



## Steriles Business Case

### RECOVERY FROM A BAD INSPECTION

When an FDA inspection ends in multiple observations, it's bad news. So it was for the European Manufacturing subsidiary of a major multinational.

The site manufactured several key sterile products, mainly vials with the major product being a beta-lactamine\*, and the FDA required a team of observers to report on sterile suite behaviour and practise; in order to implement the range of the corrective improvements needed. Observations included poor operator behaviour, incorrect gowning, compromise of the class A filling area, poor maintenance interventions and poor monitoring systems.

**Knowing Galenisys expertise in sterility assurance and aseptic processing**, the multinational Head Office turned to Galenisys to undertake the on-site work, with an experienced team of sufficient strength; in cooperation with local management and coordinated by the Boston Consulting Group and the Galenisys on-site project manager.

After conclusion of the Confidentiality Agreement and agreed Terms of Reference, Galenisys deployed our team of specialists to site. It was headed up by one of our most experienced experts.

Working in teams to observe the 24/7 operation, over a period of months, Galenisys drove the improvements in operator behaviour, and modifications to the procedures and testing practises which were required. Galenisys spent considerable time coaching key individuals in aseptic technique and relevant regulatory requirements. Separate training for the operations and maintenance teams was undertaken. After each observation session, the Production, Maintenance and Quality teams met in an adjacent meeting room where the days observations were presented, and everyone took time to discuss and agree how improvements could be introduced.

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Each week, findings and Corrective Actions were discussed with local and central management.

Galenisys included the Corrective and Preventive Actions (“CAPAs”), in the training they gave on appropriate behaviour & revised procedures including aseptic activity monitoring, process validation – sterilisation APS, disinfection and cleaning techniques (a major headache) - data evaluation and use, sterility assurance programmes and contamination prevention and control.

The final phase of the terms of reference was to verify that the required training and updated procedures were resulting in the improvements required, and product conformity.

**It's pleasing to note that the same company has now used Galenisys teams on more than 10 of their sites worldwide to improve aseptic techniques.**

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