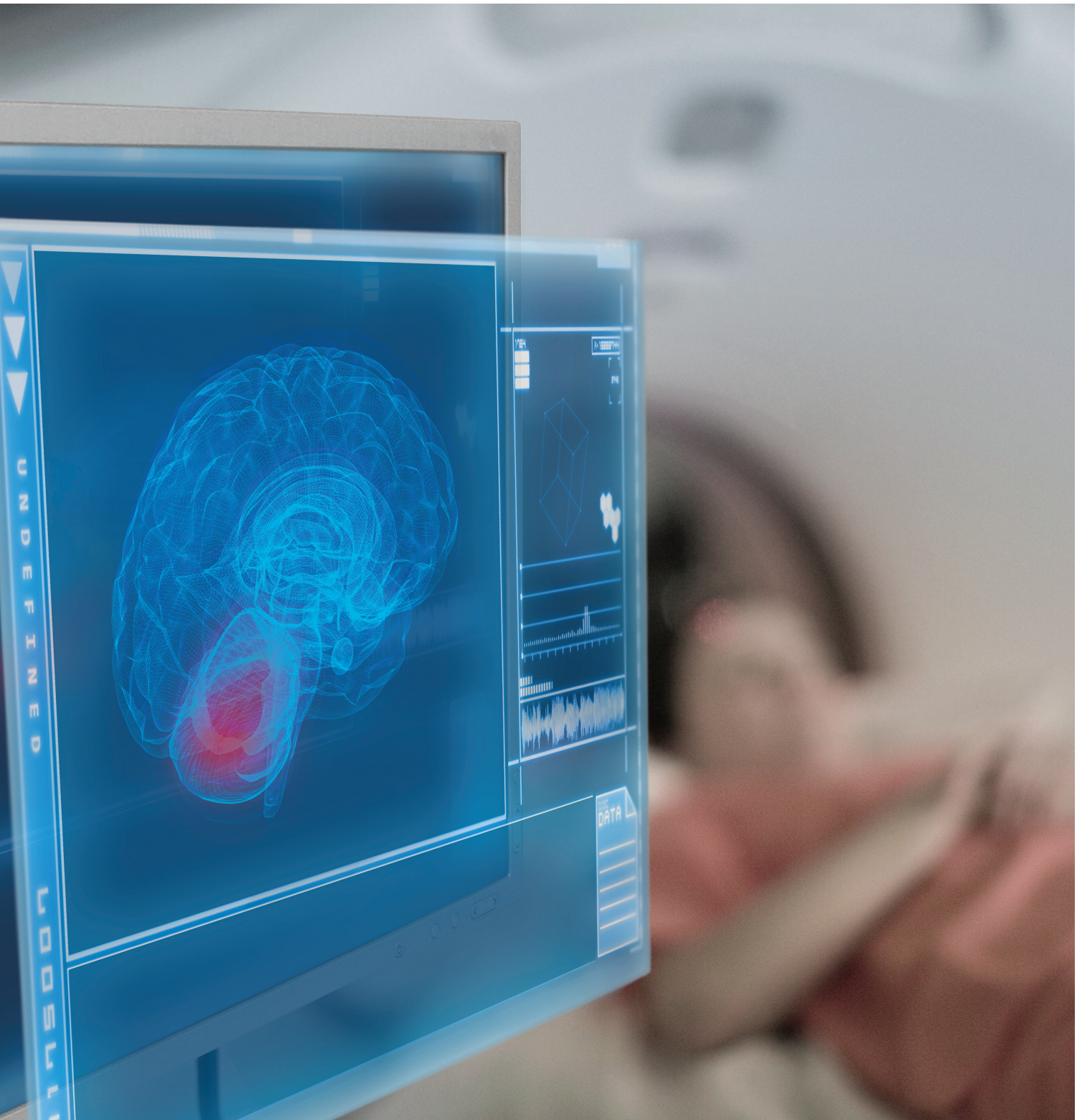
DASSAULT SYSTEMES

vias 3D

3DEXPERIENCE®

LIFE SCIENCES INDUSTRY SOLUTIONS

TRANSFORMING MEDICAL DEVICES WITH SUSTAINABLE INNOVATION



Product lifecycle management improves productivity and optimizes regulatory compliance for us. The [3DS] technology is a big step in our corporate strategy for growing business and introducing innovative life-saving products.

– Tim Anderson,
Director of Engineering,
Possis Medical

TRANSFORMING MEDICAL DEVICES WITH SUSTAINABLE INNOVATION

Every day, medical device companies face the realities and responsibilities of developing, manufacturing, and commercializing innovative products. CEOs looking to build products that improve patient quality of life are focused like never before on innovation.

To be successful, companies continually need to balance cost, value, and time-to-market in producing innovative products that are safe, easy-to-use, and at the right price, while complying with extensive governmental regulations and reimbursement. In addition, feedback from patients and healthcare professionals is becoming ever more important in creating new technologies.

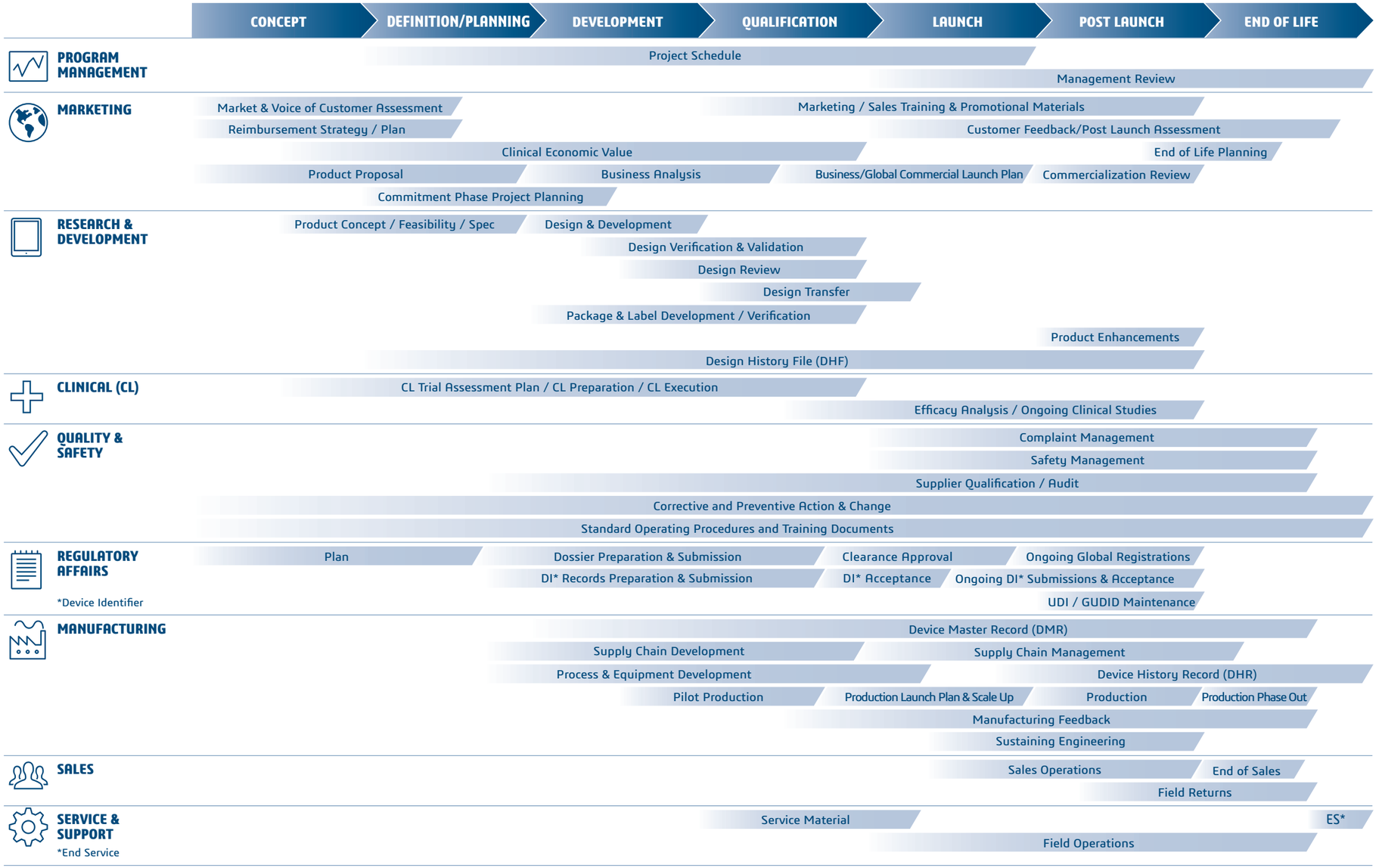
HOW CAN MANUFACTURERS BALANCE THESE OFTEN COMPETING PRIORITIES?

Today, most companies manage marketing, product development, regulatory compliance, and quality as separate processes in disparate individual silos. The results are wasted time and difficulty in obtaining correct information, presenting multiple risks around regulatory compliance, patient safety, and reporting, and stifling the innovation process.

Dassault Systèmes Industry Solution Experiences for Life Sciences powered by the **3D**EXPERIENCE® platform provide a major leap forward with a Single Source of Truth (SSOT) environment that spans the entire product lifecycle from conceptual design to end of life. These solutions for Life Sciences enhance global collaborative sharing, making compliance and innovation complementary processes that contribute to each other's and the company's success.

MEDICAL DEVICE PRODUCT INNOVATION

This chart summarizes a typical value creation process for producing breakthrough medical device innovation.



The 3DEXPERIENCE platform and the Industry Solution Experiences for Life Sciences offer a collaborative, multidisciplinary approach for delivering medical device innovation to patients.

1) Program Management
Consolidate information and systems with automated processes.

2) Marketing
Manage and include clinical information in regulatory submissions.

3) Research & Development
Streamline collaboration and align goals and user requirements.

4) Clinical
Collaborate, manage, and execute trials for regulatory submission.

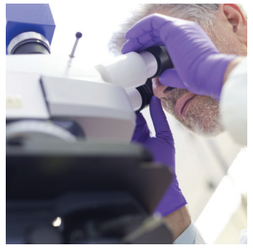
5) Quality & Safety
Leverage quality data in the R&D system for timely and fully traceable change requests.

6) Regulatory Affairs
Enforce regulatory compliance and industry best practices.

7) Manufacturing
Manage a global ecosystem with a secure master data repository.

8) Sales
Enrich the selling experience with interactive 3D demonstrations.

9) Service & Support
Respond to field requests more rapidly leveraging 3D illustrations.



ENOVIA gives us a common and consistent information management process, providing access to product information anywhere, anytime, and facilitating collaboration between distributed R&D facilities, factories, and sales channels.

– Jukka Lehtiranta, Electronics Design Coach and Project Manager, Datex-Ohmeda

MANAGING COMPLEXITY AND CHANGE WHILE ACHIEVING HIGH QUALITY, SPEED, COST, AND SAFETY GOALS

Collaboration fuels innovation. The open exchange of ideas, knowledge, and feedback can help companies improve their products and the overall patient experience.

Dassault Systèmes Industry Solution Experiences for Life Sciences provide a unifying foundation for global teams to collaborate easily across the enterprise both internally and externally, and access relevant data in real time. The benefits that could be achieved are clear:

- Improved patient safety and regulatory compliance
- Increased quality
- More market agility
- Shorter innovation cycles
- Lower development costs
- Faster time-to-market

PROGRAM MANAGEMENT

Continued improvement of information and data management are essential to efficient performance for healthcare and life sciences companies. The solutions for Life Sciences help streamline the entire product lifecycle development process from innovation through product end of life. Companies can manage product data and associated project information across their enterprise both internally and externally, enabling companies to connect everything to everybody as needed.

The holistic program and project management system provides complete end-to-end requirements traceability, from original requirements to product end-of-life, including:

- Definition of information used across a wide range of regulations that can be used to automate the creation of compliance reports for regulatory authorities
- Data from the 3D modeling applications that can be used to generate Bills of Materials (BOMs—for example, for mechanical and electrical BOMs) and printed circuit board (PCB) components
- Data used to support population of the Design History File (DHF), Material Master, Device Master Record (DMR), and Design History Record (DHR), as defined by U.S. FDA 21 CFR Part 820 Quality System Regulations

All manufacturing facilities both internal to a company and external through third-party subcontract manufacturers can leverage these capabilities, either on premise or in public or private cloud. The consolidated information and systems with automated processes help companies focus on innovation, enhance collaboration among all stakeholders, and speed time-to-market.

MARKETING

The Life Sciences solutions support marketing teams who want to validate product ideas before developing new medical device technologies. By leveraging the online market research capabilities, product marketing can view market trends (including brand reputation and competitive solutions) to help gain insights about patient use and priorities. For more intuitive training and support, marketing and sales teams can leverage 3D documentation to support activities in the field for training and product demonstrations.

UTILIZING A SINGLE SOURCE OF TRUTH

Linking global enterprise operations through a holistic system can dramatically improve engineering workflow and change management, and help increase design and supply chain efficiency. The **3D**EXPERIENCE platform provides a secure, Single Source of Truth environment that can be made accessible for all project stakeholders to help:

- Decrease number and severity of product recalls/field actions
- Improve end-to-end traceability
- Improve internal and external supplier collaboration
- Expedite product or process transfer/integration
- Remove errors associated with design transfer to manufacturing

Utilizing a Single Source of Truth can help companies mitigate and eliminate risks that could cause delays to a product launch, impact sales revenue, limit market share, or increase costs for product rework. It can help operations stay current on quality compliance requirements and avoid U.S. FDA Form 483s and Warning Letters, and shipment holds.

KEY BENEFITS FOR MEDICAL DEVICE COMPANIES

- Manage and facilitate innovation without compromising quality and safety through one cohesive platform that allows collaboration of design information and visibility across the product lifecycle from ideation to end of life
- Increase patient safety by reducing the number and severity of recalls and field actions
- Increase business agility by streamlining design collaboration and managing team activities to align project goals and user requirements
- Speed compliance processes by integrating regulations into product development (design for compliance) and e-submission
- Accelerate time-to-market by streamlining the complete regulatory submission and approval process (dossier assembly, review, submission, tracking, and renewals through end of life) by geo-global regions
- Reduce engineering re-design time and cost through simulation testing that can help expedite clinical trials and reduce product failure recalls
- Expedite product design transfer with current released documentation to facilitate the manufacturing process while maintaining end-to-end traceability throughout the product lifecycle
- Develop strategic suppliers and partners by bringing supplier quality history into the sourcing process
- Balance speed versus control by improving common enterprise processes, then tracking and measuring them as a basis for improvement
- Maintain complete product requirement traceability from ideation through development, design verification and validation, to commercialization and product obsolescence
- Drive part costs down by publishing part specifications across product lines, brands, and regions to create efficient procurement processes
- Achieve cost savings through lean and efficient re-use of Intellectual Property (IP)
- Enable design and manufacturing outsourcing by creating centrally-managed global work teams and using a single repository to store all product information throughout the product lifecycle

RESEARCH & DEVELOPMENT

The **3D**EXPERIENCE platform's design and modeling applications can help medical device companies accelerate product ideation, mechanical design (form, fit, and function), and time-to-market. 3D CAD and 3D virtual modeling incorporate component and structural design, human factors, and system and electrical engineering for the development of safe, innovative medical device solutions. The wide-ranging 3D design applications can help reduce engineering development time and the additional costs from product redesigns. In addition, data from the 3D modeling applications can be used to generate and automatically update BOMs and PCB components.

With a Single Source of Truth for information storage and management, product teams can readily utilize concurrent collaborative design information among distributed global R&D locations and align with product goals and user requirements. Realistic simulation capabilities enable designers and engineers to virtually test the functional operation of a medical device during the design stage before transitioning to clinical trials and production. This can help accelerate time-to-market while improving the delivery of safe medical devices and reducing product failure recalls.

QUALITY & SAFETY

The process of dealing with quality issues (such as Corrective and Preventive Actions (CAPA) and product complaints) is the single greatest source of regulatory risk for medical device manufacturers today. The process can get bogged down in the minutiae of documentation and fail to adequately address the critical issues regarding risk, root cause, and remediation. Medical device manufacturers and other Life Sciences organizations consistently struggle to deal with quality issues efficiently and effectively. As the complexity of products and processes increases, this predicament only promises to worsen. Meanwhile, medical device manufacturers are not getting the strategic value they should from the vast resource of valuable feedback collected in their quality systems.

These solutions, built specifically for Life Sciences, provide medical device manufacturers the ability to effectively and efficiently manage quality issues by improving QSR/GMP/ISO compliance while eliminating non-value-added activities. A single, global, online system enables companies to manage all quality issues and can provide insight into the health of the CAPA process. This can help companies avoid compliance risk, reduce waste, and increase the interconnection of team members and business processes.

With CATIA, our engineers can pay more attention to being creative and implementing new ideas. We can handle more orders. This not only makes our customers happy, but our management as well.

– Dawid Drapacz,
Deputy Head,
Production Department,
Pol-Eko-Aparatura

The key argument for 3DVIA is the speed at which you can develop [the VR] environments and the fact that you know they will work.

– Dr. Stephane Bouchard, Director, Canada Research Chair in Clinical Cyberpsychology, Université du Québec

REGULATORY AFFAIRS

The Life Sciences solutions can help companies enforce regulatory compliance and industry best practices throughout the product lifecycle, reduce errors that would pose regulatory risk, and build quality into the design process. The platform supports the definition of information used across a wide range of regulations and can be used to automate the creation of compliance reports for the U.S. FDA and other regulatory bodies.

By formulating a successful global regulatory strategy and automating the collection of information required in reports (for example, U.S. FDA 510(k), PMA), medical device companies can bring products to market with greater speed and efficiency. The Global Market Registration and Unique Device Identification (UDI) applications enable improved cross-departmental collaboration and help expedite the overall global regulatory authorization process. Linked to the UDI application, the regulatory dossier can be used to establish an enterprise process for capturing, managing, approving, and electronically submitting the Device Identification Record (DI) to the U.S. FDA Global Unique Device Identification Database (GUDID).

Data can also be used to support the population of the DHF, Material Master, DMR, and DHR, as defined by 21 CFR Part 820 Quality System Regulations. Search-Based Applications (SBAs) blend the advantages of search engines with business intelligence tools and semantic processing. The integrated index-based search engine of the **3D**EXPERIENCE platform can find and retrieve documents quickly, especially helping during U.S. FDA audit inspections.

MANUFACTURING

With the **3D**EXPERIENCE platform's manufacturing planning and execution solutions, medical device companies can synchronize global manufacturing networks, offering real-time visibility and control over the business processes performed by factories and suppliers. These can help companies handle the complexities of a globally dispersed ecosystem by maintaining a single, comprehensive product data master repository that is accessible securely to multiple functions.

All manufacturing facilities, both internal to the company and external through third-party subcontract manufacturers, can leverage these capabilities either on premise or in public or private cloud. With detailed manufacturing process support provided in part through virtual manufacturing simulation, manufacturers can speed up manufacturing output using a range of solutions from manufacturing flow process planning to general device assembly, enabling complete design and validation of manufacturing processes in a virtual digital environment.

SALES, SERVICE & SUPPORT

The **3D**EXPERIENCE platform's applications and integration revolutionize the creation and delivery of product-specific documentation. These can help product teams create up-to-date assembly and technical product service manuals (for example, electrical schematics, PCB layout, 3D mechanical interactive assembly drawings), product marketing literature, and instructional materials for use by sales and technical teams and by healthcare professionals and patients.

Documentation teams can leverage product design and virtual simulation files to create illustrations, animations, and even interactive files that can be linked to the source files to help eliminate document transcription errors and regulatory approvals by providing proper and most recently released drawings. Medical device companies can design easy-to-use and easy-to-understand programs for posting online, to help ensure that patients and device operators are using their products as intended.

3DEXPERIENCE®

DASSAULT SYSTÈMES **3D**EXPERIENCE PLATFORM

The **3D**EXPERIENCE platform is a BUSINESS EXPERIENCE platform. It provides software solutions for every organization in a company to help create value and differentiating consumer experiences. With a single, easy-to-use interface, it powers INDUSTRY SOLUTION EXPERIENCES—based on 3D design, analysis, simulation, and intelligence software in a new class of collaborative, interactive environment. It is available on premise or in public or private cloud.

Social & Collaborative Applications
Unstructured and structured environments to create social communities, experience marketing, and collaborative innovation

3D Modeling Applications
Shaping ideas into reality

Simulation Applications
Where virtual worlds meet reality through realistic simulations

Information Intelligence Applications
Revealing and dashboarding data and intelligence

ACCELERATING INNOVATION IN THE MEDICAL DEVICE INDUSTRY

Dassault Systèmes **3D**EXPERIENCE platform and Industry Solution Experiences for Life Sciences enable medical device companies and their suppliers to accelerate product innovation. They help companies in the development and delivery of cost effective, easy-to-use, safe medical devices while streamlining quality assurance processes and regulatory compliance. Our solutions help ensure global, enterprise-wide visibility of product designs and a closed-loop process for proactively managing quality and manufacturing issues.

DASSAULT SYSTÈMES INDUSTRY SERVICES

Dassault Systèmes Industry Services works with companies to help them expand innovation capacity and successfully implement the full value of the **3D**EXPERIENCE platform and Industry Solution Experiences for the Life Sciences industry. Industry Services incorporates technology, industry best practices, and methodologies that have been utilized in successful deployments across multiple business environments. Dassault Systèmes Industry Services works to enhance and personalize **3D**EXPERIENCE Industry Solution Experiences to deploy the freedom and power to help accelerate innovation and create competitive advantage.

FOR MORE INFORMATION, VISIT WWW.3DS.COM/LIFE-SCIENCES

Our **3D**EXPERIENCE platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3D**EXPERIENCE® Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 170,000 customers of all sizes in all industries in more than 140 countries. For more information, visit **www.3ds.com**.

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