

Action Technology's rubber compounding expertise enables FDA compliance, unlocks new market segment for stopper manufacturer

New market opportunities were created, potentially worth millions of dollars in sales

Action Technology products:

Custom, FDA-compliant rubber compound calendared into high performance sheet used to produce stoppers for pharmaceutical applications.

Problem

A European manufacturer of rubber stoppers for parenteral pharmaceutical applications was interested in expanding its business. However, its existing compounder could not deliver materials that would meet Food & Drug Administration (FDA) guidelines, or meet stringent new purity, color and appearance requirements. These shortcomings resulted in productivity loss and inability to grow the business into new applications.

Cause

The rubber compounder did not have the internal capability to formulate to FDA standards. Additionally, it did not have a separate white production line. Having

experienced contamination problems in the past, the stopper manufacturer knew that separate capacity was critical to avoid carbon black contamination of the new lighter grey and red products.

Solution

Access to new growth markets required FDA-compliant rubber formulations, as well the capability to meet the requirements of other global pharmacopeias. Increasingly demanding specifications for extractables, leachables and contaminants required a higher purity specialty rubber solution that could also meet the critical chemical resistance and mechanical performance requirements of the closure.

The closure manufacturer had become aware of Action Technology's significant investment in a new, state-of-the-art laboratory, with the analytical equipment and development expertise to support the innovation they sought. For this reason, they turned to Action for assistance.

Action's consistent, high-quality, customized product solution opened the door for the rubber stopper company to win more pharma business, at reduced operating cost.



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Action Technology reviewed the customer's performance and compliance criteria, then combined its material science expertise and its laboratory capabilities to develop a successful formulation for the very first production trial. Action's internal testing validated the product's mechanical performance, purity and lot-to-lot consistency.

Even after delivering the requested product, the Action team followed up to look for further ways they could provide value to the customer. The stopper manufacturer had specified that the rubber compound be delivered in rollstock to match what they had been getting. Action representatives attended the initial production runs and watched the customer work with their product. The production workers unrolled the material and cut it into sheets to feed into their compression molder, where they would form the stoppers. Action realized that together, they could eliminate labor costs and boost customer efficiency by delivering the material in cut sheets instead of rollstock. Rubber sheets were supplied for the next production run, enabling the stopper manufacturer to remove an added step and unnecessary cost from its operation.

Benefit

The rubber stopper manufacturer was able to realize multiple benefits by switching to Action Technology's customized rubber sheet. They include:

- **Improved quality and supply consistency** by eliminating contamination issues (confirmed through state-of-the-art testing at Action)
- **New market opportunities**, potentially worth millions of dollars in sales
- **FDA-compliant** stoppers, as well as compliance with other **global** pharmacopeias
- **Reduced mold fouling** from the new, specialized compound recipe resulted in faster cleaning and 15% less downtime
- Updating the finished product from sheet to rollstock **removed a production step**, reducing labor costs
- Action Technology's **global manufacturing footprint** supports companies with global operations and specifications

The manufacturer was able to realize multiple benefits by switching



Improved
quality
& supply
consistency



New market
opportunities



Compliance
with FDA
& global
pharmacopeia



Faster
cleaning
& **15%**
less
downtime



Reduced
labor costs

For additional information, please visit:
www.tekni-plex.com/action-technology