Thinking clearly

Noxilizer says it's high time to rethink an innovate in sterilisation and explains why its nitrogen dioxide technology supports bio-pharma changes

'Reduce cost and increase quality' is a demand used by the leaders of industry and government.

In the bio-pharma world, 'cost' generally relates to production costs and productivity, whilst 'quality' relates to regulatory compliance and safety, and generally, these are pulling in opposite directions, so this demand is increasingly difficult to deliver on.

To address the challenge, bio-pharma manufacturers and (passing the challenge down the supply chain) their suppliers are innovating; finding new technologies that will achieve one or both of these demand objectives. Examples include progressively more sophisticated drug delivery devices, and the ever increasing use of prefilled syringes, both of which are designed to make drug administration simpler, safer and have lower total cost.

The trend towards injectable biologic and other large molecule drugs, which are generally heat labile and cannot be terminally sterilised by traditional thermal methods, forces a trend towards aseptic processing. When administration of a drug is intra-operative (in particular), additional measures are necessary to minimize the risk of contamination of the packaged device.

As an example of the needed innovation to meet this demand, Noxilizer has developed a solution using gaseous nitrogen dioxide (NO2) to sterilise packaged injectable drug delivery devices without penetrating sterilant into, or otherwise interacting with, the drug product.

Nitrogen Dioxide (NO2) is well suited to most common packaging materials including glass, cyclic olefin (co)polymers, polypropylene, silicone, and thermoplastic polymers. It can penetrate typical secondary packaging such as Tyvek, enabling the 'terminal' sterilisation of devices in final packaging.

The sterilant is used in a room temperature process that has no effect on a heat labile drug. This is an ideal adjunct step to enhance safety and minimize the probability of microbial contamination in product packaging. This innovation addresses both elements of the industry challenge: reducing cost – by reducing the focus on the aseptic processing related to the packaging, and improving quality by reducing risk of microbial contamination of the packaged device.

In another example from Noxilizer, the same sterilant, NO2, may be used to rapidly decontaminate enclosures, such as those used in bio-pharma manufacturing. As a true gas, and not a condensing vapour (the traditional agent used is vapourised hydrogen peroxide), it readily diffuses in air and is easily removed by dilution.

Accordingly, decontamination cycle time is reduced, improving productivity, and smaller ventilation systems may be used, reducing running costs. Moreover, NO2 is an active depyrogenation agent, and has been demonstrated to provide a 104 reduction in endotoxins on treated materials.

This technology has already seen its first deployment in a collaboration between Noxilizer and Weiler Engineering, manufacturer of the Asep-Tech series of blow-fill-seal filling machines, where biodecontamination of the exposed critical zone surfaces enhances the sterility assurance of the packaged product.

As the bio-pharma industry moves forward, it's clear that the status-quo of the traditional sterilisation industry will not meet the future demands. New drugs, new materials, new delivery devices, coupled with the need for greater productivity and reduced production/running costs will require innovation in sterilisation technology.

Clean and clear: Noxilizer has developed a solution using gaseous nitrogen dioxide (NO2) to sterilise packaged injectable drug delivery devices without penetrating sterilant into the drug product