GlobalVision

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Slava Krauklis, Deputy General Manager (Quality), GENERIUM

Generium
Pharmaceuticals

Location
Russia

Industry
Biotechnology

GlobalVision delivers on its error-eliminating reputation at GENERIUM

Trust is arguably the lifeblood of the heavily regulated industry in which Russian biotechnology company GENERIUM operates. It's paramount to success, both on the part of customers and in the quality-control software that serves as the last line of defense before products hit the market. It's no small coincidence that GlobalVision has become that platform for GENERIUM.

"When I moved to Russia and joined GENERIUM, I saw a few ways we could improve our quality control," says Slava Krauklis, the company's Deputy General Manager in

charge of quality, who helped to spearhead the shift to GlobalVision. "We decided to buy GlobalVision just to be more effective regarding quality control and save time as well."

Krauklis had been working as a quality director at a separate company in his native Latvia, where he first got introduced to GlobalVision's automated quality control platform. Several vendors had vied for the business, but GlobalVision won out, in part because of its easy-to-use interface, which made routine operations simple. The results themselves had been so encouraging that once at GENERIUM, Krauklis eventually brought the software over with him.

"*Even if you have a comma missing or something like that [the Regulatory Authority] ask us to repackage the product... So [GlobalVision] saves us a lot of head-aches and we avoid the costs of recalls.*"

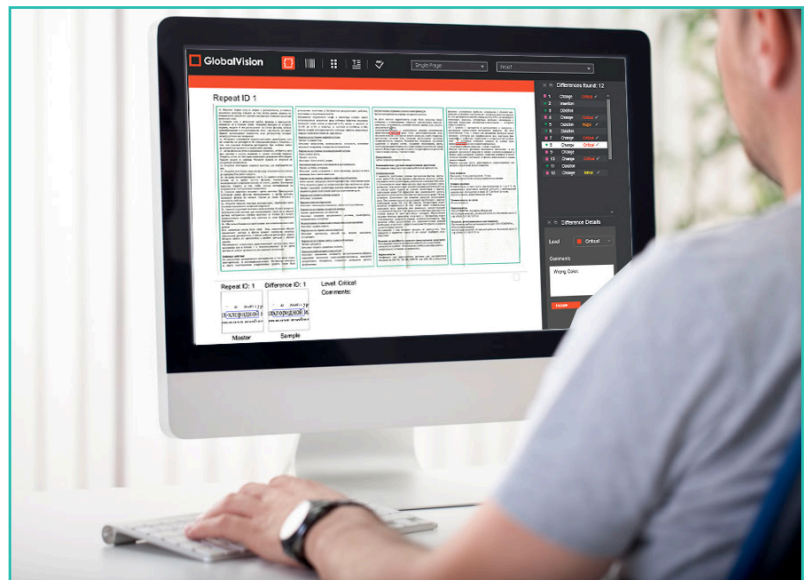**Slava Krauklis, Deputy General Manager (Quality), GENERIUM**

Moving on from manual proofreading

Prior to GENERIUM making the switch to GlobalVision, Krauklis says the proofing process left something to be desired, namely automation.

"Up to now, we've been lucky that labeling errors haven't resulted in otherwise unnecessary recalls," she concedes. "My experience from watching other companies has been that after even one expensive recall they [switch to automated software]. I wanted to be proactive before a recall costs us millions."

"It consisted of many people sitting down around the table and checking manually," he says. "If you have several products and several markets in which you sell your products, it means you work in several languages. It's not possible to [manually] check all the printed materials."

Automated Proofreading by GlobalVision

And it was clear manually proofreading was no longer an option for GENERIUM. A partner of Pharmstandard, the leading pharmaceutical company in Russia, the biotech-centric GENERIUM is split into two locations totaling approximately 500 employees. Located 100 km from Moscow, the

company's production plant takes full advantage of the GlobalVision platform installed there, especially giving the Graphics Inspection module quite the heavy workout.

"Packaging materials are very strictly regulated in Russia," Krauklis says. "For example, the main reason for product recalls is incorrect text on packaging or text on leaflets. Even if you have a comma missing or something like that they'll ask us to repackage the product... So [GlobalVision] saves us a lot of headaches and we avoid the costs of recalls."

Krauklis can attest to the efficacy of the software. In the three-plus years he's worked at GENERIUM, not once has he received a complaint from the Regulatory Authority or customers on misprinted packaging. That's a step up from before GlobalVision was brought into the fray and the quality control team still manually checked packaging materials, when, Krauklis reports, there had been an average of three incidents per month.

Key to Good Manufacturing Practices

Krauklis is appreciative of the lack of recalls since GlobalVision was adopted. However, it's by no means the only way the software has had a positive impact. The platform's complete validation package, which is run through by a GlobalVision technician during the implementation process, ensures it's compliant with current Good Manufacturing Practices (GMP) and for use in the Russian pharma industry.

"GMP requires us to record everything we do, and GlobalVision delivers very detailed reports," he says. "Inspectors who come to the plant are always satisfied with these records in which everything is reported… The [reporting feature] is very easy to use, and you can visually see the differences between what's been approved and the incoming lot of printed materials."

How he tells it, there's little way to do without GlobalVision at this point, not that GENERIUM would want to. It isn't just GMP that the company is adhering to. It just makes good sense.

"GlobalVision is a good way to prevent mistakes," Krauklis puts simply. "If we can save time doing quality control and easily check for non-conformities, we can make quick decisions as to whether or not we release specific lots of printed materials for production."