



Zero defects - a reality

The next big thing in Quality Management? No mistakes or omissions in 4 years of manufacturing at Abbott Labs plus 100% compliance with FDA GMP.

The Diagnostic Division at Abbott Labs in Dallas performed a fascinating demo of a new installed system for a distinguished group that included the Undersecretary of the Army, a member of the Army's Science Board and the Director of the Oakridge National Labs. In short Abbott Labs told them it had achieved ZERO DEFECTS in manufacturing and complied with all FDA GMP's and paperwork 100% of the time. Abbott's representatives related that this accomplishment was not the result of monitoring, Six Sigma initiatives or CAPA changes but by technological design. They revealed that with this new system implemented, they couldn't make a mistake if they tried!

Abbott's business objectives in implementing the system included improving the quality and accuracy of device history data as it is being collected in real-time. Also, Abbott wanted to provide operational process control both to improve the quality of their products and comply with all requirements and regulations. Prior to implementation, its system was largely paper based and dependent on humans. Management confided however that this second attribute was its greatest challenge. Why? As a highly regulated industry, everything must be documented from procedures

on decontamination to line clearance to testing procedures to CAPA plans and quality release requirements. Everything known about an instrument has to be included in the device history record and it has to be right and it is expected to be right 100% of the time. To accomplish this feat Dallas manufacturing partnered with QCR and a software application called SMART (System Monitoring Automated Reasoning Technology).

Abbott representatives confided that before implementing the system, whether it was the out-

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side agency (FDA) or its corporate auditors – they self-audited themselves on a continuous basis - they found many errors all of the time ranging from very easy stuff to very critical things. This prompted them to look for a solution that not just corrected what was done wrong but moved in a direction that absolutely prevented the possibility of making errors.



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They reiterated that they had tried solving problems in different ways and whether it was a manual checklist for people forgetting things, improved documentation or outright mistakes, the new system addressed all of them and really fixed them once and for all. Every time an audit observation was made, they responded immediately to fix it but it just wasn't effective. This new system addressed all of the opportunities for error and they no longer had to spend time trying to create new solutions for the same old problems.

Abbott's manufacturing personnel discussed the top level findings with the attendees: "What we found was that no SOP steps (standard operating procedure) have ever been missed. The key word (it is not a misprint) is 'ever'. Equivalent expired calibration is never used. Again, I very rarely use these words; the key words are 'never used'".

This illustrates one of the crucial differences between most systems and what Abbott has accomplished - prevention. Typically an advanced calibration system will track usage of equipment and depending on wear or time, send out notices in the form of reports, alerts, text messages or email to have the equipment sent in for calibration and maintenance. However it doesn't stop anyone from actually using it even when it's out of calibration. Abbott's system will not allow usage of the equipment! The same goes for the requirements associated with material, people and tasks. Any requirement associated with people, tools, materials or activities that are not met at the time the operation is performed the system blocks its performance and suggests an alternative.

Abbott continued relating that, "expired material is never used. That was another thing; we have a lot of material that we use that is date sensitive and we're 100% compliant. If the expiration date on material exceeds processing time the material will not be allowed to be used. Training requirements, again, it seems simple but we have a lot of revisions all the time and you could be trained on something two days ago but not build it today because the rev came out last night on second

shift. You must be trained to that. If you aren't, technically you're in violation. In the manufacturing areas where this software application is implemented, it has eliminated the errors, not Six Sigma-99.9% but ZERO."

Another aspect to installing the system included a better communication channel and understanding of the engineering documents and work requirements. "We found in training that there were some people who were actually doing work wrong because they didn't understand the documentation. However, once we put the system in, and the engineer put all the requirements in, the system forced them to follow those requirements, that's when they came and said that this is wrong and we said no it is right and they realized they had been doing it wrong all along."

This new system also has the capability to antic-

well but there wasn't proof that everything had been done correctly. As far as hard dollar savings, we consider an NCR to require approximately \$1000 worth of effort to reach conclusion, given the FDA's CAPA requirements. In our pilot area alone we were experiencing about 100 NCR's a month so that was 1200 per year right there and that was a smaller area of the business, it wasn't a higher volume area. After utilizing the software for 90 days, we hit our target, we went to zero. Now the issue is, you can catch most of those problems through inspection and audits however if you have enough errors, thousands and thousands of them then the odds go up that something escapes. We eliminated that probability with this software system!"

Abbott personnel went on to explain that their vision includes mistake-proofing the supply chain.



ipate situations that may arise and allow the most appropriate alternative to be automatically invoked and pursued. When utilized, this functionality allows "experts" to collaborate on what should happen (business rules) given a specific situation. If and when that situation occurs the system automatically branches to that business rule and enforces compliance with it.

Tom Kelly, Undersecretary, Army, asked about benefits and whether Abbott equated those to dollar savings. Abbott replied that it was estimated that, "We've paid well over 1.7 billion dollars which included plant and product shutdowns because of mistakes, and those weren't product mistakes. Like the FDA said you're product is fine, they were process related because we couldn't prove everything we said. The product tested

The system is web-based and able to interface with anything that can reach the internet. It is a truly open system that can integrate with legacy systems and utilizes either Microsoft SQL or Oracle relational databases. So suppliers, customers and reverse logistics facilities can be on the system for a cradle-to-grave implementation concept. ●

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