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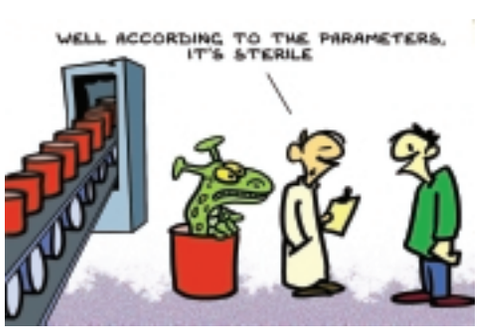
Healthcare

Accelerated Release

Companies generally have no problem investing in a new piece of equipment that provides excellent ROI. Investing in a project to achieve the same result via re-engineering of existing processes should not be any different.

In regulated industries, it is not unusual to find that the lead-time for final product testing and review of the batch documentation represents a significant proportion of the overall manufacturing lead-time. Given that long lead-times inevitably mean high levels of expensive inventory (and associated costs), it is no surprise that many healthcare manufacturing companies are beginning to take a hard look at their 'release processes' which include product testing, review and approval of batch documentation and the processing of exceptions and deviations.

For companies producing sterile product, sterility testing was typically the constraining step in the overall release process. This is because of the inherently long sample incubation period (typically 14 days). In an attempt to reduce release lead times, many companies have pursued 'Parametric Release' programmes that allow product to be released based on the achievement of validated parameters during the sterilisation process (e.g. temperature pressure, duration) rather than on the results of a subsequent test.



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When they first introduce parametric release, companies often find that the overall release lead-time remains at near previous levels. When they investigate further, they find that the remaining elements of the release process such as Chemistry test and batch record review operate with high levels of WIP and long queuing times which eat up the potential lead-time reduction.

This happens because the testing and reviewing processes are still organised in the same way as when there was an enforced 14 day minimum lead-time. Unless they are substantially re-engineered they will always struggle to consistently operate to a reduced lead-time.

The problem

Chemists and Microbiologists are typically focused only on test accuracy and individual test run efficiency. Very often, personnel are dedicated to specific tests and there is no overview or control of the progress of individual samples through a sequence of tests. In most test laboratories, you will find queues in front of tests in which individual samples wait until enough similar samples arrive to constitute an efficient test run. Usually there are no rules to govern how long a sample can be left queuing before it must be tested and if an individual sample queues and waits in front of several sequential tests, the overall test lead-time can be very long. Equally if a sample is 'lucky' and arrives at each test just before a run, the lead-time will be short.

Laboratories organised in this way will always produce inconsistent lead-times with a significant proportion of samples either late or early. Companies often respond to this lack of 'control' by investing in elaborate manual or costly IT systems to track samples through the process and then try to expedite the 'stragglers'. This approach rarely works and it is much better to invest in re-engineering the overall test process to improve sample 'velocity'. Individual samples should move through the process so quickly and so consistently that there is no need to track them.

Similarly, the processes for handling deviations and exceptions are usually not designed to maximise velocity. Very often there is no measurement of overall performance, no clear structured process and no clear definition of roles and responsibilities. The resulting lack of ownership and performance management can result in long delays in releasing affected batches.

Despite the effort and resources regulated companies put into compiling and carrying out first reviews of their batch documentation, most still have a poor R.F.T. (Right First Time) performance at the formal review stages. A significant proportion of batch files / lot histories get returned to manufacturing for correction which can add considerably to the overall release lead-time.
In many companies, batch documentation review and the various product test laboratories are seen and managed as separate functions rather than as elements of an overall release process. This results in a lack of co-ordination of activities, which can negatively impact on the overall release performance.

The solution

When the 'as is' situation is examined it is typical to find that the 'value adding' steps represent only a small percentage of the overall lead-time and that the majority of the lead-time is actually queuing before and after tests. This is good news as it means that significant reductions in lead-time are possible without having to change the test methods themselves, which would involve lengthy and difficult changes to the regulatory files.

The underlying principles of 'velocity' and consistent performance through a release process are actually very simple. To permanently improve lead-times, existing processes need to be re-engineered to incorporate these concepts. In addition, the new processes need to be supported by a modified organisation structure, which reflects the fact that there is an overall release process that needs to be managed as such. The best solutions also incorporate structured performance management and visual management techniques.

The new process will normally require substantial change in the way work is organised and moved through the process. Individual roles will also change with people required to be more flexible and to move to clear queues. As a result, significant cross training is a feature in most 'Accelerated Release' projects and because change is difficult, good change management throughout the project is critical.

Although the basic concepts and best practice for velocity in a release process are simple, integrating them into a defined process that uses resources well and is simple to manage, is quite a challenge. There is also an important project management requirement to co-ordinate the cross-training and change management elements of an 'accelerated release' project. If a project is to be successful and be delivered within a reasonable time frame, it is necessary to resource it properly. This should include significant senior management support and/or the use of external consultants with a relevant track record and excellent project management skills. Obviously this costs money and a clear ROI (Return on Investment) and measurable project Objectives should be established prior to embarking on a full project. A company would generally have no problem investing in a new piece of equipment that provided excellent ROI via substantially reducing lead-times. Investing in a project to achieve the same result via re-engineering of existing processes should not be any different.

BSM is a leading management and technology consulting company. We help clients achieve significant improvement by implementing sustainable process, people and e-technology solutions.

If 'Accelerated Release' is of particular interest to you, BSM would be pleased to visit you and make a more detailed presentation (to you and or your team) on our Accelerated Release methodology and relevant case studies.

If you require any further information or would like to arrange a meeting please contact:

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