

# ROOT CAUSE ANALYSIS, CAPA TRAINING AND CERTIFICATION



Do you know the cost of quality in your company?

Join a group of forwarding thinking companies focused on **total cost of quality (coq)** reduction.

## NSF'S RECOMMENDED APPROACH

**IDENTIFY:**  
WHERE ARE OPPORTUNITIES  
FOR COQ REDUCTION?

**EXECUTE:**  
HOW DO WE EMBED  
THE SKILL SET?

**SUSTAIN:**  
HOW TO SUSTAIN OUR  
RETURN ON INVESTMENT?

### COST OF QUALITY ASSESSMENT

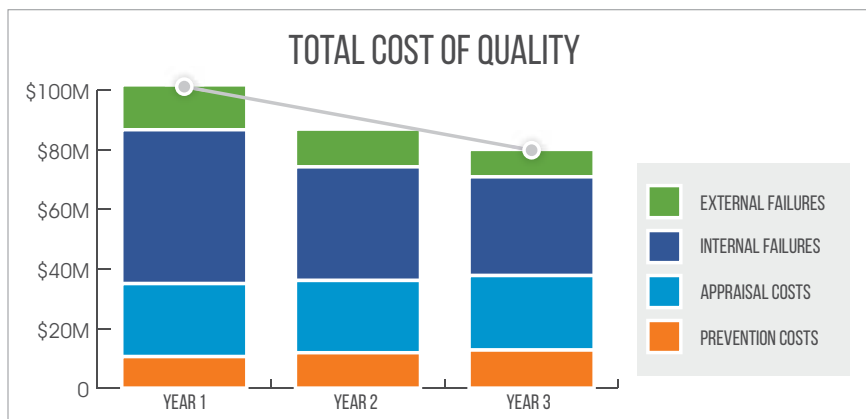
- > Methodology and evaluation of costs
- > Collection and analysis of costs
- > Road map for cost reduction

### ROOT CAUSE ANALYSIS AND CAPA TRAINING

- > Root cause analysis tools
- > Human error reduction principles and tools
- > CAPA identification and effectiveness checks

### CERTIFICATION

- > Report review and evaluation
- > Coaching/mentoring
- > Investigator qualification



## TYPICAL OUTCOME

After three years, the total cost of quality is **reduced by 20%** and **have saved \$20,000,000.**

For more information, visit [www.nsfhealthsciences.org](http://www.nsfhealthsciences.org) or contact [USpharma@nsf.org](mailto:USpharma@nsf.org).



# ADVANCED INVESTIGATION TECHNIQUES FOR QUALITY IMPROVEMENT

## ROOT CAUSE ANALYSIS AND CAPA EDUCATION

The NSF International program is uniquely designed to drive improvement within pharmaceutical operations. The core purpose and focus of the program is effective Root Cause Analysis and CAPA training in order to drive continual improvement across a manufacturing site. Key principles and tools for Human Error Reduction are included in the NSF program; drawing on deep expertise in the area of Human Error Avoidance and Reduction to ensure investigators rigorously identify and act on the Contributing Factors for human error occurrence.

## COST OF QUALITY ASSESSMENT

Cost of Quality (CoQ) assessment is an additional assessment NSF can provide in order to establish a baseline of the current CoQ elements at a manufacturing site or across a plant network. This is an optional part of the program however companies have found that the CoQ model used by NSF will effectively calculate appraisal, failure, prevention costs. This data will help management determine where costs may be hidden and what actions can be taken to realize significant savings.

## INVESTIGATION CERTIFICATION

Investigator Certification is the third leg of the NSF program which ensures the Root Cause Analysis techniques, CAPA identification, and investigation report writing are at a sufficiently mature level across the company. Companies which have included this Investigator Certification as part of their program have dramatically improved the Investigative Process, Report Writing and CAPA effectiveness.



The three components taken together provide a comprehensive approach to Quality Enhancement. Companies which have requested a CoQ assessment as part of the NSF Investigation and Root Cause analysis education program are better positioned to realize the financial benefits of the program. Companies that add Investigator Certification ensure that the principles of effective investigation, root cause analysis, robust CAPAs and high quality investigation report writing are embedded and sustainable.

**NSF INTERNATIONAL | PHARMA BIOTECH**

2001 Pennsylvania Avenue NW, Suite 950, Washington, DC 20006 USA

T +1 734 769 0109 | E [USpharma@nsf.org](mailto:USpharma@nsf.org) | [www.nsfhealthsciences.org](http://www.nsfhealthsciences.org)