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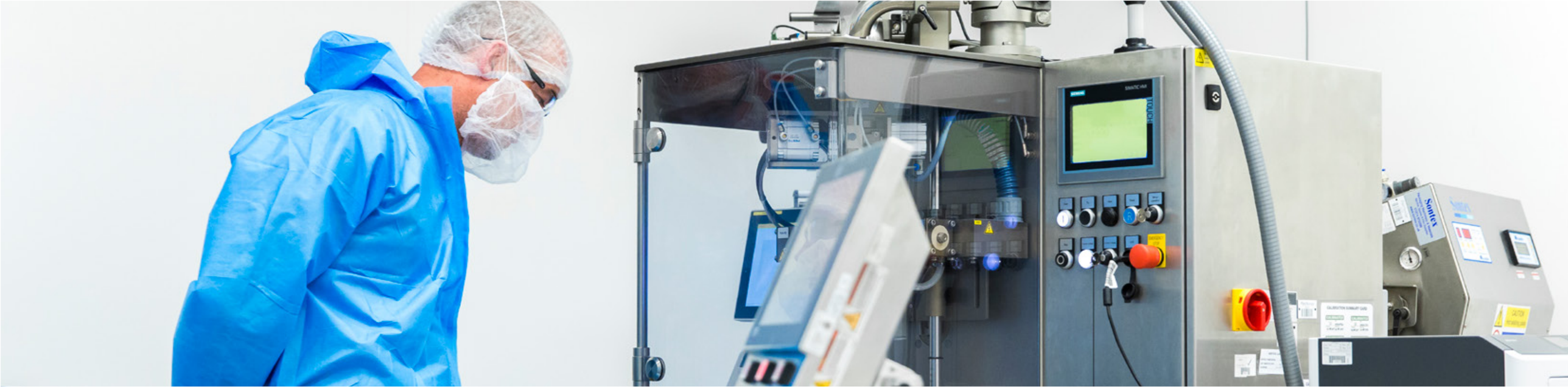
Q&A

What Does "Child-Resistant Packaging" Mean?

Q&A with Stuart Hunter, Packaging Design Manager



What Does “Child-Resistant Packaging” Mean?

Child-resistant packaging integrates the use of safety mechanisms and physical barriers to make it significantly more difficult for children to gain access to toxic or harmful substances. The term "child resistant packaging" refers to packaging that complies with one of the standards outlined below:

- BS EN ISO 8317:2004: The international standard covering re-closable packaging for any contents.
- BS EN 14375:2003: The European standard covering non re-closable packaging for medicines.
- BS EN 862:2005: The European standard covering non re-closable packaging for non-medicines.
- 16 CFR 1700.20: The US regulation covering re-closable and non-re-closable packaging applicable to both medicines and non-medicines.

When does a product have to conform to child resistant packaging?

Medicinal products presented as capsules and tablets are often colourful in appereance, which can appeal to young children therefore increasing the likelyhood of ingestion. By engineering child resistant pack solutions and introducing mechanisms that make it more difficult for children to gain access to such medicines helps reduce the potential risk of ingestion.

According to legislation, once a product is deemed poisonous when inhaled or swallowed, or cause skin corrosion it must be packed within child resistant packaging. In Europe examples of products that must adhere to this legislation would be medicinal products that contain substances such as paracetamol, aspirin or more than 24mg of iron. In the US, the list is more extensive and includes anything that requires a doctors prescription and certain OTC products that include specific amounts of aspirin, acetaminophen, ibuprofen, iron and fluoride.

How child-resistant must a product be?

The extent of how child-resistant a pack format must be very much depends on the contents. A child reistant pack is given a rating, with F1 being the most difficult for a child to open and for example F8 being easier. Medicinal products that are deemed extremely harmful to children would be contained within F1 rated packaging whereas products that are less harmful would be contained within packaging that has a lower rating. F1 rated packaging must use mechanisms that are extremely difficult for children to gain access to as many products contained within this packaging are lethal at one dose, whereas F8 packaging does not require the same level of resistance as products contained within this packaging are not deemed as harmful.

How is child-resistance achieved?

Child-resistance can be achieved by using either a unique opening mechanism or by utilising difficult-to-open proceedures. The following are examples of child-resistant components:

- Performing two movements simultaneously which is required to open the pack. For example squeezing a bottle closure while turning.
- Plastic films or foils, e.g. blister packaging that must be peeled and pulled to be opened.
- More than one action is required to open the pack, ensuring the unlocking parts are so far apart that children cannot reach them with the fingers of one hand, for example wallet style packaging that utilises a push and pull mechanism.

In summary, child-resistant packaging typically requires a special process to gain access to the product within the packaging. The opening process has to be too complex for a child to dicifer, yet easily accessable for adults.

How can end-users be sure that packinging is really child-resistant?

End-users are assured that packaging is child-resistant as the packaging undergoes stringent testing by approved bodies against specific test protocols. During the pack design process a blank prototype of the child-resistant pack is created and tested to ensure effectiveness. Typically, a child-resistant test environment will have 200 able-bodied children, aged between 42 and 51 months, attempt to open the pack. A child-resistant pack should be impossible for at least 85% of children to open within 5 minutes and for at least 80% following a silent demonstration.

Stuart Hunter

Stuart joined the Almac Group in February 2010 as Packaging Design Manager. Stuart is responsible for the packaging design, artwork generation and management of all commercial printed packaging components used in products manufactured and processed within Almac Pharma Services both in Craigavon (UK) and Audubon (US).

Stuart has extensive experience in developing packaging solutions and artwork mock ups for MA submissions for all types of European applications e.g. National, Centralised , Decentralised and Mutual Recognition Procedure for all 28 countries with all 23 languages. Stuart provides assistance to clients on the viability of joint language packs and country specific blue box information.

With almost 20 years experience in the Pharmaceutical industry, Stuart has participated in project launch teams working with Regulatory Affairs and Operations for the strategy and implementation of medicinal products in global markets including Europe, USA, Canada, Japan, Australia, New Zealand, Brazil and South Africa/other African markets.

Prior to joining Almac, Stuart worked for one of the world's largest veterinary companies where he was responsible for the management of packaging development and artwork implementation for approximately 800 products, approximately 6,000 components marketed in 110 different countries.

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