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Training and education the WHYs of cGMP to operators can make a huge difference in meeting CQV standards inside pharmaceutical manufacturing facilities

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GetReskilled CEO Gerry Creaner knew he was on the right track when Janet Woodcock (Director) and Rick Friedman (Associate Director of Quality Manufacturing), FDA were both heard to use the words “develop a Quality Culture....from the Shop Floor to the Boardroom” at the ISPE annual meeting late last year. The proposed presentation would focus on “Going Beyond cGMP: Good for Business” - how critical it is to focus (or re-focus!) on the operators handling the material used to make our medicine.

How? By going beyond the talk of a Quality Culture in posters, CEO chats with the troops and putting measurable data points in place for understanding why operators must handle materials the way GMP says they must.

This presentation will touch on the cultural taboos that make it difficult for operators in some countries to speak up, and how the use of online, science-based education can alleviate those issues.

The presentation will also look through the mirror of the CMO/Big Pharma cGMP relationship, and give specific ideas for what Big Pharma should look for inside their CMO partners’ quality programs, and conversely, what types of quality programs CMOs could be offering to differentiate themselves in the marketplace.

The presentation will go from the “bottom up” - what I mean by that is that it will hone in on the oft-forgotten shop floor/operators - and how going above and beyond on specific cGMP training - the “Whys of GMP” can be great for business, and how FDA and other regulatory agencies will look favorably upon efforts such as this, based on recent conversations that the presenter, Gerry Creaner has had at ISPE, Interhpex and other conferences.

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