



PREPARING FOR A REGULATORY INSPECTION

PROBLEM

A project had been running for ten years and had not had a regulatory inspection. There had been many staff changes and understanding the history of the evolution of the project was difficult.

SOLUTION

NSF ran a workshop with a cross-section of staff at the site. The workshop was very different from a mock-inspection approach. It was performed in an open collaborative manner to identify key topics that needed to be fully understood prior to any inspection.

We asked a key question to everyone who participated, "The project started about 10 years ago - why has it taken so long?"

The answers were rich and varied and would lead an inspector in many different directions. The most illuminating answers came from a few people who had lived through the project, mainly the staff working in the manufacturing area.

On completion of the workshop, the client:

- > Understood that no one could comprehensively explain the evolution of the project.
- > Had greater insight into who had most knowledge about the project history (and it

was not the various project managers who had changed many times).

- > Had a list of topics from which to prepare a storyboard to explain the history.
- > Had a clearly developed action plan to prepare the site for its inspection.
- > Had a clear idea about who was confident presenting to a regulatory inspector and who needed more coaching.

KEY MESSAGE

Approach inspection preparation in an open and collaborative manner. Sites will have the answers to the questions if the right people are asked.

WHEN TO CALL IN EXTERNAL EXPERTS

Companies typically call in external experts when:

- > They have a new facility or product.
- > The site is expecting an inspection from a new regulator.
- > The site is having a re-inspection.

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

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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