LIMS - now an integral part of the data structure at BCM

Whatever your preference in toiletries and pharmaceutical goods its odds on that your bathroom, and probably your kitchen too, is currently playing host to a range of products manufactured in Nottingham or Airdrie by Boots Contract Manufacturing Ltd (BCM).

Whilst BCM is an integral part (and wholly owned subsidiary) of The Boots Group PLC it has been a completely independent concern, with its own accounts and management structure, since 1993 when the decision was taken to split the Group into 'Strategic Business Units'. The Boots shops are still the major customer but there is now a wide customer base and a vast inventory of products including many of the famously marqued cosmetics, toiletries and 'medicated confectionary' that you can now stack relatively cheaply into your supermarket trolley along with a wide range of 'over the counter' preparations and other pharmaceuticals.

The control of information during the manufacture, control, test and release of these products is understandably complex and hugely extensive. But until barely a year ago the whole excercise was performed by an extremely thorough and demonstrably accurate paper based system.

Basically, samples would be taken from the production area into the QC laboratory and details would be entered onto record cards. Analysis of those samples would be performed to predefined methods and specifications, the results of which would be recorded in individual analysts lab books. The data would then be transferred to the record cards, checked, cross referenced and then eventually the material would be passed for use. The cards were stored in filing cabinets, regularly reviewed and made available for any inspection.

None of the above was in any way unsatisfactory and there is no question that an extremely successful QC operation was being enacted by a dedicated and well motivated team of people.

The main driver for reappraisal of the system was a desire to increase productivity, with an added benefit of increased accuracy and minimisation of clerical errors offered by a computer system. Importantly, there was also an awareness of the new pressures from the UK and US regulatory bodies; the MCA (Medicines Control Agency) and the FDA (Food and Drug Administration). The justified drive from these bodies to impose state-of-the art technology on the industry throughout manufacturing and control procedures is well documented and will not be discussed here but clearly this is the catalyst for major change in the industry over the next few years.

Whilst there are no formally defined standards for computer based systems at the moment the GAMP (Good Automated Manufacturing Practice) forum established by the pharmaceutical industry is currently working on this. However, licenced medicinal products must be manufactured and controlled to standards defined within the 'Orange Guide' (the Guide to Good Pharmaceutical Manufacturing) or for US and related markets, the Code of Federal Regulations. The MCA inspect against the standards contained in the Orange Guide and with a QC system companies must be able to demonstrate auditability and complete traceability. Total validation has to be proved.

Converting data from the paper-based systems into the new automated LIMS

A company will have to explain why it chose a particular system and demonstrate its confidence in it. The system will be 'challenged' (BCM do this regularly now) and put through pre-defined tests. Clearly a system which does not measure up to these tests will cost a company much more than a wasted investment.

The evaluation process for a LIMS (Laboratory Information Management System) to replace the paper based system at BCM began in October 1994. Four systems were carefully evaluated and by December 1995 the decision was made to purchase QSI's WinLIMS™. After a short parallel operation scheme the system went live on one site in mid-1996 with a 20 screen networked system. There will be around 80 users across four sites (three at Nottingham and one at Airdrie) by the time the system is fully implemented.

Heading up the team responsible for the evaluation, purchase and implementation of WinLIMS™ are Chris Hughes, (Information Systems) and Dr Richard Torr (Systems Development Manager). Whilst productivity gains were very much in mind with the conversion to LIMS there were a few immediate benefits.

"We now have a vast pool of manipuable data at our fingertips which we are already using in other areas", says Chris Hughes "ideas are still progressing as to what further we can do with this new information source - the possibilities are endless". A link into an SPC (Statistical Process Control) product compatible with WinLIMS™ is expected soon and clearly key performance indicators can be extracted from all

aspects of BCM business, including the monitoring of suppliers. Further connections will also be made into the wide range of analytical instruments at BCM.
"We are already establishing a link into our manufacturing system and we see Win-LIMS™ as becoming an integral part of the overall BCM data structure". explained Hughes.

The potential for manipulating data increases massively when other systems (word processors, spread sheets, graphics packages etc) are integrated into LIMS; an easy option with a true Windows based system like WinLIMS™.

Another benefit comes with the data entry procedure: "inputting data into a computer imposes its own disiplines that were not always there with the manual system and ambiguities can be eliminated" enthused Richard Torr.

Chris Hughes (left) and Dr. Richard Torr (right)

"Ease of use, was the major criteria for the selection of a LIMS" says Chris Hughes who was involved with much

of the initial training "people had to be comfortable with using the system and we had to be confident that they were using it correctly". The intuitive Windows based approach of WinLIMS™ is credited for much of its quick adoption by a fairly wide level of staff. Now on its third release the system was designed from its inception in Windows (unlike most others which have converted) and many of the routines are icon lead. There are also safeguards in the system (version control, specification methodologies, selection of data from pre-defined lots etc) to prevent the entry of obviously erroneous data and, although other verifications are made later in the procedure, this was important to BCM.

"Our prime application for LIMS is very much the day to day manipulation of basic QC lab data, particularly the recording of incoming samples" says Richard Torr. "We're sampling raw materials as they arrive on the receiving dock and registering results from those into the LIMS which automatically associates certain test methods against those raw materials. We're then logging in samples of manufactured materials and testing against pre-defined quality limits in the LIMS. All

calculations are performed very quickly so there's a big time saving on someone sitting there with a calculator". Clearly a major task was the input of a 'mountain' of existing data into the system. This will include raw material data, packing components, bulk, intermediate product and finished pack product data. That process is still continuing and BCM have concentrated so far on just the raw materials and the bulk intermediate products. At least sixteen weeks of dedicated data entry will be required for each site to complete their task.

In terms of hardware WinLIMS™ requires at least 8Mbyte of RAM to operate effectively and BCM are happily running some slightly older 486 computers alongside their standard 133MHz Pentiums. The central database is installed on a dedicated LAN server though the actual LIMS application has been installed on each individual PC. A 'master image' of the application sits at the centre of the network and if any software is changed then this is detected by each PC and automatically downloaded. A bonus here is that BCM have one audited system that will show every PC as having an audited version of the software.

The database is backed up every couple of hours at the File Server whilst a corporate network supervision team perform a backup every night.

Security is clearly an important aspect of any LIMS and various password levels are easily built into most of them. WinLIMS™ also ensures that the system is completely 'audit trailed' ie: who did what and when. There is never an invisible trail.

The BCM evaluation team had been clear from the start that they wanted as little customisation of the system as possible. Customisation and implementation are very quick ways to soak away a valuable budget allocation. After an initial evaluation period (resulting in a comprehensive system description) QSI implementors then delivered a fully configured and tested system within less than two months. Initial customisation was confined to status dispositions and batch header information.

Whilst achieving most of the immediate, practical objectives that BCM has set for it the institution of a correctly working LIMS allows a level of forward planning not previously envisaged: "What we're doing now is moving from a quality control system to a quality assurance system", says Richard Torr, "everyone should be looking to build quality throughout their process so that once a product has been manufactured it is certain to be 100% correct. WinLIMS™ is another step in this process as far as we are concerned".
For the future, BCM would like to see further developments in the control of sup

plier audits and approvals. In order to be sufficiently confident of their suppliers they would like to see some means of controlling audits of suppliers integrated into the LIMS itself so that when the raw material arrives they can see what level of approved supplier is behind the delivery and make extra tests if need be (they are currently doing all of this separately). The system would 'flag up' when a supplier next needs visiting for another audit and provide the facilities to record the results of that audit.

With facilities in Germany, USA, Australia and the UK, QSI (now 6 years old) is a rapidly developing worldwide corporation. There is only one product; WinLIMS™. According to UK and Benelux Managing Director Clive Collier this is the way it will stay: "We are a totally dedicated LIMS company and all our resources go into the development of WinLIMS™. We now have over 170 user sites worldwide and demand for LIMS products is clearly increasing worldwide. We intend to develop our product into a QA/QC control package rather than just a pure LIMS. This would cover aspects of document control, resource allocation and SPC. We intend to use and develop latest technology, such as Intranet applications and in particular the ability to log samples into the LIMS over the Intranet and to see results of samples over the Internet".