Print Quality Control Throughout the Production Process

IPI speaks with Dr. Andre Schwarz of EyeC GmbH about how Pharmaceuticals and medical devices require flawless printing of essential information

Q: EyeC is the only supplier on the market ensuring print quality throughout the production process, from the first artwork file to the finished product. Can you tell our readers how you started and where you are today as a company?

A: Established in 2002 by Dr. Ansgar Kaupp, Dirk Lütjens and Sören Springmann, EyeC still has its founding managing directors at the helm. Since our early beginnings to the present day, the pharmaceutical industry is still one of the main customers for our inspection systems. For example, 20 of the 25 largest pharmaceutical companies use EyeC systems in their quality control process and this is not only due to the precision of the devices, but also to the comprehensive service and expertise in dealing with regulated industries that we provide. GMP, CFR 21 part 11, FAT/SAT etc. are not alien concepts to us, but daily business, considering that we offer secured Workflows and an extended Validation Support. Over 3,000 systems are now in use by our customers, from artwork creation to sample tests, and EyeC offers a tailor-made solution for every need.

Q: Print Quality Control throughout the production process – what does it mean in terms of helping pharmaceutical companies gaining an upper hand?

A: We give pharmaceutical companies the right solution at every step of the print production process, starting from the creation of the artwork for a medicine box or a package insert, for example. This guarantees at an early stage that an error-free and legally compliant artwork is created. When printing the boxes or package inserts, all printed items can then be checked against the approved artwork, so that the print shop can guarantee that hundred percent of its production matches the printed image and the content required. The batch delivered by the printers can then be inspected directly on the customer's premises using the random sampling method. In this way, a packaging hundred percent secure can be guaranteed at any point in the printing process. Pharmaceutical customers use the random sample inspection in most cases, and our software checks artwork, Braille, 1D and 2D codes in a single pass, so that the goods can be quickly but safely transferred to the production process. The inspection is carried out using qualified devices, and we support our customers in validating their processes, so they can be carried out in an inspection-safe manner and in accordance with all the relevant pharmaceutical standards.

Q: Pharmaceuticals and medical devices require flawless printing of essential information, including recipes, batch numbers, and codes, which must also accommodate a range of materials, frequent layout changes, and text in different languages and alphabets, as well as non-textual information, like barcodes and logos. How does the automated visual inspection systems with state-of-the-art equipment designs and software algorithms enable a hundred percent evaluation of printed surfaces of all compositions and shapes and sizes?

A: The manual proofreading and the checking of print products that used to be the norm is a tedious, error-prone, and very slow process. However, the automated checking, for example, performed with the scanner based EyeC Proofiler system, is fast and efficient. Not only the artwork is compared with the printed item with pixel accuracy in a single inspection pass, but the content and quality of codes is also checked, Braille is read and the conformity of the tactile dots to standards is assessed. And all the above is done in minutes. This alone represents an added value that cannot be overestimated. Furthermore, this type of testing can always be carried out the same way, can be validated and is incorruptible and consistent; on request, with a defined workflow and reviewed by another person.

Q: In your opinion, what are the serious consequences that critical printing errors can have?

A: In the case of so-called "normal" print products, the errors are annoying and recalls cost money and can damage reputations. In the pharmaceutical sector, on the other hand, printing errors can be unforgivable and life-threatening. Whether the dosage on a package insert says 3.5 mg or 35 mg can make the difference between life and death, or at the very least, serious side effects. Accurate testing is therefore necessary under all circumstances. All the regulations in the pharmaceutical industry do not come from a vacuum but serve to protect the consumers. And we see it as our responsibility to ensure this protection. Therefore, as a pharmaceutical industry supplier we go to great lengths to make pharmaceutical products even safer, working together with manufacturers and distributors.

Q: On a given label, different areas of text have different levels of criticality. There are the regulatory guidelines, which may differ from region to region, and products going to multiple markets have to comply with multiple standards. How do your solutions help pharma companies navigate global standards?

A: Our systems offer the option of creating different parameter sets for different tasks; for example, one can also create areas with different test severities if one wishes. As the system carries out a pixel-precise check, the language is also irrelevant. Braille can also be checked in different alphabets. And thanks to our worldwide service network, one system can be used in all locations without any problems, no matter where in the world they are located. This greatly simplifies installation work and ensures that requirements are met in exactly the same way everywhere. Our customers appreciate this type of cooperation, as systems can be procured centrally and rolled out to all locations.

Q: I understand that besides pharma, EyeC is also supplying to other sectors. What other market sectors do you supply to and how do you apply lessons from other industries to the pharmaceutical sector?

A: Although the pharmaceutical industry is one of our largest customers, we also supply our systems to other regulated sectors such as the food and cosmetics industries. These have different requirements and needs, but also similarities, and this gives us a comprehensive picture of what is important and which developments are relevant across all industries. We can always learn from this in order to serve each individual customer in the best possible way. But we can also learn from working in non-regulated sectors. For example, if a supplier can solve quality problems with our systems, this is also relevant for the pharmaceutical industry. The knowledge gained from all these industries means that we can continue to improve our product.

Q: Have you noticed any recent changes in the industry? What are customers looking for now? How are you addressing these changes?

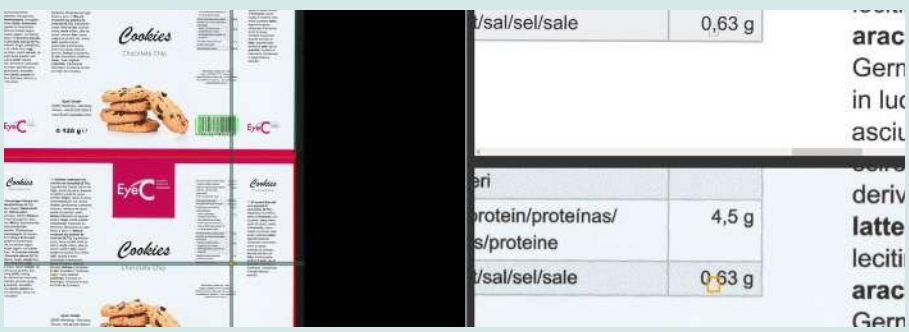
A: Digital transformation goes beyond the pharmaceutical industry; things like cloud solutions, networked systems, artificial intelligence, etc. are also on everyone's lips in this sector and will become more important in the future. We are already in the midst of this transformation and are driving forward together with our customers and partners, whether this means error (pre-)assessment using AI or networking with LIMS systems to further automate processes, to name just two examples. It is for our customers that we need to be innovative and at the cutting edge, and this is the only way we can both benefit as much as possible from the automated inspection.

Q: The pharma industry faces challenges from global competition, shorter innovation cycles, legal regulations for safety and environment, and individualised product demand. How does your company help with ramping up production and accelerate faster products to market to combat new diseases?

A: As mentioned above, we can make the inspection a decisive factor faster and more efficient. But this speed and efficiency is not at the expense of safety - quite the opposite. By integrating the latest regulations, we are the interface towards greater safety. This starts with development. All our employees, from development to product management and sales, are trained in GMP regulations so that the regulatory requirements are already taken into account when creating the software. We do not build software that is subsequently given GMP-relevant functions; instead, these are already integrated into the requirements for features yet to be developed. We take the requirements seriously – all URS are answered by a certified computer validation expert, for example and can therefore help to bring safe and error-free products to market quickly and right from the start.

Q: What is EyeC's vision for the future? And which are the projects you're most looking forward to?

A: In the future, we are going to have networked products and a comprehensive communication and documentation will be a matter of course. Our products can already be used every step of the way in the production process, but in the future these individual steps will be much more interlinked. The individual tests will be accessible anywhere on the cloud and be constantly available for review, for example, whether to the customers themselves or to the regulatory bodies. The automation of the inspections will progress, and artificial intelligence will help the user to find and evaluate all deviations to always receive a safe product. We are already working on these things - keyword Pharma 4.0 -, and it will be interesting to see how they can help us to deliver even more safety features to our customers and enable sustainable production. And this is something that should not be ignored either: with our products, not only do we help the detection of errors, but also help print shops to work as resource-efficiently and efficiently as possible. After all, if only error-free goods are printed, the waste volumes are substantially reduced, and expensive machine time is saved; and safety and sustainability go hand in hand here.



André Schwarz

Dr. André Schwarz is Director of Marketing & Documentation at EyeC. He has been employed at the company since 2016. As a computer validation expert, with a doctorate in German studies and years working in research and editing, Dr. Schwarz has steadily expanded EyeC's Validation Support department over the past six years to offer high-quality support to pharmaceutical industry customers.