

Medical Products Industry Showcase

Improving Product Design Communications with Suppliers

Accelerating Knowledge Transfer of Design Intent to Suppliers

Medical product manufacturers work with networks of more than 100 suppliers to produce innovative products for today's hospitals, reference labs, and clinics. The design, selection, purchase, and delivery of every out-sourced product component involves sometimes lengthy and iterative FDA-approved processes. Medical companies are under pressure to reduce the time and costs associated with supplier collaborations. Right Hemisphere is the leading provider of enterprise Product Communication and Collaboration solutions that enable these manufacturers to quickly and affordably incorporate precise 3D visualizations into supplier design communications and bid packages. Medical product manufacturers accelerate knowledge transfer to suppliers and improve the accuracy of component specifications with Right Hemisphere solutions.

The Challenges Faced in the Medical Products Industry

Communicating Product Manufacturing Information (PMI) and generating technical drawings for design reviews and Requests for Proposal/Requests for Quote (RFP/RFQ) processes is traditionally a time-consuming and costly process. Suppliers need precise geometric dimensioning and tolerancing (GD&T) and PMI data to understand component specifications and manufacturing requirements, but technical documentation can be inconsistent and fragmented or require specific CAD software. Miscommunications and delays slow time to market and increase product costs.

With Right Hemisphere Collaborative Development and Sourcing, the medical products industry:

- ▶ **Improves supply chain collaboration** - CAD and PLM data can be leveraged to create 3D product graphics that includes GD&T and other relevant PMI data (e.g., weld symbols, text, holes, and fasteners). The resulting graphical output can be automatically published into PDF files for inclusion into supplier design review and bid packages. Suppliers do not need any customized viewing software since data can be viewed and commented on using the Adobe Reader.
- ▶ **Avoids process changes** - The Right Hemisphere Product Communication and Collaboration solution replaces the expensive task of producing 2D engineering drawings. Instead, the company can give suppliers the ability to review orthographic and isometric views of 3D CAD models in conformance with the ASME Y14.41 standard. Without any data management process changes, and therefore without FDA re-certification, companies can streamline product graphics publishing to the supply chain. 3D drawings are substituted for traditional 2D drawings. CAD data is directly and dynamically linked to PMI data so suppliers can easily view part and assembly information from within a standard document. No costly viewers or special training is required to review the contents of the review package or bid package. Consumers of product design information, such as manufacturing, suppliers, and quality, use the same Adobe Acrobat software to review the true 3D drawing as they did with the 2D drawing.
- ▶ **Improves the quality of design communications and bid packages** - Suppliers gain enhanced views with pan, zoom, rotate, and measurement abilities. The 3D product visualizations can be enriched with integrated bills of materials (BOMs), part item callouts, and other PMI-related data. The consistent format enables suppliers to accurately interpret design intent and confidently respond to RFPs and RFQs. Because of these advances, suppliers save time by building components right the first time, making them more likely to offer preferred pricing agreements.
- ▶ **Establishes a framework for additional product graphic process improvements** - 3D product graphics are extremely useful for service (e.g., repair procedures), manufacturing (e.g., assembly instructions), and other corporate functions that rely on up-to-date product data. The implementation of Right Hemisphere software establishes a Product Communication and Collaboration framework that can be leveraged throughout other organizations.

"This is the next evolution in engineering collaboration. Since we design and think in 3D, we need to communicate in 3D. Right Hemisphere helps us automatically synchronize the engineering design with downstream supplier and manufacturing communications - all in 3D"

Engineering and Manufacturing Automation Manager, Fortune 100 Medical Device Manufacturer

Customer Spotlight: One Global Manufacturer's Transformation

One medical products manufacturer designs devices in-house and performs some light assembly. Tier 1 suppliers manufacture Instrument components, tier 2 suppliers provide tooling, and piece parts are contracted out. This company must work very closely with its 100+ suppliers to ensure components meet the required specifications and tolerances. The company's FDA-approved data management processes includes many rules and restrictions.

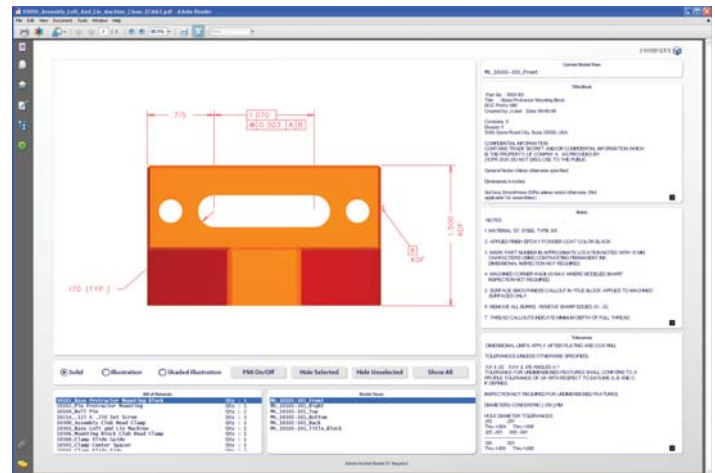
Before the transformation of its supplier collaboration processes, the medical products company provided both CAD models and 2D drawings to suppliers. Often, both were required to fully interpret component design intent, since neither the CAD model nor the drawings were fully annotated with PMI. Many years ago, the company standardized on the CAD model as the "master" to facilitate the use of CAM programs by its suppliers. ASME Y14.41 conformance and annotating PMI directly on the model addressed some of the challenges for collaboration, but it still remained difficult for suppliers to make sense out of the cloud of annotations. Publishing the PMI to non-native CAD users also remained an issue. IDEAS model views allow the annotations to be associated with orthographic and isometric views, so the company created scripts that publish model views of a part as individual 2D sheets in a multiple sheet PDF document. While the designers get the benefit of understanding a design better through the use of 3D, the downstream users still must have specialized knowledge to interpret the 2D drawings.

For example, consider a tapped hole that has one callout for several instances in the model. With 3D views, the user can simply query the annotation and all of the holes would be highlighted in the model, which is much easier to interpret. Without 3D, surfaces cannot be rotated, interrogated, or highlighted, making it more challenging to communicate design intent. Relying solely on 2D requires sufficient training and time to understand complicated parts in a drawing.

To publish the technical documentation to suppliers, the medical devices company had to adhere to file formats that varied depending on each supplier's software resources. If a supplier had the same CAD software, the company could provide native CAD models. However, only 50% of the tier one suppliers shared the same CAD system or could use IGES or STEP models. Other suppliers used different CAD software.

Therefore, the company had to provide specialized lightweight CAD models and CAD viewers that could read the manufacturer's CAD models. These were typically JT files and viewers, which required that suppliers purchase a JT license, get trained, and stay up to date on version levels. This also created desktop configuration control issues for both IT organizations. The net result of these additional steps was a slowing of the supplier collaboration process.

To create the 2D drawings, the company relied on programmatic 2D drawing creation. These 2D drawings required skilled interpretation for suppliers to fully comprehend complex parts and assemblies. Furthermore, differences between the CAD model and the 2D drawings created confusion sometimes resulting in costly changes. These differences could happen by mistake (e.g. user selects the wrong geometry to dimension) or on purpose (e.g. user makes the annotation out of scale to hurry through the change process). For example, CAD systems allow the creation of dimensions out of scale. This feature is sometimes utilized to fit parts (e.g., cables) onto a 2D drawing. When a change is needed quickly, shortcuts can be taken that may result in the drawing being updated while the model is not. These inconsistencies created communications problems.



Right Hemisphere enables 3D models and PMI data such as GD&T to be viewed for each part and assembly through the Adobe Reader.

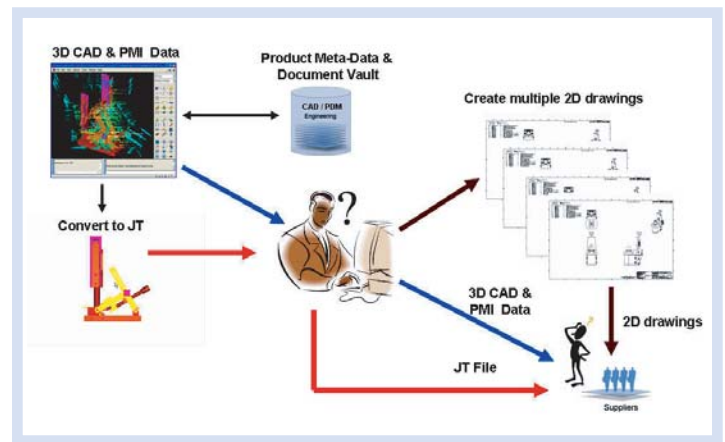


Figure 1. The medical products manufacturer's original workflow, before Right Hemisphere solutions.

An Optimized Supplier Communications Process

Right Hemisphere's Collaborative Development and Sourcing solution allowed the company to repurpose CAD data and publish intelligent PDF documents with rich 3D content without requiring re-certification of the data management processes. The resulting transformation of the company's product graphic processes enables a smooth evolution to a more streamlined generation of 3D visualizations with PMI data sent out in supplier communications (see Figure 2). The medical products manufacturer can now create technical documentation in a consistent, accessible format easily understood by its suppliers.

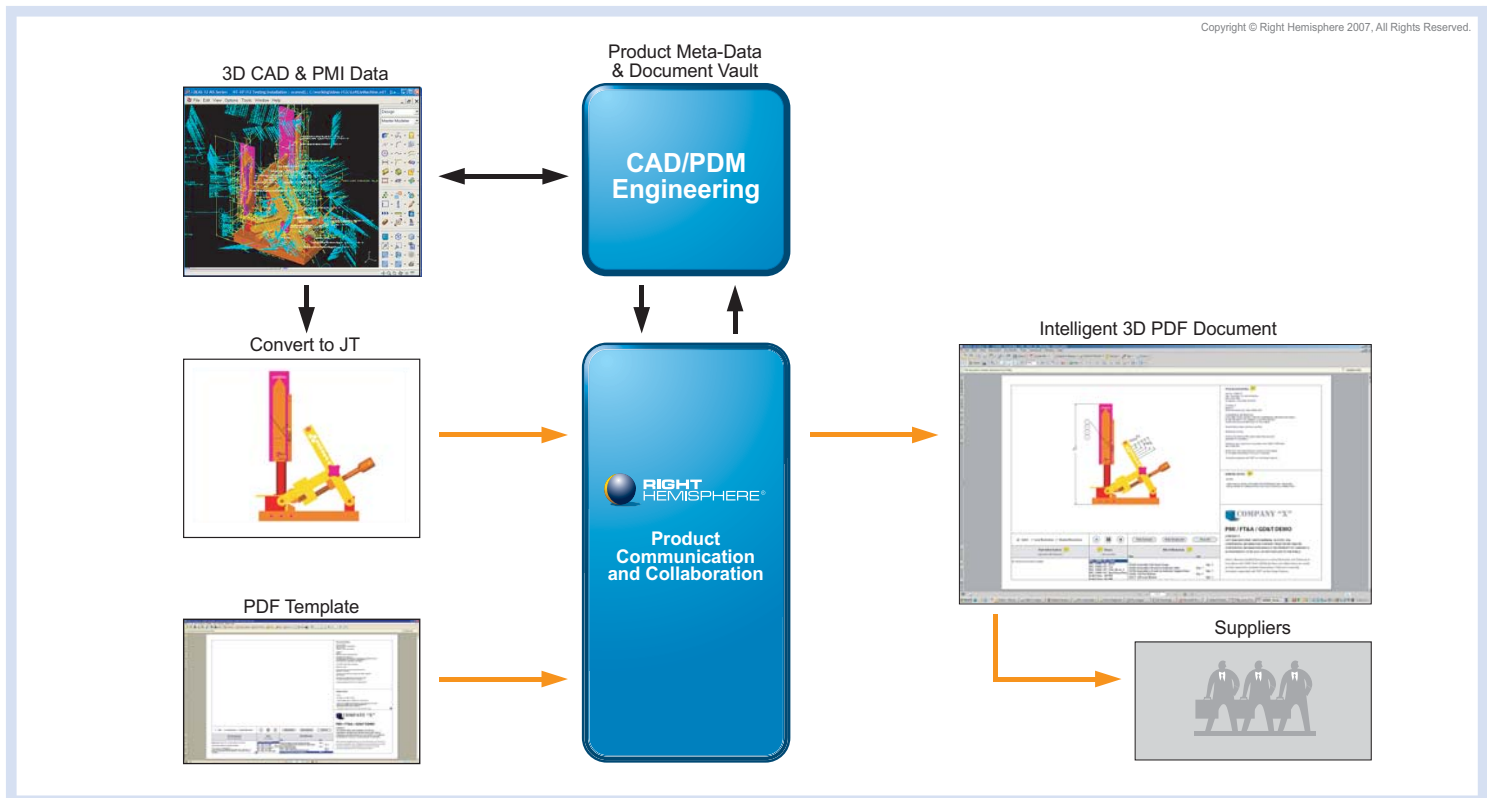


Figure 2. A workflow optimized with Collaborative Development and Sourcing

The medical products manufacturer's suppliers must understand the design intent, tolerances, and other information deemed important with regards to lot-to-lot and first-article inspections. By communicating in 3D using PDF files, and adhering to the ASME Y14.41 standard, suppliers can easily inspect surface and dimension annotations. Downstream of engineering, product information users can more accurately and quickly understand design intent. For example, it could previously take several days for a supplier to study and understand the base plate of an instrument with only 2D section views. With 3D visuals, the supplier can understand the complex parts in an afternoon. Suppliers can view the entire design review or bid package without any special CAD software or CAD file viewer. For the manufacturing phase, component parts can be constructed right the first time, improving instrument reliability and meeting manufacturability goals sooner in the product lifecycle for a shortened ramp-up to full production.

The Right Hemisphere solution complies with the ASME Y.14.41 standard, which defines viewing conventions such as model views (orthographic, isometric, sectional) and conventions for attaching specifications, annotations, and other data to the various views. The medical products manufacturer estimates that the 3D ASME Y14.41 standard can save 40% of the time typically involved in processing changes to traditional 2D drawings while eliminating potential errors. Now that the company can deliver PDF files of 3D model views with PMI data, they can eliminate 95% of their traditional 2D drawings.

Right Hemisphere was selected for the ability of the Collaborative Development and Sourcing solution to:

- ▶ **Streamline the process of publishing 3D product graphics with PMI data to PDF documents.** The effort required is significantly reduced to generate and support visuals for supplier design communications and bid packages. Right Hemisphere Deep Server software can automatically translate engineering files into a PDF file containing a 3D model with associated PMI data for different component views. This single PDF document can be distributed securely to all suppliers, simplifying the workflow and eliminating process management confusion compared to the previous set of multiple 2D drawings required for each component.
- ▶ **Adhere to industry standards for product definition information (ASME Y14.41).** Publishing product graphics conforming to ASME Y14.41 is simplified using Right Hemisphere Deep Server to create the intelligent PDF documents sent to suppliers. Suppliers do not need any CAD software or dedicated viewer software. The product graphics can be viewed using the widely available Adobe Reader software, and suppliers can "snap" to any desired view on the 3D model (e.g., orthographic, isometric, sectional). Detailed model inspection through panning, rotating, and zooming, reviewing associated GD&T data, BOMs, and other annotations can also be carried out using the ubiquitous and familiar Adobe Reader.
- ▶ **Replace 2D drawings with 3D product graphics automatically extracted from CAD data.** Standard technical documentation templates can be setup using the PDF format, providing suppliers with more consistent and descriptive criteria. Multiple 2D drawings and 3D models with pre-defined views conforming to ASME Y14.41 can be placed into a single PDF document. Including 3D product graphics into the PDF documents reduces miscommunication with suppliers. The improved design communications and bid packages are expected to decrease the time required for suppliers to clearly understand the design intent, and speed the overall sourcing process.

Improving Product Communication & Collaboration Across the Enterprise

The new Product Communications and Collaboration framework will allow the medical products company to improve other company functions beyond optimization of its supply chain collaborations. Plans include using Right Hemisphere software to enhance both service and manufacturing operations. The services organization can use 3D product graphics to enhance documented service procedures relating to field replaceable units (FRUs) and customer replaceable units (CRUs). Today, service procedures are available on the corporate intranet, but field service technicians cannot always access the company's intranet from a customer site. They need service manuals to be readily available on their laptop systems. The availability of animated 3D service procedures in multiple formats such as HTML or PDF enables easy online or offline access for field technicians and customers. The availability of animated 3D service procedures in multiple formats such as HTML or PDF enables easy online or offline access for field technicians and customers. The company estimates that approximately 20% of all FRU/CRU documentation could be more effectively presented using animated 3D procedures, and as much as 80% of some service documents could be enhanced with animation. The animated procedures make it possible to affordably deliver visuals of complex parts and procedures, reducing the requirement for other more expensive media such as video or instructor-led training classes. Using Right Hemisphere Deep Server, the medical products company can automatically propagate part changes to the 3D animated service procedures since 60-80% of part changes don't affect the method of assembly. Improving the quality of service procedures with more product graphics enables service technicians to quickly diagnose and repair instruments, lowering support costs and improving customer satisfaction. Since the company incurs the cost of maintaining the instruments, any support cost savings contribute directly to the bottom line.

Manufacturing intends to use Right Hemisphere software to improve the quality and reduce the time to create video manufacturing instructions (VMI). Today, the company must use either CAD snapshots or digital photographs of a physical instrument taken at various stages of assembly to create manufacturing instructions. A manufacturing engineer compiles all the snapshots and photographs along with assembly instruction text to create the VMI. Furthermore, the manufacturing engineer needs to recreate the digital pictures whenever there are part changes. Manufacturing would like to start earlier and save time in the VMI creation process by leveraging the engineering CAD assets. However, CAD models are not photorealistic and therefore make it difficult for assemblers to understand the instructions.

With Right Hemisphere, the medical device manufacturer can create photorealistic animations of assembly processes from the original CAD data in much less time. As the product design changes, updates for many of the manufacturing assembly animations can be propagated automatically. The ability to provide high-quality VMI earlier in the product development schedule enables the company to improve manufacturing reliability and potentially decrease the production ramp-up time. This provides an opportunity to also lower warranty costs and increase market share.

Summary: A New Workflow

The new workflow starts with a mechanical CAD file checked into the company's product lifecycle management (PLM) system. Upon check-in, a JT file is generated and Right Hemisphere's Deep Server automatically translates the JT data into lightweight 3D models with PMI. These shareable 3D models are stored in Deep Server for use in supplier design communications, manufacturing instructions, service procedures, and other technical documentation. Next an intelligent 3D PDF document is automatically created that contains the 3D models, PMI, model views, and BOM controls based on a template. The resultant intelligent 3D PDF document is uploaded to the PLM system for use in communicating design intent to the extended enterprise, including suppliers, design reviews and bid packages.

The medical products manufacturer expects to achieve significant reductions in cost and potentially time-to-market (TTM) as a result of deploying Right Hemisphere solutions across the extended enterprise. The company's studies have shown:

- ▶ **Sourced component failure rates reduced by 5-10%.** Suppliers would sometimes try to recreate fully dimensional drawings resulting in less accurate representations, missing dimensions, and out-of-tolerance parts. The company can now provide fully annotated intelligent 3D documents conforming to ASME Y14.41 that clearly communicate design intent to suppliers and approved sub-vendors (e.g., tooling shops). The intelligent 3D document can be shared while adhering to document security rules. Consumers of product design information (e.g., tooling, purchasing, manufacturing engineering, and quality) are provided the same level of visualization available to engineers.
 - ▶ These mistakes also cost about two person-weeks of resources allocated from engineering, purchasing, supplier quality, manufacturing engineering, and quality.
- ▶ **Reduced component prototype and change order costs by 5-10%.** Some prototype parts do not conform to design specifications due to misunderstanding of design intent, increasing the likelihood of prototype parts being built incorrectly the first time. Reducing the necessary number of purchased prototype parts and change orders results in substantial savings since a prototype instrument costs two to three times that of a production instrument.
- ▶ **Shortened Time-To-Market (TTM) reducing project burn-rate.** A typical new product development cycle is a few years with a project burn-rate of millions of dollars per month. Resolving component supplier issues early in the development cycle helps reduce component failure rates and increase product reliability earlier in the development cycle. This ultimately minimizes the risk of missing project milestones and helps bring instruments to market sooner. Shortening time-to-market by a few weeks can potentially save several million dollars and realize sales revenue sooner.
- ▶ **Reduced time and costs associated with ramp up to full production.** There is a smoother transition from prototype suppliers to production suppliers when design intent is clearly and fully communicated with intelligent 3D documents (ASME Y14.41). This helps enable a faster ramp up to full production.
- ▶ **Avoided costs of \$50,000 and two person-weeks for each incorrectly manufactured complex part.** Inconsistencies between 2D drawings and 3D models or communicating incorrect design versions can result in incorrectly manufactured sourced components. These complex parts then need to be remanufactured. Consider that a complex part may cost \$5,000. In a risk/buy lot of 10 parts, this can amount to a \$50,000 loss.
 - ▶ **Reduced IT desktop license and maintenance costs.** If each of the 100+ suppliers were supplied with a JT viewer license costing a few hundred dollars each, the resulting cost to the company would be tens of thousands of dollars. Many internal personnel would also need licenses, further increasing the cost. These and associated maintenance costs can be avoided using intelligent 3D documents in PDF. The Adobe Reader is free, already installed on almost every desktop, and eliminates the need to train users on special viewers. Desktop maintenance is simplified by eliminating other viewers and the associated service requests (30 minutes each).

Other Right Hemisphere Solutions: Product Communication and Collaboration

To streamline graphics publishing processes and maximize the reuse of product graphics across organizations, medical product manufacturers can also introduce additional Right Hemisphere Product Communication and Collaboration solutions. These solutions, like the Right Hemisphere Collaborative Development and Sourcing solution, represent a new category of enterprise software that automates product graphics publishing processes, manages product graphics, and accelerates product lifecycle management strategies. The Right Hemisphere solutions enable manufacturers to optimize their global product development, launch and support processes (see Figure 3).

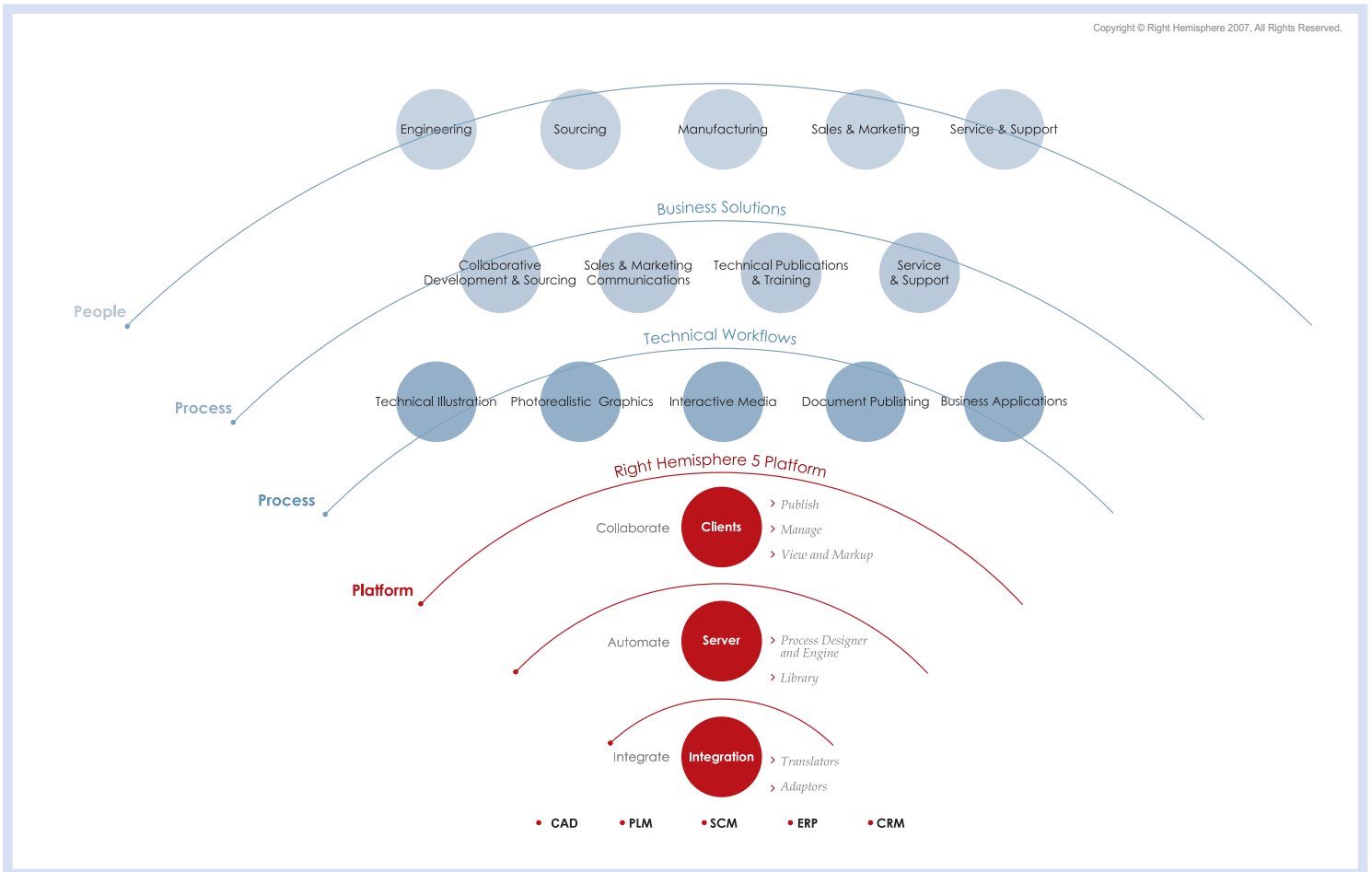


Figure 3. Right Hemisphere solutions are based on a process automation platform that optimizes business process efficiency.

Technical Publications and Training: Technical publications and training development budgets are being reduced and outsourced to lower costs. With product complexity increasing, the ability to deliver accurate and precise technical documentation is even more difficult and at times a barrier to entering global markets due to localization requirements. Right Hemisphere's Technical Publication and Training solution helps company's include more product graphics for a lower cost by eliminating manual steps in the development process. Technical publications and training can be developed concurrently with product design, thereby minimizing the risk of missing product launch dates. With high-quality product graphics replacing text, companies can improve knowledge transfer, reduce language translation costs, and reduce the time for global product rollouts.

Sales and Marketing Communications: Sales and marketing teams struggle to deliver consistent messaging and branding on limited budgets. Right Hemisphere's Sales and Marketing Communications solution enables the delivery of consistent digital product media and lets companies develop high-impact marketing communications and sales presentations using cost-effective Computer Graphic Imagery (CGI) in lieu of costly prototypes and photo shoots.

Service and Support: Service and support organizations have become important revenue generators. Right Hemisphere's Service and Support solution enables the differentiation of product support offerings with more visual, interactive, and up-to-date service documentation, training, and part catalogs. Service procedures and illustrated part catalogs are always based on the most current engineering design. Digital images enable animation and interactivity - adding dimensions that appeal to today's generation of 3D proficient gamers that make up the labor force. Improving knowledge transfer, service documentation, and illustrated part catalogs translates to increased customer service levels and product uptimes.

About Right Hemisphere

Right Hemisphere is the leading provider of enterprise product communication and collaboration solutions enabling manufacturers to optimize their global product development launch and support processes.

Organizations have invested in operational processes and IT systems to improve product lifecycle efficiencies, yet delivery of precise and up-to-date product information to the extended enterprise in a timely, efficient and usable form is difficult today.

Right Hemisphere maximizes knowledge transfer efficiency of product information to downstream stakeholders by automatically publishing product information readily available in CAD, PLM, and ERP systems into common document formats and business applications.

Learn more about Right Hemisphere at www.righthemisphere.com



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