



DOES YOUR PHARMACEUTICAL QUALITY SYSTEM IMPROVE YOUR COMPETITIVE EDGE?

by Martin Lush

There are some companies who believe that their Pharmaceutical Quality System (PQS) exists purely for regulatory compliance. We think this attitude is outdated and plainly wrong. At NSF, we believe that your PQS has only one purpose: **to improve your competitive edge** by guaranteeing the manufacture of high quality medicines at the lowest possible cost. We have worked in partnership with many of our clients to help them improve their PQS and their competitive edge. The following results give you a flavor of what can be achieved and how.

SOME CASE STUDIES

Reducing Product Rejects: How Your PQS Can Help

One company reduced its rejects from 11 percent to 3 percent across all key brands, and from 3 percent to 0.001 percent on its high-speed syringe filling lines.

Achieved by:

- > Better process control with greater investment in Statistical Process Control (SPC), which required an additional investment in new equipment
- > The company improved the quality of its raw materials by moving away from cheaper suppliers and improving its auditing and management of third parties. Instead of treating them as contractors, the firm now considers them to be partners and simply an extension of its production line. Its auditors have all been certified to ensure consistency in auditing approach so they can have confidence in audit findings
- > Problems (deviations) are now resolved within hours, not weeks. With our help, the deviation reporting system has been completely reengineered to allow incidents to be reported

and triaged (risk ranked) within two hours of any deviation incident. Investigations now start within three hours, not 30 days! Investigations now focus on preventing recurrence and using every deviation incident to drive continuous improvement. Following an extensive education program in problem solving, the attitude to deviations has now changed. Every deviation is now considered to be an invaluable learning opportunity, rather than an inconvenience

- > In the bad old days of high batch rejects, the company concentrated on starting a new batch *immediately* after a rejected one. This has now stopped. A cross functional team now completes a forensic style analysis of every batch reject to find out "why" before manufacturing the next batch. The outcome of the investigation, the Product Failure Investigation Report, is circulated widely across all divisions to share learning points

REDUCING REPROCESSING AND REWORK: HOW YOUR PQS CAN HELP

Another of our clients used its PQS to help reduce reprocessing and rework. The worst performing lines reduced rework from 22 percent to 7 percent.

MATERIAL WASTE/SCRAP: HOW YOUR PQS CAN HELP

When you have a robust and efficient PQS, you can drastically reduce unnecessary material waste and scrap. We helped one client reduce material waste from \$1.5 million to less than \$25,000 in just 18 months.



PRODUCTION LEAD TIMES: HOW YOUR PQS CAN HELP

Extended and prolonged lead times are symptomatic of an inefficient PQS. Back in 2009, one of our clients had a 15-day lead time for its number one liquid product. One day was taken for manufacture, three days for testing and 11 days to collate and review the batch record and release the product. We helped the client to reduce the lead time to just five days by helping simplify its batch record and product release procedures.

PLANT AND EQUIPMENT UTILIZATION: HOW YOUR PQS CAN HELP

One client improved utilization of its oldest plant from 71 percent to 90 percent and equipment utilization from 52 percent to 74 percent.

Achieved by:

- > Relying less on contractors
- > Developing greater in-house engineering skills and competencies
- > Adopting a rigorous risk-based approach to reliability-centered maintenance

FAST AND EFFICIENT CHANGE MANAGEMENT: HOW YOUR PQS CAN HELP

We believe that good change control is a core competency for the future. The ability to quickly and effectively review and approve changes is absolutely vital in a fast changing marketplace. One of our clients recognized their change control system was so slow and complicated it was actually dangerous... people were working around it! With our help they simplified their change control system with dramatic results:

- > The company's change control policy was simplified from 60 pages that nobody read to just 6 pages that people now do
- > In the bad old days it took 40-60 days to get approval for a change request. Now it takes 30 minutes. The saving in man hours paid for the improvement program in just 6 weeks
- > They now reject about 40 percent of change requests (they used to approve everything). This means they can focus on implementing important changes effectively rather than doing everything badly
- > Over 90 percent of approved changes are now implemented effectively. Before the improvement program less than 10 percent of approved changes actually delivered any return on investment

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.

For more information, contact pharmamail@nsf.org or visit www.nsfpharmabiotech.org

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NSF INTERNATIONAL | PHARMA BIOTECH

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF

T +44 (0) 1751 432 999 | E pharmamail@nsf.org | www.nsf.org | www.nsfpharmabiotech.org

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