

Split between regulation and availability

The vast majority of companies concentrate on improving machine availability (at the lowest possible cost) so as to increase their revenues. This is difficult enough in itself. But nowadays many companies must additionally satisfy tough laws and regulations. Intervet International at Boxmeer is such a company where the situation is slightly different. At this manufacturer of veterinary medicines it is an absolute precondition to meet stringent regulations simply to be allowed to produce. The Technical Service department of Intervet plays a prominent role in this setting.

BY NIKO WIND

Directives issued by the US Food and Drug Administration (FDA) and terms like Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) are constant themes at Intervet. These regulations obviously impact considerably on the day-to-day work of Technical Service, but how does the department cope with them in practice?

Splitting

Besides satisfying laws and regulations,

Intervet strives to maximize the availability of its production machines. According to Hans van Duijnhoven, Technical Service Manager, Intervet attaches great importance to his department. "We work in a kind of split operating between ensuring maximum quality and maximum availability," he says. "We cannot afford to have any variances in the composition or working of our products. In the production and filling of pharmaceutical medicines, an incorrectly set installation means products

will fail the quality inspection. This is even more important when producing biological medicines, where the active components are made using various processes like fermentation, microfiltration and ultrafiltration, because the total process from antigen production to approved product takes months. One wrongly set machine can therefore have disastrous consequences. Besides the rules attached to the environmental permit there are the rules laid down by various international

PREVENTIVE THINKING

A surprisingly great effort was made during the implementation process to bring about the required change of mindset of the mechanics. Van Duijnhoven: "We purposely decided not to standardize the maintenance procedures top-down, but to develop the maintenance procedures for



From left to right: Hans van Duijnhoven, Remco Jonker and Gijs Wieland (Datastream Application Manager stationed at the Technical Service department of Intervet)

all machines together with the production staff and mechanics concerned. After all, they are the people who must use them. We do this according to the Reliability Centered Maintenance method. This complete standardization means

we can minimize the risk of variations in maintenance, calibration and validation processes. We also satisfy European and American pharmaceutical laws covering performance of the work." Besides getting used to numerous fixed rules and procedures, the mechanics first had to get accustomed to the greater emphasis on preventive maintenance. Van Duijnhoven: "They were used to keeping machines operational mainly by means of corrective maintenance. But the emphasis in our new maintenance philosophy is on prevention. If equipment is maintained properly - i.e. according to regulations - the number of faults will decrease and at the same time the risk of variances will be minimized". To bring about this change in thinking, the project team organized special training courses, focused on increasing the quality of maintenance, as opposed to the efficiency of maintenance as is customary at other kinds of production companies.

authorities that watch over the production of medicines. Satisfying the regulations of these authorities often means recording beforehand what you will do and recording afterwards what you have done."

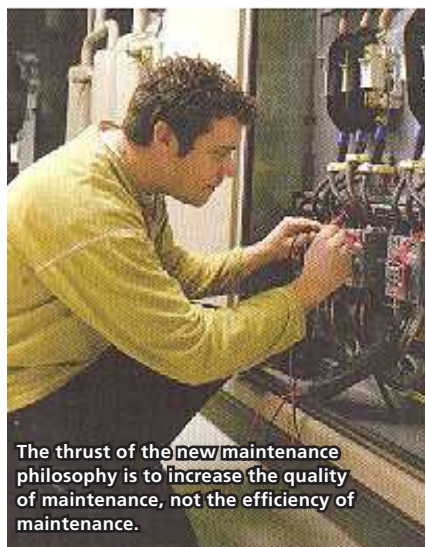
Demonstrability critical

Intervet uses a "self-built system" to record the maintenance and maintenance history



Hans Van Duijnhoven, Technical Service Manager: "The completed improvement process contributes significantly to Intervet's operating results" (photos: Michel Zoeter, Reed Business Information).

of every machine. Using this database for object management made it almost impossible to meet the requirements imposed by pharmaceutical companies. Van Duijnhoven: "Under GMP and FDA rules you must be able to prove everything by means of documents. You have to be able to show what maintenance was performed, when and by whom, but also who calibrated the instruments and when. It was not possible to enter all of these procedures in our old system and it was virtually impossible to keep paper records of them". In addition, in an industry where measures and quantities play an essential role, every maintenance operation must be performed in exactly the same way every time. Intervet launched an improvement process to get



The thrust of the new maintenance philosophy is to increase the quality of maintenance, not the efficiency of maintenance.

a firmer grip on this entire process and better satisfy the increasingly stringent (international) requirements. Central to the process are demonstrability (regulations) and improved machine availability.

External experts

So the time had come to give the management of maintenance a modern facelift. Van Duijnhoven: "After we started we quickly noticed that a modern maintenance management system was essential for success. We consciously decided to enlist experts from outside the company. The package was selected under the supervision of Remco Jonker of Mainnovation, at the time in cooperation with Cap Gemini Ernst & Young. Remco ultimately also helped us with the technical and 'mental' implementation of the system". It proved far from simple to find a system that supported the "classical" maintenance tasks like planning and history and also met the specific requirements laid down for a GMP environment. In the end, the company chose Datastream 7i.

Implementation process

Van Duijnhoven: "First we identified our future working method and determined what we want to achieve in the coming years. We had to do an awful lot of work, particularly because the system itself is also validated. We went live in the fourth quarter of 2002 at the Technical Service, Warehouse and Procurement departments". Jonker continues: "An important element of the process was that we did not regard the start-up of the system as the completion of the project, but rather as the start of improvements. Today, almost a year after start-up, the changes are beginning to take real shape. Over the past year there has been a big investment in training and supervision to bring about a different way of thinking among the technicians and validation engineers (the people who must make it all work)".

Everyday practice

Asked what the system start-up entailed in practice, Van Duijnhoven replied: "We have now switched entirely from a hardcopy work order system to an electronic system. Even today we are still elaborating the detailed work instructions. It's an enormous job, but we are already reaping the first benefits: we now perform almost all the work in a standardized way." Besides enriching the system with work instructions for maintenance and validations, the software is being used to analyze maintenance data and replace

the technical logbooks for recording maintenance data. Ultimately, this will result in the disappearance of most of the paperwork at the organization. "We identified all GMP-critical objects and maintenance processes", says Van Duijnhoven. "For example, the Quality Control department must check whether a change may affect the end-product, and Production may give new instructions or extra training. Before going live we examined the resulting work processes to see whether they would produce the right result. There was then a possibility to make adjustments, after which the procedures were frozen."

The "frozen" procedures are subject to a "change control" regime. This involves running an extensive procedure to document a possible change, both in the software and in the actual performance of maintenance. The original version of a changed procedure always remains on file to allow determination of the history at any time. The system helps to decide whether or not change management is necessary. This avoids a situation where undocumented changes occur at places where they are not allowed. Van Duijnhoven: "It means we meet both the European GMP and GLP and the very stringent 21 CFR Part 11 directive of the American FDA, which describes exactly how you must manage documents saved electronically."

Importance of calibration

Another important item for quality-driven companies like Intervet is calibration of testing devices and measuring and control instruments. Van Duijnhoven says this is one of the next improvement steps. "After all, we must state accurately in our documentation who calibrated an instrument and when. It is important to enter this information in the same system to allow the electronic traceability of data. For example, we can identify the processes or validation study in which the instruments were used." Jonker adds: "Keeping good records also makes it possible to alter the frequency of calibration, something that eventually will produce a financial gain as well. After all, calibration intervals can be lengthened if no errors have occurred within a certain period of time. You can also avoid product rejections by increasing the frequency of fault-sensitive calibrations". In everything Intervet does in this field, the number one item is the quality and constancy of the end-product.