

Case Study – Critical Environment

Marigold Industrial Gloves

at the heart of key trials

Sterile latex gloves made by leading hand hygiene specialist Marigold Industrial Ltd have proven to form an effective barrier against product contamination in extensive research carried out by pharmaceutical giant AstraZeneca.

Marigold Industrial's Suretech™ Biogel® P gloves were used by AstraZeneca in a major research project undertaken to determine the effectiveness of double gloving during the manufacture of aseptically prepared pharmaceutical products to reduce the threat of contamination.

According to AstraZeneca, the Suretech™ Biogel® P single use gloves were chosen for the project as they had been assessed as being a good quality glove.

The project looked at two areas – the quality of 200 unused Biogel® P gloves and the effectiveness of 400 gloves used for double donning, to reduce the threat of product contamination.

For Marigold Industrial, the results were extremely positive with none of the 200 unused gloves tested by AstraZeneca having any holing or showing any leakage.

In the double gloving trials involving 200 pairs of inner and outer gloves – worn by 100 cleanroom personnel in the aseptic processing area at AstraZeneca's sterile manufacturing plant in Macclesfield, Cheshire, results were again extremely positive.

The detected failure rates were found to be 8.5 per cent and 6 per cent for the outer and inner gloves respectively – but with only one instance of a puncture

occurring in both the outer and inner glove combined – but not in the same location.

Tim Eaton, AstraZeneca's sterile manufacturing specialist, says the increase in holing was associated with the stress placed on the gloves during use.

He added: "What is important is that the results demonstrated that punctures occurring to the outer glove did not penetrate the inner glove.

"For the type of gloves used in this programme, the probability of having holes in both inner and outer gloves can be considered so low as to confirm that double gloving, using good quality products, is an effective control method in reducing the threat of product contamination"

According to Marigold Industrial, the research highlighted and reinforced the quality of the Suretech™ Biogel® P gloves as well as providing invaluable performance data in a true working environment.

John Thorne, Marigold Industrial's country manager, says: "AstraZeneca has conducted some highly valuable research and we are very pleased to have been associated with it.

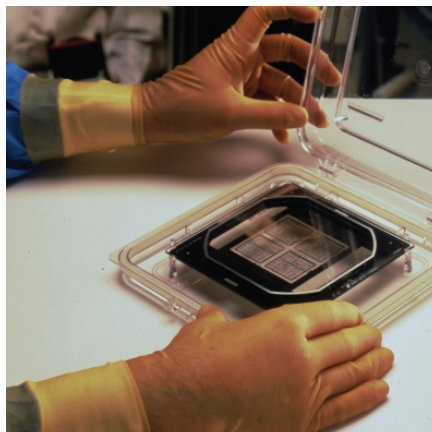
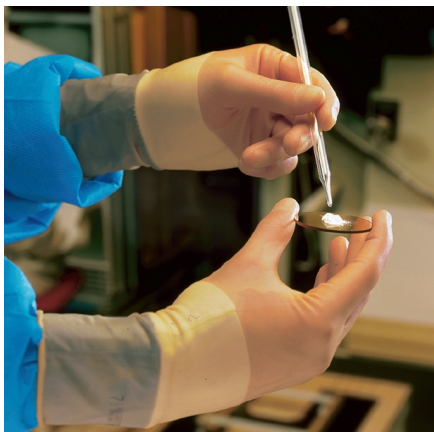
"To have our gloves placed under this test spotlight and come out in such a positive way is a testament to the

quality manufacturing processes which we adopt for our pharmaceutical gloves.

"The research shows that whilst gloves may become holed during regular cleanroom working practices, double donning is an effective control method to minimise the risk of product contamination caused by ruptured gloves and we are delighted with these findings," said Mr Thorne.



Product Focus



Marigold Industrial continues to invest in developing and manufacturing protective gloves for use in the workplace, utilising some of the latest materials and technology to produce a wide range of protective gloves that meet the changing needs of our customers.

It is this focus on innovation and NPD that has kept Marigold Industrial at the forefront of hand protection and will continue to do so for the long-term future.



Suretech™ Biogel® P S965

- Sterile gamma irradiated powder free glove
- Straight finger, micro roughened finish
- Packed in individually sealed film pair packs
- Biogel®'s unique polymer lining ensures ease of donning and exceptional levels of comfort
- 100% tested for holes, beaded cuff
- Packaged in a powder free controlled environment to minimise particulate contamination

Suretech™ Biogel® P S828

- Sterile gamma irradiated powder free glove
- Curved finger, untextured finish
- Packed in individually sealed film pair packs
- Biogel®'s unique polymer lining ensures ease of donning and exceptional levels of comfort
- 100% tested for holes, beaded cuff
- Packaged in a powder free controlled environment to minimise particulate contamination

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