



Management
& Technology
Consultants



Life Sciences | Product Life Cycle Management

Automate and collaborate across your contract manufacturing supply chain with product life cycle management



In this white paper

Changing demands increase need for contract manufacturing	3
Challenges of integrating contract manufacturing	4
Requirements for integrated contract manufacturing	4
Manage and provide access to product information	5
Make technology transfer a core competency	6
Implement a robust program for managing engineering change	8
Manage nonconformance and deviation	8
Using product life cycle management applications to support integrated contract manufacturing	9
Benefits of integrated contract manufacturing	10
Conclusion: a better approach for regulated-product suppliers	10

Executive summary

Life sciences companies and other suppliers of regulated products must be able to rapidly adjust supply chains to support variable demand. In today's operating environment, many companies are becoming more adaptable and agile by turning to contract manufacturing organizations (CMOs). BearingPoint's operating model — based on product life cycle management — effectively integrates contract manufacturing into company supply chains. Not only does this model strengthen collaboration among product suppliers and CMOs, but it also overcomes issues related to sharing product and process specifications, transferring technologies, engineering changes and managing deviations.

Changing demands increase need for contract manufacturing

Historically, life sciences companies and other suppliers of regulated products have operated in environments where product development cycles were long, product demand was predictable and, in many cases, manufacturing processes were key product patent supports. In the regulated-product environments of the past, the ability to rapidly adjust supply chains to support variable demand was much less important than manufacturing products to meet quality standards. Today, however, product suppliers face a greater need to be more agile and adaptable to significant variable demand affected by:

- Patent expirations
- Off-label use of products
- Global product launches
- Global product design centers
- New technologies (e.g., nanotechnology)
- Acquisition of competitors
- Rising customer expectations (e.g., “packaged to order”)
- Mass customization and more stock keeping units with lower volumes

Meeting variable demand requires supply chains to become more adaptable and often involves using contract manufacturing to adjust capacity or provide access to new process technologies. For many companies, it may not be practical or expedient to add new capacity internally during periods of rapidly changing demand. In today's environment, contract manufacturing has become a significant supply chain component for many life sciences and consumer packaged goods suppliers.

The challenge for these companies is to incorporate contract manufacturing as an integral part of their supply chain operating models. Contract manufacturing organizations (CMOs) are independent businesses that provide manufacturing services to multiple customers — and each customer may have a different supply chain operating model. While CMOs may consider it more efficient to provide services using a single operating model, product supply companies want CMOs to support their distinct operating models.

This white paper describes an operating model that provides better integration of CMOs into the supply chains for regulated-product suppliers. It relies on a product life cycle management (PLM) platform that allows design collaboration among qualified vendors, rapid technology transfer, engineering change process improvement, management of contractual obligations for intellectual property (IP), controlled manufacturing, implementation of quality controls to support batch releases and coordination of testing, trial and “scale-up” processes.

The classic formula of CMO integration hinders supply chain agility. Lengthy technology transfers, engineering change processes and batch-release times make it difficult to respond quickly to changes in demand. The bottom line for manufacturers: supply chains must adjust quickly to demand.

Challenges of integrating contract manufacturing

As regulated-product suppliers turn to CMOs to make products or add capacity during periods of rapidly increasing demand, several issues must be addressed:

- Rapidly equipping CMOs with information needed to supply products per specifications (i.e., rapid technology transfer)
- Integrating CMOs into the engineering change process
- Protecting product, technology and process IP
- Controlling the supply chain and meeting demand in time through the CMO or client's distribution network
- Confirming CMO capabilities before and during contracted services
- Knowing what quality controls will be used to support product-release processes (e.g., batch records, nonconformance reporting, certificates of analysis)
- Capturing product knowledge generated at CMOs and spreading it throughout the client company

A classic supply chain response or common practice for integrating contract manufacturing involves implementing a “virtual manufacturing plant” that acts as a proxy for one or more CMO partners. The virtual plant organization has access to supply chain, product and process information management systems and interacts with CMOs based on their capabilities or contract terms. In many cases, CMO integration is a paper- or static-file-based process. Consequently, more time is required to implement manufacturing processes via technology transfers at CMOs than at internal manufacturing plants with direct access to process specifications.

The same is true for managing engineering changes related to products or manufacturing processes. The virtual plant organization participates in the internal engineering change process and then manually integrates with CMO engineering change processes. Again, this paper-based integration extends the time required to implement changes and can introduce discrepancies.

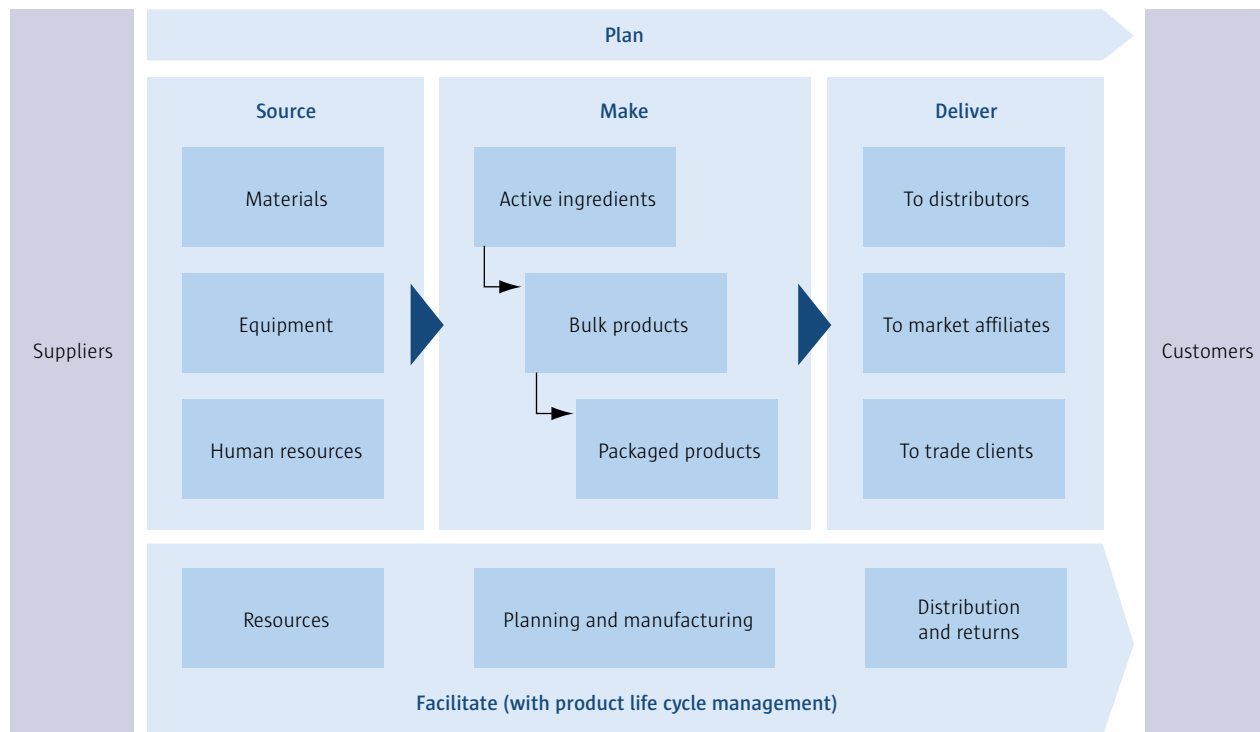
With regulated or licensed products, a third manual integration is required for nonconformance management. When deviations from licensed manufacturing processes occur at CMOs, information about deviations, subsequent investigations and final dispositions of batches must be communicated to the quality control organization to support batch releases. This paper-based assembly of batch information extends batch-release times.

In BearingPoint's experience, this classic formula of CMO integration hinders supply chain agility. Lengthy technology transfers, engineering change processes and batch-release times make it difficult to respond quickly to significant changes in demand. The bottom line for manufacturers: supply chains must adjust quickly to demand.

Requirements for integrated contract manufacturing

The operating model for integrated contract manufacturing is supported by supply chain applications focused on planning, resource management and operations. However, the process to equip CMOs with the information needed to make products per specifications can be time consuming, introducing potential risk to product supplies. To reduce the time required for this process, companies must integrate with CMOs to provide secure, direct access to product and process information and shorten technology transfer, engineering change and deviation management times (Figure 1).

Figure 1. Making the engineering change process efficient and capable of rapid change



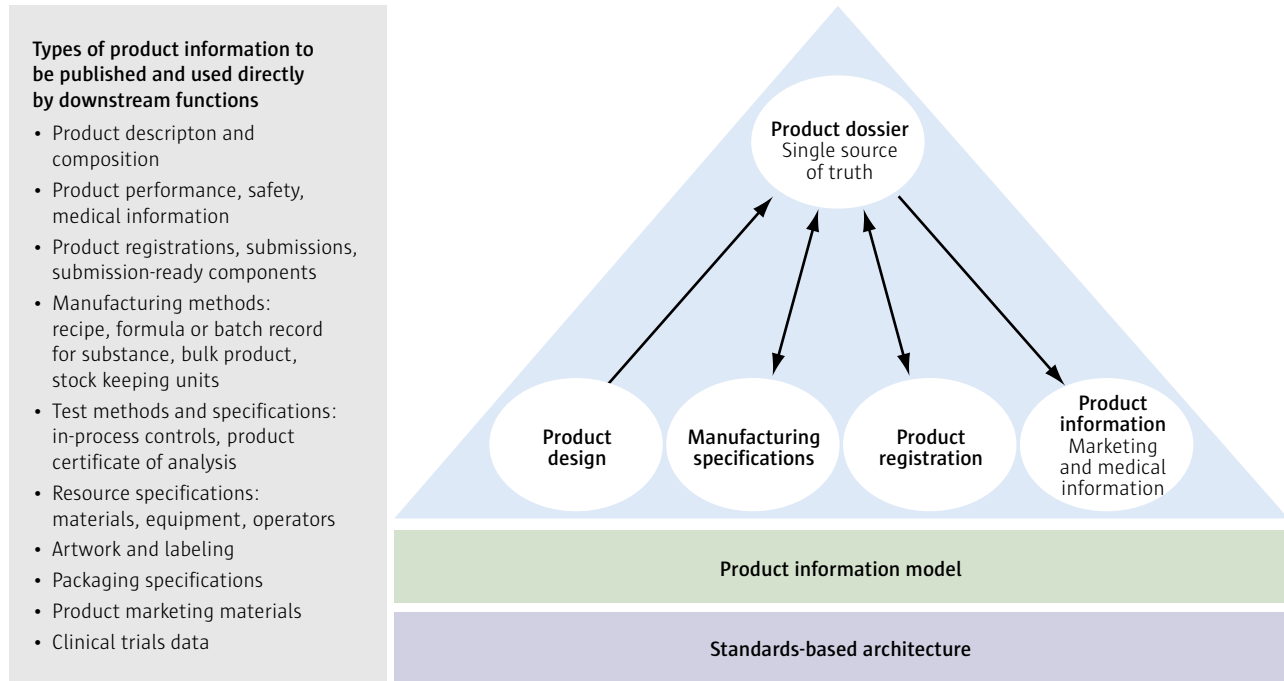
Manage and provide access to product information

Product data integration can be achieved through collaboration among business functions that create, use and maintain product information. In much the same way that life sciences and other regulated-product companies need the Electronic Data Interchange standard to support procurement functions, they also need a standard to support product data integration. The sharing and reuse of product information among business functions (i.e., collaboration) should be supported by a product information model that specifies the standard content, structure, terminology and language for ongoing collection of product knowledge. It should be based on emerging and mature standards, including the:

- Electronic Common Technical Document
- Clinical Data Interchange Standards Consortium
- ISA S88 standard for implementation of modular manufacturing processes
- ISA S95 standard for exchange of product and process definitions
- Structured Product Labeling

Collectively, these guidelines specify that industry and regulatory standards should be based on a common IT specification language (e.g., Extensible Markup Language).

Figure 2. Product information model



The product information model defines product-information publication requirements for business functions so that information can be used directly by downstream functions. When implemented, the model serves as the basis of integration among applications that support various business functions and among supply chains and CMOs (Figure 2).

Make technology transfer a core competency

As more product manufacturing is farmed out to CMOs, the significance of technology transfers¹ increases greatly and must become a core competency of product suppliers. This process must consider each aspect of the product and manufacturing processes and be accomplished through collaboration among CMOs and product suppliers. CMOs that participate in a product’s scale-up process design have a stake in the success and timeliness of the transfer process. To ease this collaborative technology transfer process, product suppliers must:

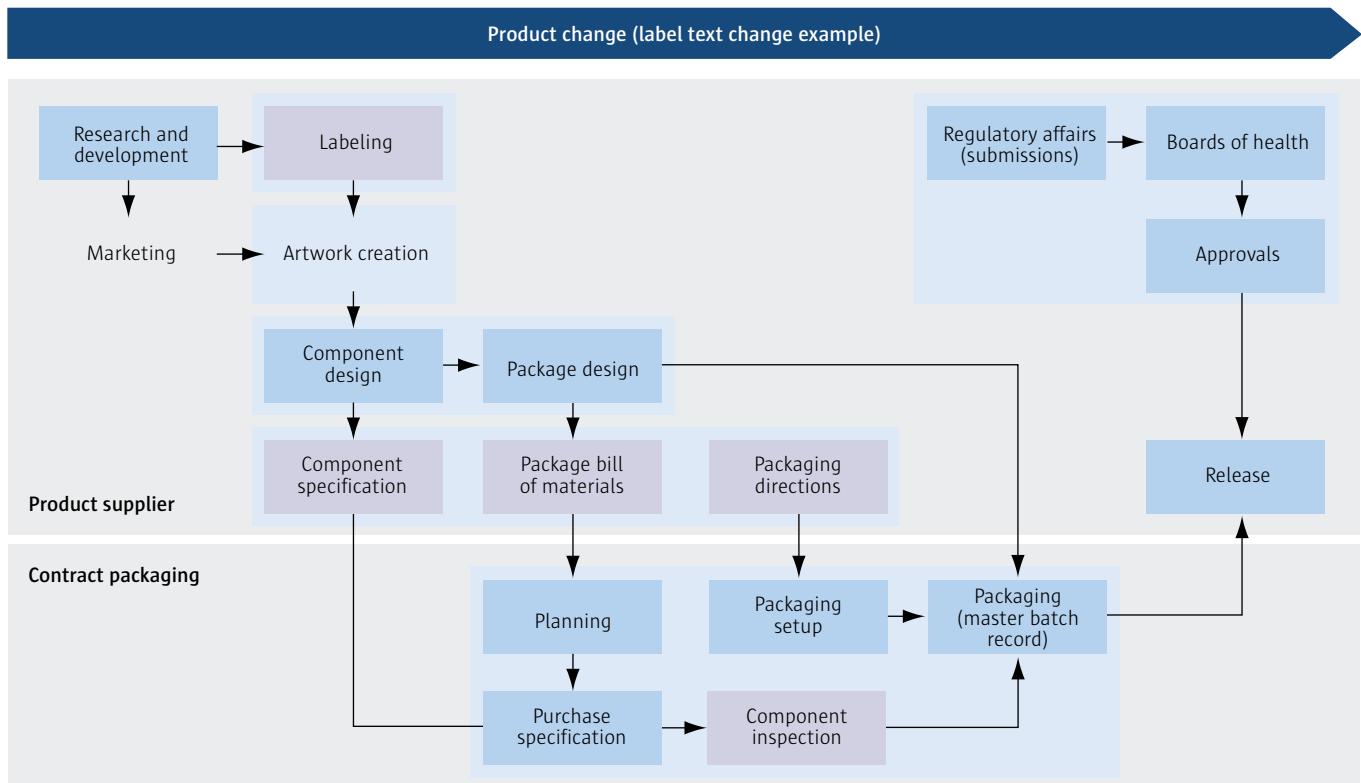
- Provide timely online access to accurate and consistent product information, including the material composition of the product and its delivery mechanism
- Support a defined manufacturing process by using standards-based, modular manufacturing
- Develop, maintain and provide shared access to a library of standard actions or building blocks that define the manufacturing process

As more product manufacturing is farmed out to contract manufacturing organizations, the significance of technology transfers increases greatly and must become a core competency of product suppliers.

¹For more information on technology transfers, read the BearingPoint white paper “A fresh look at technology transfer: Are you getting the most from your data?” at www.bearingpoint.com/techtransfer.

- Deliver access to the process science data from the product’s development phase to support scale-up and implementation of process controls for larger batches and nonconformance investigations
- Allow information exchange between members of a multidisciplinary technology transfer team that includes CMOs
- Manage technology transfers with tools (e.g., workflow, notifications) that allow CMOs to participate
- Capture feedback from CMO production to improve quality and reduce costs of current and future products

Figure 3. Engineering change process



- Product changes usually involve many related information components managed by independent systems (in this example, purple boxes).
- Product change management must coordinate/integrate with the different change management systems that manage various information components.

Implement a robust program for managing engineering change

Throughout a product's life cycle, many changes will be implemented to the product and its manufacturing process. For regulated products, these changes — including changes related to label claims, manufacturing processes or active ingredient suppliers — may affect their current registrations. Thus, changes related to a product or its manufacturing process must be incorporated into the final product and registration, whether the product suppliers or CMOs make those changes. For example, manufacturing process improvement engineering changes may be initiated by CMOs, which means that product suppliers and CMOs must collaborate on processing engineering changes.

Manage nonconformance and deviation

Instances of nonconformance or deviation from the approved manufacturing process can occur during batch productions. Typically, deviations from current process specifications are minor and do not affect product quality. However, they do require careful investigations to assess the dispositions of the batches and to identify the root causes of the deviations so that corrective and preventive action (CAPA) can be taken. For deviations, the records of occurrences, associated investigations and final dispositions for the batches must be included in the batch or product records and reviewed by the quality organization as part of the batch- or product-release process.

With contract manufacturing, the communications process for deviations can be complicated because the deviation-management and batch-release processes are spread across two companies. To streamline this process and support batch-release deadlines requires a system that allows two companies to collaborate on managing nonconformance. Examples of collaboration include:

- Recording manufacturing deviations visibly for both companies, including records for investigators, approvers, actions, documentation, release/destruction certificates and digital signatures
- Managing an investigation workflow involving business functions from both companies
- Providing feedback notices that are visible forward and backward and actionable
- Giving access to the process science data from the development phase to help investigators assess whether deviations potentially could affect product quality
- Allowing investigators to define CAPA
- Reporting results of investigations and final dispositions to the quality control organization to support batch releases

With contract manufacturing, the communications process for deviations can be complicated because the deviation-management and batch-release processes are spread across two companies.

Using product life cycle management applications to support integrated contract manufacturing

Effectively, applications that support PLM also support integrated contract manufacturing. Originally designed to manage product information, these applications have evolved to support life cycle phases, including development, commercialization and retirement. PLM platforms provide the basis for applications that support collaboration during product design, product specification, technology transfer, engineering change management and CAPA.

BearingPoint finds that ENOVIA PLM solutions from Dassault Systèmes provide a robust suite of applications and platform capabilities that readily support integrated contract manufacturing by:

- **Managing product and process data.** PLM platforms capture product data in a structured format that allows a stream of product information among business functions and partners. For example, ENOVIA PLM solutions for life sciences companies allow them to implement “design anywhere, manufacture anywhere” business models. As technology evolves, products and their manufacturing processes get more complex, requiring more robust, structured, standards-based data models to describe them; serving as the basis for information exchange among business partners; and permitting product and process technology transfer from product development to manufacturing and among manufacturing sites. For example, product specifications — which explicitly define required materials, manufacturing processes and quality controls for a product — are critical components of product data. ENOVIA solutions for specification management provide a means for developing product specifications and managing those components as integral parts of the overall product data model.
- **Managing engineering change.** ENOVIA solutions for managing engineering change and design specifications can manage product data change, including the appropriate access control and workflow changes, reviews and approvals. However, managing engineering change also requires managing the change implementation process, which requires integration with supply chain management and product registration support systems. This comprehensive approach to engineering change management is supported by ENOVIA program management capabilities, allowing product development and engineering change management to occur as activity projects. Organizations can concentrate on critical projects while standardizing business processes across their enterprises. Through project pipeline dashboards, this solution provides real-time visibility into each change in terms of scheduling, resources, costs and benefits. Ultimately, this allows for better analysis of and decisions on which changes are critical and the activities required to implement them.

Because the ENOVIA PLM solution for program management is integrated with specification and engineering change management solutions, CMOs can participate directly in the engineering change process and rely on status reporting to decide when to implement changes. This collaboration among CMOs and product suppliers is required for changes to products or manufacturing processes that affect product registration. For premarket approval changes, CMOs must wait until approvals come from the regulatory agencies of affected markets before implementing changes. ENOVIA allows product suppliers to model required activities for each type of change, then use normal project management functions (e.g., dependencies between tasks or activities) to coordinate activities performed by various business functions and partners.

- **Managing nonconformance.** Using ENOVIA PLM solutions for life sciences, product suppliers can model and implement processes for managing deviations. Each deviation can be measured against current product and process specifications and, if required, an investigation project can be launched to assess the effect of the deviation on product quality. Investigations can be managed as high-priority projects—because batch releases depend on their completions—to facilitate status reporting, resource allocation and scheduling of investigations. Deviation analysis can be performed readily based on project records. Subsequently, investigations to identify root causes or undesirable trends can begin. And core business functions (e.g., quality control) involved in engineering changes and managing deviations will have a mechanism to aggregate and review overall demand for resources.

Benefits of integrated contract manufacturing

The need for integrated contract manufacturing is clear for regulated-product suppliers striving to become more agile and responsive to variable demand. BearingPoint's approach to integrated contract manufacturing—facilitated by PLM technology—supports supply chain agility initiatives. Its operational benefits include:

- Secure, timely access to accurate and consistent product, vendor and process information
- Easy information exchange, allowing content to be created once and made readily available as necessary to internal and external customers and systems
- Shortened timetables, allowing CMOs to produce quality products per registered processes
- An integrated process for managing engineering changes, allowing supply chains and CMOs to collaborate for more rapid implementation of changes to products or processes
- An automated process for management of quality information—including nonconformance—to shorten batch-release times and comply with product registrations
- Reduced risks of noncompliance by decreasing inconsistent product information among product suppliers and CMOs
- Improved products as a result of captured production knowledge

Conclusion: a better approach for regulated-product suppliers

As requirements for supply chain agility increase, regulated-product suppliers have a greater need to integrate contract manufacturing into their supply chains. Conventional mechanisms to integrate contract manufacturing (e.g., virtual plants) that employ paper- or static-file-based information exchange will hinder efforts to become more agile and responsive to variable demand. BearingPoint's recommended approach uses standard PLM business processes, assurance requirements and technologies to effectively integrate contract manufacturing into the supply chains of regulated-product suppliers in the life sciences and consumer packaged goods industries.



Management
& Technology
Consultants

Helping our clients get sustainable, measurable results

BearingPoint is a leading management and technology consulting company serving the *Forbes* Global 2000 and many of the world's largest public services organizations. Our thousands of passionate, experienced consultants help organizations around the world solve their most pressing challenges, day in and day out. Through our collaborative and flexible approach, we help our clients get practical, sustainable, measurable results, make the right strategic decisions and implement the right solutions.

We are BearingPoint, management and technology consultants.

To learn more, contact us at 1 866 BRNGPNT (+1 508 216 2523 from outside the United States and Canada), or visit our Web site at www.bearingpoint.com.

About ENOVIA

ENOVIA is the product life cycle management brand of Paris-based Dassault Systèmes, a world-leading provider of 3D solutions. ENOVIA has remained at the forefront of virtualization technology since its inception and provides value to customers in more than 11 industries including aerospace, automotive, consumer packaged goods, medical devices, and pharmaceuticals. ENOVIA collaborative PLM solutions help global enterprises bring people, processes, content and systems together to achieve a compelling competitive advantage. For additional information, contact Dassault Systèmes ENOVIA Corp. at 978 442 2500, or visit the web at www.ENOVIA.com and www.3DS.com.

BearingPoint, Inc.
1676 International Drive
McLean, VA 22102

www.bearingpoint.com

© 2008 BearingPoint, Inc. All rights reserved. Printed in the United States.
BearingPoint® is a registered trademark of BearingPoint, Inc. or its affiliates
in the United States and other countries. Any other marks are the property
of their respective owners. C4688-1008-01-USNY