



SPHERA STORIES



MANAGING LIFE SCIENCES RISK

IN A SINGLE SOLUTION



ALL RISK, ALL THE TIME

AS A LIFE SCIENCES MANUFACTURER,
YOU KNOW THAT **RISK HAS A WAY OF
DEFINING YOUR WORK.**

You see operational and quality risk in every facet of your business, including R&D, clinical trials, engineering, distribution, sales and marketing, and—most notably—production. Without proper risk management, you can end up with impure medicines, poorly designed devices, or manufacturing errors that cost millions. Sometimes, mismanaging risk means you don't end up making a product at all.

Given the thicket of FDA rules, regulations, and guidance, not to mention ISO and ICH standards, simply being in manufacturing compliance is difficult at best, seemingly

impossible at worst. Manual compliance or active risk management involves dozens of personnel, hundreds of spreadsheets, and thousands of hours to create imperfect reports that take months to complete. So are you managing risk, or is risk managing you?

Sphera Solutions in Life Sciences

At Sphera Solutions, we have more than 30 years of experience and industry-leading products to help pharmaceutical, biotech, and medical device manufacturers manage risk efficiently and effectively—and generate insights our competitors can't.

In Life Sciences, we deliver automated solutions that manage compliance, risk and product stewardship:

- An Operational Risk solution that takes the entire Operational Risk journey from compliance through Operational Excellence, including Comply Plus, our regulatory standards solution
- Our Stature Quality Risk Management (QRM) solution provides a systematic approach to quality risk management as outlined in the ISO 14971 and ICH Standards. Furthermore, Stature enables **Quality by Design** by using scientific understanding of Drug Substances and Pharmaceutical Products.
- Chemical Lifecycle Management and SDS Authoring for Life Sciences companies, as part of Sphera's Product Stewardship solutions

ARE YOU MANAGING OPERATIONAL RISK, OR IS RISK MANAGING YOU?



COST OF A PRODUCT RECALL*



*LIFE SCIENCES INDUSTRY AVERAGE



“ We have the insights and lessons learned—not only in life sciences, but in other manufacturing industries as well—to understand where others have succeeded. We can bring these lessons together to improve all your processes. Other vendors can’t.”

— ANDY HOSMAN
VICE PRESIDENT,
OPERATIONAL RISK SOLUTIONS

Our products are backed up with the industry’s most comprehensive and most frequently updated database of regulations, guidance, and standards.

It’s not getting easier

What about the industry makes it imperative to consider our risk management solutions now? First, it’s apparent that industry trends are not welcoming for Life Sciences to manage risk.

Consider product growth areas: Large-molecule biologics requiring special manufacturing processes and extraordinary expertise. Drug-device combinations that mandate close attention to sourcing and quality, and adherence to FDA, ISO 14971 and ICH standards. Oncology and specialty drugs, difficult and expensive to produce, and for which product defects are ruinous.

Compliance for life sciences companies entails adhering to thousands of rules, regulations, and standards that govern everything from handling raw materials to worker safety to plant hygiene to product purity and quality. You need to consider traceability regulations, the enormous costs of manual compliance, and huge consequences for non-compliance—think of Warning Letters from the FDA’s Office of Manufacturing Quality, the number of which have nearly doubled from 2015 to 2016.

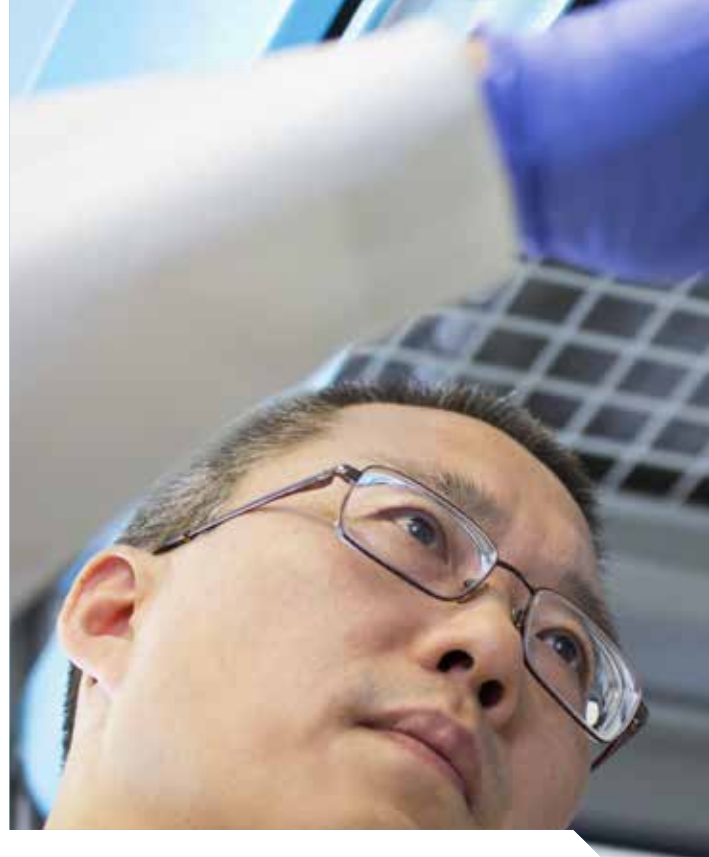
Nor are regulations ever set in stone: The constant change and churn in the regulatory environment means you’re dealing with moving goalposts.

A failure to comply with regulations and maintain quality at the highest level can translate into discarded products, recalls, bad publicity, and worse, resulting in millions of dollars in losses, ruined reputations, and harm to patients.

And the kicker? Today, meeting compliance is only a baseline necessity. Life Sciences companies should endeavor for continuous improvement in quality and mitigating operational and quality risk. To make risk management a true competitive advantage, Life Sciences companies are trying to reach Operational Excellence, taking them on a journey that never ends.

AVERAGE EFFICIENCY GAINS





HOW TO HANDLE QUALITY RISK

“What is your true cost of compliance? How much time are you spending? Are you able to interpret the raw data you’re collecting into insights to make decisions?”

— **SHABBIR RAZAKZEE**
INDUSTRY SOLUTIONS MANAGER,
LIFE SCIENCES

THERE’S A REASON **NINE OUT OF THE TOP 10 LIFE SCIENCES COMPANIES USE SPHERA SOLUTIONS** FOR THEIR QUALITY RISK MANAGEMENT AND OPERATIONAL RISK MANAGEMENT NEEDS.

Our Stature Quality Risk Management solution is the industry standard for life sciences companies. We’ve helped pharmaceutical, biotech, and med device firms save millions of dollars in reporting costs by setting a single, standardized quality risk solution for the entire enterprise. That’s not to mention the reduction in prohibitively expensive recalls and product waste Stature has helped prevent.



ENVIRONMENTAL PERFORMANCE SOLUTIONS FOR LIFE SCIENCES? **YES**

There may be parts of your Life Sciences manufacturing process that need help in meeting environmental standards. Sphera's Environmental Performance solutions don't just keep you in compliance, but, like our Operational Risk and Product Stewardship solutions, they provide a competitive advantage. Consider our [Environmental Performance solutions here](#) or



Sphera's products drive regulatory compliance, give you end-to-end traceability, and minimize compliance costs. Unlike other solutions, ours not only evaluates risk management programs, but also allows converting raw data into insights that help you make risk-based decisions.

Sphera Solutions is a complete Operational Risk solution

But Sphera Solutions doesn't just sell software that identifies regulations, helps life sciences companies stay in compliance, and drives quality risk management.

We offer a comprehensive portfolio of holistic solutions that cover all operational risk. Instead of cookie-cutter products that address a single risk or plug a gap in process design, Sphera Solutions supports the risk lifecycle in its entirety. Stature helps you complete What If analyses and HAZOPs, ensures compliance, and manages risk in Environmental Health and Safety (EH&S).

Instead of stitching together multiple solutions from different vendors—and the inevitable integration and training issues—you can turn to an end-to-end, fully integrated, fully configurable solution built for your needs, no matter where on the risk management curve you reside.

And our solutions tackle Operational Risk in all facets of the process: R&D, clinical trials, engineering, manufacturing, and even distribution. Capturing end-to-end risk in a single

platform allows companies to “roll up” risk at all levels of the enterprise, giving executives the information to improve decision making on risk-based investments.

For others, managing risk is a module, but for Sphera, it's in our DNA.

No matter the risk requirements and challenges, Stature can handle them

Every company is in a different place in terms of operational risk. Some life sciences firms are moving towards Operational Impact, Sustainability, and, eventually, Operational Excellence. Others are struggling to stay compliant. But no matter their status today, life sciences companies' ultimate goal is Operational Excellence, which demands risk management and risk-based decision making.

That's one reason our quality and operational risk solutions are so powerful: Stature and our other solutions work for all life sciences companies, no matter their status in operational risk.

That pliability makes Sphera Solutions' products dynamic in helping companies implement their own view of regulations and risk standards. Not only do we offer the most comprehensive regulatory and rules database in the industry, but our solutions are configurable to meet each life sciences company's interpretation of those regulations and risk standards.

We speak your language

What allows us to deliver end-to-end solutions in Life Sciences? Part of it is our unparalleled expertise in operational risk.

We speak your language when you're talking about PHA, HAZOP, AFMEA, PFMEA, DFMEA, FTA, ISO 14971, ICH 9, and the rest. Sphera Solutions can drive your KPIs by sharing insight and best practices in implementing a comprehensive and effective Risk Management solution.

Other spheres in Life Sciences

Sphera Solutions also offers Product Stewardship solutions for the Life Sciences industry. Our products and tools ensure proper Chemical Lifecycle Management and help meet GHS and OSHA compliance.

The increasing popularity of drug-device combinations like prefilled syringes, metered-dose inhalers, and drug-eluting stents present a whole new regulatory and risk framework—not only must companies making these products contend with FDA regulations, but OSHA and GHS

rules concerning the handling of chemicals, not to mention adherence to med device (ISO 14971) and the pharmaceutical (ICH Standards) guidelines.

These frameworks obviously have an outsized impact on medical device and diagnostics manufacturers. Siemens, whose business portfolio includes one of the world's top suppliers for medical diagnosis technology, faced an enormous challenge with meeting the GHS framework. Using Sphera Product Stewardship solutions, Siemens was able to reassess 3,500 reagents and deliver GHS-compliant Safety Data Sheets in 20 languages.

"Sphera met the challenge by enabling our Siemens team members to evaluate the chemical makeup of each product," says Maureen Gillis, Senior Manager, EHS, Siemens Healthcare. "Fortunately, we were able to use the information available from Sphera to simplify the process."

Siemens kept product delivery flowing in its key GHS-affected markets while cutting costs, ensuring its reputation, and, most critically, helping ensure the health of patients dependent upon Siemens Healthcare products.

THE TOP SIX BENEFITS OF STATURE, THE SPH

LINK CRITICAL QUALITY INFORMATION ACROSS PRODUCT LIFECYCLE

Ensure shared, appropriately linked risk assessments to meet regulation-mandated traceability requirements and get electronic approvals in accordance to 21 CFR Part 11.

1

CREATE KNOWLEDGE RETENTION—AND SHARING

Not only does our QRM solution capture and retain expert knowledge, but creates a comprehensive knowledge base of experiences, ensuring you learn from errors instead of just enduring them.

2

IMPROVE PRODUCT QUALITY

Stature's workflow capabilities allow for assignment of ownership of corrective actions, and tracking them to closure. Stature can also ensure verification and existence of required controls to drive down risk.

3

Guiding you on your journey

The strength of our solutions lies in our understanding that every life science company is different – different products, different risks, different ways to tackle those risks.

We have three decades of experience in helping companies stay compliant, guiding them on their Operational Risk journey towards Operational Excellence. We enable Life Sciences companies to meet the highest standards in Product Stewardship effectively and efficiently with our automated tools.

The world's largest life sciences know this. Managing risk is what we do. Managing risk is who we are.

SPHERA SOLUTIONS HAS:



250 ORGANIZATIONS
WITH MORE THAN
1 MILLION
USERS



550
MAJOR ENTERPRISE
CUSTOMERS



70
COUNTRIES WITH
SPHERA DEPLOYMENTS

97%
SERVICE-LEVEL
AGREEMENT
ATTAINMENT



(compared to **80%** Industry-wide
Service-Level Agreement attainment)

SPHERA QRM SOLUTION IN LIFE SCIENCES



GAIN CONSISTENCY AND VISIBILITY

Sphera's QRM solutions feature standardized definitions and applications of the occurrence, severity, and detection in calculating risk, illustrating increased visibility of your quality risks. Better still, you can produce quality risk management reports and dashboards that reveal risks you otherwise may not have detected.

4

INCREASE EFFICIENCY


Stature shortens the time it takes to conduct risk assessments and turns a months-long exercise to produce reports to minutes. On average, Stature delivers a 50% efficiency gain in risk assessment.

5

LEVERAGE A COMMUNITY OF BEST PRACTICES

Access a store of knowledge unlike any other. The content you get through a community of industry-leading peers and Sphera domain experts will accelerate your next round of continuous improvements.

6



CASE STUDIES



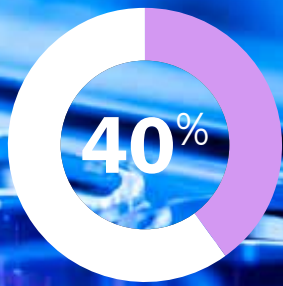
STATURE WAS JUST THE START

Going the full mile on risk

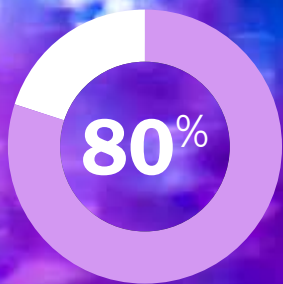
One of the world's largest pharmaceutical companies operates manufacturing facilities in a dozen countries across the globe. The company needed to centralize a far-flung risk assessment system, and eliminate the arduous manual risk assessment process that caused endless work and could result in increased product defects and recalls. With the Stature solution, Sphera implemented a FMEA framework that automated the process and eliminated thousands of spreadsheets and process flow documents that could exceed 100 pages.

Not only did Sphera's Quality Risk Management solution save millions of dollars and countless hours of work, but ensured the consistency of risk assessment data and decreased the amount of time on reporting to minutes from weeks. The Stature solution proved so effective that the company's Environmental Health & Safety teams are using Stature for What If and HAZOP analysis related to workplace safety, and they are planning on extending it to other areas of its journey towards Operational Excellence.





OF DRUG
SHORTAGES
RESULT FROM
QUALITY
CONCERNS



OF QUALITY
PROBLEMS ARE
REPEAT ISSUES

DOWN WITH SPREADSHEETS

Sphera ensures quality and saves millions

A major recall at another of the world's largest pharmaceutical companies led it to reevaluate its risk evaluation processes. The company chose a Failure Mode and Effects Analysis (FMEA), resulting in more than 100,000 analyses being performed. But when the company used spreadsheets for the evaluations, it quickly realized the enormity of doing so manually, and chose Sphera's automated Quality Risk Solution. The results were dramatic: over a three-year period, the company reduced product recalls to zero from 21, product risk reports were created in minutes instead of three months, and the cost of risk assessment effort fell 55%, or \$2.75 million a year.



FIVE REASONS SPHERA

STANDS OUT

IN OPERATIONAL RISK

1

Our Operational Risk solutions meet your company's place on the risk maturity curve. Ease of use means minimal training, and users can easily pick up an assessment months after starting.

2

Our domain knowledge in Operational Risk is unmatched. Our databases give companies the ability to develop their own knowledge libraries, helping ensure that you're not starting from scratch with new products and risk assessments.

3

Our databases of rules, regulations and standards—updated quarterly—are **the most comprehensive in the industry.**

4

Stature, our main Quality Risk Management solution, is but one part of our Operational Risk product portfolio. It's a comprehensive tool to manage Operational Risk, not just a module.

5

Stature enables **Quality by Design** as outlined in the ICH Q8, Q9 and Q10—Stature's approach links critical Quality, Process and Material attributes to process capabilities and risks for establishing an effective control strategy.

“

Stature is an enterprise-wide risk assessment tool, not just for quality risk management. Others have quality solutions, or process safety methodologies. But we offer one solution that delivers it all.”



— **BANOO BEHBOODI**
INDUSTRY SOLUTIONS DIRECTOR

About Sphera

Sphera is the largest global provider of software and information services in the operational risk, environmental performance and product stewardship markets. For more than 30 years, we have helped more than 2,500 customers and 1 million users across 70 countries optimize workflows and navigate the complex and dynamic global regulatory structure.



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