

Module 1: Introduction to Corrective Action

[On Screen]

What Evidence Indicates Inadequate Corrective action procedures in laboratories?

[Pat Lukens]: What evidence indicates an inadequate corrective action procedure in laboratories?

[David S. Korcal]: Well that quite often –

[On Screen]

Procedure Disconnect staff

[David S. Korcal]: - starts with a disconnect, I think, between the procedure and the staff.

[On Screen]

[Magnifying glass hovering over the word 'detail']

[David S. Korcal]: It might be that the staff doesn't have a lot of detail in it.

[On Screen]

[drawing of a cartoon man]

[David S. Korcal]: It might be the staff is unaware of the procedure but if you look what you'll see –

[On Screen]

[Magnifying glass with milk carton which says 'Detail have you seen me?']

[David S. Korcal]: is probably a procedure that doesn't have as much detail or is maybe even completely missing.

[On Screen]

[Animation of beakers/flasks]

No corrective action policy

[David S. Korcal]: That would be one lab maybe that's just getting into the quality systems and haven't got a policy procedure on corrective action yet. But it might be, start there. And then, there may not be any training going on so –

[On Screen]

Corrective Action

[David S. Korcal]: - when you interview the staff about corrective action process you

[On Screen]

[Cartoon drawing of man]

“yeah I think we have a process for that...?”

[David S. Korcal]: might get blank stares or “yeah I think we have a process for that” or those types of responses.

[On Screen]

Disconnect

[David S. Korcal]: And so there's a disconnect.

[On Screen]

[Image of archway]

Over

[David S. Korcal]: and they're not being trained on their own system procedures or these overarching procedures that kind of form the basis of our quality system.

[On Screen]

[Picture of file]

[David S. Korcal]: And so that translates into records. You start looking at the records generated from that type of a process.

[On Screen]

Few few few far =====> Between

[David S. Korcal]: And there's – they're going to be few and far between.

[On Screen]

[Cartoon milk carton under magnifying glass 'Missing Detail Have you seen me?']

[David S. Korcal]: There's not going to be a lot of detail.

[On Screen]

Fix the initial problem

[Cartoon Picture]

[David S. Korcal]: A lot of them will just fix the initial problem or the problem at hand. They won't go –

[On Screen]

[Bubbles with words/sentences in them]

[David S. Korcal]: -into looking for the root cause or initiating cause of that problem.

[On Screen]

[Image of lab room]

[David S. Korcal]: So that's kind of the things that we'll see in labs that are – haven't made that transition

[On Screen]

[Image of books/paper]

[David S. Korcal]: from just having the paperwork or the structure in place. To actually implementing it and

[On Screen]

[Image of chart]

[David S. Korcal]: Putting it into action and really reaping the benefits of a good quality system.