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Case Study: Medreich | Anti-Tampering and EU FMD



See how CMO Medreich PLC developed a compliant label for its EU FMD-compliant anti-tampering devices for prescription medicine packs, all while protecting the efficiency of their line systems. Medreich's poster, "Medreich PLC Designing and Using of Anti-Tampering Device," was one of 11 featured during FutureLink Barcelona's interactive Poster Sessions.

Business Challenge

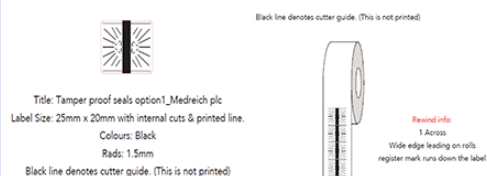
- As part of the Falsified Medicines Directive (FMD) which came into force on 09/02/2019 it was required that all Prescription Medicines have Anti-tampering device on them
- Upon opening the pack, the regulation states that the rest of the FMD printed information should still be readable
- The Anti-tampering device should continue to seal the packs until at least the use by date of the medicine

Outcomes

- To cope with the issue of not damaging the printed FMD information we decided to go with a perforated sticker
- To make it easy to see if a sticker is applied we decided to add a black line down the middle
- We also did studies of how effective the glue was by applying the Anti-tampering device to box's and placing in stability cabinets
- Once we had started testing we discovered an issue with the cutter lines, these were causing glue to leach out of cut design
- At this point we started the second design with no cutter lines and this has proved much more efficient, with less impact on machine downtime



1st Design



2nd Design



Recommendations

- Run line trials on different ATD design variations, to arrive at the best possible material which will run affectively in the production process
- Place sample ATD cartons on stability trials to see if ATD performs well in all the variable conditions
- Choose the correct size ATD, to give the best possible contact area on the carton
- Work closely with ATD manufacture to ensure the correct adhesive is used when the ATD are produced
- Review carton designs and make changes to braille positions on cartons, so that ATD in not covering the braille area
- When looking at the application of the ATD on production lines, think about how the reject system will work on cartons with ATD missing
- Check on ATD placement during production run, as 2D print must not be covered by ATD



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Case Study

European Union Falsified Medicines Directive

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