement and the potential benefits.



### 8.3 SRE Program Oversight and Management

It is important to note that although SRE falls within SRM, it is a stand-alone program that is managed outside of the typical SRM structure. Strategic oversight for SRE is provided by the Supplier Governance Council (SGC). This includes setting company-level goals and priorities, concurring with SRB recommendations as to SRE deployments, and receiving periodic updates on SRE progress.

Tactical oversight for the SRE program is to be provided by the Supplier Review Board (SRB). The SRB serves as the steering team, under which SRE operates as of November, 2010.

#### 8.3.1 Roles and Responsibilities of each SRE Team

The table below outlines the major team leaders required for each SRE and their corresponding responsibilities on the team. It also suggests ways to accomplish those responsibilities.

Role	Responsibilities	Execution
<b>Executive Sponsor</b>	<ul style="list-style-type: none"> <li>Align Key Priorities for SRE team and companies as a whole</li> <li>Resolve escalated conflicts/barriers</li> <li>Approve SRE team leads</li> <li>Engage with the SRB to track the progress of SRE teams</li> </ul>	<ul style="list-style-type: none"> <li>Quarterly Executive Reviews with Supplier</li> <li>Quarterly Governance Council Reviews</li> <li>Bi-Monthly Sponsor one:one with Supplier</li> <li>Bi Monthly and ad hoc Team Leader one:one</li> </ul>
<b>Team Leader</b>	<ul style="list-style-type: none"> <li>Integrate all existing and new workstreams</li> <li>Ensure resource alignment</li> <li>Ensure communication effectiveness to functional leads and sponsors</li> <li>Escalate issues as necessary</li> <li>Maintains performance dashboard, Facilitates Operational and Executive Reviews</li> </ul>	<ul style="list-style-type: none"> <li>Biweekly Internal Workstream lead meetings (integration, deployment balance)</li> <li>Monthly Operating Reviews (workstream, tactical and functional oversight leads)</li> </ul>
<b>Team/Project or Workstream Lead</b>  <ul style="list-style-type: none"> <li>Can include 1 or all elements</li> <li>Can include 1 or more per element</li> </ul>	<ul style="list-style-type: none"> <li>Leads specific workstream, manage technical skill set deployment</li> <li>Accountable to SRE team leader to maintain resource deployment balance</li> </ul>	<ul style="list-style-type: none"> <li>Daily/Weekly Internal Project Team Meetings</li> <li>Weekly or Bi Monthly Joint Project Team Meeting</li> </ul>

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<b>Project Manager</b>	<ul style="list-style-type: none"> <li>• Provide project management support to SRE team</li> <li>• Create and maintain share website for SRE engagement</li> <li>• Maintain master calendar and individual workstream calendars</li> <li>• Track resources spent on both Amgen and supplier side</li> </ul>	<ul style="list-style-type: none"> <li>• Ad hoc as needed</li> </ul>
<b>Functional Liaison</b> <ul style="list-style-type: none"> <li>• <b>SQM</b></li> <li>• <b>Supply Chain</b></li> <li>• <b>Process Development</b></li> <li>• <b>Business (GSS)</b></li> </ul>	<ul style="list-style-type: none"> <li>• Provides oversight to SRE team member from his/her respective function</li> <li>• Maintains effective functional leadership relationships; functional escalation</li> </ul>	<ul style="list-style-type: none"> <li>• Ad hoc as needed</li> </ul>

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The momentum and gains experienced by the SRE program to date can only be secured going forward with the support of a cross-functional team dedicated to the mission of SRE and working in a seamless and supportive way as shown above.

## **9 Conclusions**

### **9.1 Hypothesis Check**

The hypothesis for this case study included a vision in which raw material suppliers willingly partnered with biotechnology companies in pursuit of knowledge and training, the humanizing benefit to patients, and in the spirit of competitive advantage. That collaboration and partnership would then yield mutual tangible benefits around quality and processes, the benefits would bring additional interest and resources, and the program would quickly grow and gain popularity through the success of its early adopters. In addition, it was perceived that this model would soon permeate the industry as a business standard.

By the end of the case study, it was clear that there were challenges and industry nuisances that would complicate the hypothesis above. However, based on one to one feedback with nearly all organizations partaking in the pilot activities, it was clear that the SRE program filled an appetite for collaboration and an increased focused on joint customer and supplier problem-solving. That positive experience – both qualitative and quantitative – has paved the way for increased collaboration in the future, either via the SRE program or via a different mechanism.

### **9.2 Case Study's Value-Add**

It is difficult to concretely measure the benefits of this case study; however, as noted in the previous section, internal and external feedback noted that SRE addressed a desire for increased collaboration between Amgen and its suppliers. The evolution of the SRE program was done in a very systematic and process-driven way and with the input of all stakeholders. Therefore, the author is confident that the evolved SRE program better addresses the needs of both suppliers and Amgen organizations and that the added structure and definition will enable a more repeatable and robust implementation with additional suppliers. Moreover, as SRE has evolved, so has knowledge about its existence across Amgen.

Another valuable contribution SRE has had is with suppliers. Suppliers have responded positively to Amgen's desire to be more proactive and collaborative. The impact is a better reflection of Amgen as a continuous improvement leader willing to partner and collaborative for the benefit of its patients and with a sincere interest in the success of its suppliers.

### **9.3 Continued Challenges**

Fortunately, during the natural transgression of the case study the author was able to implement a "check" step and to significantly evolve the SRE program based on learnings from the pilot activities, conversations with stakeholders, and specific feedback from team members and suppliers. The recommendations for improving the program are therefore predominantly already reflected in SRE's current state and in the accompanying implementation chapter.

The following two sections address recommendations for a short and long-term focus for Amgen, Inc. in continuing to evolve the SRE program.

### **9.4 Recommended Short Term Focus**

The one-year focus for SRE is simple – Stability, Engagement & Training, and Communication. In order to expand the SRE program, the first step that is required is stability. The SRE program needs to have a stable message and definition and it needs to be the same and mean the same to different organizations. In addition, the existing teams need to continue momentum and to begin to function as stand-alone teams and not as pilot or research projects. Secondly, engagement and training is about preparing the workforce to engage with suppliers. Engagement happens via sharing the success of the pilots (via the third aspect, communication), and then by providing tools like those discussed earlier for the SRE kickoff activities. Thirdly, communication is important to spread the message to more people, thereby increasing the possible resource pool. The suggested method for achieving communication is via roadshow-type events, where individuals take information "on the road" and present it during staff meetings or in public company areas.

The short-term focus is one that requires support from the Supplier Review Board as well as the SRE Steering Team. The short-term activities can be performed with the SRE program as currently defined and without the need to deploy additional pilot activities. In other words, there should be no constraints against executing the three major steps noted in the short-term.

## 9.5 Recommended Long Term Focus

Supplier Relationship Excellence was born out of a desire to create long-term partnerships with strategic raw material suppliers. As such, it is important to not only focus on short-term tasks, but to continuously evolve the long-term focus and scope of the program. This should be done at the Supplier Review Board level, with reporting to and concurrence from the Supplier Governance Board.

There are two primary long-term goals for the SRE program. The first one involves Amgen internally and the second involves the industry as a whole. The Figure below depicts the two long-term goals.



Figure 22. Long Term SRE Focus

The first long-term goal is for SRE to become a way of doing business for Amgen. This means that SRE elements or tactics are used for supplier management across the sourcing, quality and process development organizations. For example, it means that at the time suppliers are qualified, they are introduced to SRE and asked, at that time, to agree to principles of collaboration, transparency and joint problem solving. Such a supplier screening process would ensure that Amgen, Inc. is attracting and contracting with suppliers that share a goal of continuous improvement and an interest in improving quality and in better serving patients. The challenges with making SRE a way of doing business across

the company arise from resource limitations. In order to work more collaboratively with more suppliers, naturally more team member time needs to be devoted to SRE. In addition, such a proactive approach is also a novelty to many raw material suppliers. Amgen, Inc. has to find a way to reach out to them, personally, to convey the importance of the program and the benefits to be reaped by both parties under successful partnering and collaboration.

The second long-term goal is for SRE to become a biotech industry standard or best practice for customer and supplier relationships. While evaluating one of the SRE pilot activities, it was noted that this goal was a key motivator for suppliers participating in collaborative engagements. The potential to be on the cutting edge for the next innovation in supplier relationships or for raw material variability reduction had been previously underestimated and undersold by Amgen, Inc. The major challenge against this goal is producing the quantitative results around quality, lead time and cost to continue momentum and to justify the resource-intensive cross-functional teams required.

## **9.6 Remaining Questions for Further Research**

The case study described within this document was carried out over the course of six months in the year 2010. While the project began prior to the internship and has continued following the internship, the challenge of finding ways to reduce variability and to improve quality through collaborative supplier approaches leaves much room for further work.

There are specific opportunities for further advancing the benefits of this case study. The first involves the development of metrics and concrete ways of measuring the success of a program like SRE. During the six month case study, the author was unable to generate valuable metrics to serve as an indicator of progress or as a demonstrator of success to outside participants.

Additional opportunities for further research include projects involving pilot activities, projects aimed at developing the Amgen, Inc. culture, and projects that seek to leverage developed partnership frameworks from other industries. To expand on that, further work is possible in evaluating the SRE pilot projects in

work now and in further validating the SRE elements, benefit criteria, tools and expected outcomes. As more individuals become involved with SRE, it is possible that additional stakeholders and participants may be identified. With an increased scope, the SRE framework may need to change. Next, developing the Amgen, Inc. culture is also an area of opportunity for further internship or case work. As a relatively new industry employing lean and continuous improvement concepts and as a company just beginning to tap into the power of supplier collaborations, much work is still needed in training Amgen employees to think and act like partners looking to evolve together with suppliers. This would also be an opportunity to evaluate the level of synchronization in messaging across the company and the level of permeation of the SRE program to manufacturing sites and to the personnel performing tactical work across the different organizations that interact with suppliers. Finally, it would be important to, at a later time, evaluate supplier partnership work across the biotechnology industry and across other industries to again leverage learnings from others.

Moreover, as the role of contract manufacturers in biotechnology increases in significance, it would be interesting to determine how SRE can extend to contract manufacturers and how a benefits case can be made for their participation given the labor intensity of the SRE program.

Through the continued focus on SRE pilots, Amgen, Inc. momentum around reducing variability and improving quality, and industry and customer pressures for the same, the future of Amgen, Inc. collaboration and partnerships with raw material suppliers is certain and bright.

## Glossary

**A3/A4:** Reporting tool popularized by Toyota and used as a concise and effectively 1-page communication tool. A3 and A4 represent different-sized paper.

**Clockspeed:** An industry's evolutionary rate (eg computers: fast; airplanes: slow). Term is from Charles Fine's book Clockspeed.<sup>[7]</sup>

**Electronic c of a (eCOA):** Electronic version of a Certificate of Approval, which accompanies raw material goods coming in from suppliers.

**Federal Drug Administration (FDA):** United States agency within the Department of Health and Human Services. The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation, and by regulating the manufacture, marketing, and distribution of tobacco products.<sup>[4]</sup>

**Good Manufacturing Principles (GMP):** "Good manufacturing practice" is part of a quality system covering the manufacture and testing of pharmaceutical dosage forms or drugs and active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products, and medical devices.

**Global Strategic Sourcing (GSS):** The procurement/sourcing organization in the biotechnology company in this case study.

**Operational Excellence (OpEx):** Lean and continuous improvement program across the biotechnology company in this case study.

**Plan-Do-Check-Act (PDCA):** An iterative four-step problem-solving process typically used in process improvements. It is also known as the Deming circle/cycle/wheel.

**SAP/ERP:** Enterprise application software used widely for parts tracking and other functions.

**Second-tier suppliers (and Third-tier suppliers):** Suppliers used by those contracted with a company to provide a raw material or good. Since they are supplying the suppliers, they are referred to as second-tier suppliers. Third-tier suppliers are accordingly suppliers supplying the second-tier suppliers.

**Supplier Relationship Excellence (SRE):** A program through which the biotechnology company in this case study is working collaboratively and proactively with selected raw material suppliers.

**Supplier Relationship Management (SRM):** The practice and activity of managing suppliers.

**Supply chain/value chain:** Refers to the entire life cycle of raw materials – from second/tier suppliers through first tier suppliers through manufacturing and out to the customer.

**Upstream/Downstream:** Two major phases of biotechnology manufacturing. In the upstream process, cells are cultured; in the downstream process, product extraction and purification takes place.

**Value stream map (VSM):** Value stream mapping is a lean manufacturing technique used to analyze the flow of materials and information currently required to bring a product or service to a customer.



**Workstreams:** Amgen term for categories, or topics under which to group tasks/activities.

**Zero defects:** Philip Crosby argued that the only performance standard that defines total quality is zero defects, which he defined as conformance to requirements.[8]

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