

Solution Selection Guide

**Enterprise Quality Management
Software (EQMS)**

Dan Jacob and Matthew Littlefield, March 2016



Contents

Introduction	4
EQMS Market Overview	4
EQMS Architecture.....	4
How This Guide Was Prepared.....	4
Using the Solution Selection Guide	5
Solution Providers in Detail	7
AssurX.....	7
AssurX at a Glance	8
CEBOS, a Division of QAD	9
CEBOS at a Glance	11
Dassault Systèmes	12
Dassault Systèmes at a Glance	13
EtQ.....	14
EtQ at a Glance	16
Harrington Group International (HGI).....	17
Harrington Group International at a Glance	18
Intelex.....	19
Intelex at a Glance	20
IQS, Inc.....	21
IQS, Inc. at a Glance.....	22
MasterControl	23
MasterControl at a Glance	24
MetricStream.....	25
MetricStream at a Glance.....	26
Omnex Systems	27
Omnex Systems at a Glance	28
Oracle	30
Oracle at a Glance	31
Pilgrim Quality Solutions	32
Pilgrim Quality Solutions at a Glance	34
PTC.....	35
PTC at a Glance.....	36
SAP.....	37
SAP at a Glance.....	38

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Siemens	39
Siemens at a Glance	41
SOLABS	42
SOLABS at a Glance	43
Sparta Systems	44
Sparta Systems at a Glance	46
TIP Technologies.....	47
TIP Technologies at a Glance.....	48
ZenQMS.....	49
ZenQMS at a Glance	50
Solution Provider Capabilities and Characteristics: Single View	51
Industry: Batch and Process	51
Industry: Discrete and Other	52
Functionality.....	53
Company Sizes and Geographies Served.....	54
Technology Development Platforms and Delivery Models.....	55
Concluding Thoughts	56

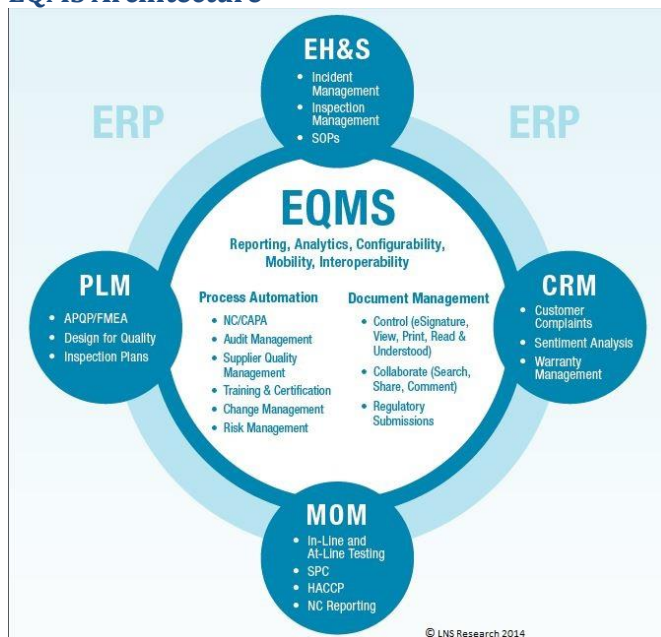
Introduction

EQMS Market Overview

Ensuring the production and delivery of high quality products is an ongoing issue in the industrial setting. In addition to the challenges surrounding quality, companies are also faced with a growing number of interconnected adversities, including shrinking operating margins and increasingly complex global supply chain, compliance, and regulation, among many others specific to industries. To overcome these challenges, organizations have traditionally created manual processes or implemented narrowly-focused solutions.

Although these disparate mechanisms improved business performance in many cases, the improvements were often localized, lacking long-term vision for scalable, interoperable, collaborative, and integrated systems. Enterprise Quality Management Software (EQMS) is replacing these disparate systems with a more holistic approach that harmonizes processes and converges corporate IT with business processes across the value chain.

EQMS Architecture



EQMS centralizes and standardizes product, production, plant, and supplier quality information,

facilitating the task of assessing, monitoring, and executing quality management initiatives at the global level. The software provides users with a set of targeted tools for managing quality in an end-to-end manner throughout the product lifecycle. Increasingly, it is being used to globally manage operations in leading companies.

Rapid evolution in the EQMS market continues. Just a few years ago vendors had gone from offering targeted solutions for targeted problems to offering global systems for managing quality. Today, the market is embracing new technology such as Mobile and Cloud to offer highly available and quickly deployable apps, and Software as a Service (SaaS) product offerings. Analytics are an area of growing investment and strategic importance.

The market is also segmenting into easy-to-use, quick deploy Cloud offerings targeted at Small and Medium Sized businesses and increasingly broad and capable solutions that are targeted at Medium and Large businesses. Some vendors are providing multiple offerings to address the needs of Small, Medium, and Large businesses either through internal development or acquisition.

Because this market is growing in complexity, it is important for companies to take an analytical and comparative approach to selecting the right solution. This guide delivers extensive information on 19 top vendors, offering readers the ability to make a shortlist of potential EQMS solutions to fit their needs. The guide also includes new features such as a vendor table to aid in comparison.

How This Guide Was Prepared

The EQMS Solution Selection Guide is designed to help leading industrial organizations identify the short list of vendors best suited to their needs. For inclusion in the guide, vendors have a compelling combination of successful multi-site and multi-geography implementations across a range of industries, broad and deep functionality, a modern technology platform, and robust roadmap with the needed resources for

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

viably continuing to improve the EQMS offering forward into the future.

The EQMS Solution Selection Guide was prepared using data collected from the various providers in a variety of ways. For most providers the process included responding to an online data entry tool followed by a Web or face-to-face briefing. Part of the data collection process included checking references provided by the vendors. Other end-user references came from members of LNS Research's Global Executive Council clients, other consulting clients, or meetings at various user group meetings or other events. Prior to publication vendors were provided an opportunity to verify particular details for factual accuracy.

LNS Research make every effort to research all of the vendors that potentially play in the EQMS market. Many vendors have not been included in this guide because they do not meet the full qualifying conditions stated above but still may be a viable choice for niche areas of the market. Some of these vendors are start-ups and some are legacy players. Some of these vendors may be covered in future reports and there are undoubtedly other vendors that LNS haven't yet heard of. If you have any interest regarding vendors not mentioned in this guide, please do not hesitate to inquire.

In a few cases vendors either declined to provide a response via the online collection tool, or to conduct a vendor briefing, or both. Some vendors could not accommodate the timing of the preparation of the Solution Selection Guide while others explicitly declined participation.

Using the Solution Selection Guide

All entries in the EQMS Solution Selection Guide represent the opinions of the authors based on their industry experience and their view of the information collected using the methods described above.

The EQMS space is growing in terms of both packaged functionalities and industry-specific solutions, which is challenging for companies trying to create a shortlist of potential vendors. Any organization interested in implementing an EQMS should take the appropriate steps for determining which solution is right for its

operations. First, current capabilities, functionalities, and IT architectures should be assessed. The identification of where investments have been made in Enterprise Resource Planning (ERP), Product Lifecycle Management (PLM), point solutions, or other applications should be used as part of the criteria for choosing a vendor.

Next, because the selection and implementation of an EQMS takes significant resources, the educational process is integral for a successful investment. The LNS Research *EQMS Solution Selection Guide* aims to simplify this process. Covering a total of 19 top vendors, it offers a snapshot of each company as well as a brief analysis. The guide also has an individualized table for each vendor, providing an extensive overview in a single location. The table covers the following:

- **Industries:** Lists the industries as well as various sub-verticals served by vendors. Ex: Life Sciences, Automotive, etc.
- **Functionalities:** Lists the quality management functionalities offered by vendors. Ex: Corrective and Preventive Actions (CAPA), Supplier Quality Management (SQM), etc.
- **Company Size:** Lists the company sizes targeted by vendors. Ex: Small, Medium, Enterprise
- **Geography Served:** Lists the regions covered by vendors. Ex: North America, Asia Pacific (Asia/Pacific), etc.
- **Technology Development Platform:** Lists the platforms used by vendors to develop and deliver solutions. Ex: Java, .NET, etc.
- **Technology Delivery Model:** Lists the delivery model options offered by vendors. Ex: On-premise, Cloud, etc.

Broken down further, each of the areas in the table is categorized in the following three ways:

- **Total Coverage Area:** Includes all areas covered by vendor regardless of strength. This section is listed in the nomenclature of each vendor and may not be consistent across all vendors

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

- **Areas of Strength:** Shows the areas in which LNS Research believes the vendor stands out relative to the vendor's own broader set of market offerings.
- **Emerging Strength:** Lists the areas in which LNS Research believes the vendor is investing resources and gaining a market presence

This version of the LNS Research *EQMS Solution Selection Guide* also includes a set of vendor tables to enable comparison. Because vendors' strengths are relative, the table simply identifies if a feature is provided by the vendor, or if the vendor is beginning to provide the feature. In order to identify more information about a specific vendor's strength in a particular area, other sources should be consulted, including the detailed vendor write-ups.

This guide serves as a critical executive resource for moving forward on the decision of selecting an EQMS. After a careful selection process, the LNS Research analyst team attained this information through a number of briefings and inquiry discussions with each vendor. We believe that the functionalities offered by each of these vendors meet the needs of the market as described in the sections.

Once a shortlist of vendors has been created with the information in the *EQMS Solution Selection Guide*, decision-makers should work with their teams to build a Request for Proposal (RFP) that can be sent to prospective vendors. After getting feedback, a cross-functional committee comprised of executives and plant managers across the value chain should make the final decision.

Solution Providers in Detail

AssurX

Located in Morgan Hill, CA and founded in 1991, AssurX is a seasoned Enterprise Quality Management System (EQMS) provider. AssurX is most widely known for support of regulated industries such as Life Sciences, Food & Beverage, Oil & Gas, Energy & Utilities, although it does have a customer base in industries such as High Technology, Automotive, and Aerospace & Defense. Its focus and strength in support of NERC compliance is unique. The AssurX software is used at several thousand customer locations and has in excess of 100,000 users. It supports large global customers as well as small and medium businesses.

AssurX provides an integrated and modular approach to Enterprise Quality Management Systems (EQMS), based on a common platform. The platform is fully configurable with no branching or custom code to simplify forward compatibility. It is architected such that all modules use a common engine and set of capabilities, thereby simplifying the FDA validation process—the platform itself needs full validation but each additional process requires only Performance Qualification (PQ). Deployments are typically six to eight weeks per business process, including configuration. Out-of-the-box processes include Audit Management, Complaints Management, Change Management, CAPA, Document Control, Management Review, Enterprise Risk Management, Manufacturing Quality Management, Customer Quality Management, Supplier Quality Management, and Training Management.

The AssurX software provides support for Governance, Risk, and Compliance (GRC), and has strong capabilities in both Governance and Compliance as well as

emerging capabilities in Risk. For instance, AssurX supports electronic Medical Device Reporting (eMDR) reporting per FDA agency requirements. Its new Enterprise Risk module positions AssurX well for the changes in ISO 9001:2015.

AssurX began providing EQMS in the cloud in 2001, and offers single and multi-tenant, private, and public cloud environments. It can also be deployed on premise. It also provides robust integration capabilities to external Document Management, ERP, BI, Salesforce and LDAP/AD systems. Integrations include Web Services, URL data linking, and SQL queries. Recently released versions of AssurX include support for mobile apps, more OOTB Best Practice Solutions, enhanced compliance libraries as well as increased configurability using the workflow builder.

AssurX is an experienced player in the EQMS with a deep subject matter expertise, particularly in Life Sciences and Energy & Utilities. Its upgraded technology platform provides much of what organizations are increasingly looking for: prepackaged, easy-to-configure processes, several deployment options, and analytics. Those in Life Sciences will like AssurX's efforts to make their system a lower validation effort platform. LNS Research hopes to see AssurX to execute on its development plan, particularly as it relates to mobile apps, and include APQP/PPAP tools both to support these increasingly widespread processes as well as improving connections to test, manufacturing and suppliers. LNS Research also hopes to see increased investment in analytics and user experience over time.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

AssurX at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Life Sciences Food & Beverage Oil & Gas, Utilities High Technology Aerospace & Defense Automotive Chemicals Consumer Goods Government/Public Sector Industrial Equipment Mfg Packaging Semiconductor Telecommunications 	<ul style="list-style-type: none"> Life Sciences Food & Beverage Oil & Gas, Utilities High Technology 	
Functionality	<ul style="list-style-type: none"> Audit Mgmt Change Mgmt Complaint Mgmt Supplier Quality Mgmt Non-Conformance / CAPA Reports, Dashboards Analytics EHS Performance Mgmt Document Control Training Mgmt Risk Mgmt Calibration Mgmt 	<ul style="list-style-type: none"> Audit Mgmt Change Mgmt Complaint Mgmt Supplier Quality Mgmt Non-Conformance / CAPA Reports, Dashboards 	<ul style="list-style-type: none"> Calibration Mgmt
Company Size	<ul style="list-style-type: none"> Small (<\$250 Million Revenue) Medium (\$250 Million – \$1 Billion Revenue) Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Medium (\$250 Million – \$1 Billion Revenue) 	
Geography Served	<ul style="list-style-type: none"> Global 	<ul style="list-style-type: none"> North America Europe 	
Technology Development Platforms	<ul style="list-style-type: none"> .NET HTML5 Web Services Integration Layer Accepts 3rd party doc mgmt 	<ul style="list-style-type: none"> .NET HTML5 Web Services 	<ul style="list-style-type: none"> HTML5
Technology Delivery Model	<ul style="list-style-type: none"> Web Client, Optimized for Mobile Mobile Apps, All Modules On-Premise Cloud, Single / Multi-tenant SaaS 	<ul style="list-style-type: none"> Web Client On-Premise Cloud, Single / Multi-tenant SaaS 	<ul style="list-style-type: none"> Mobile Apps, All Modules Mobile Apps, All Modules

CEBOS, a Division of QAD

Based out of Novi, MI CEBOS is focused primarily on providing quality management solutions to medium and large enterprises. CEBOS has a legacy of supporting discrete manufacturers in the Midmarket space (\$50M to \$1B in revenue), and has expanded its focus to Enterprise organizations (>\$1B) and continues to focus on Aerospace & Defense, Consumer Packaged Goods, Medical Devices, and High Technology. Today, most growth of the growth is being seen in Automotive, Medical Devices, and Industrial Manufacturing.

CEBOS Ltd. was founded in 1995, and was acquired by ERP provider QAD on December 31, 2012. While companies often take years to integrate acquisitions, a robust integration between QAD and CEBOS has been developed and deployed. CEBOS coordinated a reference call between LNS Research and a joint QAD and CEBOS customer. This reference customer had a history of using the production integration between QAD and CEBOS and was actively gaining value from its well-architected integrations. For example, CEBOS MQ1 Elements EQMS and QAD Supplier Management are integrated so that a receipt of goods in ERP drives inspection in EQMS, inspection status is shared with ERP, and inventory is moved to the appropriate location including a hold on payment if a supplier fails quality inspections in MQ1 Elements. The customer also gave CEBOS high marks on ease of use and deployment, as well as CEBOS' acceptability to third party auditors.

CEBOS is aggressively pursuing the Cloud EQMS space, and sees differentiation being depth and breadth of solution capability, offered in a Cloud environment. Its MQ1 Elements EQMS offering is the result of this strategy and is available in both Cloud and on premise installations. CEBOS is increasing Cloud investments, including accelerating development by increasing R&D headcount. Existing CEBOS Customers still using its legacy platform should strongly consider making the move to MQ1 Elements.

CEBOS currently provides mobile App support across all modules for workflow notifications, approvals, viewing and form configuration.

Enterprise connectivity is important, and grows in importance the larger and more global an organization becomes. CEBOS currently provides a good integration layer based on SOA Web services today, and is looking to improve that layer by providing REST and JSON support in future releases. This integration layer supports real-time integrations to systems such as Master Data Management, and between processes such as Inspection, CAPA, and Inventory, BOM, and APQP.

MQ1 Elements provides support for a wide range of processes. Processes supported include APQP and PPAP, Audit and Layered Process Audit Management, Corrective and Preventive Actions (CAPA), Non-Conformance (NC), Document Control, Gauge Calibration, Inspection and Statistical Process Control, Equipment Maintenance, Project Management, Risk Management, Supplier Management, and Training Tracking.

CEBOS provides substantial flexibility to allow organizations to easily configure existing processes to specific requirements. Configurability is tailorable by process and enables modification to fields, forms, business logic, triggers, workflow, metrics and other factors. The provided configuration tools are comprehensive, and provide a very good user experience.

Analytics and metrics are supported, including support for SPC attribute charts. The metrics and analysis are included in easy to use and interpret dashboards. The dashboards tell users what they want to know in a glance, such as number of Non-Conformances by workflow state. If deeper analytics are desired—such as Big Data or other more advanced trend analyses—then third-party analytics packages would seem to be the best choice at present.

As a whole, CEBOS's interface is relatively new, is attractive, and gets high marks for usability. It shows a focus on a positive user experience, which is important to drive user adoption and deployment success. It is browser agnostic, due to CEBOS' choice of a Microsoft Silverlight presentation layer. CEBOS is replacing Silverlight with HTML5 over the next year.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

CEBOS is increasing its support of the Enterprise market, with good technical underpinnings such as flexible processes and business rules, SOA Web services, Cloud, mobile and dashboards. LNS Research would like to see additional investment in improved analytics or identification of integrated analytics partners in order to demonstrate scalability. CEBOS also provides support for multiple industries. However, for true automated support of industries such as Life Sciences, it will be necessary for CEBOS to extend its

support of MDR to include support for an AS2 gateway to allow direct electronic communication with the FDA.

CEBOS's strategic investment in Cloud has positioned it well for a growing market that is increasingly looking to Cloud-based solutions to reduce deployment effort and sustainment cost. CEBOS should be a consideration for Medium and Enterprise organizations, particularly those interested in a robust, flexible Cloud solution with good process depth.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

CEBOS at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Aerospace & Defense Automotive Consumer Packaged Goods Food & Beverage High Technology Industrial Equipment Mfg Medical Devices Packaging Paper 	<ul style="list-style-type: none"> Automotive Medical Devices 	
Functionality	<ul style="list-style-type: none"> Audit Mgmt Document Control Training Mgmt Change Mgmt Complaint Mgmt SPC Supplier Quality Mgmt Risk Mgmt Non-Conformance Mgmt CAPA Calibration Mgmt EHS Product Quality: APQP/PPAP/FMEA Reporting/Dashboards/Analytics 	<ul style="list-style-type: none"> Audit Mgmt Training Mgmt Complaint Mgmt Non-Conformance Mgmt CAPA Calibration Mgmt APQP/PPAP Dashboards 	
Company Size	<ul style="list-style-type: none"> Small (<\$250M Revenue) Medium (\$250 Million – \$1 Billion Revenue) Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Medium (\$250 Million – \$1 Billion Revenue) 	
Geography Served	<ul style="list-style-type: none"> North America Europe Asia/Pacific South & Central America Australia/New Zealand 	<ul style="list-style-type: none"> North America 	<ul style="list-style-type: none"> EMEA Asia/Pacific Australia/New Zealand
Technology Development Platforms	<ul style="list-style-type: none"> .NET Silverlight, HTML5 Web Services Accepts 3rd party doc mgmt. Integration layer 	<ul style="list-style-type: none"> .NET Silverlight 	<ul style="list-style-type: none"> HTML5
Technology Delivery Model	<ul style="list-style-type: none"> Web Client, optimized for mobile On-Premise Cloud – single tenant SaaS Mobile apps, all modules 	<ul style="list-style-type: none"> Mobile Apps, all modules On-Premise Single tenant cloud 	

Dassault Systèmes

Dassault Systèmes is a large global organization with several product offerings that provide EQMS functionality. Headquartered in France and founded in 1981, the vendor has a notable customer base in the Life Sciences industry, with a strong platform for product data and business process management across the product lifecycle. With a long-time presence in the Product Lifecycle Management space, Dassault Systèmes delivers some fundamental EQMS functionalities to the industrial setting as part of its integrated ENOVIA PLM suite. It provides a set of manufacturing quality and analytics through its Apriso offering as a part of the DELMIA manufacturing suite. But the bulk of its quality management capabilities reside in QUMAS, a part of BIOVIA.

Built into ENOVIA, in response to the needs of the life sciences installed base, are two quality management applications: Product Quality Central and Quality Improvement Central. Product Quality Central has a Non-Conformance reporting module that touches both design and the shop floor. Additionally, Product Quality Central supports Complaint Management. The Quality Improvement Central module has CAPA and Audit Management capabilities. With Risk Management and effectivity elements, the CAPA application works to prioritize and strengthen end-to-end process improvements. It also works with process and materials change. Dassault Systèmes' Audit Management functionalities can be used externally to monitor and communicate supplier specifications and also internally for reporting.

In the last several years, Dassault Systèmes has made several strategic acquisitions in the quality space. One was the acquisition of Apriso in 2013, a leading Manufacturing Operations Management (including a Manufacturing-focused Quality) solution. Apriso has been merged with DELMIA (Dassault Systèmes manufacturing simulation and planning platform) forming DELMIA Apriso, which now features a unified data model and process management. The addition of Apriso provides Quality Master Data, Inspection Planning, Inspection Execution, and Statistical Process

Control. DELMIA Apriso provides an optional Containment Manager that provides a containment process, WIP traceability, and communication. Additionally, there is an optional Executive Intelligence Center offering that is a self-serve executive dashboard providing access to a set of rich analytics.

The other was the acquisition of Accelrys in 2014. Accelrys had acquired QUMAS shortly before its acquisition by Dassault Systèmes. Founded in 1994, QUMAS is well positioned in the Life Sciences EQMS industry. QUMAS offers Compliance, Quality Management, Document Management, and Collaboration solutions based on a diverse set of platforms, including Windows SharePoint, Documentum, Oracle, and SQL Server. This diverse set of platforms makes QUMAS appealing to a broad set of IT architectures. QUMAS provides excellent management of compliance, regulatory affairs, online FDA submissions, and enterprise content management. Along with its rules-based engine, QUMAS' preconfigured best practices and processes provide greater visibility for Life Sciences activities related to FDA and ISO regulations. QUMAS operates largely as a standalone technology stack in Dassault Systèmes' BIOVIA business unit.

Dassault Systèmes has several quality offerings. Its ENOVIA PLM-based quality offering is limited but likely of interest to existing ENOVIA customers. Its DELMIA/Apriso manufacturing offerings are valuable to companies investigating an MES system with good manufacturing quality and analytics capabilities. Life Science companies should consider QUMAS, which is a competitive offering. In an earlier review LNS Research observed the need for Dassault Systèmes to increase its EQMS development or make acquisitions in the EQMS space, and we now applaud its recent acquisitions that substantially improve the depth of its EQMS functionalities. LNS encourages Dassault Systèmes to construct a stronger integration between ENOVIA, Apriso DELMIA and QUMAS and develop a story outside of Life Sciences.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Dassault Systèmes at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Automotive Aerospace and Defense Consumer Products Food and Beverage High Tech Industrial Equipment Life Sciences Metals 	<ul style="list-style-type: none"> Life Sciences 	<ul style="list-style-type: none"> Food & Beverage Automotive Aerospace and Defense Consumer Products High Tech Industrial Equipment
Functionality	<ul style="list-style-type: none"> Document Control Audit Mgmt Training Mgmt Change Mgmt Complaint Mgmt SPC Supplier Quality Mgmt Risk Mgmt Non Conformance / CAPA Calibration Mgmt APQP, PPAP, FMEA Performance Mgmt Reports, Dashboards, Analytics 	<ul style="list-style-type: none"> Document Control Audit Mgmt Training Mgmt Change Mgmt Complaint Mgmt Reports, Dashboards, Analytics 	<ul style="list-style-type: none"> Supplier Quality Mgmt Risk Mgmt Calibration Mgmt
Company Size	<ul style="list-style-type: none"> Small (<\$250 Million Revenue) Medium (\$250 Million – \$1 Billion Revenue) Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Large (> \$1 Billion Revenue) 	
Geography Served	<ul style="list-style-type: none"> Global 	<ul style="list-style-type: none"> Global 	
Technology Development Platforms	<ul style="list-style-type: none"> Java .NET HTML5 Web Services Accepts 3rd party doc mgmt. Integration layer 	<ul style="list-style-type: none"> Java HTML5 Web Services Accepts 3rd party doc mgmt 	<ul style="list-style-type: none"> Integration layer
Technology Delivery Model	<ul style="list-style-type: none"> Web client, optimized for mobile On-Premise Cloud, single-tenant/multi-tenant SaaS Native apps, key modules 	<ul style="list-style-type: none"> Web client, optimized for mobile On-Premise Cloud, single tenant 	<ul style="list-style-type: none"> Cloud, multi-tenant SaaS Native mobile apps

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

EtQ

Founded in 1992 and based in Farmingdale, NY with additional offices in Tucson, AZ, Ireland, and Amman, Jordan, EtQ is a leader in the EQMS space, employing expertise in enterprise quality, compliance, and Environment, Health, and Safety Management software. With more than 20 years in industry, regular customer outreach through a monthly customer advisory, and a total staff of over 300 including 170 in-house developers, EtQ has an experienced, customer focused and large Quality team. EtQ has substantial customer base in nearly 20 industries, with its top five industries being Medical Device, Manufacturing, Food & Beverage, Pharmaceuticals, and Technology. It reports having in excess of 700 customers, 1,000 installations and a million users.

With a broad set of functionality and industries served, EtQ's strength was originally in the mid-market segment. However, in the last decade LNS Research has seen the company moving up market to the Fortune 100 in several different vertical industries, including Medical Devices, Food and Beverage and consumer products. Its Cloud and mobile strategy positions it well with companies as small as startups.

One of the first EQMS vendors in the space to re-architect its systems on a modern Java platform, move the system to the Cloud (first launched in 2007), and achieve SAP certification, EtQ has been one of the fastest growing companies in the space. Its flagship EtQ Reliance™ product provides a mobile app concept that both allows native mobile (build a form and make available on the mobile platform), as well as disconnected operation to support capabilities such as offline audits that resync upon next connection. It has deployed connection capabilities, supporting integration to Microsoft Office, Microsoft SharePoint, LDAP/AD, preconfigured connections to SAP HR and production data, Java and Web Services API, real-time lookups, as well as a Connection Profiles utility that enables scheduled document-based I/O using formats such as XML. It provides workflow and business logic, audit trails, checklists, configurability, as well as support for 21 CFR Part 11 compliance.

EtQ takes a modular approach to deploying capabilities. A broad range of modules and processes

are supported, and functionality is deep, for instance supporting Bow Tie risk analysis (combined top down and bottom up analysis as required by industries such as A&D), a Cloud-based Supplier Portal and libraries of pre-built reports, office integration for Doc Control, etc. EtQ's value positioning is a good blend of flexibility for mid-market and capability for large enterprise customers.

EtQ has also launched a Cloud-based offering targeted at Small and Medium Businesses called VERSE Solutions™. VERSE offers functionality for all the core EQMS processes such as Audit Management, Document Control, Employee Training, NCRs, and Change Management. The solution is single tenant, hosted, and based on the Reliance platform. Standard reporting and graphical charts including some dashboard capability. The available suite of processes is set and cannot be expanded upon with additional processes or workflows. However, workflows within the offered processes have configurable business rules capability and lists and fields can be adjusted/configured. Notifications and alerts are configurable also. Validation packages are available (extra cost) and 21 CFR Part 11 compliance is standard.

Additionally, EtQ has launched its traqpath™ issue management and CAPA product. This package is free. It is an easy to use web and mobile application that operates on iOS and Android, and provides the ability to create Events, Actions and CAPAs, following a standard process and using standard graphs. It is validated and based on the core Reliance™ platform that can perform eSignatures and audit trails, although the last two features were not in the initial release which occurred January 27, 2016. The initial release did contain workgroup features as well as secure collaboration with extended teams such as suppliers.

EtQ Reliance™ is a robust EQMS solution capable of supporting regulated and non-regulated environments with pre-configured but flexible processes and oversight. EtQ's VERSE Solutions™ provides a solution for small and medium companies. traqpath™ provides support for small companies, individuals, and workgroups within larger companies.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

EtQ should be a consideration for Large, Medium, and Small companies in its core set of industries, particularly those that are looking for a leading EQMS with acceptable analytics that integrates well with other enterprise solutions, and who have a separate

solution for Manufacturing Operations Management and Statistical Process Control. Its new offerings increase its strength in the SMB space, and provide unique offerings for Small organizations.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

EtQ at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> • Aerospace & Defense • Automotive • Consumer Goods • Food and Beverage • Government • High Technology • Life Sciences • Metals, Mining • Packaging • Telecom • Oil & Gas, Utilities 	<ul style="list-style-type: none"> • General Manufacturing • Aerospace & Defense • Medical Device • Food and Beverage 	
Functionality	<ul style="list-style-type: none"> • Document Control • NC / CAPA • Training Mgmt • Complaints • Audit Mgmt • Risk Mgmt • Calibration • Reporting / Dashboards/ Analytics • Change Mgmt • Supplier Quality Mgmt • EH&S • PPAP • FMEA • Compliance Mgmt • Performance Mgmt 	<ul style="list-style-type: none"> • NC/CAPA • Risk Mgmt • EH&S • Document Control • Audits Mgmt • Complaints • Training Mgmt • Reporting 	
Company Size	<ul style="list-style-type: none"> • All 	<ul style="list-style-type: none"> • Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> • Small (<\$250 Million revenue)
Geography Served	<ul style="list-style-type: none"> • Global 	<ul style="list-style-type: none"> • Global 	<ul style="list-style-type: none"> •
Technology Development Platforms	<ul style="list-style-type: none"> • Java • HTML5 • Web Services • Accepts 3rd party doc mgmt • Integration layer 	<ul style="list-style-type: none"> • Java • HTML5 • Web Services 	
Technology Delivery Model	<ul style="list-style-type: none"> • Web client, optimized for mobile • On-Premise • Cloud, single / multi-tenant • SaaS • Mobile apps, all modules 	<ul style="list-style-type: none"> • Web client, browser agnostic • On Premise Web-based • Cloud / single tenant • SaaS 	<ul style="list-style-type: none"> • Cloud / multi-tenant

Harrington Group International (HGI)

Based in Orlando, FL, Harrington Group International (HGI) offers software and professional services for business improvement. Founded in 1991 by Richard Harrington, HGI has expanded from desktop applications into true EQMS with the Harrington Quality Management System (HQMS). In addition to the HQMS product, the HGI portfolio includes enterprise solutions for corrective and preventive actions (CaWeb) and a Supplier Portal for supplier management (Supplier Collaboration Portal). HGI also maintains its original product suite of desktop standalone applications for point-solution quality management in small and large businesses.

HQMS has capabilities that span the core elements of EQMS from CAPA and Audit Management and Execution through Document Control and Training Management. The footprint of HGI ranges from Aerospace & Defense, through Manufacturing, and into Healthcare and Construction. The application supports conformance/compliance to numerous standards like the ISO 9000 and other international standards. Specific provision of workflow for 8-D problem solving is an indication of this organization's core strength in automotive.

HGI does provide out-of-the-box solutions that many customers use as COTS. Additionally, customers can leverage HGI's services to configure and customize a solution to fit an organization's specialized needs. HGI may also build these customizations into the source code of future releases to maintain upgradeability. This approach to customization bucks a trend we have noticed among some other EQMS vendors that are more focused on using workflow and business rules engines with associated form building tools and configurable notifications to avoid custom code.

The audit module shares the same reporting and configurability capabilities as other modules in the

solution and is particularly strong with its build-from-scratch options. The outcome of audit activity is seamlessly managed through specific tools for OFIs, CAPAs, etc. Reporting capabilities are strong with many out-of-the-box reports (250+) and the capability for building custom reports and an add-on Business Intelligence (BI) tool. Dashboards exist and provide valuable executive level visibility. LNS is looking forward to seeing increased flexibility and multiple role-based views in dash boarding as these solutions continue to develop.

The user interface is good but not of a Responsive Design, by which we mean the UI does not automatically optimize for different mobile form factors. There are currently limited mobility options, including: initiating action items, offline/mobile audits, or using the application via a browser on a connected device. Navigation is traditional, driven by a master tree control and delivers alerts and notifications for user-specific tasks that are clearly marked. The search capability for records and specific tools within this control is efficient and reliable. HGI reports that it has plans to release additional mobile capabilities, workflows and reporting in Q3 2016.

HGI is a QMS generalist, and supports all industries with a mix of a core application, configuration, and customization. It provides direct support to customers in North America, and supports a partner network in Africa, Middle East and Asia/Pacific.

The Harrington Group International's HQMS and CaWeb should be considered by organizations looking for a highly consultative engagement regarding deployment of their EQMS. The solution exhibits a traditional stronghold in core processes and the software system is complimented by deep capabilities in related professional service.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Harrington Group International at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Industrial Equipment Mfg Aerospace & Defense Life Sciences Oil & Gas High Technology Automotive Chemicals Consulting Food and Beverage Public Sector Metals Mining Packaging Paper Semi-Conductor Telecom Utilities 		
Functionality	<ul style="list-style-type: none"> Audit Mgmt Complaints Document Control Calibration Training Mgmt NC/CAPA PPAP Supplier Quality Mgmt Change Mgmt Risk Mgmt Reporting / Dashboards / Analytics 	<ul style="list-style-type: none"> Audit Mgmt Document Control Training Mgmt NC/CAPA 	<ul style="list-style-type: none"> Supplier Quality Mgmt Calibration
Company Size	<ul style="list-style-type: none"> Small (<\$250 Million Revenue) Medium (\$250 Million – \$1 Billion Revenue) Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Small (<\$250 Million Revenue) Medium (\$250 Million – \$1 Billion Revenue) 	
Geography Served	<ul style="list-style-type: none"> North America Europe Africa Asia/Pacific Middle East 	<ul style="list-style-type: none"> North America 	
Technology Development Platforms	<ul style="list-style-type: none"> .NET HTML5 Web Services 	<ul style="list-style-type: none"> .NET 	
Technology Delivery Model	<ul style="list-style-type: none"> Web UI On-Premise Cloud, Single/Multi-tenant SaaS 	<ul style="list-style-type: none"> Web UI 	

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Intelex

Founded in 1992, Intelex has become a formidable player in both EHS and EQMS. Based out of Toronto, Canada, the company's quality solution is offered independently or within a complete Environment, Health & Safety and quality package. It has grown to over 350 employees, 1,000 customers, and a million users across quality and EHS. Intelex has a presence in many industries but is particularly strong in Automotive, Chemicals, Consumer Goods, Food & Beverage, and Process Industries, and is emerging into Life Sciences and Government/Public Industries. In July 2015, Intelex secured a \$160M CAD strategic growth investment.

Evident in its success in the F&B industry with food safety and supplier management, Intelex has a strong vision of the intersection of quality and EHS. This has prompted the vendor to offer an integrated EHSQ suite. The package is made up of preconfigured modules, which are a good fit for many industries and business processes. With scalable Web-based functionality in areas including Audits, Document Control, Root Cause Analysis, Inspection Management, ISO 9001:2015 Compliance, Training Management, Integrated Management Systems, Monitoring & Measuring, Non Conformance and Corrective Action / Preventive Action, Supplier Management (SQM), Defect Tracking, Change Management, Global Action Plan Management, and Risk Management, the solution is good for users who want to get up and running quickly with the benefit of preconfigured process support.

In addition to the Food & Beverage industry, Intelex has strength in providing to companies that do not commonly utilize EQMS, such as energy or metals or minerals and mining. Traditionally, smaller companies and those with other resource constraints have done well with implementing the vendor's quality management solution. Larger organizations that had used Intelex as a point solution for specific issues are beginning to implement the solution enterprise-wide,

and now more than one-third of deployments are enterprise-wide deployments. Intelex can drive global action plans to improve global collaboration.

Intelex has made a number of advances recently. It has expanded its Quality Management Solution through the launch of a solution for Integrated ISO 9001 management. This Integrated Management System supports ISO 9001:2015 to streamline certification, and provides pre-configurations for several industry variants as an effort to reduce deployment time. Notably, it supports Life Sciences processes, 21 CFR Part 11 requirements and Validation support. It has released Product Lifecycle Management capabilities connected with core Quality processes, a Risk Register and Risk Management processes.

Intelex can be deployed on premise, but finds that most deployments are cloud-based and leverage its mobile-optimized web client. It has an online social community for EHS and Quality professions that is used by thousands daily. Its Supplier Quality Management has substantially benefited from this technology and includes a portal and powerful and easy to use Supplier Management capabilities. There are very large customers that are successfully deploying Intelex's Supplier Quality Management capabilities, including some of the world's largest retailers and restaurant chains.

Intelex is a supplier with a long history in the EQMS and EHS space that has made substantial progress both in its technology platform as well as module breadth of coverage in the past few years, and a substantial infusion of capital looks to be poised to generate substantially more progress in the years to come. Small and Medium sized businesses should consider Intelex, as should Large enterprises with recent proof of global deployment success, particularly those looking for an EQMS solution providing deep and connected EHS functionality.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

InteleX at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Automotive Aerospace Chemicals Consumer Products Government High Technology Food and Beverages Government Life Sciences Metals, Mining Semiconductor Telecommunications Utilities and Oil & Gas 	<ul style="list-style-type: none"> Automotive Consumer Products Food and Beverage Utilities and Oil & Gas 	<ul style="list-style-type: none"> High Technology Life Sciences Government
Functionality	<ul style="list-style-type: none"> Supplier Quality Mgmt NC/CAPA Change Mgmt Complaint Mgmt Audit Mgmt Compliance Mgmt Risk Mgmt Document Mgmt Training Mgmt EHS FMEA, APQP, PPAP Reports and Dashboards Analytics 	<ul style="list-style-type: none"> Supplier Quality Mgmt Risk Mgmt EHS 	<ul style="list-style-type: none"> FMEA PPAP APQP
Company Size	<ul style="list-style-type: none"> Small (< \$250 Million Revenue) Medium (\$250 Million – \$1 Billion Revenue) Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Small (< \$250 Million Revenue) Medium (\$250 Million – \$1 Billion Revenue) 	<ul style="list-style-type: none"> Large (> \$1 Billion Revenue)
Geography Served	<ul style="list-style-type: none"> Global 	<ul style="list-style-type: none"> North America Europe Middle East 	<ul style="list-style-type: none"> South / Central America Africa Australia/New Zealand
Technology Development Platforms	<ul style="list-style-type: none"> .NET HTML5 Web Services 	<ul style="list-style-type: none"> .NET HTML5 Web Services 	
Technology Delivery Model	<ul style="list-style-type: none"> Web UI, optimized for mobile On Premise Cloud, Single/Multi-tenant SaaS Mobile apps, all modules 	<ul style="list-style-type: none"> Web UI, browser agnostic Cloud, multi-tenant SaaS 	<ul style="list-style-type: none"> Mobile apps, all modules Web client, optimized for mobile

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

IQS, Inc.

Founded in 1988, IQS, Inc. is a veteran EQMS vendor that believes in providing quality solutions for all and focuses on delivering closed-loop quality management solutions to discrete, batch, and process manufacturers. The company, headquartered in North Olmsted, OH, with a European office out of Leeds, UK, and a Chinese office in Jiangyin, Jiangsu, provides EQMS with integration capabilities for Enterprise Resource Planning (ERP) and Product Lifecycle Management (PLM).

Over the past several years, momentum has been behind IQS, Inc. In the fall of 2015 the company hosted its new user conference, highlighting recent accomplishments in technology launches and customer go-lives.

New technology advancements include the use of Cloud for flexibility in deployment options, the integration of cost effective third-party analytics tools for data integration and dashboards, and the launch of the new Trubox™ platform enabling flexible global workflows, improved mobile capabilities, enhanced UI, and the development in new lightweight apps. New customer wins have shown an ability to compete and win business from global customers at the enterprise level in several different discrete manufacturing industries like automotive and industrial equipment and a diverse set of geographies, including APAC and specifically, China.

Well established in the EQMS space, IQS has a good vision of closed-loop quality management and how it fits into an industrial operation. By connecting both ERP and PLM systems, the software delivers functionalities such as managing work instructions, Non-Conformances and Corrective Actions, customer complaints, supplier related issues, and continuous improvement efforts. IQS' capabilities are also strong in Supplier Quality Management, specifically by driving profits through charge-backs and MRA for OEMs.

In general, the software's capabilities are well suited for large discrete manufacturing companies. However,

with the release of the Cloud-based Java version, IQS is also able to meet the needs of small and medium sized companies with a flexible Web-based solution.

Because many of the discrete manufacturing organizations using IQS fall outside of Life Sciences, the company has strength in providing business value by improving the quality of the product, rather than just by better management of compliance issues. However, over the past several years, IQS has improved its capabilities and customer base in the medical device industry, with compliance management capabilities and validation services.

Moving forward, LNS Research expects to see more and more of the value delivered by IQS, Inc. as coming through the Trubox™ platform, which was in development for several years and was recently deployed for the first time in late 2015. Trubox™ is already winning early praise from customers and LNS sees Trubox™ moving the IQS offering forward to compete effectively against next-generation software that provides a more consumer-like experience. These improvements include usability, mobile support, analytics, enterprise deployments and user developed apps. LNS also anticipates Trubox™ allowing IQS, Inc. to make enhancements and extensions more quickly, facilitating a future expanded support of processes adjacent to EQMS.

IQS, Inc. is a veteran EQMS provider that is heavily investing in updating its solution to provide a platform that enables next generation solutions. Customers and prospects in IQS, Inc. target markets should certainly be evaluating the provider, especially those companies looking to invest in a provider that truly believes in the motto of "quality for all." IQS, Inc. has further differentiated in the past year by providing a new licensing model that makes it easy and cost effective for a broad set of users to take advantage of and use the system, not just frequent and super users like quality and engineering professionals.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

IQS, Inc. at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Aerospace & Defense Automotive Medical Devices Industrial Equipment Mfg Chemicals Consumer Goods High Technology Oil & Gas 	<ul style="list-style-type: none"> Aerospace & Defense Automotive Industrial Equipment Mfg 	
Functionality	<ul style="list-style-type: none"> Document Control Audit Mgmt Training Mgmt Change Mgmt SPC Supplier Quality Mgmt Risk Mgmt Non-Conformance / CAPA Compliance Mgmt Calibration Mgmt Product Quality: FMEA /PPAP / APQP Reports, Dashboards, Analytics EHS Performance Mgmt 	<ul style="list-style-type: none"> Audit Mgmt Training Mgmt Change Mgmt SPC Supplier Quality Mgmt Non-Conformance / CAPA Calibration Mgmt Product Quality: FMEA / PPAP / APQP 	<ul style="list-style-type: none"> EHS Reports, Dashboards, Analytics
Company Size	<ul style="list-style-type: none"> Small (< \$250 Million Revenue) Medium (\$250 Million – \$1 Billion Revenue) Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Medium (\$250 Million – \$1 Billion Revenue) Large (> \$1 Billion Revenue) 	
Geography Served	<ul style="list-style-type: none"> North America South /Central America Europe Asia / Pacific Australia/New Zealand 	<ul style="list-style-type: none"> North America Europe 	
Technology Development Platforms	<ul style="list-style-type: none"> Java HTML5 Web Services Accepts 3rd party doc mgmt Integration layer 	<ul style="list-style-type: none"> JAVA Web Services 	
Technology Delivery Model	<ul style="list-style-type: none"> Web client, optimized for mobile On-premise Cloud, Single / Multi-tenant SaaS Mobile Apps, all modules 	<ul style="list-style-type: none"> Web client, optimized for mobile On-premise Cloud, single/multi-tenant SaaS Mobile Apps, key modules 	<ul style="list-style-type: none"> Mobile Apps, all modules

MasterControl

Founded in 1993 and based out of Salt Lake City, Utah, MasterControl is a veteran of the EQMS space. It has approximately 300 employees, of which roughly a third are in R&D. While its solution is applicable outside of Life Sciences, it is primarily focused on Life Sciences, particularly Medical Devices and Pharmaceuticals. It has created a comprehensive and modular offering with support of Quality and Life Science Compliance processes, even extending into Electronic Batch Records (EBR), Product Data Management (PDM - CAD Data management) and Product Lifecycle Management (PLM). MasterControl's core offering is primarily used by Medium and Large companies, particularly those in the \$1B-\$5B range, although the new cloud-based Spark offering is targeted at Small and Medium Businesses.

MasterControl's core platform is tightly knit with broad process support including Audit Management, Electronic Batch Records, Bill of Materials, Change Management, Complaints Handling, Non Conformance and CAPA, Design Control, Deviation and Variance Management, Device History Records, Document Control, Equipment Calibration and Maintenance, Trial Master File Management, Human Resources and Finance, Incident Reporting, Out Of Specification Results Management, PDM, PLM, Risk Analysis, Statistical Process Control (SPC), Submissions, Supplier Quality Management and Training Management. MasterControl supports this with a broad range of services, including Validation services.

MasterControl is ISO 9001:2015 certified, and its platform demonstrates this as Risk is pervasive throughout the platform. This tight connection extends to other modules as well. The Supplier Module is tightly connected to approved vendors, documents and audits. Project management capabilities interoperate with modules to allow for delegation of a task to complete a document, and when the document is signed off, this feeds back to Project Management.

We liked the Guest Connect capability which allows remote users to access the system and respond to specific requests, such as responding to an audit finding, in a secure manner without requiring full access.

The system provides pre-configured best practice workflows and forms, including intelligent routing based on risks. For instance, was a complaint that the pill bottle is hard to open, is it something more threatening, or has this occurred repeatedly? This is a lean approach that avoids death by CAPA, and something we'd expect would improve user adoption. Analytics and reports are strong, with more than 200 out of the box reports with features like scheduled report generation.

One drawback to MasterControl has historically been the User Interface / User Experience, which has been complex due to a very broad set of functionality. MasterControl has made some appreciable investments in this area by regrouping products, and will begin to deploy a modern role-based approach wrapped around defined personas, and leveraging the tile concept familiar to those using more recent Windows releases. We appreciated the attractive new start pages and dynamic tile design. It's a welcome enhancement and will begin to deploy in early 2016.

MasterControl also offers Mobile enhancements and cloud support. Its cloud offering, Spark, is of particular interest. It is based on AWS, and is targeted to be an affordable and quick-deploying option for the SMB space. It leverages proven pre-configurations, and provides full configurability. Spark is single-tenant, which allows for flexibility in validation.

MasterControl is a leader in the EQMS Life Sciences space, and with the inclusion of its new cloud offering should be a consideration for Small, Medium and Large Life Sciences businesses.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

MasterControl at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Aerospace & Defense Automotive Chemicals Consulting Consumer Products Food and Beverage Government High Tech Industrial Equipment Mfg Life Sciences Process: Metals / Mining / Packaging / Paper / Oil & Gas Semiconductor, Telecom 	<ul style="list-style-type: none"> Life Sciences 	
Functionality	<ul style="list-style-type: none"> Document Control Audit Mgmt Training Mgmt Change Mgmt Complaint Mgmt Supplier Quality Mgmt Risk Mgmt Non Conformance / CAPA Compliance Mgmt Calibration Mgmt EHS FMEA PPAP/APQP Reports, Dashboards, Analytics 	<ul style="list-style-type: none"> Audit Mgmt Change Mgmt Complaint Mgmt Document Mgmt Supplier Quality Mgmt Non-Conformance / CAPA Risk Mgmt 	
Company Size	<ul style="list-style-type: none"> Small (<\$250 Million Revenue) Medium (\$250 Million – \$1 Billion Revenue) Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Large (> \$1 Billion Revenue) Medium (\$250 Million – \$1 Billion Revenue) 	<ul style="list-style-type: none"> Small (<\$250 Million Revenue)
Geography Served	<ul style="list-style-type: none"> North America Europe Asia/Pac Australia/New Zealand 	<ul style="list-style-type: none"> North America Europe Asia/Pac Australia/New Zealand 	
Technology Development Platforms	<ul style="list-style-type: none"> Java HTML5 Web Services Accepts 3rd party doc mgmt. Integration Layer 	<ul style="list-style-type: none"> Java HTML5 Web Services Integration Layer 	
Technology Delivery Model	<ul style="list-style-type: none"> Web Client, optimized for mobile On-Premise Cloud, Single / Multi-tenant SaaS 	<ul style="list-style-type: none"> Web client, optimized for mobile On-Premise Cloud, single tenant SaaS 	<ul style="list-style-type: none"> Cloud, Multi-tenant

MetricStream

Currently headquartered in Palo Alto, California, but with offices in France, Spain, Italy, the UK, and Germany, MetricStream was founded as an EQMS and since 2007 has been more one that is specifically geared towards broader Governance, Risk, and Compliance (GRC) driven by metrics. Founded in 1999, the vendor merged with another small company, Zaplet, in 2004, and inherited the latter's executive chairman as its own as a result of the merger. Zaplet still exists, but as a Platform as a Service (PaaS) entity that delivers MetricStream GRC solutions through the Cloud. In terms of its client base served, MetricStream spans a wide range of clients around the globe, yet has expertise in Energy and Utilities, Food & Beverage, Retail, High-Tech, and Life Sciences.

With firm roots in EQMS processes, MetricStream now sets itself ahead, partially outside of the EQMS spectrum partially by embedding risk into its entire approach, but also by providing tools for customers to evaluate risk right across the supply chain and across multiple disciplines for organization-wide governance and compliance.

Many vendors have incorporated either Operational Risk Management or Enterprise Risk Management into their frameworks, and some have holistically incorporated both. The core EQMS processes of Document Control, Training, Audit, Non-Conformance and CAPA and Complaint Management in conjunction with a comprehensive supplier management portal all add up to a comprehensive offering. There are options for integration to ERP and other systems. Given MetricStream's broad set of existing EQMS customers, LNS hopes to see MetricStream over the coming years invest more deeply in integrations, particularly demonstrating capability to connect MetricStream's EQMS offering to the shop floor and engineering.

The MetricStream solution is a true enterprise platform that has an intuitive and modern user interface (UI). One stand-out element is an alternate to traditional navigation that revolves around a multi-level circular tile approach, something occasional and regular users alike would find intuitive and easy to use. Partnership with Tableau for advanced in reporting and analytics is considered a very powerful combination and bundling or separate licensing is available.

MetricStream has evidence of well known, non-manufacturing brands using the solution as the sole, enterprise tool for quality management to great effect. And given the solution helps define different risks at different levels of an organization, from site to region to enterprise, and also help clients establish a common taxonomy across risk management throughout these levels there is potential for the offering to gain ground post publication of ISO 9001:2015.

The supplier portal element of the platform is very strong from a supplier risk management and performance perspective. This is one of the areas where the new platform is particularly strong in quality

What is important to note, although MetricStream has broadened its focus to GRC, it has a number of successful EQMS customers and its solutions do address a range of quality management processes. It remains to be seen how MetricStream's GRC-centered marketing message will play out with customers in a broader market looking for more dedicated EQMS functionality, including companies not pursuing in a combined solution.

Prospective clients, especially those in retail and Food & Beverage sectors should consider MetricStream, especially if they desire a blended GRC and EQMS solution.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

MetricStream at a Glance

	Have Coverage	Areas of Strength	Emerging Strength
Industries Served	<ul style="list-style-type: none"> Government / Public Sector Education Consumer Products Food and Beverage High Technology Industrial Equip. Mfg Life Sciences Semiconductors Oil & Gas 	<ul style="list-style-type: none"> Food and Beverage 	<ul style="list-style-type: none"> Government / Public Sector
EQMS Functionality	<ul style="list-style-type: none"> Training Mgmt Calibration Mgmt Doc Control Change Mgmt FMEA NC/CAPA Compliance Mgmt EHS Performance Mgmt Supplier Quality Mgmt Reports / Dashboards / Analytics Audit Mgmt 	<ul style="list-style-type: none"> Compliance Mgmt NC/CAPA Risk Mgmt Supplier Quality Mgmt Audit Mgmt 	<ul style="list-style-type: none"> Change Mgmt
Company Sizes Served	<ul style="list-style-type: none"> Large (> \$1 Billion Revenue) Medium (\$250 Million - \$1 Billion Revenue) 	<ul style="list-style-type: none"> Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Medium (\$250 Million - \$1 Billion Revenue)
Geographies Served	<ul style="list-style-type: none"> North America Europe Asia / Pacific 	<ul style="list-style-type: none"> North America Europe 	<ul style="list-style-type: none"> Asia/Pacific
Technology Development Platforms	<ul style="list-style-type: none"> JAVA HTML5 Web Services 	<ul style="list-style-type: none"> Java HTML5 Web Services 	
Technology Delivery Model	<ul style="list-style-type: none"> Web client, optimized for mobile On Premise Cloud, single / multi-tenant SaaS Mobile apps, all modules 	<ul style="list-style-type: none"> Web client, optimized for mobile On Premise Cloud, single/multi-tenant SaaS Mobile apps, key modules 	

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Omnex Systems

Omnex was founded in 1986 and is headquartered in Ann Arbor, MI with offices in several other locations in North America, Europe, Asia, and the Middle East. Omnex's team of roughly 400 employees is a leader in Integrated Management Systems consulting and training targeted at aiding customers in many industries with Quality challenges. Omnex's software offering is provided by the Omnex Systems business unit, which was one of the first EQMS offerings with an inaugural release in 1988. Over the past several years Omnex has increased its focus on its software offering, including new leadership.

Omnex Systems focuses on Aerospace, Automotive, High Technology, Transportation, and Construction industries. The suite has been updated to support the ISO 9001:2015 revision in addition to previous revisions. EQMS Modules include APQP/PPAP, Document Control, Issue Management, Audit Management, Calibration and Gage R&R, Equipment Management, Training and HR Management, and Continuous Improvement software.

Omnex Systems has been a pioneer in Quality Management software, particularly the APQP/PPAP space. The company has deep subject matter expertise, having aided in writing standards, and published books on quality management.

Its AQuA Pro APQP/PPAP software has been fielded for over 25 years and provides integrated FMEAs, DVP&R, Control Plans, etc. in a change managed environment that promotes data re-use and standardization while permitting variation. There are many capabilities in this module, and it enables substantial efficiency gains through inheritances and master templates. This core

module reflects Omnex's emphasis on connecting quality, manufacturing and engineering. Issues uncovered in the APQP process are addressed in the Problem Solver module. Omnex is uniquely focused on APQP solution and Integrated Management System (IMS), which in its Version 6 release includes Risk Management associated with the High Level Structure of current ISO standards.

Omnex provides deep capabilities in a well thought-out framework. It supports multiple sites, multiple languages, and multiple dates. The EQMS modules are offered in a modular but integrated environment and feature a recently revamped Web-based UI, although limited mobile options exist. While it is primarily deployed on premise, single-tenant private Cloud deployments are also possible. Omnex Systems does provide dashboards and analytics, as well as some advanced capabilities in its BOSS Continual Improvement module. The BOSS Continual Improvement module can mash up data from multiple data streams to provide broad insights into health of quality execution. Omnex provides APIs for integration and is working on a full integration layer. LDAP is supported.

Omnex is a good option for companies with deep APQP/PPAP needs and is looking to expand into a full EQMS that supports an integrated management system across Operational Excellence. Organizations looking for training and consulting in addition to software should consider Omnex. Omnex has been improving its technology stack, and LNS would like to see additional investments in Cloud, Mobile and Analytics, as well as continue its improvements to its user interface.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Omnex Systems at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Aerospace Automotive Chemicals Consulting Education Food and Beverage Government/Public Sector High Technology Medical Devices Industrial Equipment Metals Mining Oil and Gas Packaging Paper/Lumber/Timber Pharmaceutical Mfg Semiconductor Telecommunications Utilities 	<ul style="list-style-type: none"> Aerospace Automotive High Technology Medical Devices Semiconductor 	<ul style="list-style-type: none"> Life Sciences Food and Beverage Chemicals Consumer Packaged Goods Government Oil & Gas Pharmaceutical
Functionality	<ul style="list-style-type: none"> Document Control Audit Mgmt Change Mgmt Complaint/Issue Mgmt Supplier Quality Mgmt Risk Mgmt FMEA NC / CAPA Compliance Mgmt Calibration Mgmt APQP & PPAP Analytics, Dashboards and Reporting 	<ul style="list-style-type: none"> Supplier Quality Mgmt Risk Mgmt FMEA NC / CAPA Calibration Mgmt APQP & PPAP Dashboards and Reporting 	
Company Size	<ul style="list-style-type: none"> Small (<\$250 Million Revenue) Medium (\$250M - \$1B Revenue) Large (> \$1B Revenue) 	<ul style="list-style-type: none"> Medium (\$250 Million – \$1 Billion Revenue) Large (>\$1B Revenue) 	
Geography Served	<ul style="list-style-type: none"> North America Europe Asia/Pacific Middle East 	<ul style="list-style-type: none"> North America Europe Asia/Pacific 	<ul style="list-style-type: none"> Africa Australia/New Zealand
Technology Development Platforms	<ul style="list-style-type: none"> .NET Silverlight, HTML5 Web Services Accepts 3rd party doc mgmt 	<ul style="list-style-type: none"> .NET.NET Silverlight Web Services 	<ul style="list-style-type: none"> HTML5

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Technology Delivery Model	<ul style="list-style-type: none">• Web client, optimized for mobile• On-Premise• Cloud, Single tenant• SaaS	<ul style="list-style-type: none">• Web Client, browser agnostic• On Premise	<ul style="list-style-type: none">• Web client, optimized for mobile
---------------------------	---	---	--

Oracle

Headquartered out of Redwood Shores, CA Oracle is one of the largest IT companies in the world, with offerings in a wide portfolio across computer hardware and enterprise software applications. For the purposes of this report, LNS Research will be evaluating Oracle on its ability to deliver EQMS functionalities across its enterprise application portfolio, including: Oracle's E-Business Suite, Oracle's JD Edwards EnterpriseOne suite of ERP applications, Oracle's new SCM Cloud, and Oracle's Agile Product Lifecycle Management solution. JD Edwards and Oracle's E-Business Suite are not covered extensively in this report as the majority of Oracle's EQMS solutions are driven primarily out of Agile PLM today and increasing on the SCM Cloud in the future.

The company relies on workflow automation capabilities and employs user-defined rules to verify that parts and products meet standards. Oracle delivers data management and automation capabilities for both product development and manufacturing processes. Built into Oracle's PLM software are Non-Conformance reporting and Corrective and Preventive Action processes. The NC/CAPA piece of the vendor's software streamlines investigations, using electronic signatures and document control capabilities. Oracle's quality management solutions also have a risk management element for prioritizing issues based on criticality. Once root causes have been identified, the applications work to prevent issues from reoccurring in the future, closing the loop on the CAPA process.

These processes are coupled with a change management application, aiming to ensure that the

identification and resolution of issues are conducted in accordance with internal best practices and industry standards. Additionally, Oracle's quality management functionalities extend into the Governance, Risk, and Compliance (GRC) space. With automation and standardization abilities, the solution aids in the control and reduction of operational risks. Additionally, because of Oracle's pervasive nature in the enterprise software space, its Agile PLM-based enterprise quality management solutions are well positioned to integrate with other enterprise applications, including ERP, CRM, and MOM. Agile PLM also works well with Oracle E-Business Suite and SAP.

For large companies that have already invested in the Oracle technology stack and Agile PLM software, LNS Research believes that investing in Oracle's quality management capabilities on Agile PLM is a natural extension. It is the PLM vendor that has accomplished the most regarding EQMS deployments, and the only PLM vendor that has a sizable set of referenceable customers leveraging both the core PLM platform as well as internal or supplier EQMS.

Oracle also has a well-defined and robust future roadmap for EQMS, although it is targeted for version 13 of its new Cloud-based SCM suite that will be available likely in early 2017. As closed-loop quality management is increasingly becoming a focal point for manufacturers and PLM strategies, LNS Research hopes to see Oracle continue to respond to this trend over the coming years.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Oracle at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Aerospace & Defense Automotive Chemicals Consumer Goods Food and Beverage High Technology Semiconductors Telecom Life Sciences Oil & Gas, Utilities Packaging Industrial Manufacturing 	<ul style="list-style-type: none"> Life Sciences High Technology Food & Beverage 	<ul style="list-style-type: none"> Automotive Chemicals
Functionality	<ul style="list-style-type: none"> Document Mgmt Audit Mgmt Training Mgmt Change Mgmt Complaint Mgmt SPC Supplier Quality Mgmt Risk Mgmt Non-Conformance / CAPA EHS FMEA PPAP APQP Reports, Dashboards, Analytics 	<ul style="list-style-type: none"> Supplier Quality Mgmt NC/CAPA Change Mgmt Document Mgmt Reporting, Dashboards, Analytics 	<ul style="list-style-type: none"> FMEA Risk Mgmt EHS
Company Size	<ul style="list-style-type: none"> Small (< \$250 Million Revenue) Medium (\$250 Million – \$1 Billion Revenue) Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Large (> \$1 Billion Revenue) Medium (\$250 Million – \$1 Billion Revenue) 	
Geography Served	<ul style="list-style-type: none"> Global 	<ul style="list-style-type: none"> Global 	
Technology Development Platforms	<ul style="list-style-type: none"> JAVA HTML5 Web Services Integration layer 	<ul style="list-style-type: none"> JAVA HTML5 Web Services Integration layer 	
Technology Delivery Model	<ul style="list-style-type: none"> Web client, optimized for mobile Mobile Apps, Key Modules On Premise Cloud, Single /Multi-tenant SaaS 	<ul style="list-style-type: none"> Mobile Apps, Key Modules On Premise Cloud, Multi-tenant SaaS 	<ul style="list-style-type: none"> Cloud, Multi-tenant

Pilgrim Quality Solutions

Based out of Tampa, FL Pilgrim Quality Solutions is focused primarily on providing quality management solutions to medium and large global enterprises in the life sciences industries, particularly sub-verticals such as medical devices, pharmaceutical manufacturing, biotechnology, blood and tissue, and related contract manufacturing markets under heavy regulation. With 125 employees, the company has a more than 20-year history of offering quality solutions to this market sector.

In May 2015 the company had a change in leadership, as Richard Lowrey was appointed as CEO. Pilgrim Quality Solutions takes its product quality seriously, and in addition to its tight controls around software development lifecycle (SDLC) the company recently certified to ISO 9001.

SmartSolve®, the company's suite of quality management products, is aimed at Life Science companies requiring strong capabilities in document management, audit management, complaints, nonconformance, corrective and preventive actions, training, and change management, and supplier quality management. The solution hones in on ensuring regulatory compliance and quality from product ideation through the manufacturing process and subsequent services. The interoperability between modules facilitates information sharing and the development of closed-loop quality management processes for maximum efficiency and accuracy.

Following significant investment from Riverside Partners in early 2011, the original founders were replaced and as a result new Product Management and Engineering leadership were brought in to steer through legacy product issues. High levels of customization were inherited and work now completed on the new platform and modules was targeted at eliminating customization and increasing configurability. This included an approach designed to lower total cost of ownership (TCO) moving forward. Bringing legacy customers along brought some discomfort but results have been positive recently and today Pilgrim Quality Solutions compete and win many deals that three years ago may not have been the case.

The company has invested significantly in expanding SmartSolve to support the global enterprise with a sophisticated and effective method for managing organizational hierarchies. The new capability allows for the effective roll-up of quality metrics at any level in the organization. Out-of-the-box decision trees, a core feature for jurisdiction compliance, ensure global organizations are not subject to gaps in regional reporting for finished products. Pilgrim Quality Solutions' investments also include improvements in supplier quality management capabilities such as assessments, automated business rules, material inspection, and risk-driven supplier scorecards. The addition of Recall Management and Portals round out the Quality Management portfolio.

Integration is addressed with a combination of Web services (broad library) and, where required, staging repositories for validation and verification. Pilgrim has evidence of successful, long-term integrations with major ERP platforms.

In 2015 Pilgrim Quality Solutions introduced a new analytics layer. This layer, provided by white-labeled TIBCO platform has meant a significant leap from the standard reporting library and report building capability to flexible insight and intelligence. Initially introduced for audits, NC/CAPA and Complaints, the scope of the analytics tool is being expanded to cover all modules, with Document Control and Change Management in production and Training Management slated for spring 2016.

With life sciences as a core focus, robust security is a key demand and this is served by its private cloud offering. Mobility, an area where Pilgrim Quality Solutions has lagged somewhat, is addressed head on by the new mobile audit module with other workflows becoming mobile enabled in the future.

Recently, the company developed "SmartStart," an optional rapid deployment model of the solution that deploys a single module in the cloud and leverages preconfigured workflows that can be adjusted. This program is based on the guarantee of deployment

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

within a 30-day timeframe, a bold offering when considering that validation is included in the package.

Pilgrim Quality Solutions should be a consideration for small, medium and large enterprises in the life sciences vertical requiring full-service quality management solutions that integrate to other enterprise systems.

The company's strategic investments over the past few years have been well timed and pertinent to the evolving demands faced in medical devices around document management and other regulations, which have paid dividends as the company has gained traction in the life sciences space over the last few years.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Pilgrim Quality Solutions at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Medical Devices Pharmaceutical Manufacturing Industrial Equipment Manufacturing Consumer Packages Goods Chemicals Food & Beverage Semiconductor Metals 	<ul style="list-style-type: none"> Medical Devices Pharmaceutical Manufacturing 	<ul style="list-style-type: none"> Consumer Packages Goods
Functionality	<ul style="list-style-type: none"> Calibration Document Mgmt Training Mgmt NC/CAPA Audit Mgmt Complaint Mgmt Risk Mgmt Change Mgmt Supplier Quality Mgmt Reporting / Dashboards / Analytics 	<ul style="list-style-type: none"> Document Mgmt Complaint Mgmt Audit Mgmt NC/CAPA Supplier Quality Mgmt 	Calibration Calibration
Company Size	<ul style="list-style-type: none"> Small (<\$250 Million) Medium (\$250 Million – \$1 Billion Revenue) Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Large (> \$1 Billion Revenue) 	
Geography Served	<ul style="list-style-type: none"> North America Europe Asia/Pacific South & Central America 	<ul style="list-style-type: none"> North America Europe 	<ul style="list-style-type: none"> South & Central America
Technology Development Platforms	<ul style="list-style-type: none"> .NET TIBCO Analytics Web Services HTML5 Accepts 3rd party doc mgmt 	<ul style="list-style-type: none"> .NET Web Services HTML5 	<ul style="list-style-type: none"> TIBCO Analytics
Technology Delivery Model	<ul style="list-style-type: none"> Web client, optimized for mobile On-Premise Cloud, single tenant SaaS Mobile apps, all modules 	<ul style="list-style-type: none"> Web client, browser agnostic On-Premise Cloud, single tenant SaaS 	<ul style="list-style-type: none"> Web client, optimized for mobile Mobile apps, all modules

PTC

Founded in 1985 as a CAD company with the launch of Pro/Engineer, PTC has evolved many times over the past three decades. Its acquisition of Windchill Technologies in 1995 paved the way for its Product Lifecycle Management (PLM) business. Its plethora of acquisitions in the Computer Aided Design / Computer Aided Manufacturing / Computer Aided Engineering (CAD/CAM/CAE), Managed Services, EQMS, Service Lifecycle Management (SLM), Application Lifecycle Management (ALM), and Systems Engineering round out a diverse product portfolio. Most recently, PTC has made substantial investments (~\$450M) in its ThingWorx Internet of Things (IoT) platform, which added Augmented Reality (AR) capabilities with the acquisition of Vuforia in October 2015.

PTC stands out in quality management through its understanding of the entire product lifecycle, particularly the incorporation of reliability, risk, and safety through the lifecycle. From design to production and field service, Windchill's functionality facilitates transparency between processes and departments, giving users information to execute quality planning. Capabilities, such as FMEA and statistical trending with FRACAS, acquired from Relex (now rebranded to Windchill Quality Solutions) mix well with PTC's existing NC/CAPA technology to escalate and correct critical quality issues. Additionally, as part of the QMS suite, Windchill now has a Customer Experience Module that manages customer complaints. PTC also has strength in understanding the crossroad of both ERP and CRM with PLM. Avoiding a linear business model by centralizing information allows PTC users to share issues that impact design and production across the company.

However, it is difficult to talk about PTC's quality offering without discussing IoT and ThingWorx.

Recently, PTC has launched Connected Quality by using its flexible IoT platform, ThingWorx, as a vehicle to combine data and analyses from multiple quality sources into quality mashups which are then connected to Windchill PLM. For instance, dynamic data from Windchill Quality Solutions, manufacturing quality systems, service quality systems, etc., can be consolidated and delivered in ThingWorx mashups which can be used to uncover issues and drive CAPAs. LNS Research supports the concept of consolidating the many disparate streams of quality data and generating analytics with corporate reporting scope. Additionally, PTC has partnered with GE's Brilliant Factories Industrial IoT vision due to the mashup visual and analytical strength of its ThingWorx platform. This partnership has the potential to positively impact quality professionals by more closely connecting them to manufacturing and product development.

Focusing on industries such as A&D, Automotive, Electronics, and Medical Device, PTC is a good choice for companies working with highly engineered and complex products. The newly acquired IoT capabilities coupled with its longstanding PLM knowledge and EQMS acquisitions offers users a unique perspective of what closed-loop quality could mean. For PTC to become a real player in the EQMS space and move beyond offering quality engineering tools, Connected Quality will have to move beyond being just an extension for existing customers to a true standalone solution that drives adoption of Windchill PLM and ThingWorx for companies that equate PLM to a business initiative and quality as the highest priority business objective. LNS would like to see more support of core EQMS processes in addition to some of the market-leading IoT capabilities.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

PTC at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> • Aerospace & Defense • Automotive • Consumer Products • Government • High Tech • Industrial Equipment Mfg • Medical Devices • Oil & Gas, Energy • Semiconductor • Telecom 	<ul style="list-style-type: none"> • Aerospace & Defense • Consumer Products • High Tech • Industrial Equipment Mfg 	<ul style="list-style-type: none"> • Medical Devices
Functionality	<ul style="list-style-type: none"> • Document Control • Audit Mgmt • Change Mgmt • Complaint Mgmt • FMEA • NC / CAPA • Compliance Mgmt • PPAP/APQP • Risk Mgmt • Training Mgmt • Reports, Dashboards, Analytics 	<ul style="list-style-type: none"> • Change Mgmt • NC / CAPA • FMEA • Dashboards / Analytics 	<ul style="list-style-type: none"> • Risk Mgmt • Audits • PPAP • Training Mgmt
Company Size	<ul style="list-style-type: none"> • Medium (\$250 Million – \$1 Billion Revenue) • Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> • Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> • Medium (\$250 Million – \$1 Billion Revenue)
Geography Served	<ul style="list-style-type: none"> • Global 	<ul style="list-style-type: none"> • Global 	
Technology Development Platforms	<ul style="list-style-type: none"> • Java/.NET • HTML5/Silverlight • Web Services • Integration Layer • Thingworx 	<ul style="list-style-type: none"> • Java/.NET • HTML5/Silverlight • Web Services • Integration Layer 	<ul style="list-style-type: none"> • ThingWorx
Technology Delivery Model	<ul style="list-style-type: none"> • Web Client, browser agnostic • Mobile Apps, All Modules • On-Premise • Cloud, Single / Multi-tenant • SaaS 	<ul style="list-style-type: none"> • Web client, browser agnostic • On-Premise • Cloud, Single tenant 	<ul style="list-style-type: none"> • Cloud, Multi-tenant • SaaS • Mobile Apps, All Modules

SAP

A longtime player in the Enterprise Application space, SAP was founded in 1972 and has its worldwide headquarters in Walldorf, Germany. Although known for its large ERP presence and versatile configurability, the company has a long history of building quality management into enterprise business processes across procurement, engineering, manufacturing, the supply chain, and more. In acquisitions over the past five years (across mobility, business analytics, sustainability, and the value chain including: procurement, manufacturing, the supply chain, and more) SAP has continued moving in the direction of focusing on creating value through orchestrating integrated end-to-end business processes. SAP has also launched an Industrial Internet of Things (IIoT) platform with its debut and continued investment in HANA, including a January 2016 partnership with OSI. OSI is a company that provides Operational Technology infrastructure through connections to sensors, operations, and people.

SAP primarily targets large industrial businesses involved in both process and discrete manufacturing. Traditionally, the company has shown strengths in CRM, SCM, PLM, MOM, and SRM, in addition to its ERP capabilities. SAP's interoperability allows companies to manage operational and financial systems under one platform. Because the software uses service-oriented architecture, its openness appeals to many businesses looking for strong ERP coverage in addition to existing in-house systems.

While SAP's ERP software is highly functional for a diverse set of industries, many users do require specific functionality around quality management. Traditionally, this has meant configuring processes and workflows in the Quality Management module that is included as part of the ERP Business Suite. If a company must leverage these services, LNS recommends working with a consulting partner that has specific and proven quality management capabilities, not just general SAP ERP skills.

SAP has also now provided a much more streamlined deployment process through its RDS (Rapid Deployment Solution) for quality, which delivers pre-built best practices and reduces the upfront time and cost of configuration. As a part of this effort, SAP has invested resources to develop SAP Quality Issue Management (QIM), which offers broader and pre-configured functionality covering four pillars: Quality Engineering, Quality Control & Assurance, Audit Management and Quality Improvement. Some newly added capabilities include process support for 8D as well as FMEA.

Additionally, SAP has included a few Quality Management screen persona apps into Fiori. Fiori is SAP's new persona-based improved User Experience platform. These functionalities do expand SAP's quality coverage, and takes it a step closer to the scope provided by dedicated EQMS providers, while remaining fully integral to the SAP framework.

In the industries with more robust quality management requirements, such as the highly regulated Life Sciences industries, there will continue to be companies that look towards third parties for additional functionality to extend investments already made in SAP ERP. This may include some of SAP's new capabilities, or leveraging SAP as a platform and customizing SAP using inherent workflow and business logic functionality to capture the other quality management processes not addressed by QIM. SAP is offered on premise or as a single tenant managed service offering. Multi-tenant capabilities are also emerging. It has powerful integration capabilities, and is well known to provide scale needed for the largest organizations.

As quality remains a critical source of competitive advantage for many SAP customers, LNS Research hopes that SAP continues down its current path to build more pre-configured quality processes as part of the standard product, complementing and extending end-to-end business processes.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

SAP at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Aerospace and Defense Automotive Chemicals Consumer Products Food and Beverage Government Industrial Equipment Mfg High Tech, Semiconductor, Telecom Life Sciences Metals, Mining, Paper Oil and Gas Utilities 	<ul style="list-style-type: none"> Food and Beverage Chemical 	
Functionality	<ul style="list-style-type: none"> Audit Mgmt Document Control Change Mgmt Complaints Mgmt Calibration Performance Mgmt NC/CAPA EHS FMEA Supplier Quality Mgmt SPC Risk Mgmt APQP/PPAP Training Mgmt Reports / Dashboards / Analytics 	<ul style="list-style-type: none"> Change Mgmt NC/CAPA EHS Analytics Calibration Performance Mgmt 	<ul style="list-style-type: none"> FMEA
Company Size	<ul style="list-style-type: none"> Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Large (> \$1 Billion Revenue) 	
Geography Served	<ul style="list-style-type: none"> Global 	<ul style="list-style-type: none"> Global 	
Technology Development Platforms	<ul style="list-style-type: none"> Java HTML5 Web Services Integration Layer 	<ul style="list-style-type: none"> Java HTML5 Web Services Integration Layer 	
Technology Delivery Model	<ul style="list-style-type: none"> Web client Native Apps, all modules On-Premise Cloud, multi-tenant SaaS 	<ul style="list-style-type: none"> Web client On-Premise Cloud, single tenant 	<ul style="list-style-type: none"> Cloud, multi-tenant SaaS Native Apps, all modules

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Siemens

Siemens is a nearly 170 year-old German-based electronics and engineering company and is one of the largest vendors in the industrial space. The Siemens PLM Software business unit (part of the Digital Factory division) customer base is spread across Automotive and Automotive supply chain, as well as other Discrete manufacturers such as Life Sciences and Mobility. Siemens has strong offerings in the PLM and MES software spaces and in the past several years has acquired a strong presence in Enterprise Quality Management Software.

Starting several years ago, as part of Manufacturing Engineering Solutions in Tecnomatix, Siemens moved to include Inspection Planning, Variation Analysis, and Dimensional Planning and Validation (DPV) capabilities, all under the single umbrella of closed-loop quality management. In February 2012, Siemens attained an 81% controlling interest in IBS AG, a German company that has strong MES and EQMS capabilities, and is now fully integrated into the PLM Software business unit alongside MES and SCADA. Then in October 2014, Siemens acquired Camstar, a manufacturing operations management company with integral manufacturing quality capabilities for discrete industries and with a focus on Medical Devices. Omneo, a product performance intelligence solution, came along with the Camstar acquisition. Siemens offers SIMATIC IT R&D Suite that includes a Laboratory Information Management System (Unilab) as well as recipe management (Interspec). These quality management prongs provide a robust quality landscape supporting quality management, risk management, manufacturing quality, LIMS and PLM/recipe management

The core quality management capabilities exist within the former IBS portfolio, now Siemens Quality Management Software. The QMS portfolio provides a mature lifecycle view of quality, following a Deming Plan: Do – Check – Act (PDCA) approach and aligned with automotive APQP processes. Planning elements include Project Management, FMEAs, Control Plans, Flowchart, Inspection Plans and Gauge Measurement. “Do” elements are PPAP and Inspections (incoming, in-process, and final assembly). “Check” elements are Reports, Statistical Process Control and Supplier

Assessments. “Act” elements are Action Management, Complaint Management, Failure Analysis, and Problem Solving (CAPA or 8D), Audits, and Supplier and Customer Portals. The Cockpit Business Intelligence dashboard and analytics system provides oversight and lifecycle visibility.

Siemens has integrated the former IBS business, and now has begun the process of technical integrations, with the first connection an integration between IBS FMEA and Teamcenter, which aligns well with Siemens PLM heritage and strength as well as providing a strategic communication bridge between quality and product development. Also, Siemens has recently announced a new Big Data Analytics platform, Sinalytics, which is applicable across the Siemens product family. This is meaningful to quality professionals in light of the widespread interest in leveraging IIoT to drive quality and reliability improvement.

Siemens has announced a robust IIoT and Big Data Analytics initiative that has already yielded some noticeable successes. The Sinalytics platform is central to Siemens Digitalization efforts, which aims to provide measurable benefits through a combination of Collaboration, Smart Data and Analytics, Cloud, and Security. The platform is a core corporate platform that is/will be leveraged by business units such as PLM, where Quality resides. Early focus is on driving improved operational reliability, availability (uptime) and quality and future waves of development will expand the scope and type of analytics.

Overall, Siemens has a good understanding of the needs of engineering, manufacturing, and IT executives, allowing it to offer a broad set of functionalities to many industries. The company’s original software strengths, however, lie within its PLM and MES solutions. Fitting well with large discrete manufacturing firms, especially in the Automotive, Aerospace, Defense, Heavy Machinery, and CPG spaces, Siemens takes a closed-loop approach to Product Lifecycle Management and Manufacturing. Its PLM functionality is strong in the areas of design for quality, manufacturing, service, and warranty. Additionally, Siemens’ MES software, SIMATIC IT, with

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

its library approach to implementation and expansion to new industries, is a viable choice for both discrete and process industries. Delivering solutions in

Production, R&D, and Manufacturing Intelligence, the MES solution has strength in managing manufacturing operations workflow.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Siemens at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Aerospace and Defense Automotive Industrial Equip Mfg Chemicals Consumer Products Life Sciences High Technology Semiconductor Food and Beverage Oil & Gas, Utilities Paper, Metals, Mining Pharmaceutical 	<ul style="list-style-type: none"> Aerospace and Defense Automotive High Tech Semiconductor Consumer Packaged Goods 	<ul style="list-style-type: none"> Chemicals
Functionality	<ul style="list-style-type: none"> Document Control Audit Mgmt Training Mgmt Change Mgmt Complaint Mgmt Supplier Quality Mgmt Risk Mgmt Non-Conformance / CAPA Calibration mgmt. EHS APQP/PPAP/FMEA Performance Mgmt Statistical Process Control Reports, Dashboard, Analytics 	<ul style="list-style-type: none"> Audit Mgmt Training Mgmt Change Mgmt Complaint Mgmt Risk Mgmt Non-Conformance / CAPA APQP/PPAP/FMEA 	
Company Size	<ul style="list-style-type: none"> Medium (\$250 Million – \$1 Billion Revenue) Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Large (> \$1 Billion Revenue) 	
Geography Served	<ul style="list-style-type: none"> Global 	<ul style="list-style-type: none"> Global 	
Technology Development Platforms	<ul style="list-style-type: none"> .NET HTML5 Web Services Accepts 3rd party doc mgmt Integration Layer Sinalytics Digitalization 	<ul style="list-style-type: none"> .NET HTML5 Web Services Integration layer 	<ul style="list-style-type: none"> Sinalytics Digitalization platform
Technology Delivery Model	<ul style="list-style-type: none"> Web client, optimized for mobile On-Premise Cloud, Single Tenant SaaS Mobile apps, all modules 	<ul style="list-style-type: none"> Web client On-Premise Cloud, Single Tenant 	<ul style="list-style-type: none"> Web client, optimized for mobile

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

SOLABS

Based out of Montreal, Canada, and with additional offices in Framingham, MA and Sacramento, CA, SOLABS is focused primarily on providing quality management solutions to Small and Medium enterprises. SOLABS' target market is specifically Life Sciences only. The company is seeing growth in this highly regulated space, especially from Medical Device, Pharma and Biotech companies where traditionally a paper-based, hybrid or legacy solution was employed. The SOLABS QM™ application is also particularly attractive to the start-up and high growth Life Science company looking to leverage a quickly deployed and validated QMS.

The company was founded in 1999, and is in use by 5,000+ users in four languages. SOLABS is aggressively pursuing the mid-market Cloud EQMS space, and sees its differentiation being best practices out-of-the-box and validation experience and maturity for a core set of QMS processes.

The SOLABS QM product runs on a Microsoft server OS and in conjunction with the business process engine and core functionality (Java/JBoss) sits on an SQL Server database platform. For reporting and analytics, it leverages the use of Excel/SSRS reporting services within MS SharePoint. For documentation and an additional control an Adlib PDF rendering engine is also included. The UI is a responsive-design with multi-platform in mind, meaning switching from PC to tablet to phone is seamless but this is the extent of mobility provision currently.

SOLABS QM provides support for a range of processes with document management and training/competence as the typical starting point for implementation. The list of supported processes is based on a library of SOLABS QM "Apps." The application library and therefore processes supported include Change Control, Deviation, CAPA, Non-Conformance, Audit, Complaint, Investigation, Out of Specification/Out of Trend, Calibration & Maintenance and Supplier Quality Management. SOLABSQM Apps exist in more than one flavor of workflow—typically two to five different

flavors. SOLABS' roadmap includes adding more processes in the form of Apps and additional workflows (flavors) for the existing Apps. Based on the Apps approach, it is clear that workflows and business rules are not built or configured (beyond metadata and picklists) by the end user. Vendor intervention is required should the out-of-the-box best practice require additional customization for specific needs.

SOLABS QM is particularly suited to organizations that have 1-10 sites or facilities and between 100-2,000 end users. The user interface is sleek and all processes have graphical representations of the workflows to illustrate stages and approvals from beginning to end. The simplicity of the UI is appealing to the occasional end user yet powerful enough to deliver on the needs of the more advanced user or consumer of data.

SOLABS is well positioned to take advantage of the maturing SaaS market and a Cloud offering is available. This fits well with a significant portion of its market and, coupled with expertise in validation, it offers an attractive proposition. It is in the area of reporting and analytics that SOLABS should aim to improve. SSRS is a powerful collection of tools but for advanced reporting, including drill-down, expertise in the MS Business Intelligence Development Studio (BIDS) is required. This means additional vendor intervention or a trained resource for the customer's team headcount. The solution ships with 30+ standard reports in Report Builder.

Integration track history exists with a number of enterprise systems, utilizing Web Services .

This solution should be considered by Small and Medium sized Life Sciences organizations to replace paper-based or hybrid approaches to QMS with the caveat that the processes available fit with the workflow(s) in existence or the to-be workflows of an organization. LNS recommends that SOLABS include eMDR support. Its ease of use and deployment model make it one to watch

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

SOLABS at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Medical Devices Pharma 	<ul style="list-style-type: none"> Pharma 	<ul style="list-style-type: none"> Medical Devices
Functionality	<ul style="list-style-type: none"> Audit Mgmt Document Management Training Mgmt Mgmt of Change Complaint Mgmt Supplier Quality Mgmt Investigation Mgmt NC / CAPA Compliance Mgmt Calibration Mgmt Reporting/Dashboards/ Analytics 	<ul style="list-style-type: none"> Document Management Training Mgmt Mgmt of Change Complaint Mgmt Supplier Quality Mgmt NC / CAPA 	<ul style="list-style-type: none"> Calibration Mgmt Reporting/Dashboards/ Analytics
Company Size	<ul style="list-style-type: none"> Medium (\$250 Million – \$1 Billion Revenue) Small (<\$250 Million Revenue) 	<ul style="list-style-type: none"> Medium (\$250 Million – \$1 Billion Revenue) Small (<\$250 Million Revenue) 	
Geography Served	<ul style="list-style-type: none"> North America Europe Asia/Pacific 	<ul style="list-style-type: none"> North America 	<ul style="list-style-type: none"> Europe Asia/Pacific
Technology Development Platforms	<ul style="list-style-type: none"> Java HTML5 Web Services Accepts 3rd party doc mgmt 	<ul style="list-style-type: none"> Java HTML5 Accepts 3rd party doc mgmt. 	
Technology Delivery Model	<ul style="list-style-type: none"> Web client, optimized for mobile On-Premise Cloud, single tenant SaaS 	<ul style="list-style-type: none"> Web client, optimized for mobile On-Premise Cloud, single tenant SaaS 	

Sparta Systems

Founded in 1994 and based in Hamilton, NJ, with additional offices in Singapore, London, UK, Berlin, Germany, and Vienna, Austria, Sparta Systems, Inc. is one of the most well established and largest pure-play vendors in the Enterprise Quality Management Software space. Its flagship product, TrackWise, is a well-established brand. Possessing one of the strongest user-groups in the space over Sparta's 21-year history has contributed to developing a keen understanding of the needs of IT and Line of Business. As a result, many customers have created a hybrid role of quality and IT.

Sparta's highly configurable set of EQMS capabilities offers the flexibility to adapt to company-specific business processes, enabling clients across diverse industries to define, track, manage, and report on the core activities and processes vital to success. It has a particularly strong focus on Pharmaceuticals and Biotech as well as other Life Sciences with emerging strengths in Food & Beverage, CPG, Tobacco, Agrochemical, and Electronics. Beyond the configurability of the workflows and business processes, Sparta Systems' real strength is in working well with large customers.

Sparta Systems does not take a modular approach, rather, once the TrackWise system is implemented, a company can configure any quality business process on the platform. Generally, this means the upfront costs can be higher in comparison to vendors that take a modular approach. However, for large companies with multiple sites and business processes that can be served with TrackWise, the long-term total cost of ownership is usually lower. Sparta Systems also offers global scale in both the implementation and support of the technology.

Finally, with a CEO focused on growing and expanding the business, Sparta Systems is making strong investments in the product. In LNS Research's last review, we discussed new capabilities planned in the BI, Mobility, and the Graphical User Interface. These new capabilities were realized, and in our most recent review of TrackWise v9.0 (due to be released mid-2016), we liked the improved ease of use and person-based user experience. For instance, the Supplier

Scorecard user interface provides a clean approach to displaying current and historical supplier performance with charts of historical performance and color-coded current actions and overall supplier status.

In 2014, Sparta released the Stratas Supplier Collaboration Suite, a cloud solution built on Amazon Web Services. This suite delivers supplier quality management by connecting suppliers when integrated with TrackWise. The Stratas platform is the integration foundation enabling Sparta's Quality Business Network strategy, discussed later. TrackWise Mobile is being updated to support off-line capabilities. Integration approaches are evolving to new REST Web Service protocols as well as a SSO gateway. Sparta has launched a "Mini app store" called QualityConnect that allows for certified partners to connect apps with the Sparta platform. Additionally, Sparta has launched a process design initiative that identifies and standardizes best practice processes. This initiative automates and simplifies processes, such as tracking a record through its lifecycle; triggers determine needed work, which are communicated to users via a configured email.

In January 2016, Sparta Systems acquired 123Compliance and launched its Quality Business Network strategy. 123Compliance is a Life Sciences EQMS offering for the SMB space developed on the Salesforce cloud platform, and provides a valuable addition to Sparta's leading presence in the Large Lifecycle segment. Sparta plans to leverage this acquisition to provide a connected Supplier-Customer Quality Management environment that allows connected parties to improve cross-organizational quality through better collaboration and visibility.

Sparta has made substantial strides in the past several years around areas in which LNS called for improvement such as Supplier Quality Management, Cloud, User Interface, Mobility, and Analytics. In the coming years, continued success for Sparta Systems will largely depend on its ability to continue to deliver for current large Pharmaceutical customers while simultaneously innovating and capturing new opportunities. Large Life Sciences organizations should continue to look at Sparta closely. With the latest

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

updates, Small and Medium Life Science companies as well as large non-Life Science businesses should also investigate Sparta. The addition of 123Compliance

provides an offering of interest to the SMB Lifesciences base as well.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Sparta Systems at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> Life Sciences Chemicals Consumer Packaged Goods Food and Beverage High Technology Industrial Equipment Mfg Semiconductor 	<ul style="list-style-type: none"> Life Sciences Food and Beverage 	<ul style="list-style-type: none"> Chemicals Consumer Packaged Goods High Technology
Functionality	<ul style="list-style-type: none"> Audit Management Training Management Change Management Complaint Management Supplier Quality Management Risk Management Non Conformance and CAPA Compliance Management Calibration Management EHS FMEA, PPAP, APQP Performance Management Reports, Dashboards, Analytics 	<ul style="list-style-type: none"> Audit Management Training Management Complaint Management Non Conformance / CAPA Supplier Quality Management Dashboards Analytics 	<ul style="list-style-type: none"> Calibration Mgmt
Company Size	<ul style="list-style-type: none"> All 	<ul style="list-style-type: none"> Medium (\$250M - \$1B revenue) Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> Small (<\$250M)
Geography Served	<ul style="list-style-type: none"> North America South / Central America Europe Asia / Pacific Australia/New Zealand 	<ul style="list-style-type: none"> North America Europe 	<ul style="list-style-type: none"> Asia/Pacific
Technology Development Platforms	<ul style="list-style-type: none"> Java HTML5 Web Services Accepts 3rd party doc mgmt Integration layer 	<ul style="list-style-type: none"> Java HTML5 	
Technology Delivery Model	<ul style="list-style-type: none"> Web UI On-Premise Cloud, Single/Multi-tenant SaaS Mobile apps, key modules 	<ul style="list-style-type: none"> Web UI On-Premise 	<ul style="list-style-type: none"> Cloud, Single/Multi-tenant SaaS Mobile apps, key modules

TIP Technologies

Based out of Waukesha, WI TIP Technologies, Inc. is focused primarily on providing quality management (TIPQA™ Quality Management Solution) and shop floor (TIPSFE Shop Floor Execution) solutions to Medium and Large enterprises. TIP Technologies' target markets include Aerospace & Defense, Medical Devices and regulated discrete manufacturing industries such Oil & Gas. The company is building upon its traditional areas of strength in A&D and regulated discrete manufacturing by expanding into Medical Devices and the Public Sector.

The company was founded in 1989, and was one of the first QMS software solutions. It provides an API integration layer that permits custom connections, as well as certified out-of-the-box connections to select ERP and MES solutions such as Deltek Costpoint, SAP, Oracle, and Microsoft Dynamics. These connections, in concert with TIPQA™ and TIPSFE Shop Floor Execution enable TIP Technologies to provide a closed-loop connection between ERP, quality, and manufacturing.

TIP Technologies is releasing a new Ease of Ownership (EoO) offering set that simplifies purchasing and deployment decisions by providing tiered combinations of pre-bundled software and implementation services. There are three levels, and TIP Technologies states that it can deploy the lowest level—TIPQA™ Essential—within five business days. TIPQA™ provides a broad set of QMS capabilities, which it is now beginning to deploy in Web-based UIs. It is also investigating a future SaaS offering. Modules include Audit Management, Training Management, Change Management, Complaint Management, Statistical Process Control (SPC), Supplier Quality Management, Risk Management, Non-Conformance Management, CAPA, Compliance Management, Calibration Management, EHS Management, APQP/PPAP, and Performance Management.

Some outstanding capabilities include Complaints Management that includes both Standard and Medical Device options, where Medical Device generates MDR per FDA regulations, ITAR support, and a capable Supplier Quality Management solution, including a communication portal as well as support for key SQM deliverables such as Certification and Rating, Audits, and CAPA.

TIP Technologies has a mature, broad and deep offering, traditionally offered in a thick client interface (non-Web-based). While it continues to support its thick client, it has begun to deploy a web client using a modern technology stack, based on Apache Tomcat, JAVA, HTML5 and AngularJS. The new Web interface has been optimized for mobile, specifically optimized for MS, iOS and Android tablets. It has one mobile-native app, Audits, which was in beta when this report was published. The company is taking a cautious approach in migrating to the web and mobile to ensure that the new user interface meets key customer use cases. New features are prioritized by user votes.

TIP Technologies is also entering the cloud, and work with third-party Cloud services providers to deliver an AWS single tenant cloud solution capable of supporting its core market, Aerospace and Defense.

TIPQA™ is a mature solution that has been refined over several decades and has a welcome and needed technology rejuvenation underway. It provides mature capabilities such as a comprehensive EQMS and MES as well as integration to common ERP and MES providers. TIPQA™ should be a consideration, particularly for companies in Aerospace & Defense and complex and regulated manufacturers.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

TIP Technologies at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> • Aerospace • Automotive • Government/Public Sector • Medical Devices • Industrial Equipment Mfg • Metals • Oil & Gas 	<ul style="list-style-type: none"> • Aerospace • Industrial Equipment Mfg • Metals 	<ul style="list-style-type: none"> • Government/ Public Sector • Medical Devices
Functionality	<ul style="list-style-type: none"> • Audit Mgmt • Training Mgmt • Mgmt of Change • Complaint Mgmt • SPC • Supplier Quality Mgmt • Risk Mgmt • Non-Conformance Mgmt • CAPA • Compliance Mgmt • Calibration Mgmt • EHS • APQP/PPAP • Performance Mgmt • Reporting/Dashboards/ Analytics 	<ul style="list-style-type: none"> • Supplier Quality Mgmt • Calibration Mgmt • Dashboards / Analytics 	
Company Size	<ul style="list-style-type: none"> • Small (<\$250 Million Revenue) • Medium (\$250 Million – \$1 Billion Revenue) • Large (> \$1 Billion Revenue) 	<ul style="list-style-type: none"> • Medium (\$250 Million – \$1 Billion Revenue) • Large (> \$1 Billion Revenue) 	
Geography Served	<ul style="list-style-type: none"> • North America • Europe • Asia/Pacific • South / Central America • Australia / New Zealand 	<ul style="list-style-type: none"> • North America 	
Technology Development Platforms	<ul style="list-style-type: none"> • Delphi 	<ul style="list-style-type: none"> • Delphi 	<ul style="list-style-type: none"> • JAVA • HTML5 • Web Services
Technology Delivery Model	<ul style="list-style-type: none"> • Web UI, optimized for mobile • On-Premise • Cloud, Single tenant • SaaS 	<ul style="list-style-type: none"> • Thick client • On-Premise 	<ul style="list-style-type: none"> • Web UI, optimized for mobile • Cloud, Single tenant • SaaS

ZenQMS

Founded in 2010 and based in Conshohocken, PA, ZenQMS offers the SMB market a scalable, exclusively Cloud SaaS solution that focusses on a core set of QMS processes. The application is aimed directly at but not restricted to Life Sciences manufacturers. One of the first of what is likely to become a wave of enterprise scalable Cloud EQMS providers, ZenQMS makes it very clear that it is focused on a core set of traditionally paper-laden processes including Document Management, Issues (NCs)/CAPA, Training Management, Audit Management, and Supplier Management.

The ZenQMS team is modest in size (25-50 employees) and aims to disrupt the traditional expensive to scale EQMS model with a SaaS alternative featuring a novel approach to pricing openly described on their website. The company does not charge based on user or site, which simplifies deployment and encourages broad system usage. Smaller, organizations ready to graduate from manual, paper-based systems are their current sweet spot, although there are some Medium sized customers as well.

The company's focus on critical processes has resulted in a very modern, and Responsive Design UI. The UI is, like many larger EQMS providers' solutions, equipped with very flexible grid views. Given the market the application is aimed at, it comes as no surprise that reporting is limited, in fact the tabulated record lists and a dashboard with Windows10-like tiles are the extent of this, although the ability to easily export all data to Excel is helpful.

Best practice workflows ship as part of the solution and fields can be configured to suit. ZenQMS provides deployment services to support that configuration, as well as to perform other implementation tasks including data migration and training.

The Responsive Design should accommodate most mobile platforms but this is not offline capable at this time. A number of useful features like PDF rendering, approvals that are both serial and broadcast and geo-referenced supplier locations are included. The provision for validation in FDA regulated scenarios is strong with IQ/OQ managed for the customer.

Since our initial meeting with the company last year the application has had two major releases addressing document collaboration, rest API, new security features (2FA) and local account backup. Future areas of interest include preventive maintenance, external document sharing and electronic forms (batch records).

ZenQMS would be a giant leap for those using paper-based systems currently but may be outgrown ultimately. It will be important for ZenQMS to mature further in reporting and analytics when as its customer base demands more than compliance management.

ZenQMS should be considered by small-medium businesses (less than 1,000 employees) struggling with the overhead of compliance in quality management activities and are looking for a low-risk, cost effective way to escape a paper-based approach.

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

ZenQMS at a Glance

	Total Coverage Area	Areas of Strength	Emerging Strength
Industry	<ul style="list-style-type: none"> • Medical Devices • Pharmaceuticals • Chemicals • Consulting • Packaging • 	<ul style="list-style-type: none"> • Medical Devices 	
Functionality	<ul style="list-style-type: none"> • Audit Mgmt • Document Control • Change Mgmt • Training Mgmt • Complaints • NC/CAPA • Risk Mgmt • Supplier Quality Mgmt • Reports / Dashboards / Analytics 	<ul style="list-style-type: none"> • Document Control • Training Mgmt • Audit Mgmt 	<ul style="list-style-type: none"> • Supplier Quality Mgmt
Company Size	<ul style="list-style-type: none"> • Small (<\$250 Million Revenue) 	<ul style="list-style-type: none"> • Small (<\$250 Million Revenue) 	
Geography Served	<ul style="list-style-type: none"> • North America • Europe 	<ul style="list-style-type: none"> • North America 	<ul style="list-style-type: none"> • Europe
Technology Development Platforms	<ul style="list-style-type: none"> • .NET • HTML5 • Web Services 	<ul style="list-style-type: none"> • .NET • HTML5 • Web Services 	
Technology Delivery Model	<ul style="list-style-type: none"> • Web client, browser agnostic • Cloud, multi-tenant • SaaS 	<ul style="list-style-type: none"> • Web client, browser agnostic • Cloud, multi-tenant • SaaS 	

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Solution Provider Capabilities and Characteristics: Single View

✓	Have Coverage
✘	Emerging Coverage
	No Coverage

Industry: Batch and Process

Company	Chemicals	Consumer Goods	Food & Beverage	Metals	Mining	Oil & Gas	Packaging	Paper	Pharmaceuticals
Assurx	✓	✓	✓			✓	✓		✓
CEBOS		✓	✓				✓	✓	
Dassault Systemes		✘	✘	✘					✓
EtQ		✓	✓	✓	✓	✓	✓		✓
Harrington Group Int'l	✓	✓	✓	✓	✓	✓	✓	✓	✓
Intelex	✓	✓	✓	✓	✓	✓			✘
IQS Inc.	✓	✓				✓			
MasterControl	✘	✘	✘	✘	✘	✘	✘	✘	✓
MetricStream		✓	✓			✓			✓
Omnex Systems	✘	✘	✘	✓	✓	✘	✓	✓	✘
Oracle	✘	✓	✓			✓	✓		✓
Pilgrim Quality Solutions	✓	✘	✓	✓					✓
PTC		✓				✓			
SAP	✓	✓	✓	✓	✓	✓		✓	✓
Siemens	✘	✓	✓	✓	✓	✓		✓	✓
SOLABS									✓
Sparta Systems	✘	✘	✓						✓
Tip Technologies				✓		✓			
ZenQMS	✓						✓		✓

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Industry: Discrete and Other

Company	Aerospace & Defense	Auto-motive	Consulting	Consumer Goods	Public Sector	High Tech	Industrial Equip Mfg	Medical Devices	Semi-conductor	Telecom	Utilities
Assurx	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
CEBOS	✓	✓		✓		✓	✓	✓			
Dassault Systemes	✗	✗		✗		✗	✗	✓			
EtQ	✓	✓		✓	✓	✓		✓		✓	✓
Harrington Group Int'l	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
InteleX	✓	✓		✓	✗	✗		✗	✓	✓	✓
IQS Inc.	✓	✓		✓		✓	✓	✓			
MasterControl	✗	✗	✗	✗	✗	✗	✗	✓	✗	✗	
MetricStream				✓	✗	✓	✓	✓	✓		
Omnex Systems	✓	✓	✓	✗	✗	✓	✓	✓	✓	✓	✓
Oracle	✓	✗		✓	✓	✓	✓	✓			✓
Pilgrim Quality Solutions				✗			✓	✓	✓		
PTC	✓	✓		✓	✓	✓	✓	✗	✓	✓	✓
SAP	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
Siemens	✓	✓		✓		✓	✓	✓	✓		✓
SOLABS								✗			
Sparta Systems				✗		✗		✓	✓		
Tip Technologies	✓	✓			✗		✓	✗			
ZenQMS			✓			✓		✓			

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Functionality

Company	Functionality																	
	Analytics	APQP	Audit	Calibration	Change	Complaints	Dashboards	Doc Control	EHS	FMEA	NC/CAPA	Performance	PPAP	Reports	Risk	SPC	Supplier Quality	Training
Assurix	✓		✓	✗	✓	✓	✓	✓	✓		✓	✓		✓	✓		✓	✓
CEBOS	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓
Dassault Systems	✓	✓	✓	✗	✓	✓	✓	✓		✓	✓	✓	✓	✓	✗	✓	✗	✓
EtQ	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Harrington Group Int'l	✓		✓	✗	✓		✓	✓			✓			✓	✓		✗	✓
Intelx	✓	✗	✓		✓	✓	✓	✓	✓	✗	✓		✗	✓	✓		✓	✓
IQS Inc.	✗	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓
MasterControl	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓
MetricStream	✓		✓	✓	✗	✓	✓	✓	✓	✓	✓			✓	✓		✓	✓
Omneq Systems	✓	✓	✓	✓	✓	✓	✓	✓			✓		✓	✓	✓		✓	✓
Oracle	✓	✓	✓		✓	✓	✓	✓	✗	✗	✓		✓	✓	✗	✓	✓	✓
Pilgrim Quality Solutions	✗		✓		✓	✓	✓	✓			✓			✓	✓		✓	✓
PTC	✓	✓	✗		✓	✗	✓	✓		✓	✓		✗	✓	✗			✗
SAP	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✗	✓	✓	✓
Siemens	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
SOLABS	✗		✓	✗	✓	✓	✗	✓			✓			✗			✓	✓
Sparto Systems	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗	✓
Tip Technologies	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
ZenQMS	✓		✓		✓	✓	✓	✓			✓			✓	✓		✓	✓

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Company Sizes and Geographies Served

Company	Company Size			Geography Served					
	Small	Medium	Large	Africa	Asia/Pacific	Australia/New Zealand	Europe	North America	South/Central America
Assurx	✓	✓	✓	✓	✓	✓	✓	✓	✓
CEBOS	✓	✓	✓		✓	✓	✓	✓	✓
Dassault Systemes	✓	✓	✓	✓	✓	✓	✓	✓	✓
EtQ	✗	✓	✓	✓	✓	✓	✓	✓	✓
Harrington Group Int'l	✓	✓	✓				✗	✓	
Intelx	✓	✓	✗	✗	✓	✗	✓	✓	✗
IQS Inc.	✓	✓	✓		✓	✓	✓	✓	✓
MasterControl	✗	✓	✓		✓	✓	✓	✓	
MetricStream		✗	✓		✗		✓	✓	
Omnex Systems	✓	✓	✓	✗	✓	✗	✓	✓	
Oracle	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pilgrim Quality Solutions		✗	✓		✓		✓	✓	✗
PTC		✗	✓	✓	✓	✓	✓	✓	✓
SAP			✓	✓	✓	✓	✓	✓	✓
Siemens		✓	✓	✓	✓	✓	✓	✓	✓
SOLABS	✓	✓			✗		✗	✓	
Sparta Systems	✓	✓	✓		✓	✓	✓	✓	✓
Tip Technologies	✓	✓	✓		✓	✓	✓	✓	✓
ZenQMS	✓						✗	✓	

Solution Selection Guide: Enterprise Quality Management Software (EQMS)

Technology Development Platforms and Delivery Models

Company	Technology Development Platforms							Technology Delivery Model								
	Java	.NET	HTML5	Silverlight	Web Services	Accepts 3rd party doc mgmt	Integration Layer	Web Client	Web Client, browser agnostic	Web Client, optimized for mobile	On Premise	Cloud, Single Tenant	Cloud, Multi-tenant	SaaS	Mobile Apps, key modules	Mobile Apps, all modules
Assurx		✓	✓		✓	✓	✓	✓	✓	✗	✓	✓	✓	✓		
CEBOS		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
Dassault Systemes	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓	✗	✗	✗	
EtQ	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓
Harrington Group Int'l		✓	✓		✓			✓			✓	✓	✗	✓		
Intelex		✓	✓		✓			✓	✓	✗	✓	✓	✓	✓	✗	✗
IQS Inc.	✓		✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗
MasterControl	✓		✓		✓	✓		✓	✓	✓	✓	✓		✓		
MetricStream	✓		✓		✓			✓	✓	✓	✓	✓	✓	✓	✓	✓
Omnex Systems		✓	✗	✓	✓	✓		✓	✓	✗	✓	✓		✓		
Oracle	✓		✓		✓		✓	✓	✓	✓	✓	✓	✗	✓		
Pilgrim Quality Solutions		✓	✓		✓	✓		✓	✓	✗	✓	✓		✓	✗	✗
PTC	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓	✗	✓		
SAP	✓		✓		✓		✓	✓	✓		✓	✓		✓		
Siemens		✓	✓		✓	✓	✓	✓	✗	✗	✓	✓		✓	✓	✓
SOLABS	✓		✓		✓	✓		✓	✓	✓	✓	✓		✓		
Sparta Systems	✓		✓		✓	✓	✓	✓			✓	✗	✗	✗	✗	
Tip Technologies								✗	✗	✗	✓	✗		✗		
ZenQMS		✓	✓		✓			✓	✓				✓	✓		

Concluding Thoughts

Quality management plays an important role in every part of the value chain, from product ideation all the way through distribution and customer feedback. Because of the direct impact it has on each of these areas, quality can be strategically utilized as the centerpiece for managing operations. Facilitating an environment for cross-functional communication and collaboration, EQMS is becoming the standard platform for managing quality across operations. The information in this guide is intended to serve as a critical resource for executives at the starting point in their journey toward selecting an EQMS solution. By breaking down vendors by industries served, functionalities, technology delivery platforms, and so on, executives can create a shortlist of potential solutions that meet their needs and expectations. Selecting an EQMS can be a laborious and complex process, however, market leading companies have greatly benefited from the solution's power. LNS Research would be happy to participate in the entire process of selecting a vendor, including confirming which vendors should be on the shortlist, managing the RFP process, and making the final decision. More specifically, LNS Research can help in the following ways:

- Prepare draft RFP document, review, and finalize with client
- Send RFP to approximately 5-7 top vendors and manage all subsequent communications

- Collect all responses and prepare summary report for client executives
- Analyze results in conjunction with client and provide recommendation for choices 1, 2, and 3
- Act as advisor on any subsequent proof of concept projects

For more information on how LNS Research can facilitate the solution selection process or for any questions or comments, please contact us by email at info@lnsresearch.com.

Executives interested in an EQMS implementation may also be interested in the following LNS Research reports:

- [**Benchmarking Your Quality Maturity: Turning a Cost Center into a Profit Center**](#)
- [**Closed-Loop Quality Management: Connecting the Value Chain**](#)
- [**Big Data: Driving Quality Intelligence at the Speed of Manufacturing**](#)