



Ovation LIMS Implementation Methodology

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Implementation Methodology Overview

In this document, we review our tried-and-true Ovation LIMS implementation methodology. While there are certainly unique aspects to every LIMS implementation, we've used our experience to build a roadmap—complete with tools and resources—to manage every implementation efficiently and effectively.

Key Success Factors

There are two key success factors to our approach: **Defined Project Structure** and **Defined Implementation Team**. By adhering to them, we'll remain aligned throughout the implementation with clear goals and expectations, while executing swiftly.

Key Success Factor: Defined Project Structure

In our experience, successful LIMS implementations use a well-defined process with key milestones, set within a manageable timeline and scope. We'll provide a well-defined project plan with phases, deliverables, and checkpoints.

Our methodology follows a four-phase approach that leads to continued lab success:

Kickoff & Planning > Configuration & Functional Testing > Production Build & System Validation > Go-Live

Your lab will be provided with two Ovation LIMS software environments:

- **Sandbox:** For training and practice use of the software. The sandbox environment will be used during the first three phases of implementation and then again if there's a need to modify your configuration. Do not put protected health information (PHI) into the sandbox environment at any time.
- **Production:** For live sample processing. Following your acceptance testing of the sandbox environment, configurations will be transferred to the production environment for final lab validation and will serve as the live environment for sample processing.

The first two implementation phases will happen in the sandbox environment, and the last two phases will happen in the production environment.

Upon project kickoff, our Project Manager will collaborate with your team to create a custom implementation plan with timelines and associated resources. At this point, you'll have already decided on what you want to implement: all of your assays and integrations simultaneously or take a modular approach (deploying a single assay at a time and adding certain integrations later).

Key Success Factor: Defined Implementation Team

It's essential that, for both companies, there are clear roles and responsibilities, escalation paths, and empowered decision makers. Implementation begins by identifying the members of your organization who will serve as part of the implementation team and work closely with Ovation throughout the implementation.

The implementation team will meet regularly for the duration of the project. Not all individuals on the team will be involved in the day to day implementation process, but as the project moves through major milestones the larger group will reconvene to celebrate accomplishments and look ahead to what's next.

Implementation Team

Ovation Implementation Team

You will always have an Account Manager, who will serve as the primary point of contact regarding all aspects of your account with Ovation. During initial implementation or any current open project, you will have an implementation team comprised of members of the Customer Success Team. This includes multiple customer success individuals, but one person may hold multiple roles depending on the volume of projects, type of applications you're running, and more. Our team members have world-class industry domain expertise and their specialized knowledge will help you determine the optimal system configurations for your lab.

The Ovation folks whom we worked with through implementation had a deep level of understanding of what the molecular diagnostic workflows really look like and what the needs are. It felt like we were talking to people who come from the lab, which was a breath of fresh air. With Ovation, what we were communicating was thoroughly understood. Ovation truly appreciated what we were asking and developed the workflow to capture that."

Dr Tariq Adwan, Ph.D.
Chief Scientific Officer
GeneIQ (Ovation LIMS customer)



Key Contacts

Account Manager	Overall relationship manager to ensure continuity and success with Ovation. This is your contact for all things related to business: subscriptions, pricing, quotes for new projects, etc. Once your implementation is complete, they'll conduct business reviews with your account to keep you informed and help your lab evolve and grow.
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Customer Success Roles

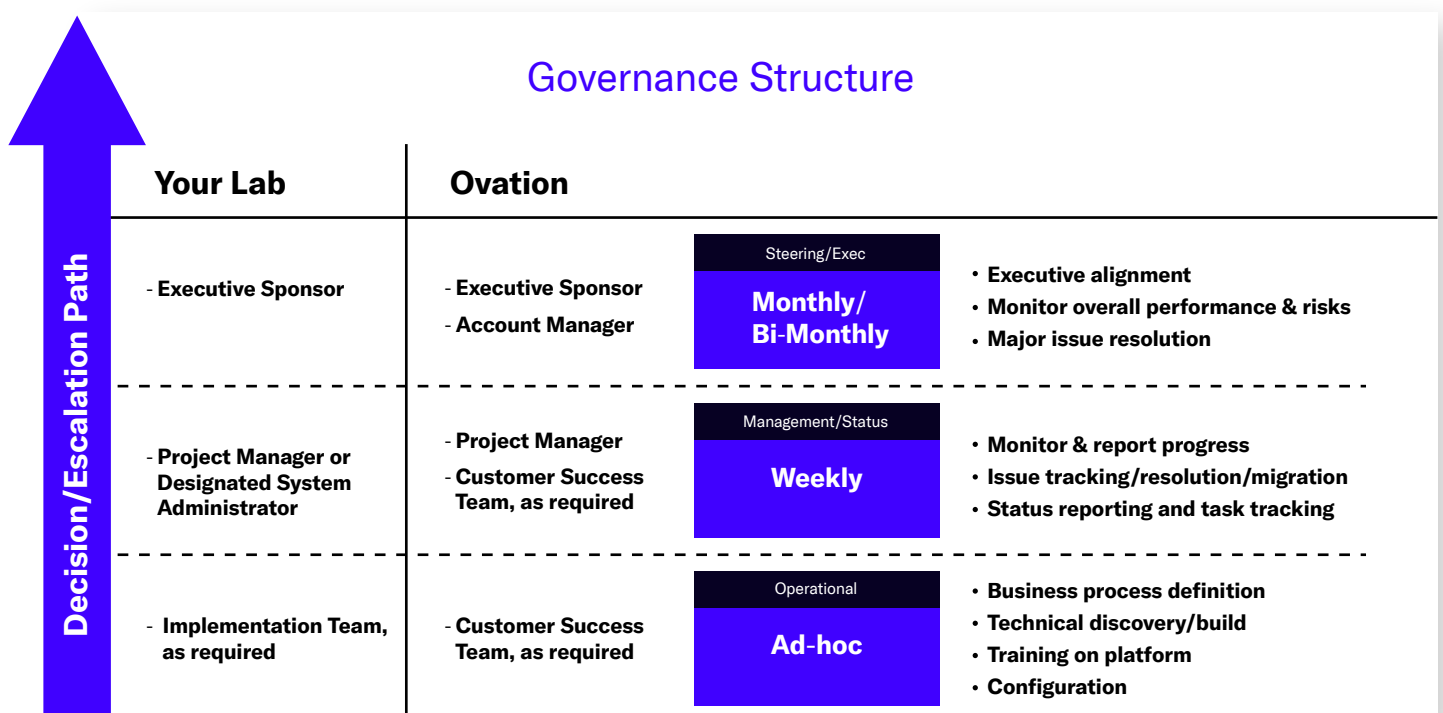
Project Manager	Main point of contact for your implementation; participates in all meetings, trainings, and testing of Ovation LIMS. Brings in additional Ovation resources as needed. They'll also manage any projects that you request after your implementation is complete.
Customer Success Engineer	Responsible for the back-end build of your Ovation LIMS. They're the technical lead on the project and will manage the build of your workflows, and sample routing.
Integrations Lead	Manages any and all integrations with Ovation LIMS. As well as managing coordination with third-party vendor when required for HL7 integrations.
Configuration Lead	Responsible for configuring the Ovation LIMS product that can be adjusted directly in the user interface including roles and permissions, projects setup, plate mapping, loading initial provider accounts, requisition setup, patient report setup and more. They'll be the point person for testing your workflows and report generations after the Customer Success Engineer completes the build of your organization. They'll also take the System Administrators in your lab through training.
Solutions Design Lead	Responsible for the overall design of your workflows based on your stated needs and SOPs. They apply a combination of Ovation expertise and lab experience to create the best possible solutions within Ovation for your lab. They're also your resource for help in designing and executing a System Validation of your Ovation LIMS instance.
Executive Sponsor	Conducts periodic check-ins with your organization's Executive Sponsor; serves as point of contact for your organization to escalate any concerns.

Once implementation is complete, you'll be in great hands with your Account Manager who will provide continued engagement, and the Ovation Support Team.

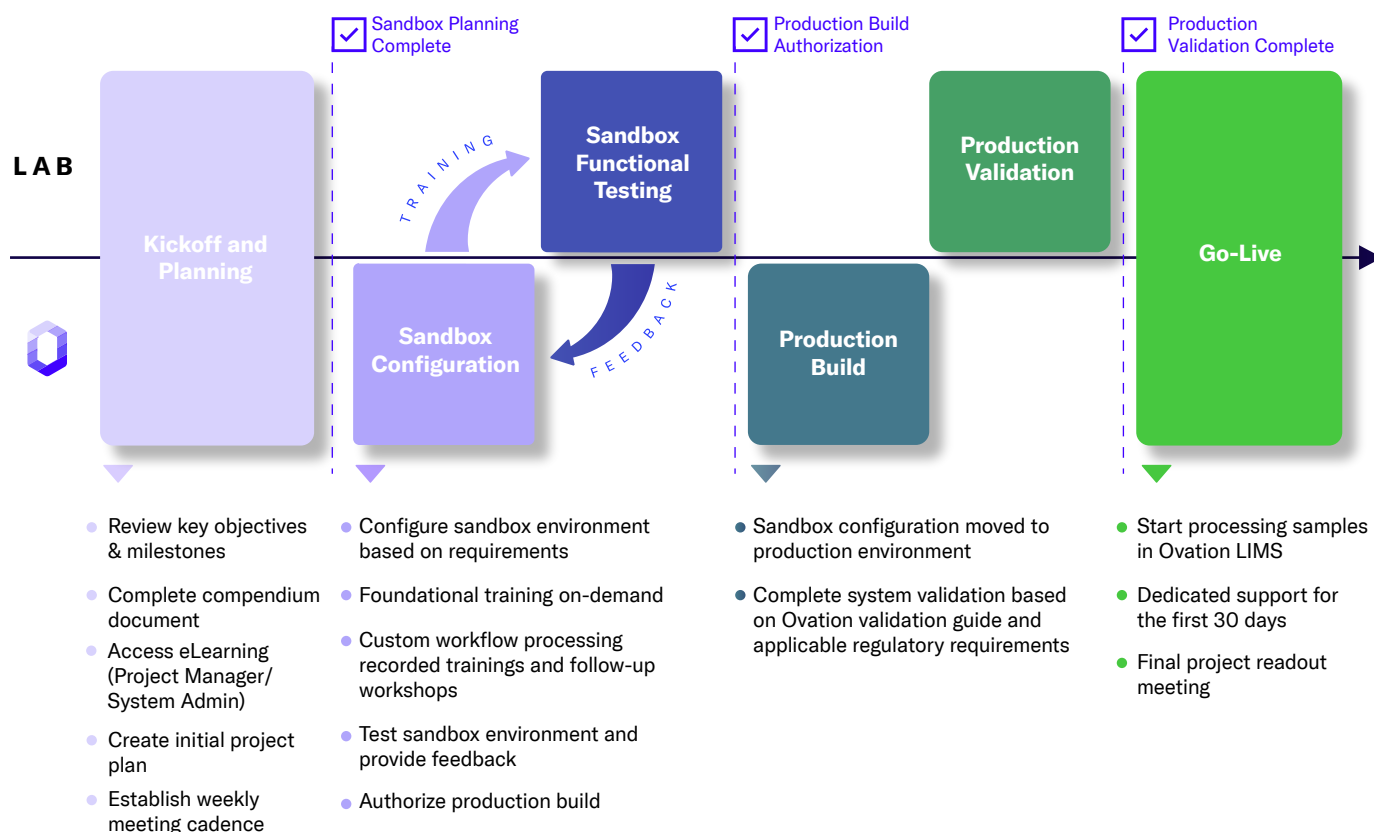
Your Lab's Implementation Team

This will vary depending on each organization's makeup and objectives for their Ovation LIMS. In our experience, a core team of individuals who hold defined roles and have decision-making authority are critical to the success of a LIMS implementation. This includes:

Project Manager	This person will serve as the main point of contact and is responsible for ensuring project deadlines are met. They'll be present for all of the implementation and are responsible for performing testing, performing validation of your production environment, ensuring users have been trained, and responding to requests from the Ovation implementation team.
Executive Sponsor	Conducts periodic check-ins with Ovation's Executive Sponsor; serves as a point of contact within your organization to escalate any concerns. This is typically the person within your organization who signed the Order Form.
Designated System Administrator	In absence of a Project Manager, serves as the primary point of contact.
Technical Contact	This may be required depending on whether your implementation includes third-party vendor integrations.



The Implementation Process



Phase 1: Kickoff & Planning

During the Kickoff & Planning phase, you'll be introduced to your Ovation Project Manager as the project transitions from the sales process to implementation. Your Project Manager will lead a Kickoff Meeting with your team, reviewing the key objectives of the project along with milestones, and implementation expectations.

The Ovation Project Manager will provide your Project Manager with a Compendium document which will be used to provide Ovation with all the foundational information they need to perform initial configuration of your system according to the agreed upon Work Order, in the Sandbox environment. A separate Compendium document will be provided for each third-party integration that is included in the implementation.

Please note that third-party integrations are subject to third-party timelines that the Ovation implementation team cannot always control.

Project Managers or System Administrators will be given access to an eLearning project in their sandbox environment which will help them begin hands-on training immediately.

Once the Ovation Project Manager receives the completed Compendium, the Configuration phase can begin. While we understand that this can take some time to complete, it helps make the implementation ultimately move faster.

The Ovation Project Manager will use what they learn from this meeting and the Compendium document to assemble an initial project plan including concrete timelines, deliverables, and parties responsible.

A weekly meeting cadence will be established to ensure that the team is meeting regularly throughout the project to discuss progress and timeline, and proactively address issues.

Note on change management

During the Kickoff & Planning phase, either your organization's Project manager or Executive Sponsor (someone who champions the project and the benefits Ovation LIMS will bring to your organization) should begin to prepare the organization for change. Clear, regular communication with your staff through the implementation, highlighting the benefits of the product, changes to processes and policies, recent milestones of the project, required trainings, and ways to find more information are key to a successful implementation. You'll want to speak clearly and directly to the concerns that staff members might be having.

Stage Gate: Delivery of completed compendium(s) and examples of all requested data files = Kickoff & Planning complete

Phase 2: Configuration & Functional Testing

Once planning is complete, the Configuration & Functional Testing phase starts.

Sandbox Configuration

The Ovation Implementation Team will configure your sandbox environment based on gathered requirements. Our configuration goes through comprehensive quality assurance testing to ensure that your solution is of the highest quality.

During this process, we'll also work with your team to develop any necessary integrations. Similar to configuration development, our technical leads will work with you to review your integration needs, build the integration, gather feedback, and iterate until it functions as desired.

Stage Gate: Ovation build and initial test of the sandbox environment = Sandbox Configuration complete

Training

Ovation uses a "Train the Trainer" approach, providing instructor-led training to Project Managers and System Administrators on system use and best practices. The Ovation Project Manager or Configuration Lead will provide your Project Managers or System Administrators with a recorded training of your lab's custom workflow processing. They'll then host two hours of live, virtual follow-up workshops with those same individuals to answer any questions or further clarify any concepts.

Prior to viewing the customized recorded training and attending the workshops, Project Managers or System Administrators will need to complete the necessary foundational eLearning. This will allow for the workshops to be more focused on your institution's specific processes.

A full business day of customized training onsite at your organization can also be scheduled for an additional cost.

Sandbox Functional Testing

Your team will complete a thorough testing of Ovation LIMS in the sandbox environment and provide detailed feedback to the Ovation Project Manager. We expect there to be an iteration of the configuration in sandbox to accommodate your feedback. However, any request that's outside of the agreed upon Work Order may require scoping and an additional Work Order(s) which may carry an additional cost.

Once the system has been thoroughly tested by your team, Ovation will request completion of a final testing checklist and production build authorization so that your lab can perform electronic system validation. The production environment can not be built without production build authorization, and will be a direct reflection of the thoroughly tested and approved sandbox environment.

Stage Gate: Production build authorization = Sandbox Configuration & Functional Testing complete

Phase 3: Product Build & System Validation

Production Build

This is the phase where the configurations you had been testing in the sandbox environment are officially moved into your production environment, where your lab staff will actually do their day-to-day work.

Production System Validation

We'll assist you through the validation process and provide your lab with a validation guide based on industry standards. This guide includes instructions on how to verify the proper configuration of the Ovation LIMS product based on your lab's functional requirements.

Your team will perform (at a minimum) the test cases provided by Ovation in the validation guide. You should evaluate the validation guide to determine if it complies with all regulatory guidelines required by your organization. Additional validation activities may be performed, but are not required by Ovation. We also offer premium Validation Services that can be scoped and charged as an Expert Service.

Change Control

Issues found during Sandbox Functional Testing or Production System Validation will be addressed by the Ovation Implementation Team. Should configuration modifications be required, Ovation will make the changes in sandbox where they'll be tested and approved by your team before they're promoted to production.

Requested changes that significantly differ from the agreed upon Work Order will need to be requested using a Project Request Form and may incur additional costs. The Ovation Team will create a new Work Order to represent this work.

**Stage Gate: Completion and delivery of the Ovation validation guide
= Production Build & System Validation complete**

Phase 4: Go-Live

The final phase of the Ovation implementation process is Go-Live—when staff at your organization start using Ovation LIMS! Once validation is complete, Ovation LIMS can be deployed to end users and used for sample processing based on your organization's timeline.

The first 30 days after go-live comprise the dedicated support period, during which the Ovation Team will closely monitor usage and all of your users will have access to a single Technical Support Representative to ensure consistency as they're asking questions and reporting any issues. During this period, the Ovation Team will work at an accelerated pace to resolve these issues.

Following the dedicated support period, your Ovation Project Manager will hold a final project readout meeting with your organization's team. During this meeting, we'll discuss the outcomes of the implementation, identify any issues that remain unresolved, and set up a plan for ongoing communication and to transition you from implementation services to account management.

If your implementation is modular and includes further projects (such as additional assays and integrations), your Project Manager will direct you to the Project Request Form, where you can submit additional project requests.

Note on change management

Users will be experiencing Ovation LIMS on their own for the first time, so it's important to reiterate why the product is being used and what the long-term strategy and goals are during these initial growing pains. It's also important to ensure that all end users understand that our deep and continuously growing Knowledge Base of online educational articles and videos is readily available to them via the help beacon within the LIMS.

Completion Criteria

If you believe for any reason that the Project has not been completed consistent with the terms of the Work Order—despite appropriate escalation channels—we ask that you promptly notify Ovation in writing (in no event more than 30 days after receipt of Ovation's completion notice), and we will discuss any issues in good faith. If you do not do this, all aspects of the Project are deemed accepted without objection, provided that any of the following conditions exist:

- Both parties agree the project is complete, or
- You give written notice that services are no longer needed, or
- Final confirmation for internal system validation has been received or deemed confirmed, or
- Your Ovation LIMS instance is being used to process patient samples.

Following your implementation, your Account Manager will continue to engage with your team to ensure continuity and ongoing success with Ovation LIMS. Scheduled check-ins and business reviews will ensure that you're tracking to hit key business objectives.

Our cloud-based software and modern development processes allow us to roll out new Ovation LIMS features and bug fixes without any downtime. As these updates occur, we'll provide you with notifications and new help documentation to make sure you're getting as much value out of the product as possible.

Your staff will have a direct line to the Ovation Support Team through in-app, phone, and email, which means no questions will go unanswered, and issues will be resolved in a timely manner. You will also have access to our online Knowledge Base, written and maintained by our product experts.

Note on data migration

Any request to migrate data from legacy systems into Ovation LIMS will constitute a separate project with its own Work Order. Unique configurations (both of the legacy tool and of Ovation) mean that every data migration is different, and will be scoped differently. Once Ovation configuration is complete and we've agreed on how extracted data will be represented in Ovation, we'll commence data migration into your production environment.

Implementation Best Practices

The following are lessons that our clients and our customer success team have learned that can help your organization be as successful as possible deploying Ovation LIMS in your lab.

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| 1. Select a steering committee | Select a strong steering committee, led by an engaged Executive Sponsor, to serve as the primary stakeholder for the project and ongoing relationship with Ovation. During the implementation, the steering committee is in charge of overseeing and supporting the implementation team. After implementation, it should remain the steering committee's responsibility to oversee the ongoing use and maintenance of Ovation LIMS. |
| 2. Consolidate Ovation information | Consolidate all the information regarding your Ovation implementation in a central place. This kind of resource is a great place to put links to other assets like our Ovation Knowledge Base. |
| 3. Facilitate communication | Clear, consistent communication to staff throughout implementation is important. Highlight the benefits of Ovation LIMS to the organization, as well as process changes that will benefit them directly in order to improve buy-in. |
| 4. Be proactive about support | Rather than waiting to find out about issues your staff may be having, check in proactively with staff so they can ask questions or raise any concerns. |
| 5. Create a clear support structure | Once your organization is using Ovation, it's essential to have a clear support structure in place for your users. This way staff know who to contact with their questions, whether it's your organization's internal support desk, or contacting Ovation Technical Support. It's also important to be clear about when Ovation can help and when they are not the right resource, for instance if the question is regarding the policies of your lab. |
| 6. Embed Ovation LIMS in any new hire onboarding | Don't forget to revisit your onboarding materials and include Ovation LIMS training. |
| 7. Thorough testing in sandbox is critical to long-term success | The production environment will be a direct mirror of what has been approved in sandbox. Finding issues once you're in the production environment that you have not accounted for during your sandbox functional testing will delay your implementation, and can lead to frustration from users. |