



# 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](mailto:pharmamail@nsf.org) or visit [www.nsfpharmabiotech.org](http://www.nsfpharmabiotech.org)

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Cite as: NSF International. May 2018. Preparing for a Regulatory Inspection. NSF: York, UK

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