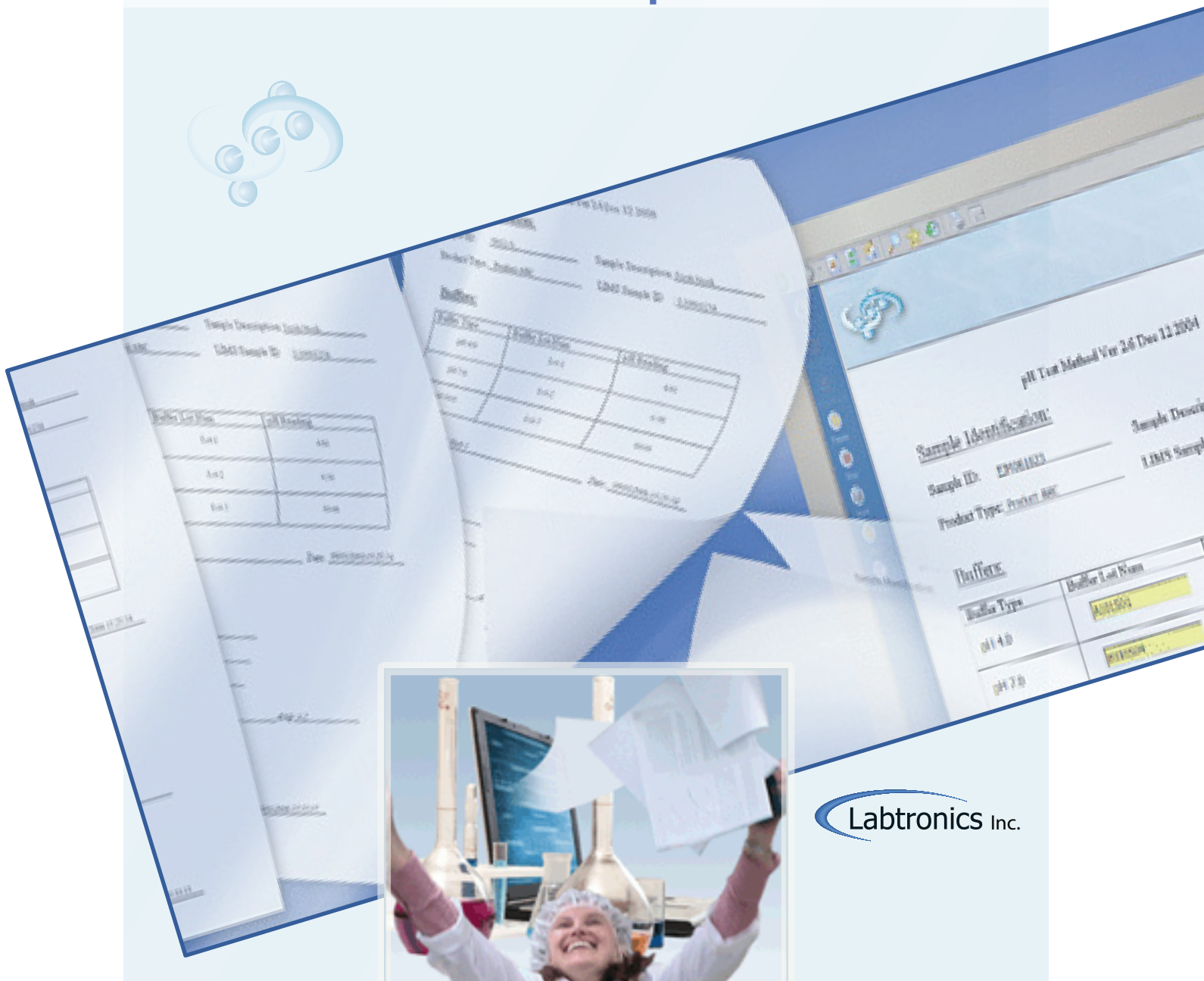


ELN and the Paperless Lab



Labtronics Inc.

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Chapter 1: Introduction

I have been involved with Labtronics Inc since its inception, 25 years ago. Initially the company focused on interfacing instruments to LIMS and then expanded to interfacing any lab system. Over the last 5 years we have also been involved in developing other types of laboratory informatics systems.

For 25 years we have worked closely with developers of systems such as LIMS, SDMS and ELN, helping them interface their products to instruments and to each other. We have seen the market place from the point of view of the informatics systems developers and at the same time we have worked directly with their customers giving us an understanding of their point of view. This has given us a unique insight into this industry.

It is a combination of this unique perspective and our realization that many people do not understand ELN that led us to launch ThePaperlessLab.COM web site several years ago. This web site is filled with technical information that helps users to better understand the tools that can help them reduce or eliminate paper use in the lab. Much of the focus is directed on ELN.

This year we decided to take this project one step further, by publishing this book.

The purpose of this book, “ELN, and The paperless Lab” is to bring together some of the best articles that have been written about ELN in the last couple of years. This book will be a great reference book for anyone who is in the process of implementing an ELN or considering the implementation of an ELN. It will also be a good information resource for anyone who is interested in the automation of labs.

This book is a collection of essays, each of which has been written to stand on their own as separate articles. Rather than try and rewrite them to fit a standard book format, we have decided to leave each one as originally written. You will find some overlap in topics, but this format will allow you to read the essays in any order that suits your needs.

The Evolution of Electronic Laboratory Notebooks

A very pragmatic view of ELN is that it is an electronic replacement for the old fashioned lab paper notebook. Wikipedia does not indicate when ELN was first invented but I suspect it was the early 1990's. By 2000, some commercial products were being offered and some early adopters were implementing ELN.

In the next 5 years ELN started to become more prevalent. Companies were ‘test driving’ products to give the technology a limited try. Most of this activity was taking place in R&D labs.

The initial driving force for ELN was to provide a better way to capture Intellectual Property (IP) and the customers most interested in this were synthesis chemists working in pharmaceutical companies. Capturing discoveries for this group was a significant issue and the promise of a better, electronic way, to capture IP was very attractive. Synthesis chemists led the way.

Initial commercial ELN products were very much geared to R&D work. What these customers required was a secure way to 'write' out their experiments. The work that is done in R&D requires a system that is very flexible – as flexible as a blank piece of paper. An ELN for R&D fulfills those requirements and also prevents alternation of the data, incorporates electronic signatures to ensure proper tracking of IP information and provides better tools for data mining.

In 2005 Labtronics Inc was the first company to release an ELN specifically designed for the QA/QC market place. To differentiate it from 'R&D ELN' it was given the product class designation "qELN".

Over the next 5 years the R&D ELN gained a solid foothold on the market place and many customers have adopted those products. Much slower growth was seen in the QA/QC labs. For them the concept of an ELN is still very new today.

The requirement for a QA/QC ELN is quite different than for an R&D ELN. The QA/QC lab is all about process control. Each analyst should be doing each test exactly the same way. "Flexibility" in documenting work is just not acceptable. This is the main reason for the development of two distinct types of ELN. These differences are further explored in some of the essays in this book. Understanding the differences will help you to better understand your own requirements.

In the last couple of years there has been an increase in interest for an ELN for biology and biotechnology. This group also has special requirements. This ELN needs to be more flexible like the R&D ELN, but it also has to deal with more complex data such as DNA profiles.

There are now some 30 different commercial ELN products on the market. With the exception of two companies who are focused on the QA/QC side, they all focus on R&D ELN.

What do Customers Think?

The above section is written from the perspective of a market analyst, but what does the customer think?

Atrium Research (Atrium Research & Consulting LLC) has done a number of surveys over the years and is a very good resource for more information. The 2010 Atrium report¹ indicates that:

- 47% of Biopharmaceutical organizations have at least 1 department using ELN
- 18% of QA/QC labs make some use of ELN

¹Atrium Research & Consulting LLC, "2010 Electronic Laboratory Notebook Survey"

- 25% of the market knows little or nothing about ELN
- 40% of the market understands the difference between ELN and LIMS (from 2008 study)

These numbers confirm what we see in the market place. Much of the “talk” about using ELN is focused on the R&D labs and ELN trade shows focus on R&D products. QA/QC labs are just now starting to consider ELN as a product for solving some of their issues. The essays in this book discuss many of these issues.

For the most part customers are not clear about the role ELN, LIMS and SDMS play. Why is this?

For one reason, most customers have never worked in a lab that has been automated with all three systems. It is difficult to understand a system if you have never used it.

Secondly, software developers are trying to be everything to everyone. A prospect commented to me that a leading R&D ELN developer had told them that their product would meet their LIMS needs. That statement is not true. LIMS companies on the other hand are making significant claims about “ELN functionality” in their product. There is certainly some overlap when you compare ELN and LIMS, but rarely will one replace the other.

It is important to understand the basic design of ELN, LIMS and SDMS and their specific purpose. Articles in this book will provide that information and once you understand the differences you will be in a better position to evaluate commercial products.

The 2010 Atrium survey also measured ELN perceptions. Participants in the survey who had some interest in ELN or who had used ELN were asked “What statements most closely matched your view of an ELN”:

- 42% said an ELN is a portal or entry point into all of the laboratories systems and databases

I find this surprising. As far as I know companies selling ELN do not position their product as a portal into other labs systems. In fact most commercial ELN shy away from integrating their product into other systems. The idea of using an ELN as a way to review results in LIMS or to view documents in SDMS is not practical, except in those cases where the ELN generated the data in the first place.

The essays in this book will help clarify the role of ELN for your lab.

Robert Pavlis
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