Writing Effective Nonconformity Statements

Auditing Medical Device Manufacturer Quality Management Systems

NSF

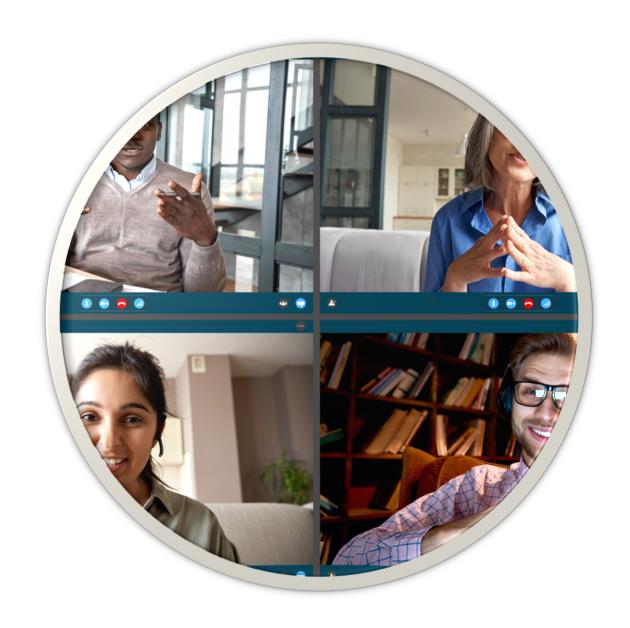# Objectives

At the end of this training, you will be able to:

1   *Identify* useful techniques to apply when writing effective nonconformity statements

2   *Review* fundamental terminology important to writing effective nonconformity statements including audit, objective evidence, audit criteria, and nonconformity

3   *Evaluate* the use of the acronym FOCAL as a tool for developing an effective nonconformity statement.

4   *Apply* the three key principles when writing a nonconformity statement.

Group Discussion

Why Implement a Quality Management System?

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1. **Safety:** Assures devices are free from unacceptable risk

2. **Efficacious:** Assures clinical evidence supports device labeling claims, assures the device does what it is purported to do

3. **Customer Satisfaction:** Improved quality of life to patients resulting in satisfied customers, maintains or improves market share resulting in satisfied shareholders

4. **Uniformity:** Assures device is designed and manufactured consistently 'over and over' again

5. **Regulatory Compliance:** Satisfies existing market expectations, makes new markets available

6. **Educates:** Allows for continuous improvement through monitoring, measurement, data analysis, management involvement/review, etc.

7. **Self-Assurance:** Colleagues understand their responsibilities and authorities, expectations of their roles, understand device defects, etc.

A quality management system 'secures' your business just as a lock, fence, and guard secure your facility. Will this security fail now and then? Yes. However, a QMS prepares you to react to those excursions.