Exploiting the Benefits of Electronic Signatures with a Chromatography Data System

Charlotte Kornbo[1] and R.D.McDowall[2]

[1] Analytical Control Production
H.Lundbeck A/S, Ottilavej 9, Valby
DK-2500, Denmark

[2] McDowall Consulting
73 Murray Avenue
Bromley, Kent BR1 3DJ, UK

Introduction

In a previous article, the potential of designing the use of electronic signatures into a LIMS workflow and highlighted some of the benefits [Ref 1]. In this current article, we want to discuss the ways that the design of electronic signatures can be implemented into a chromatography data system (CDS).

Reiterating the principle from the last article, that implementing electronic signatures on an existing paper based process is not just a matter of electronically signing the calculated results. It requires a different philosophy and also requires a good understanding of the regulations that an organisation has to be compliant with and the business processes that will use electronic signature.

It is unlikely that an organisation will benefit implementing electronic signatures on an existing process unless it has been implemented to work electronically [Ref 1].

A prerequisite for this approach to succeed is the need for any software to be technically compliant with the requirements of 21 CFR 11.

Case Study Description

To illustrate this principle, we will examine a case study where electronic signatures were designed into the process. The CDS is installed in a pharmaceutical quality control laboratory where the system used for both raw material and finished product analysis; there are approximately 50 users of the system. The current CDS version is not fully compliant with the technical requirements of 21 CFR 11 and is being upgraded to a new compliant version of the software. Before the implementation of the new version, the current process was mapped and analysed to see if there were any opportunities for improvement and to make effective use of electronic signatures.

Please note that these are interim results as the system is not yet implemented but the potential cost savings from this case study make a compelling business case for the implementation of electronic signatures. Further details will be published after the system has been validated and we can assess the impact of the redesigned process.

There is also a LIMS that is operational in some of the sections within the Laboratories, however at the moment there is a mixture of both lab notebooks and a LIMS being used.

The Current Process

The first task is to map the current process. This is relatively quick and the current laboratory high level process is shown in Figure 1. We can see that there are parallel electronic and paper activities when chromatographic analysis is undertaken. For example, when a chromatograph is set up, a paper

record (Lab Book) needs to be updated and checked. When results are calculated the report and chromatograms printed out and the Lab Book updated and checked again.

It is important to analyse the current process, for instance:

- What are the process metrics? For example, how many samples are analysed and what are the turnaround times?
- Analyse the turnaround times: what are the reasons for fast and slow turnaround?

Answers to these questions will give you the information to start to improve the process and make it more effective and efficient.

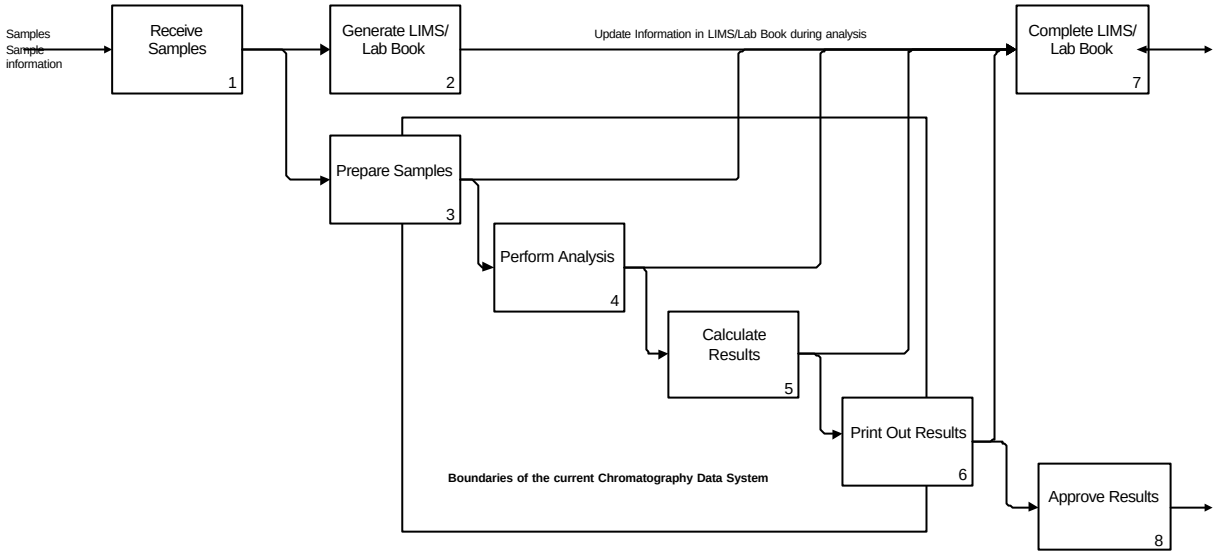

Figure 1: The current process highlighting the boundaries of the current version of the CDS

The boundaries of the current version of the data system are also shown in Figure 1. In the current system the approval of results occurs outside of the chromatography data system on paper. How could you implement electronic signatures in this situation? You would need to change the way of working to do this.

The Redesigned Process

Knowing the problems and improvement ideas from the analysis the current process can be redesigned to exploit the use of electronic signatures. It is important at this stage to ensure that the new process is compliant and that the new version of the CDS can support the new process as well.

The redesigned process is shown in Figure 2, the main differences are:

- Elimination of the need to update the Lab Book for chromatographic analysis. This is a quick win that is estimated to save about 0.3-2.6 FTE (Full Time Equivalents or person years). This is independent of implementing electronic signatures in the CDS
- Expanding the scope of the CDS. In effect the approval of electronic records and calculated results takes place in the CDS and the printout is an option.
- Using the CDS to carry out all calculations rather than use a calculator or spreadsheet, this streamlines the whole process for calculating, reviewing and approving results.

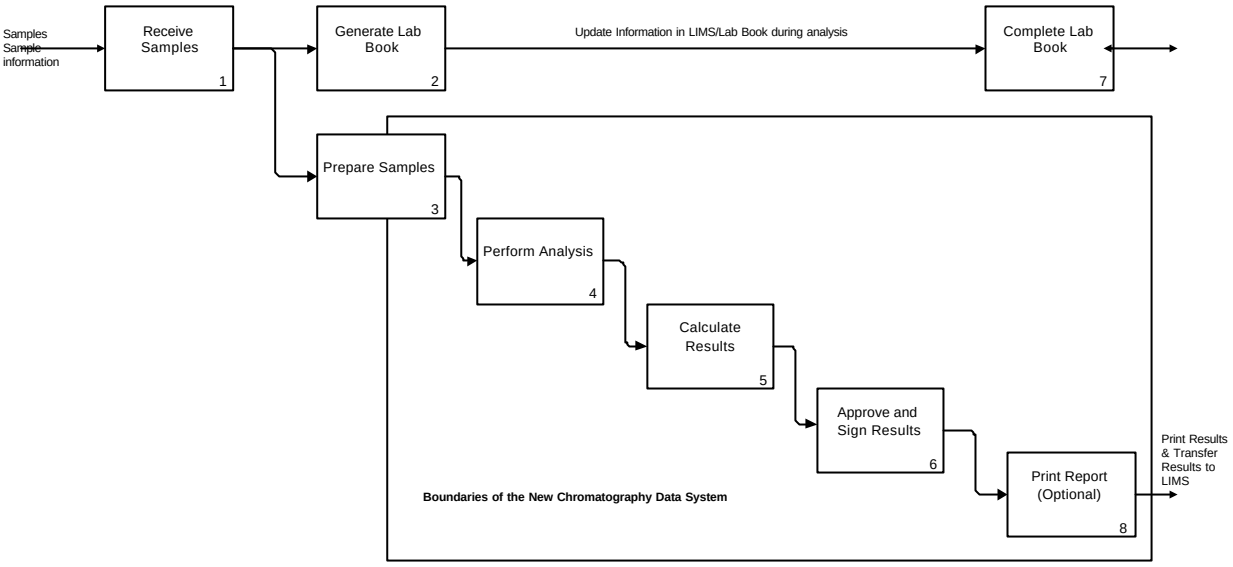

Figure 2: The redesigned process highlighting the extended boundaries of the new version of the CDS

The benefits of the process redesign when the CDS is linked to the LIMS would be in the region of 6-12 FTE. This is a surprising benefit but enables more capacity to be generated with the current resources. As the LIMS / CDS link will not be implemented until later in 2002, the current estimate of savings in the region of 0.5 – 3 FTE.

References

1. R.D.McDowall, Designing LIMS Workflows for Electronic Signatures, Scientific Computing and Instrumentation