

TOTAL COST OF OWNERSHIP

7 TRUTHS TO CONSIDER WHEN DEPLOYING
AN ENTERPRISE COMPLIANCE MANAGEMENT SYSTEM

WHITE PAPER



MANAGEMENT SUMMARY

Life sciences companies, as one of the most heavily regulated industries, are faced with the need to accurately manage, track, and trend a vast number of quality (GxP) and regulatory compliance issues. This is time consuming and expensive as indicated by recent research findings:

Compliance with global standards typically means 35% higher manufacturing and maintenance costs and studies estimate the “Cost of Poor Quality” 10 - 40 % of a company’s turnover for cost of poor quality ([Marcus Thomasson & Johanna Wallin, Cost of Poor Quality: definition and development of a process-based framework](#)).

Through automation, these organizations are documenting tangible, bottom-line benefits based on process modifications, reduction in document cycle times, improved collaboration across the enterprise and cost reductions associated with the avoidance of regulatory penalties. Additionally, these organizations have identified that the adoption of an enterprise compliance management system that is configurable versus highly customized is critical to the early realization of benefits. Furthermore, the Total Cost of Ownership (TCO) differences between these two approaches are significant and undeniable.

BIOVIA has developed this white paper to provide insight and guidance into the TCO process and its place in the overall solution sourcing and management process. Using this guidance, the TCO calculator and the TCO ‘truths,’ you will be able to build a best-in-class TCO model that will assist you in differentiating and analyzing alternative solutions.

HOW MUCH DOES IT REALLY COST – MASTERING THE CONCEPT OF TCO

While the terms, TCO and ROI are used interchangeably, they are not the same. Each measure has a different purpose and it is important to use each correctly so as not to impair your ability to justify and quantify your Enterprise Compliance Management System investment accurately.

ROI

ROI (Return on Investment) is the most common financial analysis needed by organizations to support requests for capital expenditure.

Return on Investment (ROI) is focused on measuring the benefits of a proposed business change, to establish if they exceed the costs of implementing a specific project. ROI analysis will also identify the timeframe for benefits realization e.g., at what point will your new application break even and pay for itself.

TCO

The Total Cost of Ownership (TCO) is a simple calculation that totals all the costs associated with a particular IT investment. TCO was developed in the late 80s by Gartner Research. Over the years, this methodology has been accepted as the standard way to evaluate total costs of an IT solution. Once a baseline TCO has been established, it may be used for internal or external comparisons, or tracked periodically in scorecards and dashboards.

In addition, TCO analysis is a critical tool for assessing and comparing alternative IT solutions during a sourcing exercise. In this context, choosing the correct solution is not just about cost, there is a broader agenda where criteria other than cost need to be examined. Companies wishing to address this broader agenda develop a vendor evaluation model that includes wider selection criteria, ensuring a holistic solution assessment (figure 2). These criteria are weighted by stakeholders to reflect their specific requirements and unique circumstances and each vendor is scored accordingly. The most suitable vendor is then easily differentiated and identified.

Criteria for Evaluation	Weight	Solution 1	Solution 2	Custom Solution
Technology				
TCO				
Functionality				
Service and Support				
Vision of Current/Future Industry				
Viability/Ability to Execute				
Cultural Fit				
Totals				

Figure 2:
Vendor Evaluation Model
(Summary)

TCO FOR ENTERPRISE COMPLIANCE MANAGEMENT SYSTEMS IN LIFE SCIENCES

Simply stated, TCO consists of the costs, direct and indirect, incurred throughout the lifecycle of an asset, including acquisition, deployment, operation, support and retirement. Many businesses fail to understand and calculate TCO properly. Additional studies by Gartner show that nearly 80 percent of total IT costs occur after the purchase of a solution, and that nearly half of these lie outside the IT department’s budget. With the right analysis, you can identify these direct and indirect costs and implement best practices to contain them.

Costs in Enterprise Compliance Management Systems in Life Sciences fall into two main categories: direct costs and indirect costs. These are broken into three sub-categories: technology, personnel and operations and processes.

- A direct cost item can be positively traced to an accounting line item, a purchase order, accounts payable, a payroll or a budget line item.
- An indirect cost item is defined as resources assigned to different cost centers that are performing functions composed of a line item in the TCO chart of accounts.

For example, if a regulatory employee is providing IT technical support to another associate, then the cost of the regulatory employee’s time to diagnose, troubleshoot and resolve that IT issue that should be allocated will be an indirect line item within the TCO chart of accounts.

We have developed a TCO calculator template (figure 3) and guidance to help you build your own Enterprise Compliance Management System Model. The TCO Calculator identifies the cost elements we most frequently encounter on Enterprise Content Management Systems projects.

Using the TCO calculator, you will be able to:

- develop a baseline for quantitative analysis and comparison of proposed solutions
- develop the ROI model and the business case for capital investment
- develop scorecards / budgets and metrics for the life of the solution

Gartner estimates that as many as 70% of IT projects are never completed – not to mention those that are overbudget, take months or years to deploy, or don’t deliver the specified features.

TCO TRUTHS

TCO Truth #1: Evaluate the initial software price as just the beginning of the Lifecycle costs.

Some life sciences companies make the mistake of looking only at the initial deployment price of the software and use that as the main driver in selecting a system. In most cases, in exchange for an initial lower license cost, they give up functionality. They further compound their error by assuming they can make up for the trade-off in features by undertaking customization projects to retrofit the software to the unique needs of their environment.

Attempting to perform the customization in-house places an additional burden on the IT department and frequently is not achieved because IT fire-fighting tasks always get top priority over more strategic projects. If the life sciences organization turns to the vendor to assist with customization, they may end up paying as much as three times the initial software deployment costs and may never have access to the final code and related knowledge transfer. This is assuming that they successfully complete the project! Gartner estimates that as many as 70% of IT projects are never completed – not to mention those that are over-budget, take months or years to deploy, or don't deliver the specified features.

TCO Truth #2: Look for easily configurable software

Just about every firm wants to perform some customization to integrate the enterprise compliance management system with their existing systems. A true enterprise compliance management system assumes you will be using the software across different departments and allows you to configure the software easily without changing the code. This means you can add users, set permissions and enforce business rules based on role and desired level of security by simply checking "tick boxes" within the system. A good rule of thumb is that 80% or so of the value of any system can be captured relatively quickly and easily and that the remaining 20% can often be so difficult to capture, it is not worth pursuing. As new capabilities are bought, not built, this approach can deliver results quickly and inexpensively.

TCO Truth #3: Approach a modular solution with caution

Another pitfall is the so-called "modular approach" where you purchase standard features as separate modules. These can include features such as workflow, rendering and watermarking. Again, robust systems include these features as standard options rather than forcing you to buy into an "integrated" approach.

TCO Truth #4: Evaluate only those vendors that offer lifecycle support

With all the effort you'll be putting into making an enterprise compliance management purchase now, wouldn't it be great to avoid the same process again in 12 to 18 months as your business matures? For this reason, evaluate only those vendors that offer support for every stage of the customer lifecycle – submissions; manufacturing, marketing, clinical, packaging – whether or not you intend to purchase for all these departments up-front. This approach means you can add licenses and easily roll the solution across your enterprise when you're ready.

TCO Truth #5 – selecting highly configurable software means you can avoid hiring a highpriced IT babysitter

Administration - Highly customized solutions not only take months and even years to deploy but continue to be complex in terms of administration, configuration and ongoing usability – all of which results in a significantly increased TCO. What this means is the business managers in your organization must cede control of your compliance system to IT to manage your system and extract true value. IT inherently is under-resourced and time-pressed. Dedicating an IT person to maintain your system can run in the \$150K range annually on a fully loaded basis. More and more life sciences firms are making "low IT footprint" a mandatory requirement in deploying or even replacing an enterprise management compliance system. In particular, they are looking for systems that are intuitive and business-focused to appeal to the widest range of users and assume that not all users will have the same skill-set.

TCO Truth #6 – don't try to build a compliance system using a non-compliant solution

Many vendors market their Enterprise Compliance Management System as being “compliant”. Professionals working in the Life Sciences industry know that this is not possible – it is the process of validation and operational procedures that renders a system ‘fit for purpose’ and compliant. However, these same professionals fully recognize and appreciate the benefits to be gained from purchasing a system whose primary focus is compliance and, furthermore, is built and continuously upgraded to meet current and emerging regulatory requirements, such as: security and integrity, traceability, workflow, version control and management and instance and deviation reporting.

Some organizations have fallen into the trap of implementing point solutions such as CAPA systems, or generic document and content management solutions in the mistaken belief that they will achieve a cost effective compliance management solution. However, the opposite is true with these approaches typically resulting in a significantly higher TCO.

Niche solutions will often require expensive and extensive integration and customization with a range of other point solutions to make them truly compliant enterprise compliance solutions – indeed Gartner has stated that Life Sciences companies implementing point compliance management solutions are likely to spend up to ten times more¹.

Generic content management solutions, (e.g., Oracle and Documentum) on the other hand, may require extensive programming, manual procedures and work-arounds in order to become compliant because they were not developed with compliance in mind. This frequently results in a significantly higher TCO due to the development and management of cumbersome ancillary compliance processes and associated documentation. True Enterprise Compliance Management Systems will contain standard functionality that meets all of the regulatory requirements for compliance with many disparate regulations, resulting in a substantially lower TCO.

TCO Truth #7: A Custom System Significantly Increases Validation Costs and Time to Market

Validation and the cost of re-validating software contribute to additional direct and indirect costs. In addition to GxPs themselves, regulatory compliance in the life sciences requires validating that the systems used to support the GxPs are working the way they were intended to work and that they are fully secure. The purpose of validation is to gather objective evidence that the system reliably functions to meet requirements and must be readily available to the FDA in the event a process is called into question.

Good practice dictates the following validation steps:

- To verify the proper installation of the system and that the hardware and system software meet technical requirements in an Installation Qualification (IQ);
- To test functions in a validation environment in the Operation Qualification (OQ);
- And verify that the system meets requirements as used in the company process in a Performance Qualification (PQ).

In a custom system, Torque Management research shows **that validation can represent up to 40 percent of the cost of the total development**². These costs include building extensive validation and training materials under strict change control. Recognizing this cost, off-the-shelf application vendors provide a complete set of validation starter documents, templates and test protocols to accelerate validation and shorten deployment times. These templates represent significant cost savings in the time it takes to complete them coupled with the time to execute, test and trace requirements.

After the initial implementation, any time you change the code of your custom solution, these materials will require updating, re-approval and re-validation (and many companies find the upgrade process so complex and time-consuming that they prefer to run on old technology rather than upgrade). Off-the-shelf solutions require less re-validation and, where it is required, vendors provide updated materials and guidance as part of the upgrade package – all covered by the standard maintenance agreement.

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Cost Categories	Cost Elements	Year 1	Year 2	Year 3	Year 4	Year 5
Technology	Hardware - Server(s)					
	Hardware - Client(s)					
	Software Licenses					
	Escrow License					
	Hardware Maintenance					
	Software Maintenance					
	Software Customization					
	Software Configuration					
	Data Migration					
	Software Support					
	Interface Development					
	Networking and Communication					
Additional Security Costs						
Total Technology Costs						
One-off Personal Costs Associated with Implementation	Project Management					
	Regulatory Oversight					
	Risk Management					
	Installation and Commissioning					
	Testing					
	Implementation					
	Training Content Development					
	Training Delivery					
	Validation Master Plan Development					
	IQ, OQ, PQ, Development					
	Validation Execution					
	DR / Continuity of Operations Plan					
	DR / Continuity of Operations Test					
	Procedures and SOP Development					
	Change Management					
Application Support						
Key Metrics Development						
Total Personnel Costs						
On-going Process and Operating Costs Associated with Operating the System	System Operations					
	System Administration					
	Application Operations					
	Application Administration					
	Programming Support for Customization					
	Programming Support for Interfaces					
	Database Operations					
	Database Administration					
	Database, System and Application Security					
	Configuration Management					
	Change Management					
	End User Support					
Retirement						
Total Operations and Processes Cost						
Total Cost of Ownership						

Figure 3:
TCO Calculator Template

ESSENTIAL GUIDANCE FOR CREATING YOUR TCO MODEL:

1. Tools for creating a TCO Model

Some companies have tools available to assist with building TCO models but most organizations build an excel spreadsheet. If using a spreadsheet, create a worksheet for each proposed solution. Based on our extensive Life Sciences experience, we have included the most commonly encountered cost elements associated with acquiring and implementing an Enterprise Compliance System, but you should review this list and add any other unique cost elements that apply to your environment.

2. Understand the system 'footprint'

It is important to know the eventual potential size of the system in order to build a credible TCO. So, where your initial implementation is for 100 people but the ultimate aim is to implement with 700 people, build the model based on 700 users. Failure to do this will result in a flawed TCO.

3. Gather Costs

Examine the proposed system 'footprint' and gather all costs, direct and indirect under each cost element. There are two cost sources:

1. Vendor proposals – costs should be itemized at a sufficiently granular level to enable you to accurately cross reference each cost element line to the vendor proposal, ensuring a trail of evidence for future reference.
2. Internal personnel costs - these costs will be associated with:
 - a. one-time activities associated with the implementation phase
 - b. on-going support for operations and processes to run the system productively over time

For clarification, our TCO calculator splits out these costs so that it is easy to see the initial investment requirement versus the genuine on-going, long-term costs of operating and managing the system. When you complete the calculator for a number of alternative solutions it is easy to see where each solution is more or less expensive.

Establishing accurate personnel costs can be tricky, but worth the effort. Personnel costs should be fully loaded (your finance function should be able to provide specific company guidance). In the event that such guidance is unavailable, consider using an industry standard of 2.5-3 times the annual salary of each resource involved in the activity to calculate a fully loaded employee cost. Remember that you will need to scan the organization and calculate who will be required, and for how long, in order to arrive at a reasonable calculation.

For example:

Number of Project Manager Resources x number of days x fully loaded cost = Project Management Cost

Don't forget personnel and tasks that are required on an occasional basis e.g., security officer review of access logs (.25 day per week on average). These seemingly small costs when aggregated can make quite a difference to a TCO.

Plot costs onto the correct column of the TCO calculator model: one time or annualized. An example of a one time cost might be data migration downtime.

4. Technology Costs

Technology costs include all hardware and software related costs associated with the initiative, e.g., application programs, servers, clients etc. This will be described in vendor proposals as the initial purchase or lease costs. Divide those costs by the expected life of the asset to get the annual figure. The costs of associated hardware (storage, network, equipment, etc) are also included.

5. Personnel Costs

Personnel costs include all of the one-off human resources costs (employee and contractor) associated with the initiative. This will include new hires, overtime and temporary hires. To help you complete this section we have identified many of the common tasks where you will need to apply resources during your project. This information may already be available in the project plan. If not, the TCO model becomes an invaluable input and 'heads up' for the project manager.

Custom solutions can be more difficult to maintain, especially if much of the knowledge base lies with the vendor or an outside consultant. Accordingly, the day-to-day glitches in servers or interactions between software and hardware that causes a mere blip in a more standard implementation, can have significant performance issues in a custom environment.

6. Operations and Process

A direct cost calculation, this measure includes all additional on-going labor costs that are required to run the system such as technical operations and support as well as the help desk.

7. Additional Indirect Costs

Other indirect costs, while important, are perhaps not as visible, include downtime and the employee productivity lost from the inability to access critical documents and workflows. Custom solutions can be more difficult to maintain, especially if much of the knowledge base lies with the vendor or an outside consultant. Accordingly, the day-to-day glitches in servers or interactions between software and hardware that causes a mere blip in a more standard implementation, can have significant performance issues in a custom environment.

However, the greater risk for organizations in highly regulated markets is regulatory fines and penalties, and legal fees. The damage from non-compliance extends far beyond mere fines, also translating to a loss of customer confidence, decreased stock price and market value and overall blow to brand equity. Trust is a currency that can never be regained once lost.

CONCLUSIONS

Total cost of ownership (TCO) is a financial estimate designed to help consumers and enterprise managers assess direct and indirect costs related to the purchase of any capital investment, such as (but not limited to) computer software or hardware. Building a TCO model is a best practice and it offers an assessment that reflects not only the initial cost of purchase but all aspects in the further use and maintenance of the equipment, device, or system considered.

In selecting an enterprise compliance management system, you have essentially two choices: custom development or commercial-off-the-shelf. Custom development initiatives are very costly and often yield unimpressive results. They are expensive to maintain, costly to validate and can take years to deploy and return value. Given that regulatory requirements are dynamic in nature - many prudent organizations are seeking off-the-shelf, highly configurable solutions to address global regulatory requirements. Highly configurable solutions provide faster deployments and time to value as well as an overall lower Total Cost of Ownership.

Organizations who decide to source a commercial off-the-shelf package are already on the way to a lower TCO. Building a TCO model as part of the vendor assessment process will improve your chances of selecting the correct solution. It will also:

- Accelerate your decision process
- Make cost differences between solutions visible at a cost element level
- Provide quantitative data for your Vendor Evaluation Model
- Provide input to your project plan
- And provide input for project, budgetary and scorecard reporting.

ABOUT BIOVIA

Dassault Systèmes Biovia Corp. (BIOVIA) provides global, collaborative product lifecycle experiences to transform scientific innovation. Powered by Dassault Systèmes' **3DEXPERIENCE**® Platform, BIOVIA solutions create an unmatched scientific management environment that can help science- and process-driven companies create and connect biological, chemical, and material innovations to improve the way we live. The industry-leading BIOVIA portfolio integrates the diversity of science, experimental processes and information requirements across research, development, QA/QC and manufacturing. Capabilities include scientific data management; biological, chemical, and materials modeling and simulation; open collaborative discovery; scientific pipelining; enterprise laboratory management; enterprise quality management; environmental health and safety; and operations intelligence. BIOVIA solutions are used by more than 2,000 companies in the pharmaceutical, biotechnology, energy, chemicals, aerospace, consumer packaged goods and industrial products industries, as well as academic and government entities.

REFERENCES

[iSix Sigma, Apply Cost of Poor Process and Product Quality to Life Sciences Industry.](#)

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