LIFE
SCIENCES

THE SEARCH FOR CONTROL

TOTAL QUALITY IN LIFE SCIENCES

DASSAULT SYSTEMES

TOTAL QUALITY CONTROL AND SYSTEMS DESIGNED FOR THE WAY YOU WORK

In life sciences, continuous innovation helps people live healthier lives, but it also brings significant challenges for companies. Stringent regulations and patient and physician expectations demand quality, precision and accuracy at all times. No excuses.

Inconsistent business processes, systems that lack transparency and barriers to collaboration all threaten quality efforts, increase costs and hold innovation back. Delivering excellent patient experiences requires total quality control and systems designed for the way life sciences works today.

QUALITY AND COMPLIANCE AT THE HEART OF INNOVATION

Innovation keeps life sciences moving forward. As companies strive to meet and exceed external and internal expectations, innovation enables them to develop pioneering advancements that help change lives for the better.

But competition is fierce, industry changes are rapid, and the pressure to deliver superior patient-centric experiences has never been higher.

Neither has the need for accuracy and precision: Industry regulation is tight and penalties are severe.

To consistently deliver high-quality, safe and effective healthcare solutions and to compete and grow in challenging markets, life sciences companies need total quality and compliance in product lifecycle management. Without it, patients' health could be put at risk, costs could escalate and time-to-market could suffer.

To mitigate these risks, companies need complete control over the inputs, outputs and processes at work in their organizations.

Unfortunately, gaining such control is easier said than done. A variety of external and internal forces and challenges undermine the drive for total quality and compliance.

THE EXTERNAL ENVIRONMENT	THE INTERNAL ENVIRONMENT
Life sciences companies operate in a dynamic market where digitization and technological innovation is changing the face of healthcare. Patient demands are rising, disruptors are entering the marketplace and competition is fierce. Increasing and geographically varied regulations challenge enterprises to maintain compliance in global markets. If compliance or quality issues lead to a product recall, the damage can be serious and long-term.	Established enterprises are likely to operate with a number of unconnected legacy systems. This results in isolated pockets of knowledge, under-utilized data and inefficient ways of working. Teams are often geographically spread out, hindering collaboration. As a result, progress can be slow. There is constant pressure from within the business to increase quality while cutting costs and meeting challenging delivery schedules.

THE NEED FOR CONTROL – NOW MORE THAN EVER

Life sciences companies must be able to manage operations closely to deliver high-quality products quickly and cost-effectively. And they need the flexibility to adapt as conditions change so they can meet the challenges of:

REGULATION AND GLOBALIZATION	RISING EXPECTATIONS	LENGTHY AND COSTLY DEVELOPMENT CYCLES
Regulations are complex, stringent and always evolving. As companies globalize, they must adhere to the different regulations applicable to the markets they serve.	Pressure is high to continuously innovate to meet physician and patient expectations. Healthcare is evolving with demand for increasingly sophisticated diagnostics, individualized healthcare and convenient patient monitoring.	To remain competitive, time-to-market needs to be short and quality high, but product development cycles are complex. Mandated changes to a process can stop progress or require costly workarounds.

Non-compliance puts patients at risk and can result in product recalls that jeopardize company reputations. The cost of correcting the problem, along with potential fines and even lawsuits, can be significant. Long-term brand damage is also a serious possibility.

In fact, a report from McKinsey explores the potential sums involved and notes that, "Costs of a single non-routine quality event, like a major recall, have been as high as $600m in medical device companies."[1]

If life sciences companies are to innovate at the levels required in order to remain competitive, they have an absolute need for accuracy, precision and compliance. The pressure to get things right is intense and requires pinpoint control of manufacturing and development.

THE TOP CHALLENGES OF QUALITY AND COMPLIANCE

While regulatory non-compliance may be the risk that is felt most strongly, it is not the only one. Slow, inefficient processes can strain budgets and delay products getting to market, threatening first-mover advantage and squeezing profit margins.

It's no surprise that an LNS Research study revealed a range of internal and external factors in the list of pressures perceived by life sciences executives. Regulatory requirements for quality management topped the list (cited by over two-thirds of respondents); regulatory requirements for serialization and traceability was second (cited by over half), while over a quarter felt the pressure of competition from emerging markets.

Meanwhile, 37% mentioned pressure to reduce costs and 33% cited collaborative business models with third-party research and manufacturing companies. Twenty percent mentioned the pressure to speed new products from research through clinical trials to patients.[2]

These findings illustrate the dual pressures of external and internal challenges and the need for operations and processes that support life sciences in delivering quality, compliant products while managing costs and maximizing time-to-market.

> "These challenges highlight the need for total quality and compliance technology in life sciences, to provide insights and collaboration while ensuring compliance."
>
> –LNS Research, 2018

INTERNAL PROCESS SHORTCOMINGS

A range of factors may underlie the internal issues companies face.

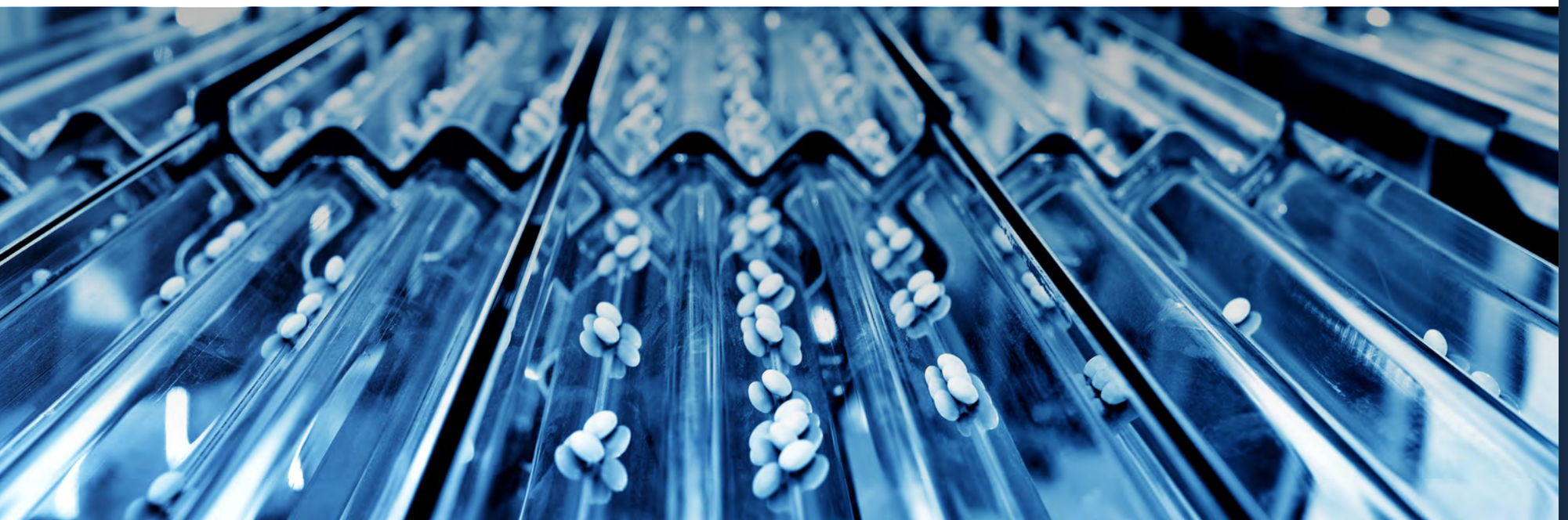
> Unconnected legacy systems often don't provide full visibility, traceability and control over processes

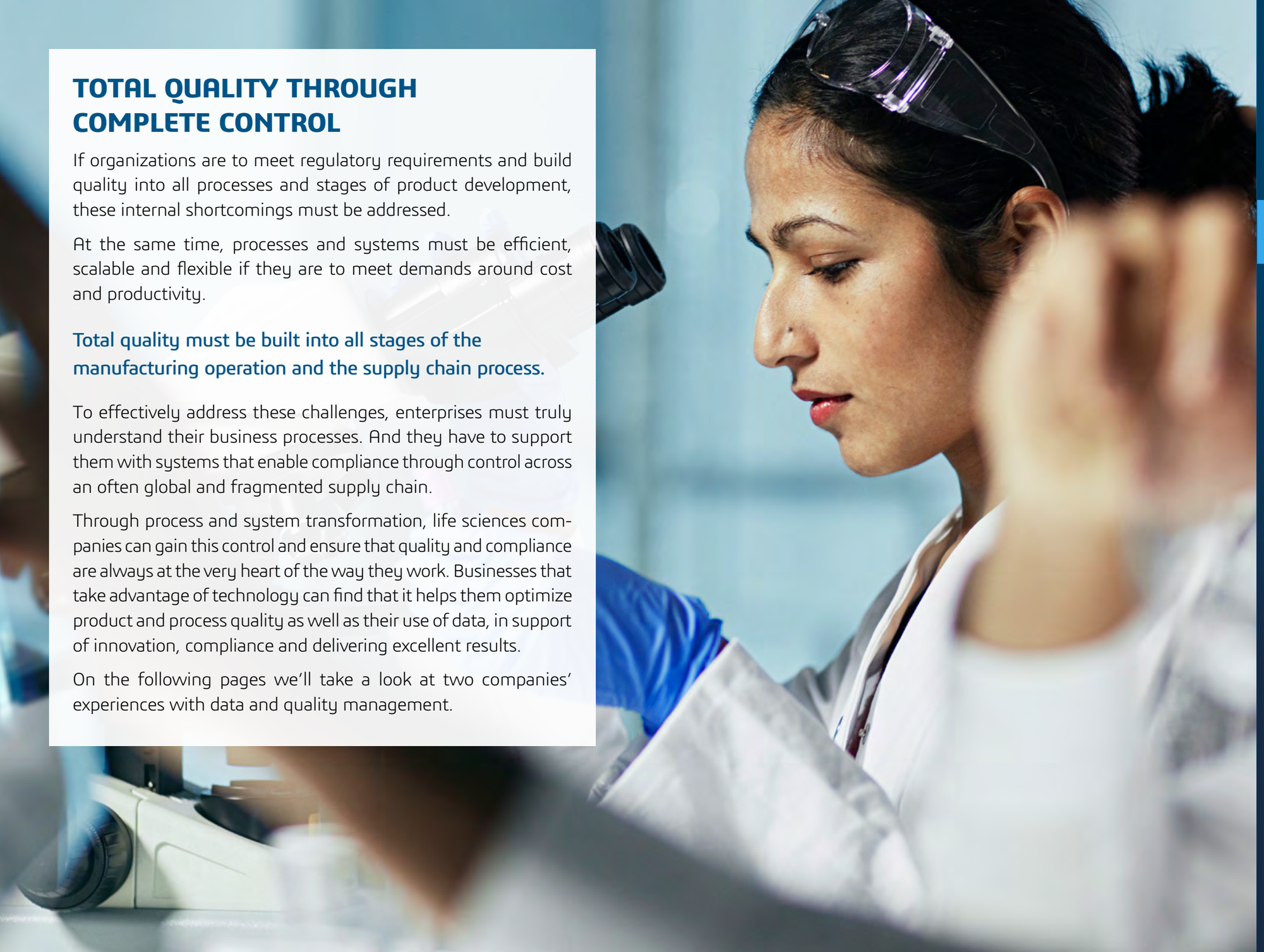
Legacy work processes often rely on multiple unconnected systems and applications that don't span the entire organization and supply chain. This hampers collaboration, makes it hard to work quickly and efficiently, and jeopardizes the ability to track and report. This monitoring capability is important for compliance and for revealing areas of potential improvement.

To trace activities and decisions during product development, full visibility, traceability and control are essential – a single line of sight from the start of a project all the way through to completion. Audits require such information be readily available. Full control over development and manufacturing is compromised when systems don't link up or can't be accessed by everyone who needs them.

> Companies can struggle to maximize return on the knowledge within their own organizations

What's more, the organization is restricted in how well it can capitalize on the breadth of experience within its teams. Expertise exists in pockets across departments, and success often depends on tapping into that expertise. Yet, with growth, acquisition and expansion, this knowledge may become spread out and isolated, both physically and organizationally. The enterprise can't make the most of its knowledge when its processes and systems fail to facilitate the free and easy exchange of ideas. This can slow progress, hinder innovation and reduce the enterprise's competitive edge.





TOTAL QUALITY THROUGH COMPLETE CONTROL

If organizations are to meet regulatory requirements and build quality into all processes and stages of product development, these internal shortcomings must be addressed.

At the same time, processes and systems must be efficient, scalable and flexible if they are to meet demands around cost and productivity.

Total quality must be built into all stages of the manufacturing operation and the supply chain process.

To effectively address these challenges, enterprises must truly understand their business processes. And they have to support them with systems that enable compliance through control across an often global and fragmented supply chain.

Through process and system transformation, life sciences companies can gain this control and ensure that quality and compliance are always at the very heart of the way they work. Businesses that take advantage of technology can find that it helps them optimize product and process quality as well as their use of data, in support of innovation, compliance and delivering excellent results.

On the following pages we'll take a look at two companies' experiences with data and quality management.

hVIVO: CONTROL IN A TIME OF RAPID GROWTH

Biopharma company hVIVO was experiencing rapid site expansion and consolidation. As a result, its ever-growing paper files, inefficient manual processes and cumbersome approval cycles were unsustainable.

It needed a more efficient and effective way to work, one that would be able to adapt as the company opened new sites, hired new employees, reorganized departments and undertook collaborations on new products.

hVIVO

hVIVO is a UK-based specialty biopharma company. The industry-leading service provider of viral challenge studies puts humans at the center of disease modeling.

MANAGING QUALITY DOCUMENTS AND PROCESSES

Hard copies of critical documents – including approximately 700 standard operating procedures (SOPs), policies, work instructions, forms and templates, corrective and preventive action (CAPA) documents, and QA audit reports – were stored in various locations. Upon initial release and revision, each required physical sign-offs for peer review and department head approvals. This mass of documents was managed using labor-intensive spreadsheets.

THE CHALLENGE:

Improve document and process management in a time of rapid growth and change without jeopardizing ongoing clinical testing operations.

DOCUMENT AND PROCESS COMPLIANCE

hVIVO replaced this cumbersome and risk-fraught system with a new system designed for document and process compliance. Now, user-friendly interfaces give everyone who needs it access to all regulatory, quality and compliance tasks in a single view.

By phasing the deployment, hVIVO was able to train employees so they were comfortable using the new system for SOPs before extending it to CAPAs and QA audits.

Only minor adjustments were required to map the old paper-based system to the new document compliance workflows for approvals, distribution and archiving.

hVIVO: INTEGRATED DOCUMENT, REGULATORY AND QUALITY GOVERNANCE

hVIVO's fully integrated quality management system also addresses the compliance and quality requirements of regulatory bodies such as the UK Medicine and Healthcare Products Regulatory Agency (MHRA).

The new system drives enterprise-wide control, consistency and compliance throughout every phase of a document's lifecycle – from creating, reviewing and editing to approving, releasing and distributing SOPs, CAPAs and other quality documents. And by accurately identifying all documents linked to an activity, the system fosters continuous improvement.

Today, hVIVO scientists share information and collaborate more effectively. Using comprehensive reporting tools, they can generate "dashboard" management information displays and key performance indicators (KPIs).

By making it easier to track and report on controlled documents and processes, read & understand (R&U) compliance, overdue CAPA actions and quality KPIs, their new system of document management is helping drive a total quality culture.

RESULTS:

- **Total Quality Culture:** Having procedural documents all in one place brings together and simplifies document, process and quality governance
- **Enhanced Compliance:** The ability to accurately identify all documents linked to an activity enhances compliance while supporting continuous improvement
- **Better Performance Tracking:** Reporting tools generate dashboards and KPIs related to controlled documents
- **Effective Collaboration:** Data is shared more easily in integrated system
- **Simplified Training:** Self-service online training videos can be extended to other sites and functions across the business as needed

ELEKTA: ENSURING REGULATORY COMPLIANCE

Like all life sciences companies, clinical solutions provider Elekta must closely monitor and adhere to regulations established by a range of bodies, including the U.S. Food and Drug Administration (FDA) and other international regulators.

To do so, Elekta must manage vast amounts of data. During an audit, the company must be able to quickly provide any document related to its products and its development processes.

ELEKTA

Elekta is a pioneer in innovative clinical solutions for the treatment of cancer and brain disorders. Based in Sweden and with approximately 2,500 employees worldwide, it is the global leader in image-guided and stereotactic clinical solutions for radiosurgery and radiation therapy. Elekta gives radiation oncologists and neurosurgeons an unprecedented capability to aggressively treat tumors with ultra-high precision without damage to nearby healthy tissue.

Elekta realized the paper-based data management system it relied on was no longer workable and that the company needed a new approach to product development and compliance.

THE CHALLENGE:

To manage vast amounts of product data effectively and to be able to locate documents and process information for audits easily and quickly.

FLEXIBLE, ENTERPRISE-WIDE PLM

Elekta transformed its data management through a flexible, enterprise-wide product lifecycle management (PLM) solution that covers all areas of product development – administration, security, workflow, integration… everything.

Their new system provides a single digital source of information, consolidating all engineering data and processes across the product lifecycle.

ELEKTA: CENTRALIZATION, CONSOLIDATION AND COLLABORATION

Elekta has design centers in Sweden, the UK and China. Each office is responsible for designing distinct parts of a treatment system. Today, teams collaborate more easily and can include their sales, service and production facilities, as well as external resources when necessary.

The new system is also used to manage parts and bill-of-material (BOM) and to drive global product development.

With a user interface that's intuitive and that provides a smarter view of work, everyone is assured that they're all looking at the same information.

It's now much easier to find a particular document or plan, saving Elekta employees valuable time. And transparency in the system helps avoid mistakes and misunderstandings.

Computer Aided Design (CAD) data is integrated, and Elekta plans to expand global collaboration between offices and to include more partners. That way, purchasers will be able to work with subcontractors who are already in the system. And by linking its enterprise resource planning (ERP) system, data can be shared easily between the two.

Elekta is now able to provide auditors with whatever information they require immediately. An FDA audit was a complete success, with inspectors very satisfied with the system and praising Elekta's "excellent control" over their information, which gave auditors a clear and honest view of operations.

RESULTS:

- **Collaboration:** Elekta's global product development teams are unified
- **Visibility:** Everyone looks at the same information – a "single version of the truth"
- **Accessibility:** Documentation is immediately accessible
- **Successful audits:** There is a clear and honest view of operations and excellent information control
- **Systems integration:** Linked systems enable seamless data transfer
- **Time-saving:** Now it's easier to locate documents

REDUCING RISK, IMPROVING QUALITY

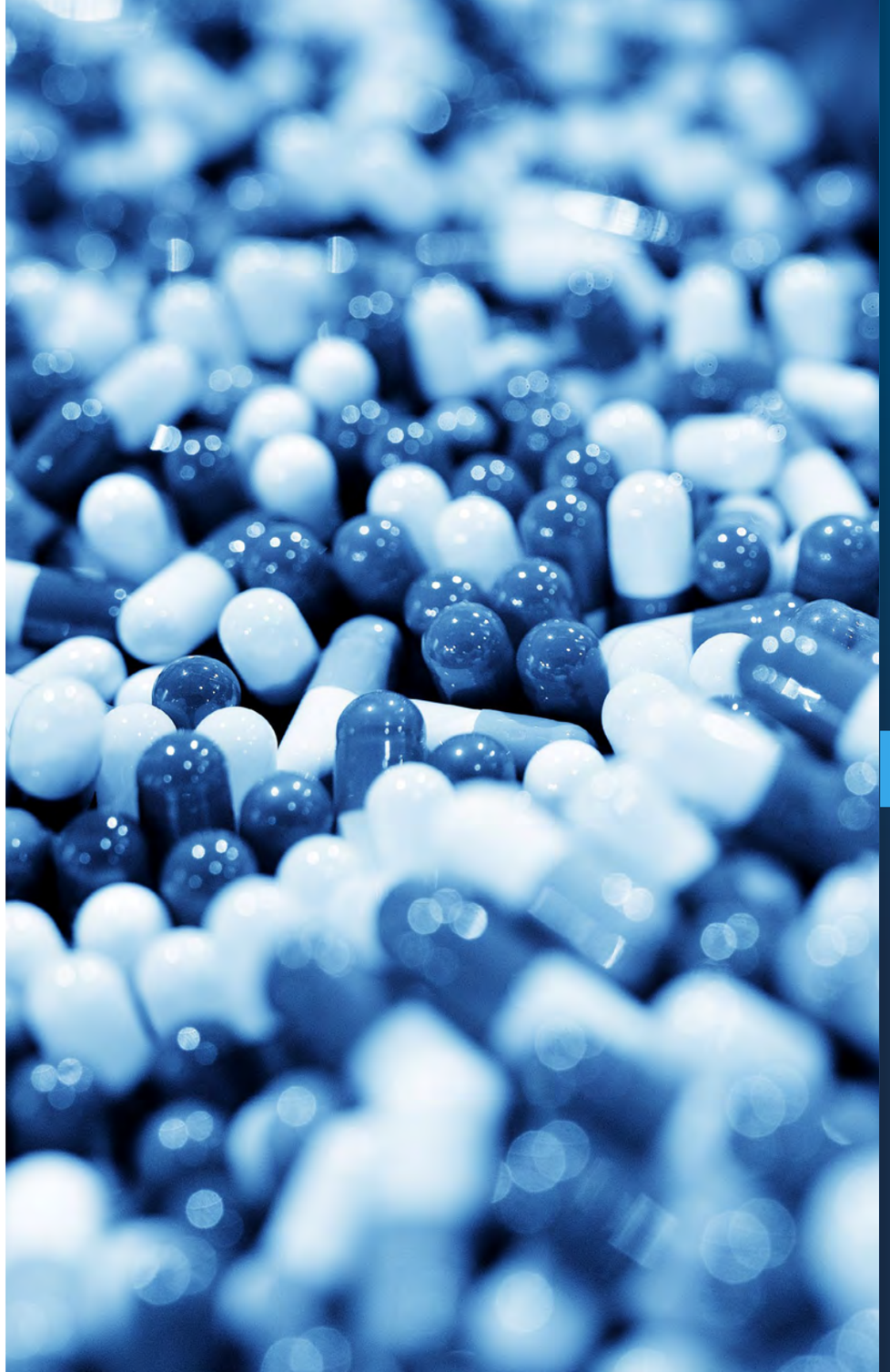
As they design, develop, deliver and manage products, life sciences companies need to be confident that their systems and processes give them the level of control they need. Often, this means transforming the way they operate to:

- enable collaboration
- ensure full visibility and traceability of actions and decisions
- make data available throughout the organization
- enable data-driven decision-making.

By digitizing workflows and processes, enterprises can help reduce risk, improve quality, maintain compliance and enable competitive, innovative product development.

Total quality systems must work for all stakeholders to provide:

Control of every stage of product development and quality operations.	**A single source of truth** of data collated from all sources and made available to all stakeholders.	**Scalability and adaptability** to manage shifting volumes and demands as the enterprise grows and globalizes or adds systems through merger or acquisition.
End-to-end visibility of the entire process in one place so that root causes of deviations can be detected and removed early in the process.	**Collaboration** of all stakeholders (including third parties and possibly even physicians and others) and the means to incorporate all contributions from teams around the globe.	**Global regulatory compliance** to ensure standards for each market are adhered to and tight program control is in place from beginning to end.



COLLABORATION AND CONSISTENCY

Digital solutions enable all parties to connect, collaborate, design and test. They can transform processes and overcome the challenges and risks associated with manual, paper-based, unconnected systems.

By bringing all data into one place, the business maximizes insight to drive actions and decision-making. Additionally, it gains end-to-end visibility and traceability for total quality in every stage of research, development and manufacturing.

> "Forward-thinking businesses should take a platform approach to EQMS*, breaking down informational silos, connecting quality data across the corporation, and enabling all functions to play their role in leading with data-driven quality decisions."
>
> – LNS Research, 2018[2]
>
> *Enterprise Quality Management System

Enhanced collaboration across widespread teams can lead to improved design and testing. Issues can be resolved more quickly, and products can get to market faster. Just as important, consistency and compliance is facilitated when all stakeholders (both within the company and across the supply chain) use integrated systems and a common data platform to drive operations.

In support of total quality management, systems designed for today's life sciences can give companies control over their processes to help them mitigate risk and continue innovating to deliver superior patient and physician experiences.

DASSAULT SYSTÈMES: ENSURING QUALITY IS THE TOP PRIORITY

Dassault Systèmes supports life sciences companies in achieving compliant innovation. Its collaborative environments help extended ecosystems work more efficiently to meet regulatory demands and patient expectations. This in turn can help improve time-to-market and competitiveness.

Speed, efficiency and consistency are important and can all be improved with a platform facilitating multi-site collaboration for better management of resources and operations. For compliance, regulatory best practice should be embedded throughout the development process and traceability should be facilitated across the supply chain and throughout the product lifecycle. Dassault Systèmes' life sciences industry solutions help consign disconnected, manual processes to the past for better efficiency and control, and total quality outcomes.

To learn more about how your business can achieve total quality and compliance, click here.

[1]The Business Case for Medical Device Quality McKinsey Center for Government, October 2013
[2]DIGITALIZED QUALITY IN LIFE SCIENCES: Roadmap to Sustainable Growth and Speeding Profitable, High-Quality Products to Market LNS Research, 2018

Our **3D**EXPERIENCE® platform powers our brand applications, serving 11 industries, and provides a rich portfolio of industry solution experiences.

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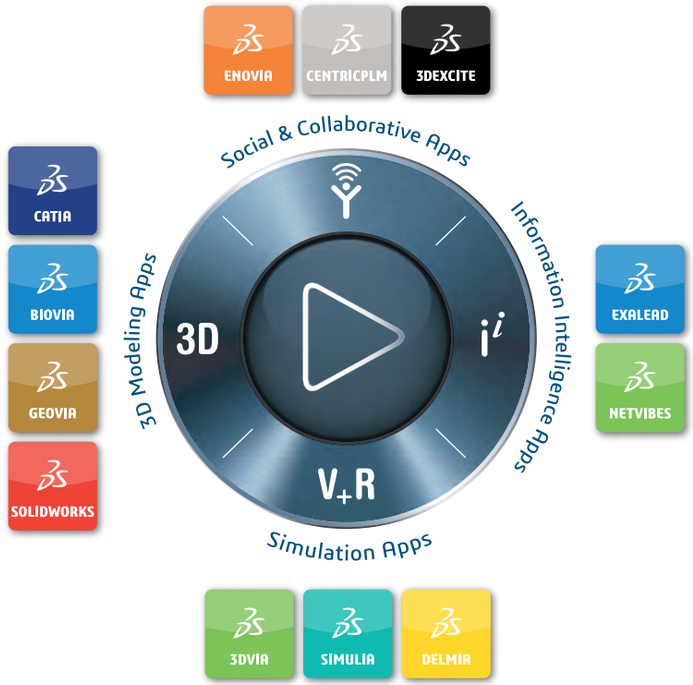

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