MANAGING A QUALITY SYSTEM WITH A 50% STAFF REDUCTION

by Lynne Byers

Imagine you are the Quality Director of a site manufacturing critical medicinal products or medical devices. You have a sickness absence rate of 50% of QA and QC staff. The government is keen for the site to produce as much product as possible. You need to develop a plan to keep the site in compliance whilst freeing up resources to help with daily QA/QC activities.

Activities can be STOPPED, DELAYED or CONTINUED.

STOPPING ACTIVITIES

Stopping an activity may seem to be extreme but with a 50% reduction in staff, actions should be taken proactively before the Quality System slips out of control. An activity that could be stopped is change controls that have not been implemented. As an action, all pending change controls should be reviewed and only those mandatory changes (e.g. linked to regulatory commitments) should be implemented. This will have the effect of reducing validation effort, regulatory affairs work, QC testing and documentation updates. Being extremely stringent with limiting change controls can free up QA and QC resources. Similarly, any improvement plans such as introducing a new IT system should be halted, again freeing up resources.

DELAYING ACTIVITIES

Delaying compliance activities feels wrong, but in extremes this can be done using the quality system. Any temporary changes should be made using the quality system.

EXAMPLES OF POTENTIAL DELAYS

Quality System	Potential Changes	Controls
Documentation updates, e.g. SOPs, test methods	Extend the review period by three months	> Change control > Anything linked to a mandatory change, e.g. pharmacopeial update to be updated in the appropriate timelines
Self-inspection (SI) program	Re-plan and move some SIs	> Perform a risk assessment on existing plan, re-schedule lower risk SIs
Annual product reviews (APRs)	Allow an extra month to complete the APR Potentially outsource the activity	> Change control
Product complaints	Immediately triage all complaints Extend the timeline for minor complaints	> Change control > Extend timeline for completion of minor complaints by 15 days
Regulatory commitments	Wherever possible these should not be delayed	> If any regulatory commitments may/will not be met, then the regulatory authority must be informed promptly

CONTINUING ACTIVITIES

Activities that should be continued in accordance with existing SOPs are those linked to batch release and testing activities. It is important to ensure that there are sufficient QA/QC staff to support production activity and, if necessary, to reduce planned output. If action has been taken to stop some activities at the site and delay others, then perhaps some staff can be re-deployed to bolster frontline staff.

Deviations and out-of-specification/trend activities should be performed in a timely manner to ensure product flow and also to identify any problems as early as possible.

In summary, taking a hard look at all activities that consume resources and applying a risk assessment approach can help to free up some resources to bolster direct product fulfilment activities and thereby keep critical medicinal products flowing to patients.

ABOUT THE AUTHOR

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Ms. Byers has gained more than 35 years' of extensive pharmaceutical manufacturing management and QA experience working for three major international pharmaceutical manufacturers, culminating in the role of Global Head (VP) of External Supply Operations QA for Novartis in Switzerland. In addition, she worked as Head of Inspectorate and Licensing for the MHRA from 2004-2006. She joined NSF in 2017.

Ms. Byers has broad experience in manufacturing management and QA of a wide range of sterile and non-sterile dosage forms, and is fully conversant with current EU and FDA GMP regulations and requirements. She has extensive experience in international QA auditing of a wide range of pharmaceutical manufacturers who are suppliers to the pharmaceutical industry worldwide. She also has extensive experience in managing QA teams in country affiliates.

Ms. Byers is eligible to act as a Qualified Person and was a QP assessor on behalf of the Royal Society of Chemistry from 1999 to 2004. During her tenure with the MHRA she was responsible for agreeing to QPs being named and removed from manufacturing authorizations.

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