

# INSIGHTS

## Contract Management Excellence: Building A Framework for Success

By Christopher Smith

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**con·tract** \kän-trakt/ *n* **1** : An agreement between two or more parties, esp. when legally enforceable **2** : A formal document containing the terms of such an agreement

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Effective, efficient, and compliant contract management is on the minds of senior management of every life sciences organization in the United States. Clarkston Consulting estimates that 50-70% of large pharmaceutical corporation sales are under contract. The issues associated with contract management are numerous and include:

- Increased government scrutiny of contracting and pricing practices.
- Changing regulatory guidance.
- Commercial customer consolidation.
- Increasing contract complexity.
- Challenges in managing customer compliance.
- Significantly increased business under contract.

The increased complexity in commercial contracting could have an adverse impact on compliance and busi-

ness performance in the government markets. Government oversight and scrutiny over manufacturers' pricing compliance has increased significantly. For example, commercial pricing is linked to Medicaid pricing of pharmaceuticals as well as to all product pricing on government contracts under the Federal Supply Schedule (FSS). Commercial contracts must meet all health-care compliance regulations and guidelines on business practices between healthcare manufacturers and customers. In addition, according to the Sarbanes-Oxley Act, executives must certify all financial reports.

The cost of non-compliance can be significant, with recent government fines reaching hundreds of millions of dollars. A failed audit or non-compliance in one area of the business could have significant impact on other areas. The negative consequences associated with these issues can be significant, ranging from loss of revenue, government penalties and fines, to corporate integrity agreements and debarment.

The following pages present Clarkston's suggested framework for developing and managing a compliant and sustainable contract management strategy that will limit exposure to these issues and their impact on an organization.

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### A Framework for Contract Management Improvement

An effective contract management strategy should be developed using a foundation of four components:

- Policy
- Process
- Systems
- Organization

It is critical that the strategy cross all traditional corporate boundaries including marketing and sales, operations, finance and administration, legal, manufacturing, and distribution.

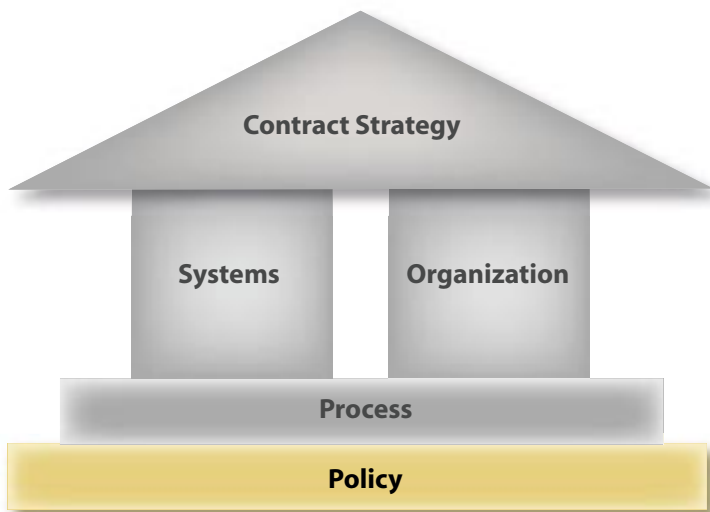
Organizations must take a proactive approach to developing a contract strategy. By being proactive in developing a strategy, contracts developed and put in place will conform to company policy and will be managed efficiently and effectively by the supporting systems and organization. The following sections discuss the components of an effective contract strategy in more detail.

### Policy

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**pol · i · cy** \pə-le-se\ *n* **1** : Prudence or sagacity in the conduct of affairs **2** : A course of administrative action **3** : Any system of management

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Contract management policies are statements that represent the organization’s position on business activities and issues specific to contracting. In an ideal environment, they must be established prior to the design, development, and implementation of all other areas of the contracting strategy--process, system, and organization. Policies form the foundation of an effective contract management strategy, and it is critical that they be formally documented and effectively communicated throughout the organization.

Formal commercial and government contracting policies provide guidance and define corporate position with respect to key issues such as:

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- Measuring and enforcing compliance with contract terms and conditions.
- Monitoring and compliance with government regulations.
- Standards for key calculations and disclosures.

Policies that clearly represent the company’s stance on developing manageable, executable, measurable, effective, and compliant contracts allow process owners and other individuals involved to make timely and consistent contracting decisions.

**Process**

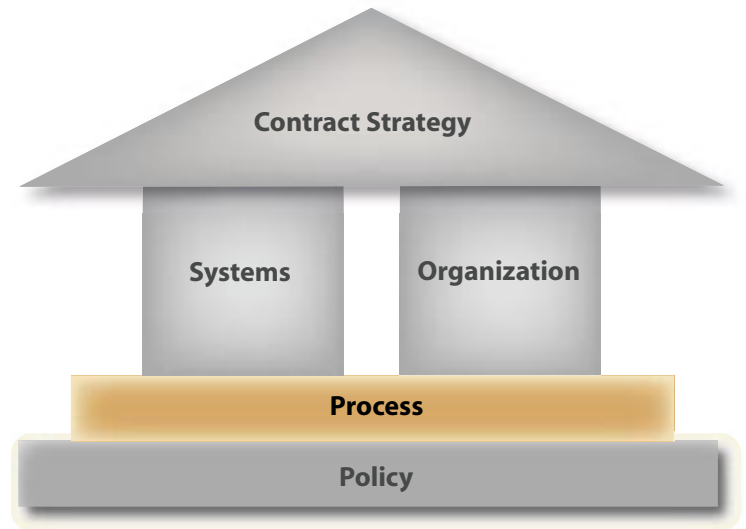
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**proc · ess** \ˈprā-ses\ *n* **1** : A course or method of operations in the production of something **2** : A forward movement or continuous development

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Using a comprehensive set of commercial and government contracting policies as a foundation, processes should be defined and documented to provide guidance to the individuals involved as to how, what, when, and where they should perform their duties.

These processes should be defined using cross-functional process mapping workshops. Including a cross section of the organization in the definition of processes provides two key benefits to the outcome. First, it ensures that the perspective of each function is represented in the discussions that take place during the development process. Second, it helps to build ownership from every part of the organization, which is beneficial during implementation.



The goal should be to create a comprehensive set of contracting process maps and standard operating procedures (SOPs) that cover the entire contract management lifecycle, and which will serve as the foundation for all contracting activities. The processes should be designed to:

- Support all contracting policies.
- Minimize compliance risk.
- Maximize the efficiency of contracting operations.
- Be flexible enough to accommodate ongoing environmental, business, and government changes without being ambiguous.

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- Define key process metrics and enable them to be tracked and measured to improve performance and efficiency.
- Understand and manage the linkages between commercial and government contracting to minimize compliance risk and exposure.

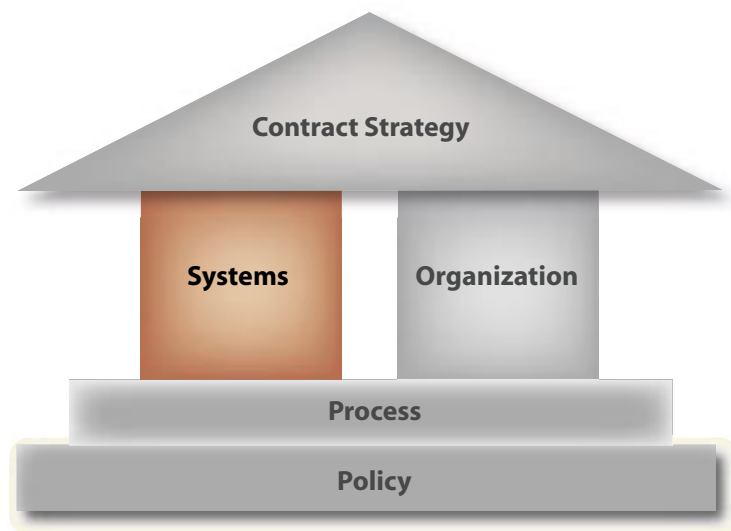
Once processes have been defined and mapped (documented) at a high level, sufficient detail should be added to create lower level process maps. These can then be used to develop SOPs, which should be thoroughly documented, well understood, and consistently executed. The most effective method for accurate and consistent implementation of SOPs is the use of supporting systems and technology.

### Systems

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**sys · tem** \ˈsɪs-təm/ *n* **1** : A group or arrangement of parts that relate to or interact with each other in such a way as to form a whole **2** : Any orderly group of logically related facts, principles, beliefs **3** : An orderly method, plan or procedure

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Most organizations do not have the systems in place to formalize and manage the contracting process (to support current policies and processes). There are currently few, if any, commercially available solutions to help support and manage the contracting lifecycle with technology. Because of this, even in organizations that have well defined policies and processes, consistent implementation of those policies and processes is difficult.

Once policies and processes have been designed, the organization should conduct an analysis of the current systems in place, if any, that support the contract management lifecycle. In addition, an investigation of the commercial systems currently available should be conducted with a gap/fit analysis based on the defined policies and processes. The information gathered should then be used to design a system that combines the best components into an integrated solution. A budget and plan for implementation of this “ideal technology solution” to support the entire contract management lifecycle should be developed and used to determine whether the organization can undertake the substantial effort.

Often, an organization chooses to implement a technology solution in critical areas such as government price calculations and reporting, contract administration and rebates, and payments. It should be noted that the use of technology in

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the contracting management lifecycle is not always necessary for an organization to be considered best-in-class and fully compliant with government regulations and guidance.

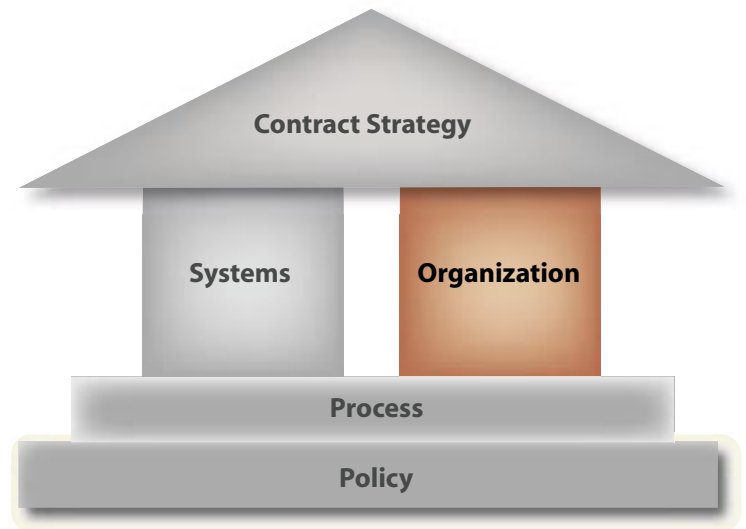
Regardless of the final technology approach taken, a contract management system should:

- Support existing policies and processes while providing the ability to adapt to future changes in the contracting environment.
- Enable seamless management of contracting processes from creation through expiration.
- Provide visibility to both commercial and government contracting information, and allow that information to be shared throughout the organization.
- Ensure a high level of data integrity and provide clear audit trails.

## Organization

**or · gan · i · za · tion** \ör-ge-ne-'zà-shen\ *n* **1** : The manner of being organized **2** : Any unified, consolidated group of elements; systemized whole

It is critical that an organization exists to manage not only the day-to-day work involved in the contracting lifecycle, but the policies, processes, and systems used to support it. This compliance organization typically consists of at least one permanent member, the Compliance Officer, and a number of committee members who represent key areas of the organization involved in the contracting lifecycle (sales/offer development, contract administration, government pricing, finance, etc.). These committee members will often serve in a short-term (one- to two-year) capacity, and are replaced by other members of their respective areas on a rotating basis. The compliance organization should meet on a regular basis and ad-hoc, as specific circumstances or issues require.



The compliance organization and governing body should be responsible for managing and implementing all necessary changes and updates to policies and processes as required to respond to changing market conditions, as well as changes in both business direction and government and statutory requirements. Other areas of responsibility for the compliance organization should also include the review

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and interpretation of government compliance regulations and guidelines, establishment of health care compliance (HCC) guidelines, review of HCC issues and concerns and resolution of contract-related disputes within the organization.

In conjunction with the creation of the compliance organization, it is important to establish organizational size and structure within each area of the company to balance responsiveness to market conditions with control over structure and compliance.

Other important organizational considerations include:

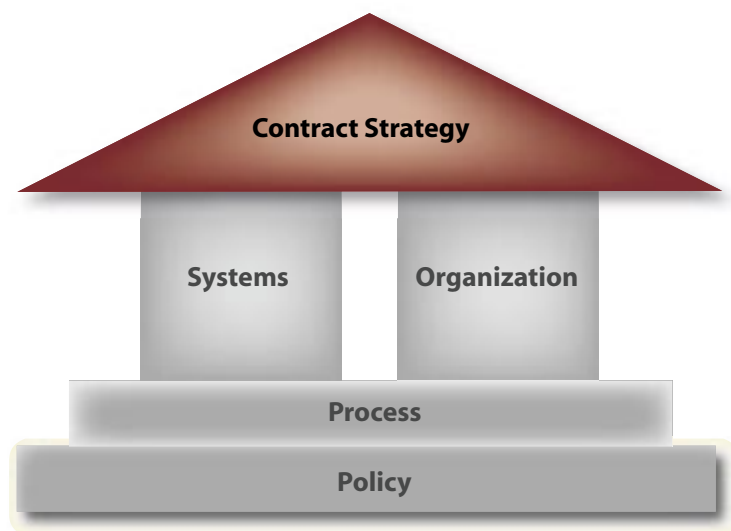
- Appropriate distribution of departmental and centralized key responsibilities.
- The establishment of both initial and ongoing training programs to maintain adequate and current skills.
- Transparency across organizational boundaries (e.g., information sharing across sales and government compliance organizations).

### Strategy

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**strat · e · gy** (strat-e-jè) *n* **1** : The science of planning and conducting military campaigns on a broad scale **2** : Any plan based on this **3** : The use of stratagem as in business, politics **4** : Skill in management **5** : An ingenious plan or method

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Although the four components already discussed (policy, process, systems, and organization) are the foundation of an overall contract strategy, there are other key items to include in the final development of a comprehensive contract strategy. It is imperative that the organization determine strategic position on critical issues that influence contracting such as contract models and pricing strategies, as well as acceptable flexibility and variability across contracts ( e.g., corporate versus divisional treatment of contracts).

A solid contract strategy must include these well defined and “proven” contract models, pricing strategies, and pricing templates/matrices. Contract models should be developed that are proven to be profitable and can be managed efficiently—whether technology is used to support contract management or not.

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Pricing strategies should be defined, and pricing templates/matrices should be provided that efficiently implement those strategies.

### Compliance and Sustainability

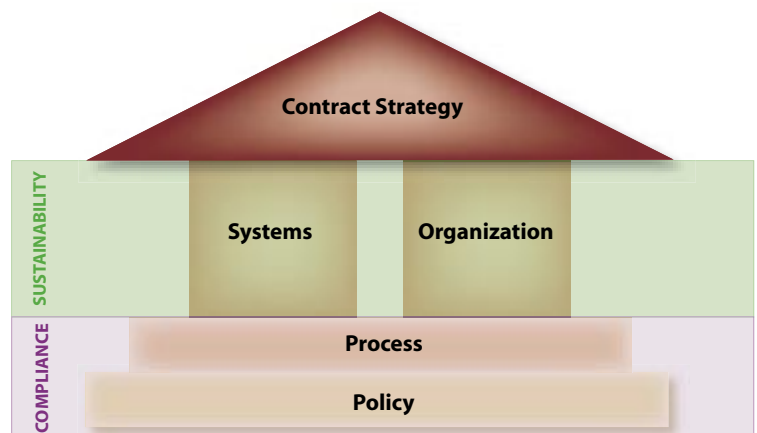
Of the four primary contract strategy components, policy and process establish compliance, while systems and organization create sustainability. Critical to consistent government compliance is the formal institution of clearly communicated policies and procedures.

The key federal organization responsible for enforcement of government compliance, the Office of the Inspector General (OIG), has provided the following guidelines on the establishment of an effective compliance program:

- Establishment of a compliance officer and committee.
- Distribution of Code of Conduct and written policies and procedures.
- Delivery of general and specific training, with certification.
- Mechanisms for open disclosure and communication.
- Regular and independent reviews of systems, processes, policies, and practices.
- Practices governing suitability of new hires and contractors.
- Prompt recognition and reporting of offenses, with corrective action.

These guidelines point almost exclusively to policy and process as the key to successful government compliance. Although compliance is required and must be met, sustainability is the advantage of effective contract management to the organization. An organization that develops a contract management strategy that is supported by state-of-the-art technology and an optimized organization should gain significant competitive advantage.

The resulting environment will be adaptable and sustainable into the future, providing long-term benefits to the organization.



### Long-Term Benefits

There are significant benefits to proactively addressing contract management, including enhanced government compliance (with minimized risk of negative

consequences from a government audit), and avoiding negative publicity and costs associated with government investigation. In commercial contracting, a reduction in unwarranted contract deductions and payments can result.

Benefits relevant to both commercial and government contracting include:

- Cost reduction and avoidance through more efficient contract management and improved operational efficiency.
- Increased contract profitability through improved contract models and pricing strategies.
- Increased revenue by ensuring compliance with contract terms, volume, pricing, and market share.
- Improved customer satisfaction and relationships through more efficient and simplified offer and contract development, more timely payments and reporting, and more effective contract management.

## Conclusion

When viewed individually, many components of a complete and effective contract management strategy are fundamental to a life sciences organization, and are often in place, specifically policy, process, and organization. What is often NOT in place, are those components developed and maintained in concert and supported by state-of-the-art technology.

Written policies placed in binders and put on shelves may satisfy auditors, but they will not create sustainable compliance. Processes developed and performed by individuals in isolation will not create an efficient organization. Typically, the most overlooked components of a contract management strategy are systems and organization. An organization must be tailored to the contract management policies and processes developed and it must be dynamic—with the agility to change as the competitive and regulatory environments do. In addition, technology must be developed and implemented to support the management of the entire contract management lifecycle as a single system. In order to create competitive advantage, contract management policy, process, systems, and organization must be developed together to create a holistic contract management strategy.

## Reference

Webster's New World Dictionary of the American Language, Copyright 1984.

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#### **About Clarkston Consulting**

Clarkston Consulting is a nationally recognized management and technology consulting firm that provide validation, compliance and implementation services to address issues that its clients face in FDA-regulated environments. Nearly half of the top 50 pharmaceutical companies in the world have worked with Clarkston's consultants, who deliver award winning expertise and exceptional customer satisfaction. Clarkston Consulting's approach focuses on the key business drivers aimed to improve productivity of product development pipelines; communications between sales, marketing, and customers; and business processes centered on new product launches. To learn more about Clarkston Consulting, visit [www.clarkstonconsulting.com/whitepapers](http://www.clarkstonconsulting.com/whitepapers).



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