

Boehringer Ingelheim SA. in Colombia implements LabWare LIMS Pharma Template in record time.



Boehringer Ingelheim is a research-driven group of companies dedicated to researching, developing, manufacturing and marketing pharmaceuticals that improve health and quality of life. The business consists largely of Human pharmaceuticals (consisting of Prescription Medicines, Consumer Health Care and Biopharmaceuticals) as well as Pharma Chemicals and Animal Health. Boehringer In-

gelheim SA, Colombia (BICO), who has been a presence in Colombia since 1962, made the decision to advance their technology base in order to deliver higher levels of compliance in supporting of Quality and Product Control to its plant. One of the key elements was the installation of a Laboratory Information Management System (LIMS). LabWare LIMS was chosen for this task in 2008 with the

goal of completing this task by the end of that year. LabWare decided to take on the challenge by leveraging their Spanish and Latin American resources with their knowledge of the Pharmaceutical industry.

Implementation Goals

BICO planned a project in June 2008 and decided to begin the implementation in August of 2008 with the expectation to complete the

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project by January 2009. The scope of the project was to replace the legacy LIMS and paper based systems as well as interface with the existing ERP system (BPCS). Validation efforts were to be completely taken over by BICO validation personnel with minimal assistance from LabWare. BICO and LabWare decided to utilize the Pharma Template for the bulk of the requirements. They also elected to utilize as base the existing BPCS interface which was also used by PROMECO (Boehringer Ingelheim Mexico, was implemented in 2004 by LabWare Spain). Due to the criticality of the project and the quick turn-around time required it



was decided to limit the scope of the project to the following functionality:

1. Stability Studies
2. Bulk and Raw Materials
3. BPCS interface
4. Database execution in DB2

5. Approval of methods and specifications
6. COA generation
7. Completely replace legacy LIMS (Q-DIS)

Once the scope was defined, LabWare and BICO created the implementation team using LabWare's GOLD Methodology which heavily involves the client resources. This methodology was adopted by BICO to ensure a successful completion to the project. The implementation team was defined as follows:

- 1.5 LabWare consultants
- 1 full time LIMS Administrator from BICO
- 1 IT BICO analyst
- 1 Laboratory BICO Validation analyst
- 2 Laboratory BICO data entry analysts
- All laboratory staff for testing

How was it accomplished?

The project began in August 2008 with training of the key team members within BICO. The requirements were then written and approved by the BICO team members as well as the end users. LabWare advised and assisted BICO minimally during this period. The BICO LIMS Administrator involved

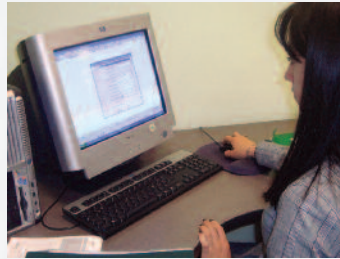
the laboratory staff in the definition of the requirements, and the testing, and validation of the system. Because the Pharma Template was utilized for the implementation, the validation kit included in the Pharma Template was fully leveraged to streamline the validation efforts. Typical pharmaceutical implementations which



require a validation, such as LIMS, generally require a ratio of implementation effort to validation effort to be approximately 1:2 (i.e. twice as much validation activity as implementation activity). The LabWare validation KIT, however, reduced this ratio to approximately 1:¼ resulting in a significant cost and timeline savings. Adhering to the GOLD methodology, the implementation was conducted in workshops where LabWare consultants worked with BICO analysts to show them how their requirements would be met by the Pharma

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Template. Once each workshop was completed, the BICO team would take over



and complete the configuring of the system either manually or using the auto input functions within LabWare LIMS to populate the required information. Validation was done in parallel to the implementation and a final push was necessary at the end of December and beginning of January 2009, when BICO went live with minimal support from LabWare. Once the system went live in the beginning of 2009, BICO decided to take on some of the functionalities which were deemed lower priority during the implementation project. Because of the high degree of involvement in the project, BICO was able to accomplish these implementations with minimal involvement from LabWare.

Conclusion

Luisa Fernanda Gaviria Gomez, the BICO LIMS Administrator says: "To deliver this project in such a short time three elements were fundamental: determination, follow-up and support. The determination from *Boehringer Ingelheim Colombia* of wanting to implement the project in



such a short time, which in turn required to adjust the resources and requirements so that this was possible always supported by the steering committee (Plant Manager, IT Manager and Quality Manager). The follow up and support of ICR3* was fundamental for the totality of the activities of the chronogram were executed at the time required. We want to give a special thanks to the work of the lead consultant since he was a

person committed to the project; he always adjusted his workload and gave all his available time to assist us to complete the activities at the required time"

The reasons that a Pharmaceutical LIMS implementation and validation was completed in 5 months become clear when one focuses on the decisions made by the team at the beginning of the project:

1. BICO decided to become fully involved in their implementation (IT, Lab and strong Leader)
2. LabWare delivered the Pharma Template and validation KIT to BICO (COTS).
3. The team prioritized and defined the Scope which was approved by BICO
4. The decision of BICO to "own" the implementation (GOLD Methodology).

By involving LabWare in their implementation effort, and adopting proven template functionality and implementation methodology, BICO was able to achieve all their goals for their LIMS implementation.

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