

TRACKWISE TO TRACKWISE DIGITAL CONVERSION GUIDE

Honeywell

Sparta
Systems

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TRACKWISE DIGITAL SOLUTION OVERVIEW

1.0

TrackWise Digital is a quality and compliance solution that offers fully integrated solutions for managing quality, documents, training, complaints, risk and supplier quality.

Built on over two decades of quality experience, TrackWise Digital combines industry-leading quality and compliance best practices with the user-friendly and trusted Salesforce platform. TrackWise Digital is also the industry's first quality management solution with AI-augmented decision-making capabilities, enabling a shift from reactive to proactive quality management.

The agile cloud system can be quickly implemented, updated and accessed anywhere on any device. Quality teams can leverage quality data to strengthen their quality culture and impact company-wide performance with reporting and analytics across all processes.



PROACTIVE QUALITY



Digital Enterprise Quality Management Platform



Intelligent Workflows | AI Insights | Enterprise Visibility

2.1 | CASE FOR CHANGE

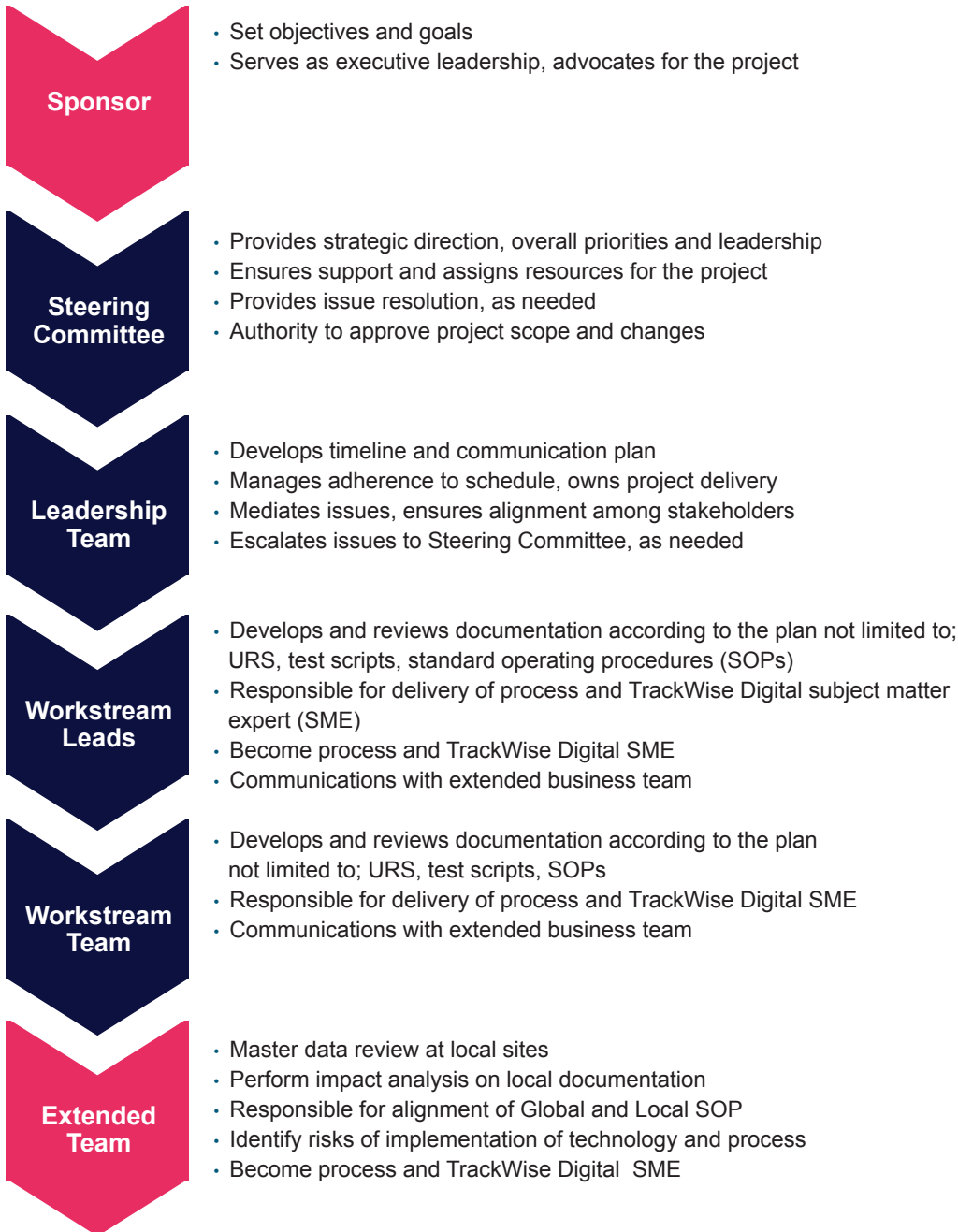
Sparta Systems, a Honeywell company (Sparta) has collaborated closely with the world's leading Life Sciences companies to develop industry best-practice processes for the core quality system capabilities to serve their value chain and patients. These best practice processes are instantiated in the configuration of TrackWise Digital via what we term quality process accelerators (QPAs). As a result, TrackWise Digital is the combination of cloud technology, multi-tenant where you want it to be, and single-tenant where you need it to be; a true Software-as-a-Service (SaaS) platform that delivers a fully managed infrastructure. This allows these processes to be fully validated in the TrackWise Digital platform along with the base functionality of the Salesforce foundation and the GxP-compliant layer on which TrackWise Digital is built.

The success of TrackWise to TrackWise Digital projects has been driven by executive alignment and clear responsibilities defined at the onset. Cross-functional teams are necessary to execute a TrackWise to TrackWise Digital conversion fully.

These teams include:

- Information technology (infrastructure and target/source systems for integrations; legacy data movement); integrated systems managers
- Business (process, site, specialty areas)
- Human resources and training teams
- Computer system validation team

2.2 | DEFINED STAKEHOLDERS AND PROGRAM SPONSORS



3.1 | PROCESS REVIEW EXERCISES

It is recommended to complete an initial assessment to support the migration efforts between a company's TrackWise on-premises quality management system (QMS) and TrackWise Digital, leveraging the predefined QPA. This assessment intends to provide the customer with an analysis of areas in which the current processes differ from the out-of-the-box QPA processes and propose a strategy to address any gaps found during the research.

The QPA assessment methodology and a comprehensive report are developed to be leveraged as input for project-specific plan documents, such as project plan, integration plan, migration plan, validation plan and training plan, as the project moves into future phases.

The discussion points, enhancements and decisions are discussed and validated in this assessment and will be used in subsequent project phases. The multi-tier strategy involves the delivery team and the Sparta Center of Excellence (CoE) and the sales leadership team to determine the appropriate recommendations for the implementation strategy of the TrackWise Digital implementation engagement. The partnership between Sparta and the company for this assessment included understanding the current as-is processes to best align with the out-of-the-box TrackWise Digital products while adhering to the project guiding principles and advising on best practices and efficiencies for the future state.

The QPA assessment is part of a larger strategy that involves data management and archival, integration points and Web Services, and the process assessments. The strategy is developed over time through scoping workshops, including pertinent business partners throughout the client's company. The assessment methodology workflow depicted below provides an overview of the holistic assessment approach to the key deliverables.

3.2 | FORMAL PROJECT PLAN DEVELOPMENT AND AGREEMENT

The statement of work (SOW) is the primary scope document for the project. The SOW is created by the customer engagement manager (CEM) with input from the solution engineer (SE) based on what was shown during the demo and committed during the sales cycle. All appropriate information must be transitioned correctly to the services team. Therefore, the project manager will facilitate the sales to services transition meeting where the sales team will complete and present the appropriate documents/information to the services team, which includes a demo of the system used to show the functionality of the customer.

Changes in scope must follow the change management process and be communicated to all appropriate stakeholders and any impacts on the project budget and timeline.

3.3 | DOCUMENTATION CHANGE PLAN

Guidance and appropriate planning will be necessary across business units to plan for the software change within the quality unit and other impacted areas. In addition to the software development life cycle (SDLC), the change plan will establish a transition plan in correlation to the go-live strategy for procedures, work instructions and other quality management documentation impacted by the TrackWise to TrackWise Digital conversion.

3.4 | VALIDATION STRATEGY DEVELOPMENT

TrackWise Digital has been thoroughly tested internally according to the Sparta SDLC procedures. Sparta conducts formal QA testing and documentation processes before the product is released. As a matter of course, we fully expect the client's QA/IT team to go through its validation process in its configuration and implementation of the product. Sparta recommends performing validation by FDA Guidance and GAMP guidance for configurable off-the-shelf applications. Validation of TrackWise Digital is available and in compliance with FDA requirements for life-science companies and 21 CFR Part 11 and EU GMP Annex 11.

According to the acceptance criteria set during the design phase, the system is qualified for production usage in a pre-production (validation) environment. The locked design configuration will be migrated to the validation environment to evaluate the BTG validation team. During this phase, discrepancies or issues reported from the qualification of the system will be discussed by Sparta and the client, agreeing with the corrective course of action for the client to approve and sign off the designed products' acceptance.

A TrackWise Digital subscription includes a base validation package, which contains the FRS, URS, IQ, OQ, and validation plan used by TrackWise Digital to validate our applications. Depending on your validation and risk strategy, the client may opt to use our validation package and evidence as to your base documentation and test only the configuration enhancements you make. TrackWise Digital provides updates to the validation package for all enhancement releases.

3.5 | TRAINING STRATEGY DEVELOPMENT

This training strategy aims to ensure that personnel using the TrackWise Digital (TrackWise Digital) software and the associated quality processes have sufficient education, background, training, and experience to ensure that all activities required by their role are correctly performed. This strategy shall establish procedures for identifying training needs and ensuring that all personnel are trained to perform their assigned responsibilities adequately and how this training will be documented.

Sparta Prerequisite for TrackWise Digital (12 hours)

- Salesforce platform basic
- Data management
- User engagement
- Data modeling
- Salesforce mobile app
- Reports & dashboards

A Salesforce admin best understands how to make the platform work for their company's unique needs. Some companies may employ many people in this role. A Salesforce administrator's colleagues can rely on them to:

- Maintain the platform
- Make it as easy as possible for users of any technical level to use Salesforce
- Stay updated on the platform's new tools, capabilities, and updates

Sparta recommends that designated administrators continue to take the following Salesforce Trailhead courses and prepare for the administrator certification exam. Administrators will be granted Salesforce training orgs as part of the Trailhead. The training orgs will be available to them throughout their training cycle. TrackWise Digital users will be given access to a designated sandbox org for the duration of the training only.

Admin Beginner | Salesforce Trailhead (20 hours)

- Salesforce platform basic
- Data management
- User engagement
- Data modeling
- Salesforce mobile app
- Reports & dashboards

Admin Intermediate | Salesforce Trailhead (20 hours)

- Formulas and validation
- Picklist administration
- Data security
- Salesforce flow for automation

Trail – Study for the Administrator Certification Exam (self-study)

Trailmix – Prepare for your Salesforce Administrator Credential (self-study)

Once this core training is completed, Sparta recommends TrackWise Digital training.

These trainings are categorized by module (platform, EQMS, complaints, etc.). It is recommended that platform training be completed first, followed by process-specific modules. These live sessions are designed to accommodate questions and interact with the instructor. The instructor will conduct a complete walk-through of the entire module and provide hands-on learning tasks.

CAPABILITY DETERMINATION

4.0

Solutions engineering run workshops where we leave a sandbox with a client to review internally for a short time.

The preliminary workshops are completed to ensure the client teams understand basic software functionality. When extended proof of concept studies are needed to ensure that client teams are comfortable with the product, a sandbox may be issued by services to pilot limited configuration for the client to test and enable decision making for future project phases.



5.1 | DEVELOPMENT OF PROGRAM ROADMAP

During initial discussions, the client business teams are engaged to understand the building blocks for the project plan. These include processes in scope and the order or focus areas that would be appropriate for project phasing either by process or business unit.

Sparta leverages the industry-standard Agile methodology to create a practical, modified Agile approach for project implementations. The implementation lifecycle practices accelerate implementation time using successive, rapid design sprints and showcases, encouraging all project stakeholders to see, comment and refine the design before system finalization.

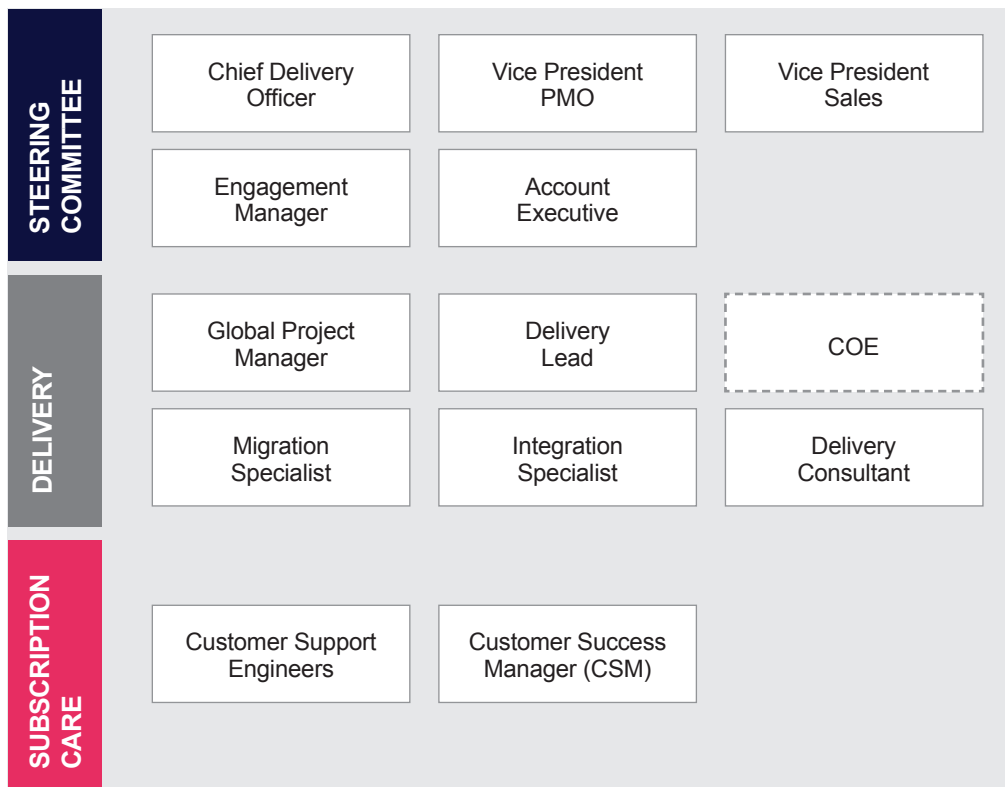
Sparta takes an interactive approach to development, working with the client team throughout the sprint to further refine requirements and allowing hands-on early testing of completed work items before the sprint Showcase. Upon completing all development sprints for a module, Sparta will demonstrate the final design and confirm meeting all approved in-scope specifications.

A sprint is a timebox in which the development team will deliver the goals of that sprint. Sprints include mechanisms for requirement (user story) uptake and refinement, solution development/implementation, review and acceptance. Once a sprint has been completed, the design is locked to proceed to the subsequent implementation phase. Any changes or follow-up tasks related to a completed sprint are added to the next sprints as new user stories, bugs, or tasks.

An epic is a method of grouping user stories to form a larger story. Assigning user stories to an epic allows for better organization. Epics can span more than one sprint; user stories are given and completed within individual sprints.

5.2 | GOVERNANCE PLAN

Every project will leverage Sparta's team and governance structure (illustrated below). The project will be supported, but the Sparta PMO and Executive Sponsor will also serve as escalation points for the team and the customer. The escalation path is defined by the structure illustrated in the project management framework and the image below.



5.3 | RISK AND ISSUE MANAGEMENT (RAID LOG)

The global project manager is also accountable for managing project risks such as resource constraints, adjusted deliverable dates, and budget/schedule/scope issues. The global project manager will partner with the project manager (or designee) to establish risk mitigation (preventative and corrective) steps and appropriately manage and close each risk by leveraging the RAID log. The RAID log is a project planning tool for identifying key (R)risks, (A)assumptions, (I)ssues, and (D)dependencies. At the beginning of the project, the global project manager identifies events, activities, and individuals that will or could impact the successful completion of the project. Risks are to be communicated to the appropriate levels.

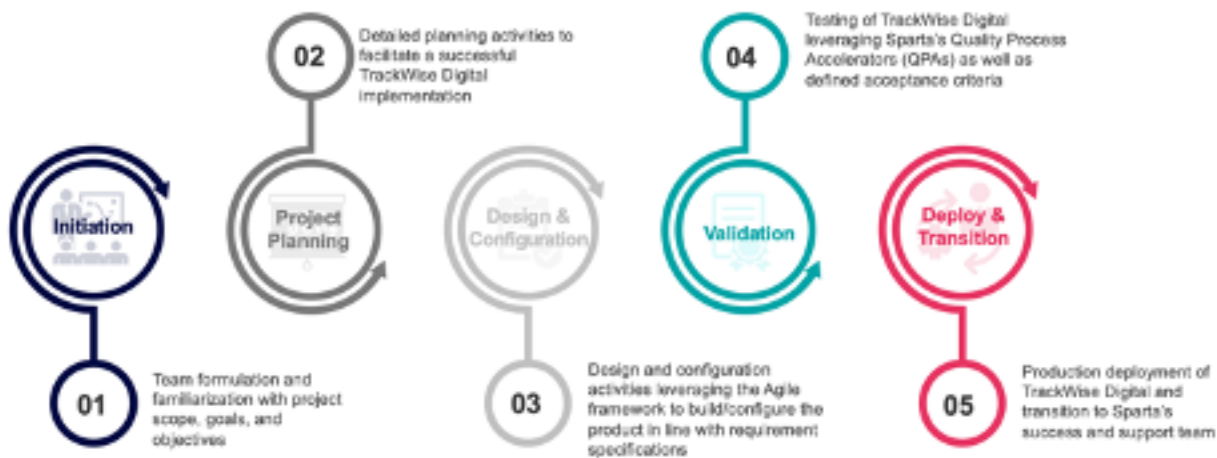
5.4 | DEVELOPMENT OF PROGRAM TRACKING TOOLS

The project manager is accountable for managing all aspects of the implementation lifecycle with support from the project team and internal cross-functional teams. The project manager will ensure that all prerequisites and deliverables are met to traverse through the various phases of the implementation lifecycle. In addition, the project manager will leverage the implementation lifecycle deck during the Initiation phase to help the customer understand our implementation methodology and set and manage expectations for both parties.

Dashboard reporting within Salesforce shall be completed for regular reviews to include a high-level overview of project health for PMO oversight.

The project manager will create and manage the project plan to deliver the product per the scope detailed in the SOW and within the allocated project budget. In addition, the project manager will leverage the Project Execution Playbook to ensure that all appropriate project activities are planned/included to facilitate successful implementation and enhanced customer experience. In the event of any changes in scope, the project plan will be updated accordingly, re-baselined with the customer and adequately communicated to appropriate stakeholders.

5.5 | DEVELOPMENT OF PROGRAM TRACKING TOOLS



5.6 | CENTER OF EXCELLENCE OVERSIGHT

A COE technical review aims to build quality by leveraging best practices and providing guidance for consistent, reliable and predictable results from each deployment. The functional requirement session drives feasibility, constraints, sizing issues and other development needs – the sales to service handoff coincide closely with the start of gathering requirements. If a model is available, it can be reviewed at this time. Technical design review and technical assessment occur after requirements are determined and a design is reviewed. The technical test and validation reviews appear after all configuration and development are completed but before validation. Finally, postmortem reviews occur after the business go-live to support the lessons learned discussion and customer success transition. The project manager will ensure that design reviews are appropriately scheduled for all projects and if support is needed during a phase, ad hoc reviews are scheduled. For further information, refer to the COE Implementation Review Work Instruction.

5.7 | COMMUNICATIONS PLAN

The global project manager is accountable for leveraging suitable communication protocols throughout the project.

- **Project Status** – The project manager will provide weekly status reports that include project scope, schedule, and budget updates. It will also include burndowns, etc. In addition, ad hoc communication will be provided as required.
- **Meeting Minutes** – The project manager is responsible for providing meeting minutes to accurately capture the topics discussed during the meeting and ensure alignment on the following steps/action items.
- **Executive Sponsor/Leadership Reviews** – The project manager will coordinate with the customer to schedule monthly reviews to provide visibility into project status and challenges for the executive sponsors to assist with critical decision-making and remove roadblocks and impediments for the team.
- **Business Reviews** – Post-implementation strategic partnership reviews.

5.7 | KNOWLEDGE TRANSFER APPROACH

Knowledge transfer from the Sparta team to the team will be scheduled at the end of the project before going live. The knowledge transfer will include the following topics with additional information discussed during the subsequent project phases.

- Overview of the top-level design and workflows
- Configuration review
 - Workflow rules
 - Custom objects
 - Scheduled actions
 - Automation
 - Configuration workbooks
- TrackWise Digital Setup for Business Admins
 - User setup
 - Audit trail
 - Report templates
- Interface Overview
 - End-user features
 - Backend setup
 - Technical components
- Any other customizations

6.1 | VALIDATION

Focusing on Sparta's SaaS Service, TrackWise Digital, we provide our customer validation packages that satisfy both sides of the Double V from the Validation V Model. Sparta provides its customers with individual validation packages that support the TrackWise Digital Platform and one for each solution. This allows customers to focus their assessment and deployment without unnecessary noise addressing features they don't use. It also limits the cross-functional impact that system-wide updates could cause. Sparta also provides the same offering for each QPA, which provides customers with productized configuration, allowing for accelerated deployments of our most commonly used configuration. While no customer ever uses a system completely as-is, this offering significantly reduces the cost and risk of deploying a new QMS.

As mentioned, Sparta provides customers with validation documentation that covers all of the TrackWise Digital solutions and the QPAs themselves. This allows flexibility in how you decide to implement your system, be it as a QuickStart where you are closely aligned to the provided QPAs or as a highly customized solution. Regardless of how you choose to proceed, there are a couple of items to keep in mind:

TrackWise Digital Solution requirements do not change as part of an implementation.

- This means that no active validation tasks are required for TrackWise Digital platform and platform solutions (EQMS, Complaints, DMS, etc.).
- Sparta provides the IQ/OQ validation packages covering all base system functionality.

QPA Requirements are used as a starting point.

- A gap analysis should be conducted between corporate policies and procedures and the QPAs
- Identified gaps are reviewed for feasibility and impact on the current design
- Requirements are changed or appended based on the customer's SDLC
- Once you begin a deployment based on a QPA, you are no longer implementing that QPA, but a customer-specific version of that QPA

6.2 | PROJECT TRANSITION FROM SERVICES TO SUCCESS

Internal knowledge transfer from the project team to the customer success and support team occurs as the validation is brought to a close. In addition, knowledge transfer shall extend to the client administrators responsible for the TrackWise Digital system after deployment. The project manager and CSM shall maintain management and confirm validation activities through business go-live.

Cutover

The project manager will ensure that the project team and the customer are jointly ready for go-live and ensure that the Sparta Command Center is stood up and prepared to support the production deployment.

- Review/complete checklist of prerequisites
- Production org deployment
- Setup and validate integrations
- Complete initial data import, migration activities and SSO
- Customer checkout and go-live confirmation

Transition to Support/CSM

Approaching the project's conclusion, the customer will be transitioned from the project team to Sparta's customer support and success team. The project manager will schedule the "Welcome to Support" meeting. The transition to Support/CSM is critically important to ensure the proper closeout of the project. It also provides a seamless experience for the customer and instills confidence that they'll be supported appropriately post go-live. A few critical aspects of the transition are:

The customer

- Needs to understand who the Sparta points of contact are for various items
- Needs to understand Sparta's support model and expectations

CSM/Support

- Need to understand what's been implemented and any pertinent information about the project/pain points/known issues
- Need access to the project documentation folders
- Need the completed transition to support document

TRACKWISE RETIREMENT STRATEGY

7.0

A retirement assessment should be conducted to support the transition efforts for decommissioning a company's legacy system(s), including TrackWise on-premises QMS.

This assessment intends to provide an evaluation that delineates the respective elements to be considered for decommission planning included in the larger strategy that involves Data Migration, Data Archival and Infrastructure evaluations.

Upon completion of the retirement assessment, the decommissioning roadmap is established and accounted for within the program timeline. It is considered in the total cost of ownership and implementation lifecycle.

GET IN TOUCH

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Sparta Systems, a Honeywell Company, is the world's premier provider of cloud and on-premises quality management software. For nearly three decades, companies in the life sciences have relied on Sparta for the innovative tools, analytics and expertise that speed up quality and compliance.



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