

Actikem Ltd

Customer Case Study 2

Customer Industry Type: Pharmaceutical Drug Manufacturer

Problem/challenge?

Actikem works with several companies under strict confidentiality agreements to ensure customer information and knowledge is secret and secure. Actikem work with customers who operate in the highly regulated pharmaceutical market for the manufacture of cancer drugs.

Actikem were approached by their customer and asked to streamline the supply chain of a product we supplied to them in the bio fermentation stage of a drug manufacturing process.

The change in supply chain meant that the product, which was packed into small 350ml HDPE bottles had to undergo gamma irradiation before the product was supplied to the customer. This process required additional supplier services and the identification of the most suitable sterilisation service supplier.

The packaging required additional sourcing of gamma radiation labels. These labels were needed to ensure the correct dose of radiation was applied to the product and ensure the required level of sterilisation was achieved.

Explanation of job / service provided?

Actikem supply products and services into the highly regulated Pharmaceutical market as processing aids in bio fermentation reactors. We pack down from IBC's and drums into small packs which can then be used a single dose additive in the process. The customer was previously sterilising these bottles of product themselves through a third party sterilisation services supplier. They wanted to change the supply chain to simplify the stock and ordering process and required Actikem to assist with this.

How did we satisfy the customer's needs and help them reach their goal?

As a highly regulated industry, Actikem identified the right sterilisation service partner who could perform the gamma radiation service, sourced the required gamma radiation labels and changed the repackaging and labelling process to meet the needs of the customer. Actikem also took on the responsibility of purchasing the Performance Qualification. Actikem staff were able to complete the necessary paperwork to meet the customer's FDA audits.

What were the benefits of using Actikem?

Actikem were able to quickly change the supply chain, simplify the order process, reduce the stock holding and reduce the delivery lead time of the product to the customer. This also had the advantage of reducing the level of waste material the customer had to dispose due to out of shelf-life product.

Did we encounter any problems doing the job, and if so, how did we overcome them?

The detailed paperwork ensuring change control, performance qualification and FDA criteria is a challenge in this industry sector. Actikem staff have experience of the requirements of this sector and can assist customers when required.

What factors contributed to our success in doing the job?

Actikem provide a number of chemical repackaging services to customers who operate in the pharmaceutical market. Their staff understand the exacting regulatory requirements for change control and traceability in this market and can deliver these requirements. They are able to adapt and offer additional added value services to customers to help ease the supply chain and reduce costs and waste.

To find out more about how Actikem can assist you with the supply of products and services to the pharmaceutical industry, please call us on [01925 593900](tel:01925593900) or email sales@actikem.com

To find out more information on pharmaceutical regulations, please visit:

<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>