



RAPID CHANGE CONTROL

IS YOUR CHANGE CONTROL SYSTEM FIT FOR PURPOSE?

by Martin Lush

USE THIS FREE “HEALTH CHECK” TO FIND OUT

Charles Darwin famously said:

“It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is most adaptable to change.

In the struggle for survival, the fittest win out at the expense of their rivals because they succeed in adapting themselves best to their environment.”

The same applies to pharmaceutical companies. Those that can adapt to the rapidly changing environment will succeed. Those that can't won't. Pete Gough's regulatory update in each Journal always provides valuable insight to what is on the horizon, and there is always something! Combine these regulatory changes with those many of you routinely face and the challenge to your change control systems is considerable. Changes related to buildings, processes, equipment, procedures, systems, third parties, organization... they all have to be reviewed and assessed quickly. **In short, the speed and effectiveness of your change control system is crucial to your future success.**

So, is your change control system fit for purpose? Is it fast and robust, and at the same time flexible and effective? Use the following “health check” to find out. Get together with a few users of the system and answer the following 10 questions with a simple yes or no.

1.	Is your change control system owned by all parties, not just QA?	Y <input type="checkbox"/> / N <input type="checkbox"/>
2.	Was your system designed by a multidisciplinary team including all user groups?	Y <input type="checkbox"/> / N <input type="checkbox"/>
3.	Can your change control system review and approve a change request in 30 minutes?	Y <input type="checkbox"/> / N <input type="checkbox"/>
4.	Does your change control system reject at least 30-40 percent of change requests?	Y <input type="checkbox"/> / N <input type="checkbox"/>
5.	Do you use a risk-based impact assessment form to assess change requests?	Y <input type="checkbox"/> / N <input type="checkbox"/>
6.	Is every change request supported by a business case (cost vs benefit)?	Y <input type="checkbox"/> / N <input type="checkbox"/>
7.	Is your change control procedure simple to understand?	Y <input type="checkbox"/> / N <input type="checkbox"/>
8.	Do you follow up every approved change to ensure it worked?	Y <input type="checkbox"/> / N <input type="checkbox"/>
9.	Have those responsible for implementing changes received training in change leadership?	Y <input type="checkbox"/> / N <input type="checkbox"/>
10.	Do you review and improve your change control procedure every year following consultation with all users?	Y <input type="checkbox"/> / N <input type="checkbox"/>



If you have answered yes to all of the questions, congratulations, your system is fit for purpose. Darwin would be pleased. If you have a few no's, please let us help you – register for our course on Rapid Change Control.

Don't worry...you don't have to completely re-engineer your system to improve it. We will provide you with tools and techniques (and a few shortcuts) that you can implement with ease.



ABOUT THE AUTHOR



Martin Lush has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

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Cite as: NSF International. October 2017. Rapid Change Control. NSF: York, UK.

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