CASE STUDY | PHARMA BIOTECH

HOW TO CORRECT AN UNEXPECTEDLY DIFFICULT GMP INSPECTION AND PREVENT A RELAPSE

THE SITUATION

The client received an FDA 483 report following an inspection of a European manufacturing facility with significant non-conformances identified, many associated with QC data trails and data integrity. A second site in the network experienced the same concerns during a subsequent FDA inspection. As an established CMO supplying global markets, the organization needed to respond quickly and thoroughly to avoid market action and loss of reputation.

THE METHODOLOGY

Our team began a rapid process to determine the root causes of the non-conformances, understand the broader and site-based systems that had not predicted or addressed the issues before they came to light, and embark on a dialogue to engage the company's leaders and SMEs to accept the reality of the situation and engage in objective, science-based decision making. Being able to call out the issue and apply multiple perspectives in resolving and preventing recurrence was absolutely critical in helping to decide the best-fit actions.

The methodology followed NSF's BITE Toolkit and was designed to diagnose the issues; assess the risks to products, patients and the supply chain; and then apply carefully designed corporate and site-based changes.

THE EXECUTION

The priority was to assess the risks and identify any need for market withdrawal and recall. This involved first-hand review and assessment of QC data trails against the ALCOA expectations. Policies, SOPs and local routines were redesigned to ensure staff know when and where a data integrity risk exists and how to address it. NSF led a series of systems-based gap analyses, group and 1:1 coaching, and oversaw and verified CAPAs. A combination of audit, consultancy, coaching and education made sure that all changes were proportionate, sustainable, easily justified and targeted to prevent risk.

THE RESULTS

Thanks to the team approach, the site avoided a warning letter and could justify that no market withdrawal was necessary, preventing interruption of supply to a range of life-saving drugs. The client's reputation – in the eyes of the regulator and their client base – was actually enhanced by the speed, diligence, commitment and simplicity that characterized the changes made. The client was inspired by NSF to change the behaviors and mindset that led to the non-conformances, re-aligning priorities and resources to enhance the wider team and restoring confidence that they were structured to do the right thing for the short- and long-term.

For more information, contact **pharmamail@nsf.org** or visit **www.nsfpharmabiotech.org**

Cite as: NSF International. September 2018. How to Correct an Unexpectedly Difficult GMP Inspection and Prevent a Relapse. NSF: York, UK.

NSF INTERNATIONAL | PHARMA BIOTECH

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF
T +44 (0) 1751 432 999 | **E** pharmamail@nsf.org

2001 Pennsylvania Avenue NW, Suite 950, Washington, DC 20006 USA
T +1 (202) 822 1850 | **E** USpharma@nsf.org

www.nsf.org | **www.nsfpharmabiotech.org**