



STARLIMS



STARLIMS Integrated Solution and Professional Services

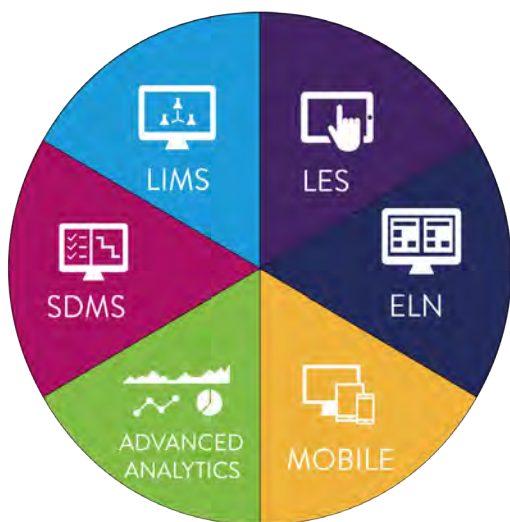
From R&D to Manufacturing to Quality Compliance, our informatics solutions support your entire product lifecycle.



THE INTEGRATED SOLUTION

To compete successfully in today’s crowded global marketplace, your business must offer top quality, safe products and services. But complying with industry regulations and staying competitive and sustainable means facing challenges. From the need to streamline processes to save costs, to pressures to reduce energy, water and resource use, every business expects to maximize efficiency and value from investments in hardware, software, raw materials and resources. And whatever your field, you need the assurance of process transparency, traceability and compliance across your whole organization.

It’s a tall order. It’s why we developed STARLIMS.



Your customers expect quality products, services and results. You should expect the same from your Laboratory Information Management System (LIMS). We developed STARLIMS informatics solutions to simplify the complexity of your entire product lifecycle management process. Easy-to-use and adaptable to your organization’s needs, STARLIMS solutions support data management needs across your organization. With STARLIMS solutions your data is safe, accessible and insightful to support mission-critical decisions.

STARLIMS lets you seamlessly collect and collate, share and analyze data to drive development that will take your businesses to the next level. Our solutions offer opportunities to improve processes, identify bottlenecks and minimize delays, so that you can bring high quality and safe products to market faster.

Fig. 1 - Optimize data management accessibility and integrity with our single platform

Whether you work in a single lab, operate multiple manufacturing plants, or share your sensitive data on research and development (R&D) with collaborators across the globe – your processes and data define your next directions.

STARLIMS offers the functionality to support operational excellence. Interface with your existing software systems, automate and standardize your procedures and workflows across your organization to meet regulatory requirements.

From sample tracking and lab test scheduling, to results reporting and certificates, STARLIMS automates key data workflows and offers complete audit trails for your data, so you can ensure its integrity.

STARLIMS is also flexible and user friendly. Configure features easily to meet the needs of one or more sites. Set permissions to make sure that only qualified staff can authorize key processes or view and amend critical data. Do not lose a result, misplace a report, or forget to pass on important information.

Maximize the knowledge, experience and innovation of all your people. STARLIMS reduces manual data tasks, errors and repetition so that your most valuable assets can get on with the job of making your business grow.

WHAT STARLIMS WILL DO FOR YOU

- Perform resource and test planning.
- Consolidate product sample data and documentation.
- Produce flexible reports as well as Certificates of Analysis (CoA) or General Certificates of Conformity (GCC) for product and/or samples that meet specifications.
- Analyze trending, support testing standards and compliance efforts, e.g. International Conference of Harmonization (ICH), United States, Japanese, European Pharmacopeias (USP, JP, EP) and others.
- Support compliance with FDA 21 CFR Part 11, EMEA Annex 11, ISO 17025, ISO 9000, Good Manufacturing Practice (GMP), Consumer Product Safety Act (CPSA), and other regulatory requirements and best practices

WHAT YOU CAN DO WITH STARLIMS

- Manage your data by exception rather than reviewing results that are nominal
- Automatically flag and immediately compare results in real time against defined specifications for immediate response
- Fully trace your lots and your inventory using built-in features such as lot genealogy and chain of custody support improving regulatory compliance
- Manage and track auditable electronic records
- Derive an integrated picture of every laboratory resource taking part in a specific analysis (scientists, equipment and standard operating procedures)
- Manage your product development data
- Create your protocols, studies and have visibility into when and what needs to be pulled and tested
- Manage your product shelf life (Stability Management)
- Perform trend analysis and process control charts

ABOUT US

Our focus is not on who we are, but on what we do. And since 1987 we have worked continuously to ensure that our informatics solutions help our global customers respond to their day-to-day challenges and succeed in their markets.

Our Quality Management System is established to meet the requirements of ISO 9001:2015 and ISO 13485:2016 from the BSI certification organization for the design, development, realization and implementation of laboratory information management products and medical devices. We also operate an Information Security Management System which complies with the requirements of ISO/IEC 27001:2013.

For more than 30 years STARLIMS has helped hundreds of laboratories and organizations around the world to increase cost savings and productivity, decrease turnaround times and fuel growth.

These are the industries that we serve:

-  Pharmaceutical & Biotech
-  Food & Beverage
-  Chemical
-  Automotive
-  Environmental Science
-  Clinical Research
-  Biorepositories
-  Forensics

SECURE, CONFIGURABLE, USER-FRIENDLY

Our powerful LIMS sits at the center of the STARLIMS Integrated Solution. Integrate with our Laboratory Execution System (LES), Electronic Laboratory Notebook (ELN) or Scientific Data Management System (SDMS), and enrich your operations with advanced analytics and mobile features.

STARLIMS LABORATORY INFORMATION MANAGEMENT SYSTEM (LIMS)

FAST DEPLOYMENT FOR YOUR INDUSTRY

With preconfigured industry-specific features and capabilities, STARLIMS can get your LIMS solution up and running quickly.

COMPLETE LIFE CYCLE MANAGEMENT

STARLIMS goes beyond data management. Our LIMS is a smart solution that improves quality and safety throughout the entire product lifecycle. From R&D to manufacturing and compliance, STARLIMS lets you configure workflows for a wide range of development projects and laboratory processes.

Designed by industry experts, STARLIMS is configurable to match your workflows and standards, whether for research and development, quality assurance, quality control or testing and monitoring.

INSIGHT AND ANALYSIS

STARLIMS provides valuable data and analysis insights at every stage in your processes. Powerful data visualization features and analytics tools empower you to make confident decisions.

VERSATILE LABORATORY INTEGRATION

STARLIMS offers the versatility to meet the needs of different laboratories, without time consuming programming, custom coding or complex configurations.

Interface STARLIMS with your measurement and analytical systems and take data straight from your instrumentation into the LIMS.

GET PRODUCTS TO MARKET FASTER WITHOUT COMPROMISING ON QUALITY OR SAFETY

POWERFUL DECISION-MAKING TOOLS

Oversee your lab workflows with intuitive dashboards. Search across multiple datasets quickly to understand and react to emerging trends or find ways to improve product quality, workflows and resource planning.

QUALITY AND SAFETY

Built in audit trails, electronic signatures, and chain of custody simplify the quality control process by ensuring that SOPs and business rules are being followed.

STARLIMS has been designed to help organizations comply with a wide range of different regulatory standards, including FDA 21 CFR Part 11 and the EU Annex 11 guidelines, ISO 17025, ISO 13485, ISO 9001, and cGxP.

LOGISTICS AND TRACEABILITY

Leave day-to-day operations management to the LIMS. STARLIMS can help manage product inventory, storage capacity, analyst training and certifications. Our LIMS supports flexible order management, resource and test scheduling, equipment management, qualification and reporting and data analysis tools. And all this backed by comprehensive audit trails and electronic signatures.

INTEROPERABILITY

Data sharing across systems is easy. STARLIMS can interface with enterprise systems, such as SAP, Empower, and Chromeleon, and with your internal business-specific software.

SEAMLESS UPDATES

STARLIMS is a multi-tier solution with independent technology, data, and business layers. Updates can be made to one tier without interfering with the others. This reduces risks, lowers the cost of ownership, and simplifies validation needs.

HTML5

STARLIMS Integrated platform supports Google Chrome browser for the HTML5 compatible forms and IE browser for the traditional STARLIMS XFD compatible forms related to third-party integrations that are not still available in HTML5 format.

REQUEST MANAGEMENT PORTAL

Manage your customers' requests for testing. STARLIMS Quality Manufacturing solution provides a single point for collaboration and exchange of information such as results and Certificate of Analysis (CoA). The Request Management Portal allows your customers to create and submit test requests directly to a Contract Lab (internal STARLIMS users) – submit material tests, approve, reject and request more information. Our Request Portal allows customers to track the progress of their requests at all times.

SAP S/4 HANA INTERFACE

We have certified STARLIMS Quality Manufacturing Solution with SAP S/4 HANA. The STARLIMS interface with SAP S/4 HANA is an extension of our existing interface with SAP QM-IDI and ESS. The interface allows the mapping and exchange of information between the two solutions.

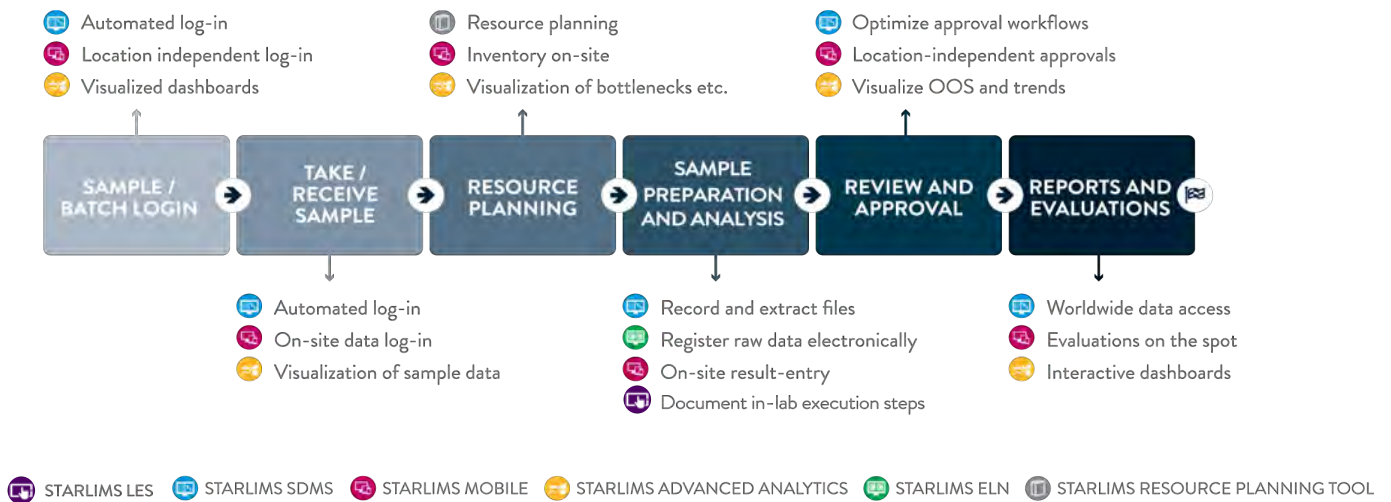


Fig. 2 - STARLIMS-support along your workflow

LES

Easily document important method execution steps at the moment they are performed (in-lab execution). STARLIMS Laboratory Execution System (LES) helps to ensure Standard Operating Procedures are being followed, avoiding transcription errors and paper-based inefficiencies.

EFFICIENT, ACCURATE AND COMPLIANT IN-LAB EXECUTION

Laboratory processes are nowadays still often documented on paper. Even in laboratories that have implemented software solutions like a LIMS, this sometimes happens because the software cannot be conveniently accessed on touchscreen devices that can easily be operated by the lab technicians without disrupting their daily routines.

With the STARLIMS LES (Laboratory Execution System), lab users can easily document their work at the moment they are executed (in-lab execution). This helps to ensure Standard Operating Procedures (SOP) compliance, improves efficiency, prevents transcription errors, and can make some otherwise required peer-review steps in GxP regulated environments unnecessary.

EASY ADOPTION BY LAB PERSONNEL

With an intuitive, touch-screen user interface, lab technicians training is simplified, and they can rapidly start using the solution.

PAPERLESS LAB APPROACH

STARLIMS LES can support organizations working towards a paperless lab approach, minimizing transcription errors and paper-based inefficiencies.

SUPPORTS DATA INTEGRITY

With STARLIMS LES, the required validation checks can be performed: data integrity is supported by ensuring that only the right equipment (within maintenance), lab personnel (certified individuals) and materials (within expiration) are being used.



Fig. 3 - LES module

ELN

STARLIMS Electronic Laboratory Notebook (ELN) offers a powerful electronic replacement for paper lab notebooks and other homegrown solutions for recording lab data across your whole organization. The easy-to-configure user interface provides a flexible canvas to capture and store all your experimental and laboratory data in standardized formats.

INCREASE EFFICIENCY, REDUCE ERROR RATES AND REPETITION, AND PROMOTE REGULATORY COMPLIANCE

STARLIMS ELN enables full traceability and features electronic signatures, so you can maintain compliance and adhere to record retention policies across your organization. Make it easy for everyone in your lab to use the same methods, adhere to SOPs and recording and reporting requirements, so you can compare results and experiments and get maximum value from your data. Our ELN features method execution instructions alongside data entry screens to ensure consistency and reproducibility, and reduce the need for unnecessary duplication or repetition. The easy-to-use interface is similar to standard Microsoft Excel spreadsheets.

Configure STARLIMS ELN to run verification checks at the end of each workflow stage, so you can be confident that your results and analyses can be relied on to drive critical decision making.

- Use your lab's existing templates and formulas.
- Record structured or unstructured data and attach files, annotations, diagrams, charts and tables.
- Interface with simple and complex analytical and measurement instruments to capture results directly.
- Check for missing, erroneous or out of specification data.
- Automatically route data entry, approval and release data to relevant departments or individuals.

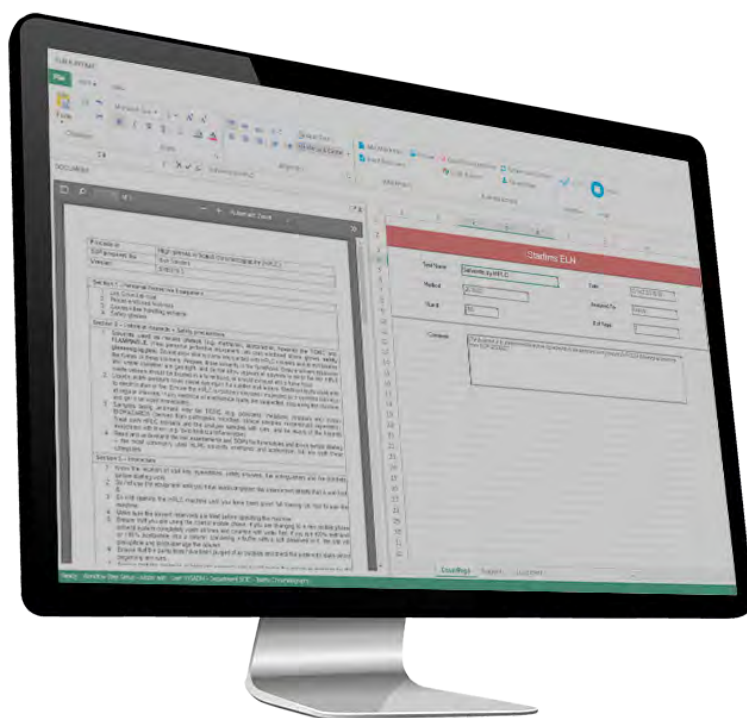


Fig. 4 - ELN module

SDMS

STARLIMS Scientific Data Management System (SDMS) will change the way you manage and process data across your organization. Acting as a central repository for scientific data, SDMS seamlessly integrates with the complete STARLIMS Integrated Solution, so you can access all your laboratory data from a web browser, virtually wherever you are in the world.

KEEPING IT TOGETHER

Easy to set up and configure, STARLIMS SDMS makes it easy and safe to organize, review and share information across a business, either locally or globally. With all your data stored within SDMS, you can be sure not to misplace or lose those important results or reports.

- Manage a wide variety of documents and data files, from written documents and reports to raw instrument data.
- Pull in unstructured data from measurement or analytical devices.
- Use powerful search capabilities to locate any record instantly, whenever and wherever you need it. Search by keyword, metadata, and free text to find files and results, wherever they are.
- Back up and store raw data indefinitely.

FAR MORE THAN JUST A REPOSITORY

Interface STARLIMS SDMS with your equipment to acquire analytical results automatically and reduce manual data entry and errors.

Make the most of unstructured data. SDMS features parsing and recognition capabilities that can transform unstructured file types into searchable data, with keywords, graphs and data tables.

AUTOMATE FILE PROCESSING AND APPROVALS

The SDMS Grabber automatically picks up and processes new files from designated locations so nothing gets left behind. Save time by creating approval processes for standard operating procedures (SOPs), test methods and other document types efficiently and with full traceability, without relying on potentially fallible paper trails. Set the system to initiate file approval workflows and data will be routed automatically to the right places and people, without delay.

REGULATORY COMPLIANCE WITH ADDED VALUE

SDMS supports 21 CFR Part 11, encompassing:

- Record creation.
- Audit trails.
- Electronic signatures.
- Data security.
- Data storage in original format.

Add value and cut complexity, handling errors and delays by personalizing the system to comply with your in house rules and practices for data and document approval, retention and archiving.



Fig. 5 - SDMS overview

ADVANCED ANALYTICS

Transform your data into actionable insights. STARLIMS Advanced Analytics solution makes it easy to analyze all laboratory data according to your criteria, so you can improve efficiency, increase productivity, and lower costs.

Advanced Analytics lets you map out your laboratory processes, find bottlenecks and improve laboratory operation across the board. Use the intuitive predictive analysis tools to drill into your data and identify trends and patterns, so that you can make better business decisions, faster.

Create personalized dashboards and colorful visualizations so that you can view and assess your lab operations from a fresh perspective, highlight issues and act proactively. Follow trends over weeks, months or longer to identify patterns.

With Advanced Analytics you can quickly and effectively:

- Answer questions for root cause analysis
- View lab visualizations on smartphones and tablets
- Track performance indicators
- Identify bottlenecks and other causes of performance issues
- Build a business case for new resources
- Recognize new opportunities for improvements
- Follow progress as a result of remedial activity



MOBILE

STARLIMS Mobile Solution lets you stay connected and access all your laboratory data on the move, see and authorize results, workflows and reports, and keep up-to-date with laboratory activities, all in real time. Mobile Apps can also be used in an offline situation and synced back when network connection is restored.

STAY CONNECTED, KEEP TRACK, REDUCE DELAYS, INCREASE PRODUCTIVITY

With STARLIMS Mobile managers have key information at their fingertips when they are away from the lab, so they can make key decisions without delay. Field scientists can enter sample data directly into STARLIMS through their mobiles and tablets at the point of collection, and add GPS data, photos and notes. Lab technicians can use tablets at the workbench to access their samples and enter data when there is no desktop nearby. Warehouse staff can use the barcode scanning function to identify, track and update inventory.

EASY-TO-USE AND DESIGNED FOR TABLET AND SMARTPHONE SCREENS, THE STARLIMS MOBILE APP GIVES YOU KEY STARLIMS DESKTOP FEATURES, IN A TRULY PORTABLE PACKAGE

STARLIMS Mobile offers user-friendly, off-the-shelf templates to get you started without delay. Alternatively, use the HTML5 and Mobile Designer and inbuilt STARLIMS coding features to create custom apps for your organization, for both iOS and Android devices, from the same platform. Deploy your iOS and Android solutions through the STARLIMS Mobile app on the Apple or Google Play app stores.



Fig. 6 - Mobile

LES, ELN, SDMS, Advanced Analytics and Mobile are all key components of STARLIMS Integrated Solution.



PROFESSIONAL SERVICES

We're not just an informatics provider, we're your long-term partner. As an extension of your lab organization, our dedicated team will make sure that your LIMS solution not only meets your lab goals of today, but also supports your lab's future needs.

EXCEED YOUR LAB'S GOALS WITH A DEDICATED PARTNER

Every customer is assigned a team of STARLIMS consultants with capabilities in project management, business systems analysis, technical design, quality assurance, and much more. No matter the size, requirements, or industry that your lab operates in, our Professional Services team will configure a LIMS solution to fit your lab's needs.

A POWERFUL FRAMEWORK FOR THE FUTURE

From reducing costs, ensuring quality, or enabling a paperless lab, our Professional Services team will tailor a solution that supports your lab's goals today and for years to come. Built on the powerful .NET framework, our solutions enable your lab to upgrade to new versions or integrate other technologies and instruments as needed. Mobile, Advanced Analytics, and Cloud Services capabilities ensure that your LIMS streamlines productivity and efficiencies with the up-to-date technologies.

WORLD-CLASS INDUSTRY DOMAIN EXPERTISE

Our team members have an average of 20+ years of prior experience or operational expertise in various domains.

This specialized knowledge helps us determine the optimal system configurations for your lab and meet distinct, industry-specific standards and software regulations.

PROVEN IMPLEMENTATION METHODOLOGY

Our thorough and proven implementation methodology helps ensure that your software implementation happens on time and on budget, with no surprises. Throughout the process, our Professional Services teams will act as a true extension of your lab to ensure a successful implementation.

Our approach consists of the following:

Discovery & requirements definition

We get to know your business from the inside out. First, we'll learn about your goals and business needs. An application training will ensure that your team fully understands STARLIMS out-of-the-box solution.

- A gap analysis and review of your lab workflow and equipment integrations will help us identify areas of improvement and opportunity.
- And finally, alongside your IT infrastructure team and other lab stakeholders, we'll work together to define software requirements and plan for a successful data migration (migration strategy, data source analysis, migration design, implementation and testing, revisions and maintenance).

System installation, configuration & quality assurance

- Using the project plan as a roadmap, our software engineers configure and implement the solution, collaborating closely with your team throughout the process.
- Our development goes through comprehensive quality assurance testing to ensure that your solution is of highest quality.
- Transparency and effective communication is key during this time, so we'll constantly share the project's progress, preview features, and make adjustments as needed.
- Hands-on training will ensure that your team fully understands how to operate and maintain the system for future enhancements.

Validation

- The time and resources required to validate a new LIMS, or even implement an upgrade is a barrier for many organizations. With a tool that automates the process of running test scripts, go-lives of new software implementation will be faster and the execution of regression tests for software upgrades will

be simplified. In addition, with an automated tool, the likelihood of human error during manual execution of test scripts would be significantly reduced.

- With STARLIMS Automated Validation Framework and Testing Kit, the time required to validate a LIMS system in-house will be reduced. If the STARLIMS Quality Manufacturing Solution QM12.2 is not being utilized as delivered out-of-the-box, the test scripts can be modified.

Training & support

- After your solution has deployed, we'll still be here to help answer your day-to-day questions, provide ongoing technical support, and plan for your future needs.
- We offer multiple in-person training sessions in four of our global offices, in addition to online training. Our comprehensive training offerings will ensure that your team is armed with the skills needed to get the most out of your LIMS solution.

Adheres to the following standards & memberships

- GAMP5
- ISO 9001
- PMBOK 2000
- HL7
- ITIL v3
- ASTM International
- Project Management Institute
- American Society for Quality
- International Society for Pharmaceutical Engineering

Our success is your success. We are committed to building long-term relationships with every customer and focused on delivering customer satisfaction and quality results. We are passionate about what we do, and we believe in your lab's work, in whatever environment you are in.

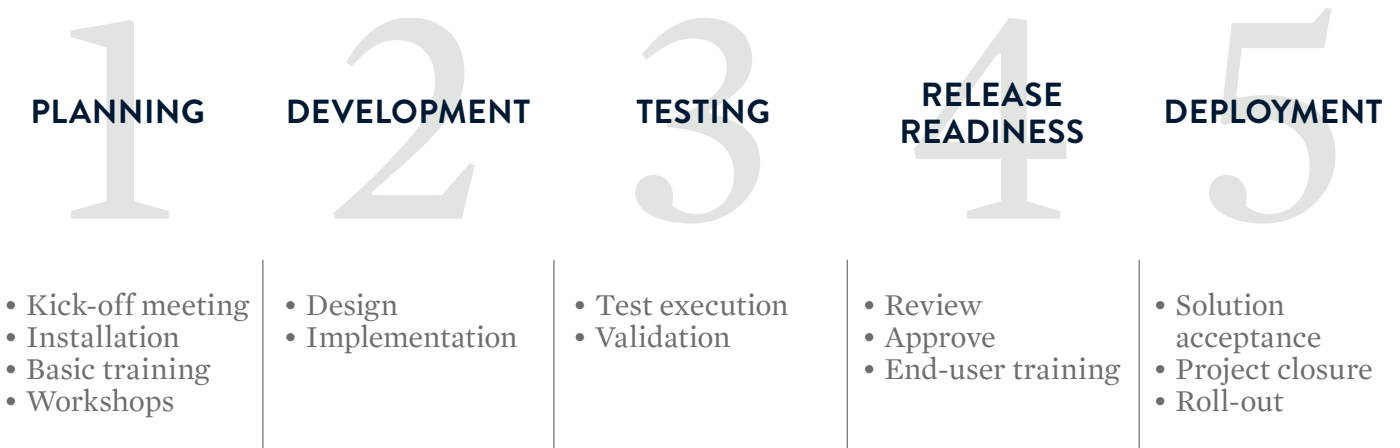


Fig. 7: Professional Services Process - Overview

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