

Implementing a learning management system globally: An innovative change management approach



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This article describes how Aventis Pharmaceuticals, in partnership with IBM, is implementing a learning management system (LMS) globally both in the Research and Development organization and in clinical groups within the Commercial Operations organization. It also discusses how Aventis is applying an innovative change management approach that meets challenges to this implementation globally across its matrix organization. The LMS relies on strong business involvement to keep the system current and relevant. Two critical organizational solutions in this effort involved establishing (1) a two-tiered governance structure to globally manage the system's consistency on business and technical levels and (2) a network of LMS contacts to provide the necessary business support and material content to keep the LMS relevant and current across geographical regions. Governance boards and LMS contacts enable global communication and coordination, creating a robust learning environment. After only one year, the LMS has achieved widespread acceptance within the organization and has been implemented in three target regions, allowing rapid response to organizational change and new business requirements, and placing the company in a strong competitive position. Aventis is currently exploring extension of the LMS to external partners.

Learning management systems (LMSs) have become an increasingly important tool in business today, not just for the improved training capabilities these systems offer, but also for the business advantage they provide for managing training and tracking regulatory compliance. This article describes how Aventis Pharmaceuticals, in partnership with IBM, is undertaking global implementation of a learning management system based on software from Saba Software, Inc.,¹ both in Research and Development

and in clinical groups within Commercial Operations (ComOps), an organization comprised of sales, marketing, medical, clinical, and legal functions. The primary business driver behind implementation

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was facilitation of regulatory compliance by having one system to track, manage, and deliver training globally, using a common platform for all these target organizations. Before developing an implementation strategy, however, Aventis first needed to identify the key challenges that might potentially jeopardize or prevent a successful rollout of the LMS. This paper takes an in-depth look at the solutions used to overcome these challenges, including a unique change management approach that enhanced business input to the process and provided support and maintenance for the LMS in all the organizations involved. We also show how achieving the implementation goals ultimately provided benefits both to business units subject to extensive regulatory requirements and agency inspections (regulated businesses) and to those not subject to agency inspections (nonregulated businesses).

DESCRIPTION OF LEARNING MANAGEMENT SYSTEMS

Learning management systems are becoming an integral part of small- and large-scale learning environments and can provide a range of capabilities and features. An LMS allows users to access and deliver training content, leveraging a variety of training media throughout all departments and thus enhancing an organization's knowledge level.² It also includes tools for tracking and reporting user-training performance. More specifically, an LMS provides the following capabilities:

- Registration for instructor-led training
- Assignment of instructional responsibilities
- Setup of courses and curriculum planning
- Delivery of tests and assessments
- Tracking and reporting of student progress and performance
- Generation of certifications and regulatory compliance reports

CHALLENGES IN A REGULATED ENVIRONMENT

The pharmaceutical industry is highly regulated and subject to inspections by a variety of different agencies worldwide. Regulatory inspectors often request documentation of training for those individuals performing regulated activities. Departments therefore need easy access to their training records to fulfill these obligations. The vision for the LMS was to have it become the single, organization-wide tool for tracking all training necessary to meet

regulatory requirements, rather than having each individual department use a different tracking method.

The LMS implementation targeted the Drug Innovation and Approval (DI&A) organization and businesses within the ComOps organization for the LMS rollout because these both have a high percentage of regulated activities. Functionally, DI&A is comprised of sites, project teams, global departments, and support functions. The sites are responsible for managing Disease Groups (DG) projects and for moving projects from the exploratory stage through the early clinical stages of drug development. The early-stage global departments, Lead Generation (LG) and Lead Optimization (LO), provide staff and technology to support the sites. Late-stage functions, such as Product Realization (PR) and Global Regulatory Approvals and Marketing Support (GRAMS), provide worldwide coordination of clinical studies and submission strategies to optimize clinical trial data, facilitate simultaneous global submissions, and provide life-cycle management of products.³ Specific groups targeted within Commercial Operations included U.S. Medical Affairs (USMA) and Global Medical Affairs (GMA), which conduct U.S.-based and global clinical studies respectively for DI&A and must also adhere to regulatory requirements. It was believed that these highly regulated areas would benefit most immediately by having a common platform to access and track training.

LMS BENEFITS FOR REGULATED AND NONREGULATED BUSINESSES

The case for LMS implementation for regulated business components was compelling because of the need for these organizations to ensure compliance with regulatory agency requirements. The LMS would provide for them a centralized capability to easily document and access training records for inspections. However, it was also realized that ultimately all business organizations within Aventis could benefit from an LMS because even non-regulated areas must track and manage training. Specifically, the LMS enables businesses to:

- Document training requirements for existing and new employees, including requirements driven by both global and local standards and policies
- Reduce duplication of training tracking methods

- Ensure training compliance with business standards
- Follow SOPs (standard operating procedures) consistently across functions
- Enable online training venues to reach larger numbers of learners and thus eliminate associated travel costs
- Efficiently manage rosters for instructor-led training
- Document course completion

The LMS also enables employees to:

- Register online for instructor-led training
- Personalize training records by documenting training taken outside the LMS, including attendance at professional meetings and conferences
- Access other corporate-wide training activities to meet cross-functional business needs
- Conveniently participate in online training to accommodate personal schedules

To realize the full potential of the LMS, several critical steps needed to take place before the system could be implemented in the target businesses.

PREPARATION FOR IMPLEMENTATION

Before the work described here, the Saba-based LMS was already in use within Aventis in the U.S., albeit sporadically, primarily to qualify employees before granting them permission to use enterprise management software from SAP AG.⁴ The proposed implementation, however, globally targeted the entire DI&A organization and clinical departments within Commercial Operations. Before any implementation activity could begin, the LMS plan needed endorsement from senior management within DI&A, specifically the Drug Innovation and Approval Leadership (DIAL) team. The membership of this team includes leaders from all DI&A functions in which the LMS would be launched, including PR, GRAMS, LO, PPPM (Productivity, Portfolio, and Project Management), LG, and DG. Without DIAL team endorsement, the LMS implementation could not progress further.

In January 2002, a workshop was held with technical and business experts to develop a case for implementing the LMS. The output from this workshop was then used to request the DIAL team's endorsement and support. The business experts

involved in the workshop were comprised of cross-functional middle to upper management who were directly responsible for training or compliance within their areas. As part of this process these participants became familiar with the LMS vision and became proponents of its short-term and long-term benefits. Technical experts were IS (Information Systems) organization leaders, some of whom had been directly associated with small-scale LMS efforts conducted earlier or who were familiar with other large-scale system implementations.

All participants understood the internal challenges that might potentially impact this global LMS implementation and were willing to contribute as members of the new LMS team that would be formed if the DIAL team endorsed the system. Together, these experts outlined a proposed approach that identified the business and technical support needed to ensure long-term use and maintenance of the LMS throughout the diverse business units.

In February 2002, the DIAL team agreed to this comprehensive approach and approved formation of the LMS team. The LMS team sponsors then spoke to leaders within the Commercial Operations Global Medical Affairs organization and obtained their endorsement as well.

CHALLENGES TO IMPLEMENTATION

To implement LMS for all organizational functions, disciplines, and regions, the LMS team first had to further develop an approach to address the series of challenges described in detail in the following sections.

Differing regional data privacy and protection requirements

Data privacy and protection requirements vary from country to country and are established to protect users from unauthorized sharing of personal information. Before making the LMS available globally, the team had to address specific European data privacy requirements, particularly for France and Germany, the first EU (European Union) countries targeted for the LMS launch.

Lack of a centralized training department

Historically, training within Aventis had been managed independently within each department or, in some cases, for a few departments. There was no

mechanism for each department to know what training material was available or in development throughout the organization, leading to duplication of training activity efforts. The lack of a centralized training department to coordinate efforts also put undue burden on training resources tasked with supporting training in more than one area.

Lack of a single business owner

Typically initiatives such as the one described here are owned by one business area, which manages planning and rollout activities. The LMS did not have a single, long-term owner to centrally manage issues. Instead this role was taken on by the sponsors of the project, in this case the authors of this paper. There was, however, a single focused source of technical support that addressed business needs across the organization, the head of Enterprise Content Management and LMS, Americas.

Diverse training needs across a matrix organization

One goal of the LMS implementation was to use the Saba software with as little customization as possible. However, it was also recognized that the system had to meet the business needs of over 30 different departments globally. Moreover, Aventis is a matrix organization, best described as a network-centric environment involving a dual reporting structure among regions. In Aventis “project and functional managers share responsibilities for assigning priorities and for directing the work of individuals,”⁵ as is typical of a matrix organization. Employees may have several roles within their local organization and receive direction from managers in other regions or from project leaders when the employee is involved in special initiatives. Communication between departments and functions is therefore of great importance when setting priorities in this environment, and proper collaboration is a critical requirement in order for these organizations to achieve their collective goals. It was thus very important to understand these business priorities and the associated training requirements to ensure that the LMS would achieve long-term success.

Possible resistance to the LMS being accepted as the single unified training system

Historically, managers and staff functioning as department-based training resources were responsible for tracking training to meet regulatory

requirements for their areas. These tracking methods varied across all businesses. Although there was a strong desire to move to a unified, consistent approach, a mechanism did not exist to do so. It was recognized that implementation of a single LMS system would foster consistency in tracking, delivering, and managing training throughout the organization. The goal was to have each department define its individual training requirements within the LMS and eventually own the maintenance of the related content. However, to achieve this ownership and stimulate usage, it was important that managers and their LMS users appreciate the value of the LMS to their daily responsibilities. Otherwise, resistance to the LMS could be expected.

SOLUTIONS TO THE CHALLENGES TO GLOBAL LMS IMPLEMENTATION

In many organizations, these challenges would have been enough to stall, if not stop the implementation. However, the LMS group successfully adapted common change management principles, including stakeholder alignment, knowledge transfer, governance, alignment of individuals and teams, and performance management to bring about the desired global, cross-functional change. Solutions involved every level of the organization from senior and middle management to operational-level staff. Several solutions, both practical and innovative, helped address these challenges.

These solutions to the challenges facing LMS implementation included both (1) fundamental and technical solutions to address data privacy requirements and diverse business needs and (2) innovative organizational solutions that facilitated rollout of the LMS and that continue to enhance both the effectiveness of the LMS and employee acceptance of this new tool. *Figure 1* summarizes the fundamental, practical, and innovative solutions needed to overcome the challenges facing LMS implementation. These solutions are described in more detail in the sections that follow.

Fundamental and technical solutions

The solutions to these challenges involved fulfilling data privacy and protection requirements, enhancing user independence, providing for unique curricula needs, and facilitating regulatory compliance.

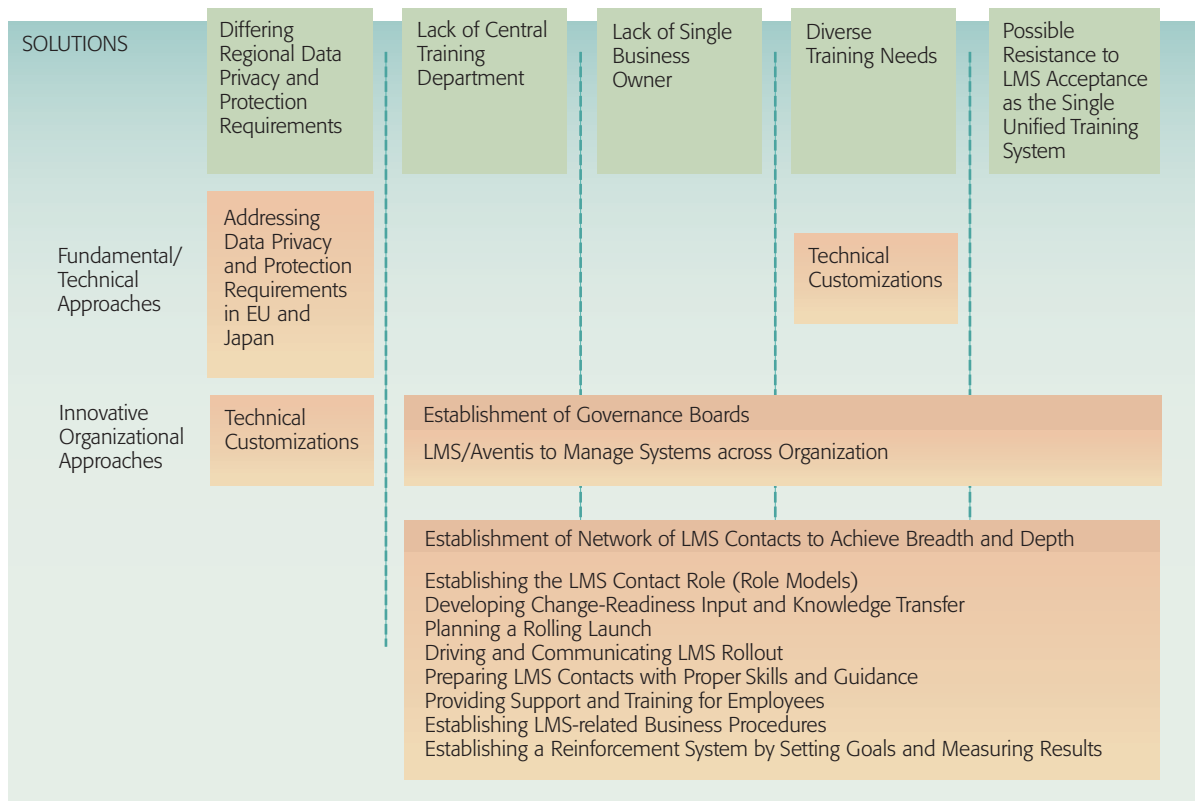


Figure 1
Solutions addressing the challenges of implementing the LMS globally

Data privacy and protection requirements

Data privacy and protection requirements had to be addressed before making the system available in Europe and were accomplished through the support of the various business units, corporate IS (Information Systems), and legal organizations. Because data privacy requirements in Europe differ from those in the U.S., it was necessary to create two separate LMS environments by establishing two servers, one in the U.S. and the other in Frankfurt, Germany. This preserves a secure environment in Europe, allowing the LMS implementation to address the specific requirements of European privacy laws.

The U.S. server includes material and records necessary for U.S. employees to access the LMS, while the Frankfurt server covers France, Germany, and Japan. New EU countries joining the LMS will access the LMS on the European server, while other countries will access the LMS on the server most consistent with their legal requirements. As part of this process, a privacy statement and a user consent form were developed and approved by the CNIL (La

Commission Nationale de l'Informatique et des Libertés) in France and the Privacy Officer and Aventis legal department in Germany.

Meeting diverse business needs

Although the original intent was to minimize customization of the Saba software, it did prove necessary to modify the system to meet certain diverse business needs for the organizations involved. Customization was therefore designed to:

- Enhance user independence within the system by automating daily usage and minimizing the administrative burden
- Allow departments to create unique curricula to meet diverse business needs while drawing from a common source of material
- Facilitate EU data privacy and CFR (Code of Federal Regulations) 21, Part 11 requirements⁶

The expertise of the Aventis e-learning technical team (also referred to as the Applications, Architecture, Integration, and Standards (AIS) technical

team) was critical in achieving these goals. Saba was, in fact, impressed by the sophisticated nature of the Aventis improvements, which significantly extended the capabilities of the base product to create a stronger focus on usability.

Enhancing user independence. The LMS shifts training responsibility to the user in several ways. In the case of instructor-led classes, customizations allow users to self-register from a list of available days, times, and locations. Users can also cancel registrations themselves if they need to switch to another class, so that instructors and their support staff do not have to manage schedules but instead are able to simply review the final roster.

In order for the LMS to become the single tracking system used in Aventis, it is important that employees have the ability to track any training they complete, including training taken outside the company. The LMS allows users to track training offered outside of Aventis as well as courses not specifically included in the system. The *ad hoc learning* screen in the LMS is used for this purpose. Although this function was originally only available to managers, employees are now able to personalize their training records themselves. This has shifted the responsibility to update training records from the manager to the employee.

The LMS was also modified to allow first-time users to self-register using a customized *personal information* screen, rather than relying on administrators to load or update this information. Users can later make any necessary changes to a field themselves, whether it be, for example, a change in last name reflecting a life change or a transfer to another position within Aventis, affecting manager name, job type, location worked, or global department.

Regulated areas often require that current resumes be available during an agency audit. Modifications allow employees to include their resumes on the personal information screen through a template that they can update throughout their careers. This may not be desirable or advisable for all businesses, particularly those in Europe with different data privacy requirements, but the system does provide this option for groups who wish to use it. Employees can build their resumes by copying the appropriate content into an LMS text field, preserving the

preferred format. (The modification does not allow attachments to avoid the risk of viruses.)

The ability to send out e-mail notifications to employees is a basic feature of the LMS system. In Aventis the LMS team requested that only a few notifications remain active, but one that was deemed critical was the messaging that notifies registered employees when new materials or modified versions of existing materials are added to their required training. This message identifies the specific material added to a given job type and requests the employee to review the material in order to remain compliant. It is the employee's responsibility to fulfill this requirement.

Meeting diverse business needs. The LMS contains learning material used by many of the targeted businesses, such as global SOPs and reference material, Microsoft PowerPoint** slides, classroom training, and other online training. An important requirement was that businesses be able to define their own unique training requirements, but also be able to use subsets of common learning material. To enable separate curricula for different business units, the technical team enhanced the certification functionality to allow criteria to be established for custom certifications. Departments can now independently group certifications in any combination and assign them to certain jobs, referred to as *job types*, which in turn are specific to a given department. For example, *clinical monitor* and *study manager* may exist as separate job types in the LMS, but both jobs require knowing the standards associated with investigator meetings or selecting investigators and sites. These common standards can be assigned to both job types and then combined with other standards unique to the respective roles to establish certification criteria for the individual job types. **Figure 2** illustrates the types of training that are now available in the LMS and used by many departments throughout the organization.

Through the self-registration process, employees select the job category (job type) identified by their organization to be most relevant to their role in the department. Selecting a job type then leads to display of a filtered list of material required for that specific job. The filtered list is referred to as a *certification gap* and enables users to see the status of material assigned to them as a result of their job

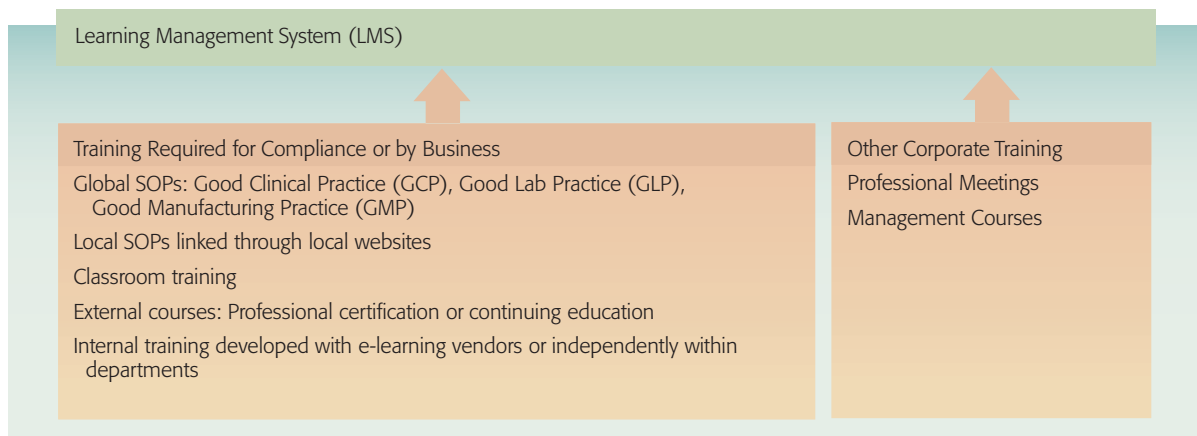


Figure 2
Types of training available in the LMS

type. Employees are trained to check their progress and to register for training through the certification gap. They may also select other job types through the certification gap (while maintaining their original registered job type) to see available material outside their individual requirements. Anyone with an intranet ID may navigate freely in the LMS to access material by a variety of methods. They can either locate material associated with predefined requirements corresponding to a specific job type or search and complete any material available in the *learning catalog* (a listing of all material linked to the LMS that is viewable in an employee's domain).

Some departments prefer that their employees take self-assessments as part of the learning process in order to test their knowledge. An additional enhancement to the basic Saba system involved developing a course shell (wrapper) to allow training materials (e.g., PowerPoint slides, Adobe Acrobat** files, and SOP documents) to interact with the LMS by using AICC-based communication to present test questions to employees to establish satisfactory completion of the training. (The Aviation Industry Computer-Based Training Committee [AICC] is an international association of technology-based training professionals that develops training guidelines for the aviation industry and establishes standards that apply to the development, delivery, and evaluation of technology-based training courses.) This enhancement also enables the system to track employee completion of requirements.

Departments rely heavily on reports to measure their training progress and to document that they have met their regulatory obligations. The personal information screen includes a *global department* field, which employees must select and which is necessary for reporting purposes. The original version of the Saba LMS used a two-dimensional hierarchy based on employee reporting structure and the cost center involved. The technical team added the business unit as a third dimension. This addition allows increased flexibility in report generation.

In some cases, business units prefer to limit access to their material by other departments, particularly when the material covers sensitive topics, such as processes related to animal handling. The global department security model also controls user access. Based on the country, function, and global department selected, the security model can filter and thereby limit an employee's view to a very specific subset of the overall training available in the LMS.

Meeting EU data privacy requirements

Originally, the system allowed managers to view records within multiple layers of the organization. In compliance with EU privacy requirements, managers can now see training records and activity only for people reporting directly to them. This is consistent with data privacy requirements within the EU, but is also applied to information on the U.S. server.

Many departments using the LMS are regulated and are required to document their training records for

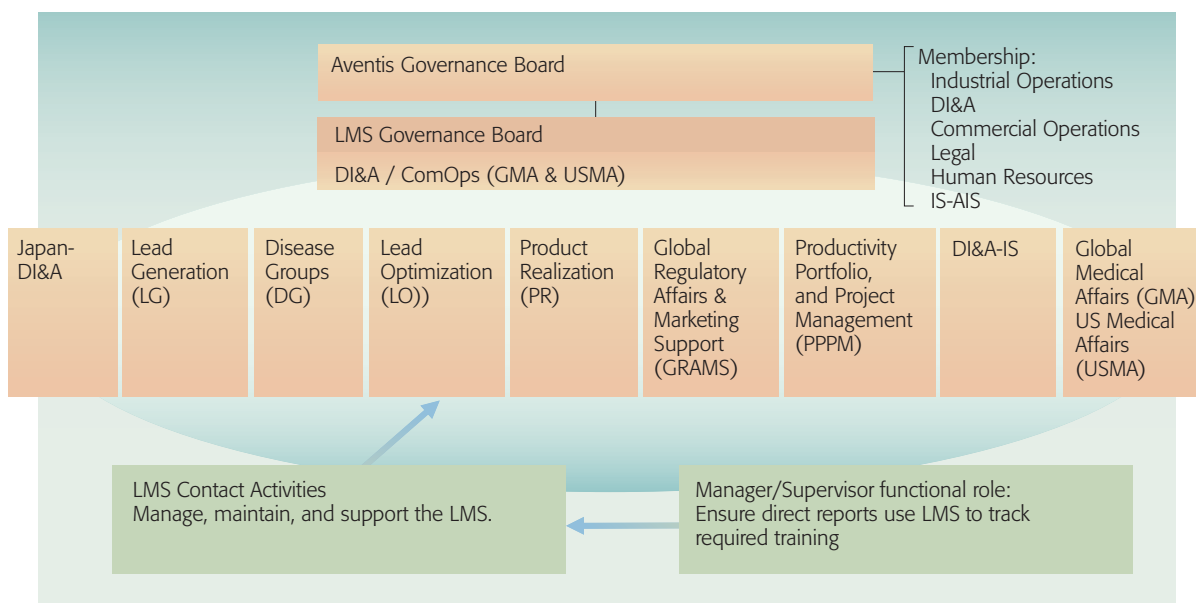


Figure 3
LMS governance: a two-tiered approach

regulatory agencies. This means that their systems and electronic records must be validated to ensure they are compliant with CFR 21, Part 11. Prior to launch, the LMS was fully validated. To address ongoing technical updates, the Aventis Governance Board addresses and approves all change control requests, as appropriate, to ensure that the system maintains its validated state.

Innovative organizational solutions

Innovative organizational changes included the establishment of governance boards and an enterprise-wide LMS-contact network.

Establishment of governance boards

Figure 3 shows the two-tiered governance-board structure adopted in this project. It includes both the Aventis Global Governance Board and the LMS Governance Board. Both governance boards are characterized by cross-functional and cross-organizational membership, creating collaborative forums and encouraging shared ownership. Each is led by a chairperson who serves an annual appointment, which in turn is rotated among board members. Each governance board also has defined and documented operating principles that guide the members in planning and implementing their decisions globally.

The Aventis Global Governance Board. The Aventis Global Governance Board represents the top layer of the governance structure and has the following goals:

- Support a global solution for the Aventis learning community
- Manage change control consistently across functions to maintain a validated state
- Share information on training technology capabilities and tools

Members have met since April 2002 and are comprised of global leaders expected to advocate the LMS within their respective organizations, which include Industrial Operations (IO), DI&A, ComOps, Legal, Human Resources (HR), and IS. Currently, DI&A, ComOps, Legal, and IS have actively rolled out the LMS, and discussions are underway with IO and HR. Regardless of their rollout status, all groups have active board members who discuss complex proposed system changes requiring change control approval, and the resulting implications for potentially affected businesses.

The chairperson was elected to lead the group during the first year because of his experience pioneering the planning and implementation of the LMS in DI&A. As chairperson, he presided over all

meetings, ensuring that work was conducted efficiently and effectively; he helped guide and mediate Global Board actions with respect to organizational priorities and governance concerns; and he encouraged advocacy of the LMS.

This Board is governed by operating principles that outline voting rights, overall mission, and member roles and responsibilities. The Aventis Governance Board also addresses issues raised by the LMS Governance Board to ensure communication within the two-tiered structure. Issues can include data privacy, overall access to the system, and data protection issues affecting both the global rollout and the overall conduct of business.

The LMS Governance Board. Based on the recent LMS Governance Board Operation Plan dated May 2004,⁷ the LMS Governance Board is defined as a global forum to address business and technical operational issues that affect the tracking and delivery of training managed through the LMS. The Board has a cross-functional representation of managers from the DI&A and Commercial Operations Medical Affairs departments. Commercial Operations membership includes management from departments involved in conducting clinical studies and marketing approved products, namely Global Medical Affairs and U.S. Medical Affairs. The LMS Governance Board is in the process of assisting the EU contacts to organize an EU working group and identify a leader who would serve as a member of the LMS Governance Board. As other organizations roll out the LMS in their areas, they have the option of establishing their own governance board to address their own operational topics. The LMS Board meets monthly and is responsible for:

- *Ensuring LMS implementation and utilization*—The board advocates LMS use through formal and informal communications, provides periodic review of key performance indicators to measure business usage and regulatory compliance, and communicates to management the areas needing improvement to fill gaps.
- *Facilitating LMS management*—The board ensures that target businesses identify LMS contacts to provide business support; liaise with the user community as appropriate; address data privacy, access, and data protection issues affecting the global rollout; and provide input on decisions regarding LMS scope and budgets. The board is

also involved in identifying and recommending e-learning vendors and ensuring that the proper internal parties are involved in identifying and contracting these vendors.

- *Promoting knowledge sharing*—The board encourages knowledge-sharing forums and networking among functions to introduce new content into the LMS. It also collaborates on joint training programs among organizations and raises unresolved technical issues to the Aventis Governance Board.

The LMS Governance Board developed a separate operational plan documenting the Board's mission, rollout schedule, communication venues, training and user support, and governance structure. This plan addresses the roles of the LMS Governance Board members, leadership, and network of LMS contacts from the functions who advocate and coordinate the LMS in their departments. The operational plan identifies processes required to maintain information linked to the system regarding business contacts and database owners and administrators. It also provides guidance for businesses interested in exploring e-learning options. The plan is updated as new decisions are made.

The LMS Board chairperson position is a one-year appointment. The chairperson is responsible for the overall leadership of this Board, serves on the Aventis Governance Board, brings topics forward when necessary, and is responsible for communication with the user and LMS contact communities on behalf of the Board.

The LMS Board's first chairperson was a manager in one of the more regulated and diverse functions. Her input and perspective were particularly helpful during the first year because she also was directly involved in a global database that would be the first source of standards and reference material linked to the LMS.

Based on the high activity level seen in the first year, the LMS Board decided to establish a dual leadership role, adding a vice-chairperson position to assist the chairperson in the planning effort. The vice-chairperson also represents the Board's interests at LMS-related meetings and addresses issues from the functions. The vision for this dual leadership role is to create a mentoring partnership between the chairperson and vice-chairperson that facilitates a smooth transition should the vice-chairperson agree

Business Responsibilities:	Technical Responsibilities:
Work with management to identify new or existing required training to meet regulatory compliance and business needs Identify the names of Job Types for users to select that define jobs within department; identify subgroups within Job Types as needed, based on common sets of responsibilities Coordinate historical training records Respond to business questions from LMS users within department Report business issues to LMS Governance Board representative	Link material identified by the Business Contact to the LMS Establish Job Types and Job Roles in the LMS and link to relevant material Incorporate historical training information into individual records Maintain material in LMS - update links to new versions, add links as new material is identified and developed

Figure 4
LMS contacts: Business and technical responsibilities

to take on the chairperson role the following year. The current chairperson is a manager within the PPPM group, and the vice-chairperson is from the Biostatistics and Data Management group within the larger clinical Product Realization organization. Their combined skills are leading the group through another productive year.

Creation of a network of LMS contacts across the organization to facilitate implementation

Ownership of the LMS was placed in the hands of the departments by establishing a network of LMS contacts. Collectively, the LMS contacts provide the operational depth, both domestically and globally, required for long-term acceptance and usage. The rollout program relies heavily on these contacts to provide continuous business support and to ensure that LMS material is relevant and current. To augment current material, LMS contacts are also involved in change management responsibilities that are critical to embedding the LMS into employees' daily activities. Typically, a change in employee mind-set occurs only when employees understand the need for change and agree with that need.⁸ Engaging the LMS business contacts early built a strong foundation of ambassadors who supported the system and heightened LMS awareness. The following steps were involved in creating the network of LMS contacts:

- Establishing the LMS contact role
- Developing change readiness input and knowledge transfer
- Planning a rolling launch

- Driving and communicating the LMS rollout
- Preparing LMS contacts with the proper skills and guidance
- Providing support and training for employees
- Establishing LMS-related business procedures
- Establishing a reinforcement system by setting goals and measuring results

These steps are described in detail in the following sections.

Establishing the LMS contact role. Management first needed to select appropriate LMS contacts in their departments. Since training was typically managed independently by department, it was important that contacts be selected who were involved in training activities and thus likely to see the direct benefits of the LMS in their daily responsibilities.

As summarized in **Figure 4**, roles and responsibilities fell into two categories: business and technical. Within a given department these roles might be performed by one or more employees depending on skill sets and experience levels. Initially, the e-learning team carried out technical responsibilities for each business unit. Eventually, each business decided how to distribute these responsibilities within its respective departments.

Given the matrix structure of Aventis, having LMS contacts as focal points provided the appropriate input to management to ensure that the proper training requirements were defined for each business unit. As trainers, these contacts also could be

considered role models because they fulfilled the basic criterion of being in a “position of influence.”⁸ Although management endorsement was a critical factor in employees accepting change, LMS contacts in training roles made a major contribution to acceptance within departments because employees viewed them as local LMS authorities and ambassadors. The establishment of LMS contacts, in combination with continued management endorsement, was a key success factor in the departmental rollout of the LMS system.

Developing change-readiness input and knowledge transfer. The LMS contacts continually monitored issues that needed to be addressed and served as ongoing readiness gauges. These functions were particularly important in an implementation on the scale involved in this project. Issues were brought to the LMS Governance Board, which in turn evaluated the impact of these issues on DI&A and the business units within ComOps and addressed them accordingly. Issues affecting all units, such as requests for “more LMS awareness,” were addressed on a larger scale than issues that were unique to one or two departments. The latter were handled within the affected areas.

Setting up a network of LMS contacts and getting them involved at the outset enabled knowledge transfer to occur very early in the implementation process. Although knowledge transfer is typically considered when an implementation plan is first created, it is often carried out only in the later stages of implementation. Providing a high level of understanding to LMS contacts at the beginning of the project fostered a sense of ownership for the contacts, thus increasing their level of support.

Business contacts who had already configured their departmental learning material in the LMS shared their organizational models with their regional counterparts to assist them in incorporating their own learning materials into the LMS. This allowed the counterparts to simply adapt the existing model to include their local requirements, reducing setup time and expediting their own LMS rollout.

Planning a rolling launch. The implementation used a rolling launch approach involving activities on two levels: a regional/country level and a departmental level. LMS contacts and their management played an important role in both levels of activity. They

played a supporting role for the regional/country launches and helped introduce their respective groups to the system by identifying initially limited but relevant content. During this time they also became more familiar with the system as observers of the LMS team and e-learning teams who drove the regional/country level rollouts.

LMS contacts and their management then subsequently drove the launches within their respective departments. They identified specific material required for their business and worked with the LMS team to categorize it based on job responsibilities in their area. The contact often trained department staff on the LMS using the department’s own business-specific content. This established the contact as an LMS authority for the area and provided someone who was familiar with the system and able to answer business questions from users.

A rolling launch, although unconventional, was effective in putting the LMS in the hands of more employees quickly. It introduced them to the system and its features through familiar content. It also allowed units to roll out the LMS within their organization when ready, without having to wait for all the other units in a given region or country to also be ready. *Figure 5* illustrates the two levels of the rolling launch, detailing the activities and the purpose of each step.

We found that the bulk of the rollout activity occurred at the department level. After senior management provided their endorsement, acceptance relied completely on how well the contacts and employees understood and accepted the new tool and their respective responsibilities. Again, the network of LMS contacts played a critical role in change management efforts within departments.

Driving and communicating the LMS rollout. This implementation involved a significant culture change, because it shifted responsibilities for tracking training from management to employees. Thus, the communication effort had to clearly state the purpose of the new tool and also motivate business groups to use it. Regulated areas quickly appreciated having centralized access to a tool that could help them easily prepare for agency inspections. Non-regulated areas, however, did not immediately see

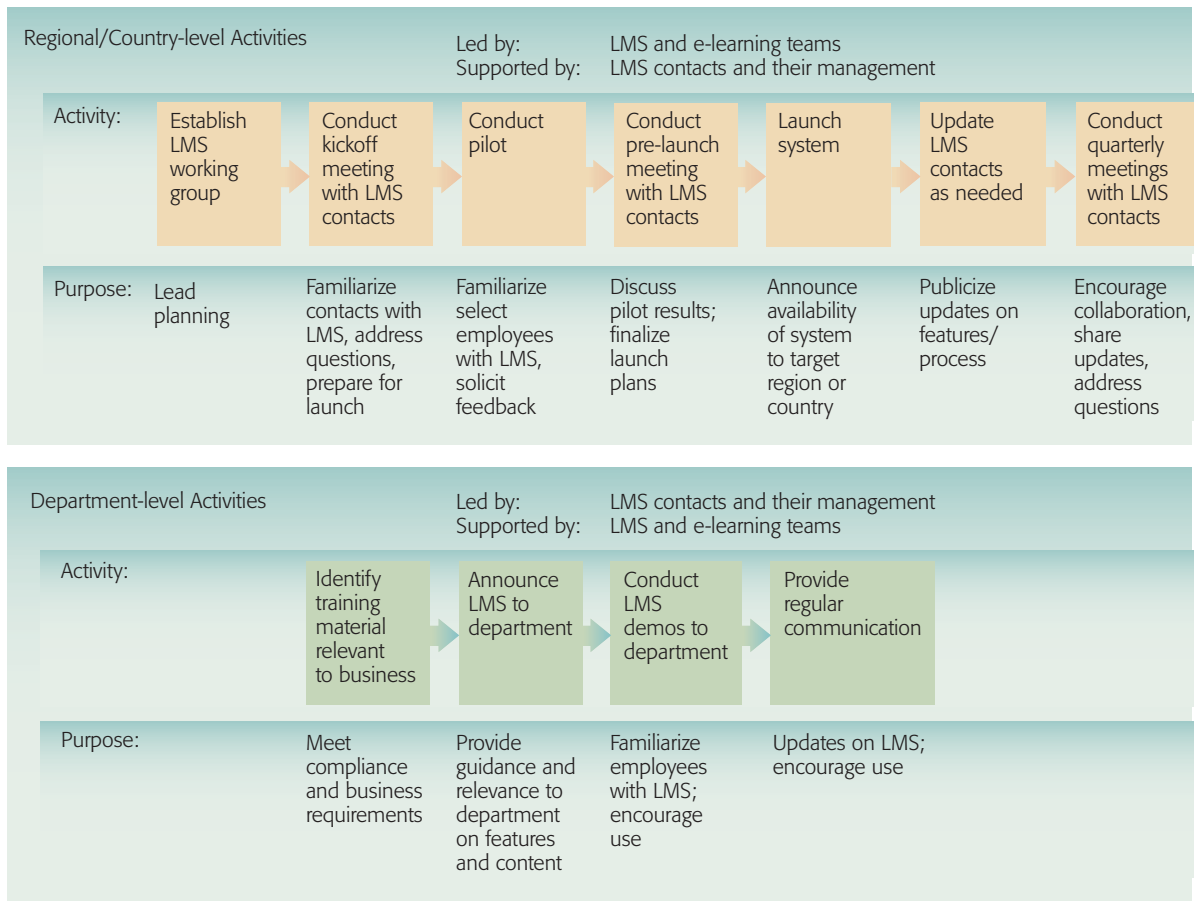


Figure 5
Rolling launch activities

the added value in tracking. In some cases, they preferred their former methods. As additional communication efforts were directed toward these groups, there was growing acceptance in these nonregulated areas as a result of the availability of tracking features and the convenience of finding training requirements in one centralized location.

Previous studies have shown that the most successful change management initiatives have support at all levels: senior management, middle management, and frontline employees. In addition, for successful change management, an understanding of both respective responsibilities and the reasons for the change is also very important.⁹ The communication effort at Aventis therefore used both top-down and bottom-up approaches to reach the many levels of users and stakeholders. Communication was first directed to management and LMS contacts through kickoff meetings, which provided

background on the practical points of the system and enabled contacts to better understand their roles, both as contacts and as LMS ambassadors for their areas. An LMS awareness campaign was then directed to the users, again involving management and LMS contacts on the regional and department level. Contacts and their management publicly endorsed the LMS and encouraged employees to use it, taking advantage of scheduled face-to-face meetings on all levels. The LMS team also used various mechanisms to publicize the LMS, including mass e-mail messages, town hall meetings (which are typically well attended by DI&A employees), articles published on the Aventis intranet, and kickoff meetings focused on updating and providing information to the LMS contacts. Announcement material was always accompanied by a Frequently Asked Question (FAQ) document, which addressed the common questions and concerns raised in previous discussions. A Quick Reference Guide was

created to simplify navigation of the LMS and to highlight the log-in and registration processes required for first-time users. The LMS contacts continue to meet quarterly to discuss their progress, collaborate on training opportunities, and learn more about the global rollout.

Preparing LMS contacts with the proper skills and guidance. To perform these business responsibilities, LMS business contacts needed to have a better understanding of the system and its features. IBM, in partnership with the e-learning team, met with contacts to understand the diverse nature of their groups and then discussed with each of them how to (1) efficiently set up the LMS with material relevant for their departments and (2) minimize maintenance when new material was added or new versions were developed.

Together management and their LMS contacts provided input on setting up requirements for the LMS for their respective areas. In many areas, LMS contacts were empowered to take on this responsibility themselves. They started with the global documents that comprised the bulk of required training for regulated areas. This provided a comfortable starting point for the contacts to begin identifying material relevant to their businesses. It was particularly helpful that Aventis has a group that manages all global documents through a Global Quality Manual, which is available through the Aventis intranet and which includes over 250 global SOPs, guidelines, and standards. Content from this site was initially linked to the LMS. A list of these documents was then generated and circulated to all contacts so that they could more easily begin identifying specific requirements for jobs within their business areas. In Europe, these global documents were often translated into the local language. Efforts are currently underway to ensure that other databases addressing the local needs of various European countries using or launching the LMS are linked to the server in Europe.

The e-learning team conducted hands-on classroom training for anyone with LMS technical responsibilities. LMS business contacts were also welcome to attend to obtain a better appreciation for the internal workings of the system. Technical contacts, once trained, were offered an individualized one-on-one session to review activities specific to their area, and were then granted authorization to update the

system. Additional one-on-one sessions were provided as the contacts grew in their roles until they became totally comfortable with their responsibilities. The e-learning team continues to provide support to technical contacts not yet trained and guidance to contacts as issues arise in their departments.

Providing support and training for employees. Formal classroom training is not required for the general user to learn how to use the system. However, the LMS is a validated system and requires users to document that they have taken some form of training to become familiar with the LMS. Online training is available either through the online tutorial or a comprehensive user guide. Both tools are now available in English, French, German, and Japanese. These online tools are also available as references while users are logged in to the LMS.

LMS contacts also provide LMS orientation and demonstrations that augment the online tools, including “Lunch and Learn” sessions as well as discussions at staff and management meetings. Several businesses, particularly groups outside of the U.S., prefer conducting hands-on training to provide a more in-depth experience and to ensure that employees register in the system. Train-the-trainer material has also been developed for the contacts and contains annotated screens addressing many of the questions received from users since the first launch of the system.

Establishing LMS-related business procedures. The LMS requires several business procedures to guide its use. These procedures are currently being developed into formal guidelines that will become required reading for all LMS contacts to ensure that they understand their responsibilities on these topics.

The LMS relies on a constant feed of current and relevant material. A procedure was therefore developed for managing updates to global documents from one centralized source. All global LMS contacts are notified directly when this global database is updated with new material or new versions of existing material. In addition, contacts provide necessary input on how material needs to be updated for their respective business units. As part of this procedure, the system sends e-mail to all employees registered in an affected job type to notify

them of the requirement to complete this new training. Although this procedure specifically pertains to the global source of reference material, LMS contacts can also adapt it to local material managed and owned by their own departments.

For new countries interested in using the LMS, there is a documented procedure on how to set up material in the LMS, based on the scenarios already used successfully by others. New approaches are constantly being considered, but businesses with similar roles often approach the LMS with similar requirements and can learn from the experiences of earlier LMS adopters in related areas.

A procedure is also in development which will guide employees in personalizing their training records through the ad hoc learning function. This will allow them to include attendance at professional meetings and conferences and any other learning important to their job responsibilities that is not already available in the LMS. LMS contacts and management will help guide their groups on the appropriate uses of this feature.

As departments began adopting LMS, they had to decide how best to address historical training records. They could either (1) begin building training records in the LMS from an identified time forward, while continuing to rely on their previously established historical records for earlier training information, or (2) update the LMS to include existing historical records. Many LMS contacts are also responsible for ensuring that department training records are current and thus are often involved in identifying the necessary information to establish training as complete in the LMS. Based on this knowledge, individual contacts chose an approach to deal with historical records in their departments, documented their decisions, and arranged to carry out the chosen approach.

Establishing a reinforcement system by setting goals and measuring results. Organizational designers agree that the setting of targets and measurement of performance, with accompanying financial and nonfinancial rewards for success, should be consistent with the behaviors people are being asked to carry out or accept. If the desired behaviors are not properly reinforced, employees are less likely to adopt them consistently.⁸

At Aventis each employee has professional goals, known as SMART (Stretched, Measurable, Aligned, Relevant, and Timely) goals. These goals are established each year with the employee's direct supervisor and are reviewed on a quarterly basis. As departments began to understand the value of the LMS, many departments also began incorporating specific LMS implementation target dates and activities into the SMART goals for their LMS contacts. Goals for department staff have also begun to include targets for use of the LMS system and completion of requirements. This association of the LMS with SMART goals represented a clear management endorsement of the learning system and established the LMS as a required and measured part of employees' work activities.⁸

Management and LMS contacts can also use LMS reports, which can be generated for a department at any time, to measure how well their groups have complied with requirements. Several departments have already incorporated this discussion into their regular staff meetings.

After establishing the overall governance structure and network of LMS contacts, implementation activity began in the targeted regional organizations.

PROGRESS AFTER ONE YEAR OF IMPLEMENTATION

The LMS was first launched in the U.S. in June 2003. After data privacy issues were resolved, the LMS was launched in Europe in February 2004 and in Japan in May 2004. By the end of 2004, the LMS rollout is expected to be complete and to reach over 5400 employees within the targeted businesses in these four countries. The vision is then to have the LMS available to the rest of the worldwide organization. When one considers other ongoing initiatives outside the current target business areas and regional organizations, it turns out that the LMS is currently being used by a total of over 14,000 Aventis employees worldwide. These numbers illustrate the depth and breadth of penetration of the LMS into the overall organization.

A summary of the activity and usage measured in the target regions and businesses after one year follows.

Measuring usage: Uptake and percent complete

We employ several key performance indicators to measure usage after the system is launched in a

region. The LMS Governance Board reviews these indicators on a quarterly basis. The first measure is *uptake*, which is defined as the percentage of users who are registered in the LMS and have at least one completed training record. In addition to uptake, we also measure *percent complete*. This number is an aggregate measure of the percentage of the training gap already completed over all departments at a given time in a given region. Results to date are shown next by region.

United States—Since the LMS was launched in the U.S. in June 2003, uptake reached 30 percent after the first 3 months, over 63 percent after 6 months, and 93 percent at the beginning of the third quarter of 2004, slightly one year after the launch anniversary. The percent complete figure has also been climbing in the U.S. since launch, and after one year it stands at approximately 22 percent.

Both regulated and nonregulated groups in the U.S. have come to understand the benefits of the LMS, and over 50 percent of all departments have now rolled out this system. The remaining departments are actively preparing for their own rollouts.

France and Germany—France and Germany launched the LMS in February 2004, with over 60 percent of the departments having business-specific material available at the time of launch. The communication effort in Europe began 5 months prior to launch with a kickoff for the LMS contacts to help them better understand the system.

A pilot was conducted as part of the prelaunch activities, enabling contacts to begin both identifying relevant material and encouraging employees in their departments to participate. As noted previously, formal training on the system is not usually necessary because online training is available. In Europe each participant was asked to complete a short survey on the usefulness of the online training tools in helping them navigate the system. As a result businesses requested that more hands-on training be made available. In response, the Governance Board approved the development of train-the-trainer material for LMS contacts with the end goal of enhancing usage. Starting in February, 2004, France and Germany had a combined 7 percent uptake at the beginning of the third quarter of 2004. In addition the combined percent complete

performance measure in France and Germany was approximately 12 percent.

Japan—Japan launched the LMS in the second quarter of 2004. They first established a cross-functional working group that met regularly with the e-learning and LMS team representatives to address issues and questions in order to meet their launch goals. This working group has driven all launch activities and has made great progress since being formed in August 2003. Their leader represents Japan on the LMS Governance Board to ensure that the LMS team is fully informed of progress.

Japan began their LMS activities with an introduction to the system in September 2003. They then developed a launch strategy and conducted a kickoff in September 2003 for the working group, as well as several open-house sessions where employees could see the system in informal training sessions.

Before the March 2003 pilot in Japan, the Japanese working group received the technical training necessary for the business units to maintain the LMS. They also identified instructor-led training, regulated documents, and PowerPoint presentations with self-assessments, so that pilot participants could have a full complement of material with which to work. The pilot involved a small group of users who first became familiar with the system and then responded to a feedback survey regarding both the online training and functionality. Pilot participants often became part of the growing number of LMS ambassadors in the businesses and contributed to enhanced acceptance. Survey results were summarized and used in the ongoing communication effort to make the launch in Japan a success.

One aspect of the implementation which is unique to Japan is that the role-based feature of the system is not used and job types have not been created. Instead, requirements are managed outside of the LMS, and staff are encouraged to register for required training through the LMS Learning Catalog. As in other regions, LMS reports are being used to prepare for agency inspections. Four months after launch, their percent complete performance measure was approximately 27 percent.

Other areas—Discussions are underway with the other countries in the EU and with the rest of the

Table 1 Evaluating an enterprise-wide learning management system

Factor	Description	How the LMS measures up
High Availability	Serves diverse needs of thousands of learners, administrators, content builders, and instructors	Over 14,000 users had registered in LMS by September, 2004 throughout Aventis in all functions
Scalability	Infrastructure should expand to meet future growth in volume of content and users	Expanding use to remaining 25 EU countries as well as countries in rest of world
Usability	Supports...automated and personalized services, such as self-paced and role-specific learning. Access, delivery, and presentation must be easy-to-use and highly intuitive.	Individual learning paths available through role-based training (required training setup by roles within department)
Interoperability	Supports content from different sources and multiple vendors' hardware/software solutions, the LMS should be based on open industry standards for Web deployment (e.g., XML, SOAP) and support the major learning standards (AICC, SCORM (Sharable Courseware Object Reference), and IEEE)).	Growing e-learning content compatible with LMS requirements
Stability	LMS infrastructure can reliably and effectively manage a large enterprise implementation running "24X7."	Already supports large volume of global users on two servers
Security	Selectively limit and control access to online content, resources, and back-end functions, both internally and externally, for its diverse user community	Ability implemented to limit access internally for groups with sensitive training requirements and externally, as security models are tested for outside partners to access LMS

worldwide Aventis organization to begin implementation of the LMS in these areas as well.

The collaboration and support of both business and technical teams contributed to the progress seen thus far. All global business activities were fully supported by the LMS team, the governance boards, management of the business units involved, and IBM Business Consulting Services. Technical activities have been fully supported by the e-learning team.

Evaluating LMS as an enterprise-wide system

Industry experts use several factors to evaluate learning systems and their implementations.¹⁰

Table 1 illustrates how Aventis has adapted these criteria and how the Saba-based LMS has met all the characteristics required for an enterprise-wide system. (Descriptions in Table 1 are taken from Reference 11.)

IMPACT OF THE LMS ON THE ORGANIZATION

The rollout of the LMS is still ongoing, but it is clear that the LMS has become embedded globally into the training culture of DI&A and the clinical departments of ComOps. There is clear evidence

that the LMS, in line with current learning trends, is providing the organization with an increased ability to respond to the change inherent in the pharmaceutical industry. Specifically, the LMS creates a shift wherein employees become more empowered to influence when, where, and what they learn.¹² Through the LMS, they can obtain online training at times convenient for them or manage their own registration in traditional classroom training. Users are now responsible for ensuring they have no training gaps, and they can also personalize their training records based on their professional goals. The LMS allows employees to manage their own training records electronically, rather than through the paper records that have been managed by others in the past. (These paper records can be voluminous if an employee has been with the company for many years.) Employees' LMS records follow them regardless of where they work in the organization. To document a change, an employee simply modifies the personal information screen to accurately reflect current department, job type, and immediate supervisor. In addition, e-mails help alert employees when new material relevant to their responsibilities becomes required.

The LMS also shifts “the focus of learning beyond learners as individuals to include learners as teams and organizations.”¹¹ Institutionally, the pharmaceutical industry is subject to myriad organizational changes ranging from small-scale internal departmental reorganizations to corporate mergers, resulting in an ever-evolving environment with constantly changing learning requirements. In particular, the LMS supports team and organizational learning by bringing new perspectives to entire teams “by quickly aligning employees with changing organizational priorities, strategies and structure.”¹¹ To facilitate change, management can arrange for employees to receive alerts on timely and pertinent information affecting their daily responsibilities. Regardless of the degree of change, the LMS provides flexibility to help an organization remain agile and to efficiently deliver and train employees on new processes and procedures. In a regulated environment this helps ensure continued regulatory compliance, but it also allows businesses to meet new demands throughout the organization and helps maintain competitive advantage.

“Learning is becoming a vehicle to enhance relationships across the enterprise and the full value chain.”¹² The LMS provides not only central access to and increased visibility of requirements throughout the organization, but also a network within which the community of LMS contacts and governance boards can collaborate. Many of these relationships existed previously, but the LMS has strengthened existing ties and fostered new ones. In particular, the LMS is causing many business units to look beyond their immediate requirements to consider how they can formally increase their employees’ familiarity with other groups with whom they are interdependent. Many groups are setting up nonrequired training to heighten awareness on several levels. Over just the last year, there has been a noticeable increase in collaboration between departments that in turn has led to more creative thinking across functional boundaries. Another result of these innovative rollout approaches has been the creation of a self-perpetuating support system which can help prepare the organization for future changes.

NEXT STEPS AND BEYOND

Although the LMS has been implemented without a single business owner, it is becoming clear that an official business owner will be necessary to ensure

long-term success. The existing governance boards will continue to provide forums to discuss issues potentially affecting other areas, but a single business owner will provide necessary authority within the organization. The vision is for the owner to receive support from two or three full-time employees, who would help manage and support the system on business and technical levels and be responsible for:

- Raising issues that require input beyond the governance structures
- Centrally coordinating implementation of the system in new countries, leveraging successful experiences of businesses with similar requirements
- Addressing data privacy
- Identifying new contacts for areas joining the LMS community and replacing current contacts when necessary
- Coordinating and conducting orientation for contacts and users
- Coordinating quarterly meetings and regular communications with the worldwide network of LMS contacts

The LMS rollout continues and is expanding into many other countries. France and Germany continue to roll out the system to a few remaining departments. As of this writing, discussions are underway with many countries within the EU that are enthusiastic about using the LMS, particularly in light of the training program currently underway regarding compliance with the EU Clinical Trial Directive. In addition, the rest of the worldwide Aventis organization has agreed to coordinate LMS activities and begin organizing training requirements to allow them to begin documenting training through the LMS.

The extensive rollout thus far demonstrates the success of the LMS team in overcoming the original challenges to the LMS implementation. As progress continues, the LMS is expected to exceed the geographic reach originally envisioned.

FUTURE IMPACT OF THE LMS ON THE ORGANIZATION

To date LMS activity has focused on internal businesses, but the LMS leaders have a broader vision that goes beyond existing internal uses of the system. In particular, the team is also looking for

ways to further exploit LMS features to allow external partners to access the LMS.

A specific example involves clinical trials. Organizations often rely on external partners, such as contract research organizations and independent contractors, to perform study-related activities that are in turn regulated by government agencies. Aventis is responsible for providing training directly to these groups to ensure they are well-versed in the Aventis policies and procedures required to perform their jobs. Work is underway to develop a security model that will allow external staff to access the LMS, but limit them to material pertinent to their immediate responsibilities. Without permission, they will not be able to view other training on the LMS or access other information within the Aventis intranet.

Another group of external partners includes clinical investigators and their study staff, who often conduct studies for the pharmaceutical industry. Orienting the study staff for a new study or amendments to existing studies requires training and guidance to ensure that the study is being done correctly. This initially involves meetings where all the investigators are gathered to introduce a study. It also involves training for other medical and administrative support staff and usually requires travel expenses for a number of people. On-site trainings can be costly. There is ongoing discussion on how to bring the LMS into the offices of these external partners to deliver, manage, and track their training.

If the current momentum continues, the LMS team should easily meet its global implementation goals and begin to explore these other innovative possibilities. In today's changing environment, realizing this vision would provide not only tremendous cost savings, but also a wide variety of functional improvements throughout the organization and, potentially, the broader pharmaceutical industry.

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