

**EXCHANGING IDEAS.  
CREATING SOLUTIONS.**

2011 Emerson Global Users Exchange



# Busting the Myths of the new Process Validation Guidance

Survey Results

November 2011

# Busting the Myths of PAT

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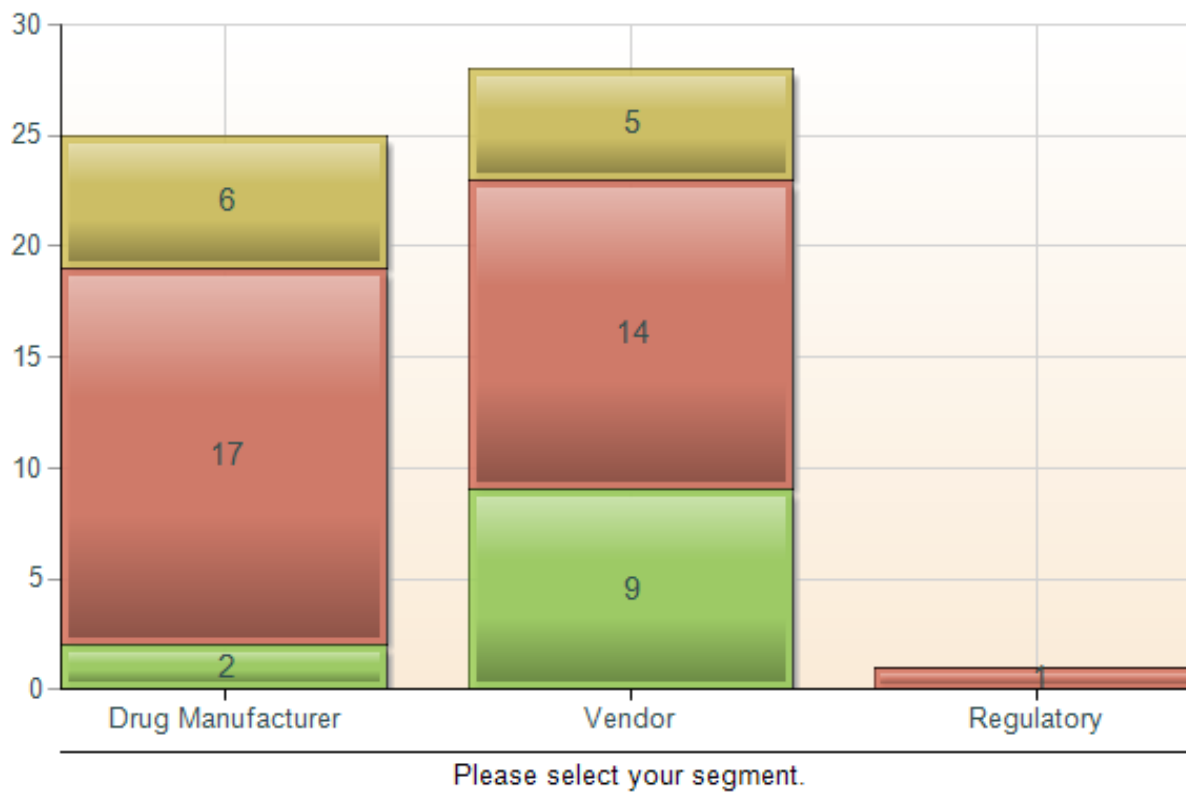
**The following “Myths” surrounding PAT and the new Process Validation Guidance were discussed during the Life Science Industry Forum at Emerson Exchange in Nashville, TN.**

**A zoomerang survey was also conducted that paralleled the Industry Forum and the results of the survey are presented.**

# Myth 1

The industry has been asking for clarity on PAT since the original guidance was issued. The new Process Validation Guidance provides clarity on how FDA will interpret PAT.

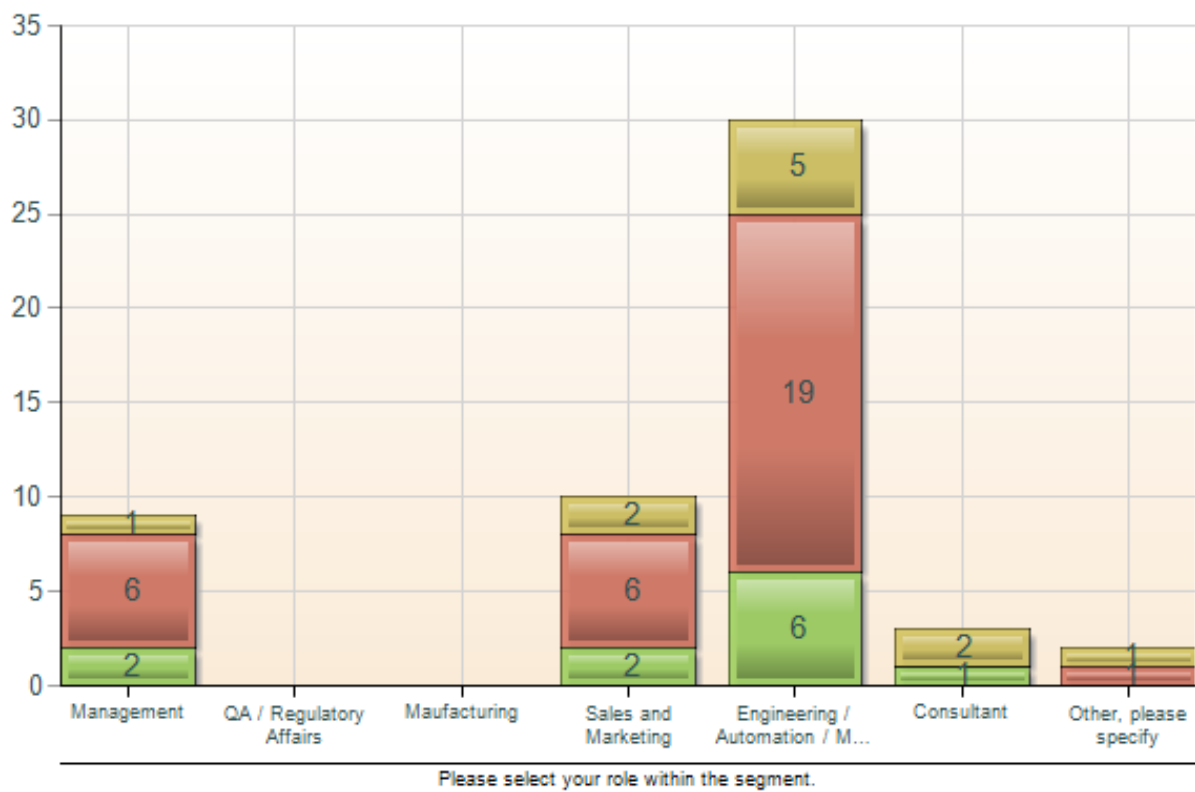
■ BUSTED ■ PLAUSIBLE ■ CONFIRMED



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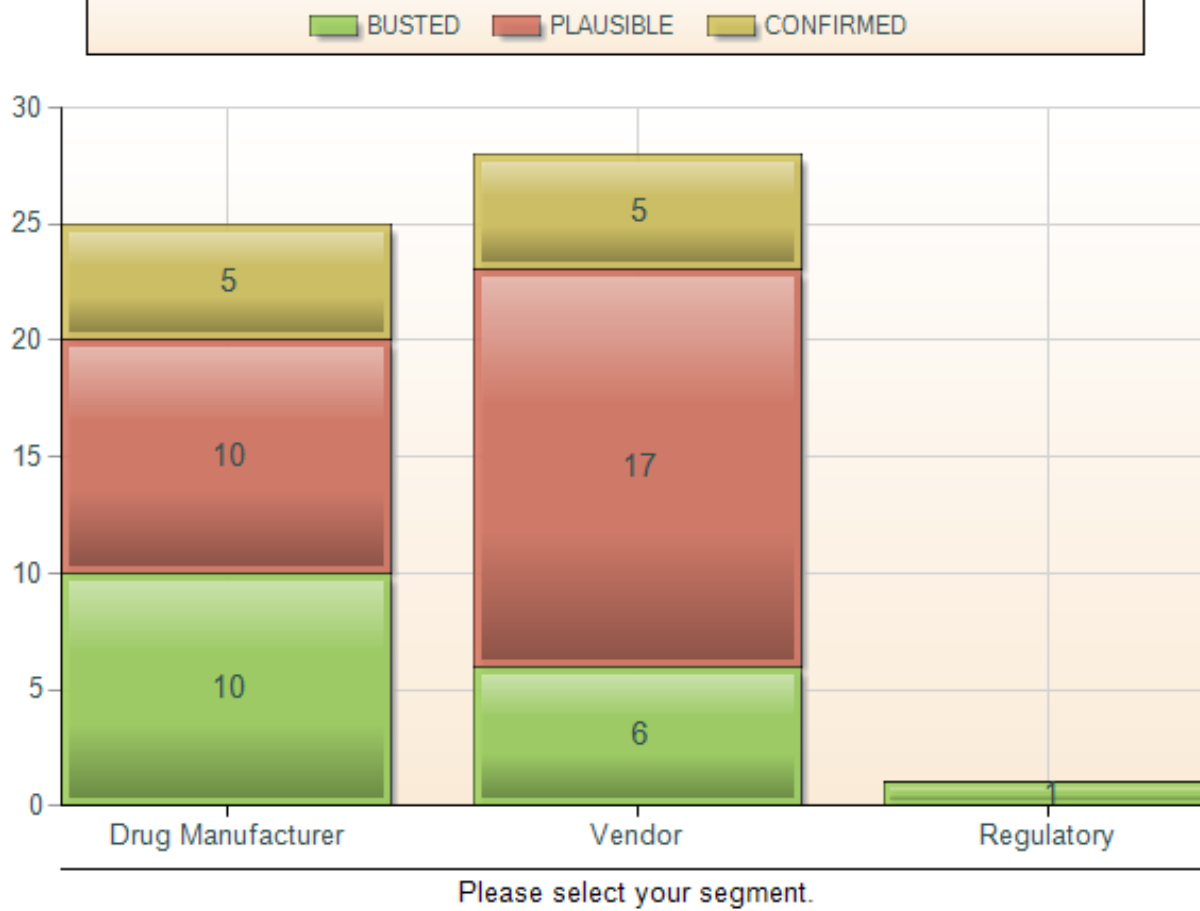
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# Myth 2

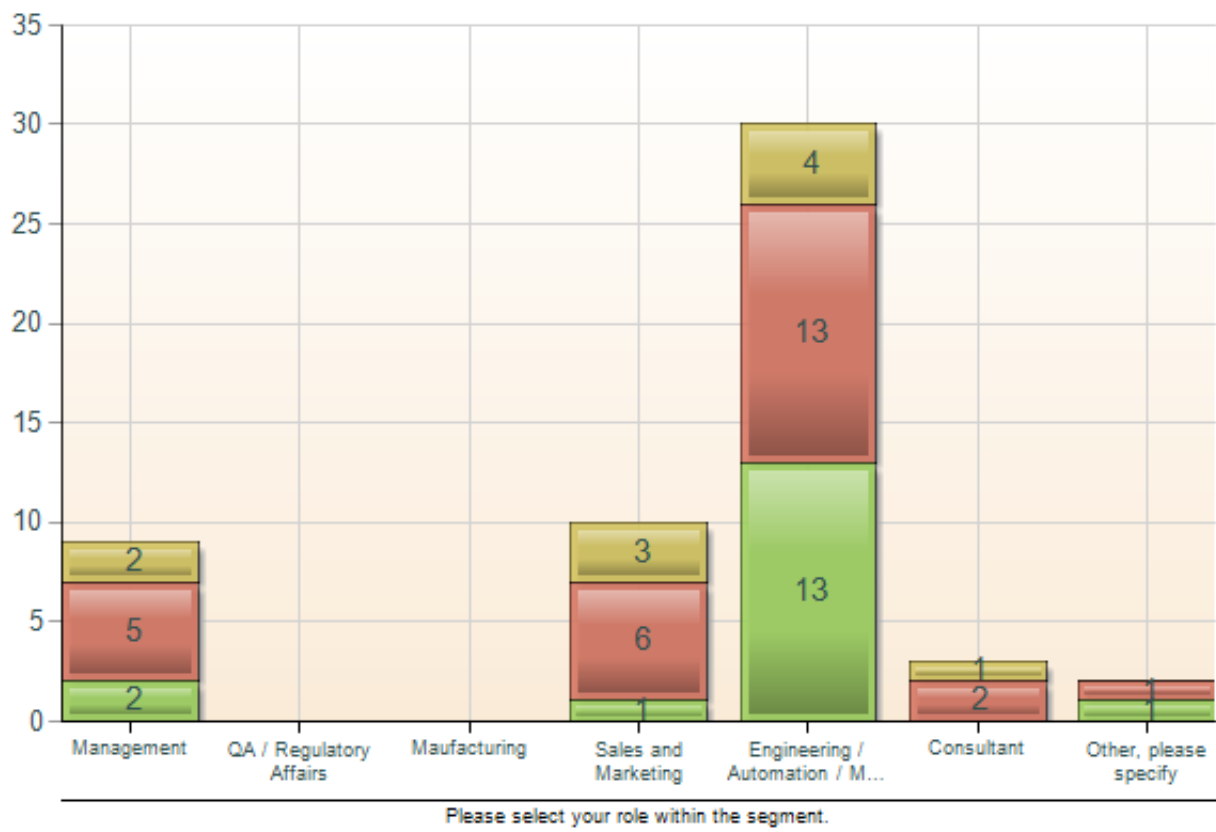
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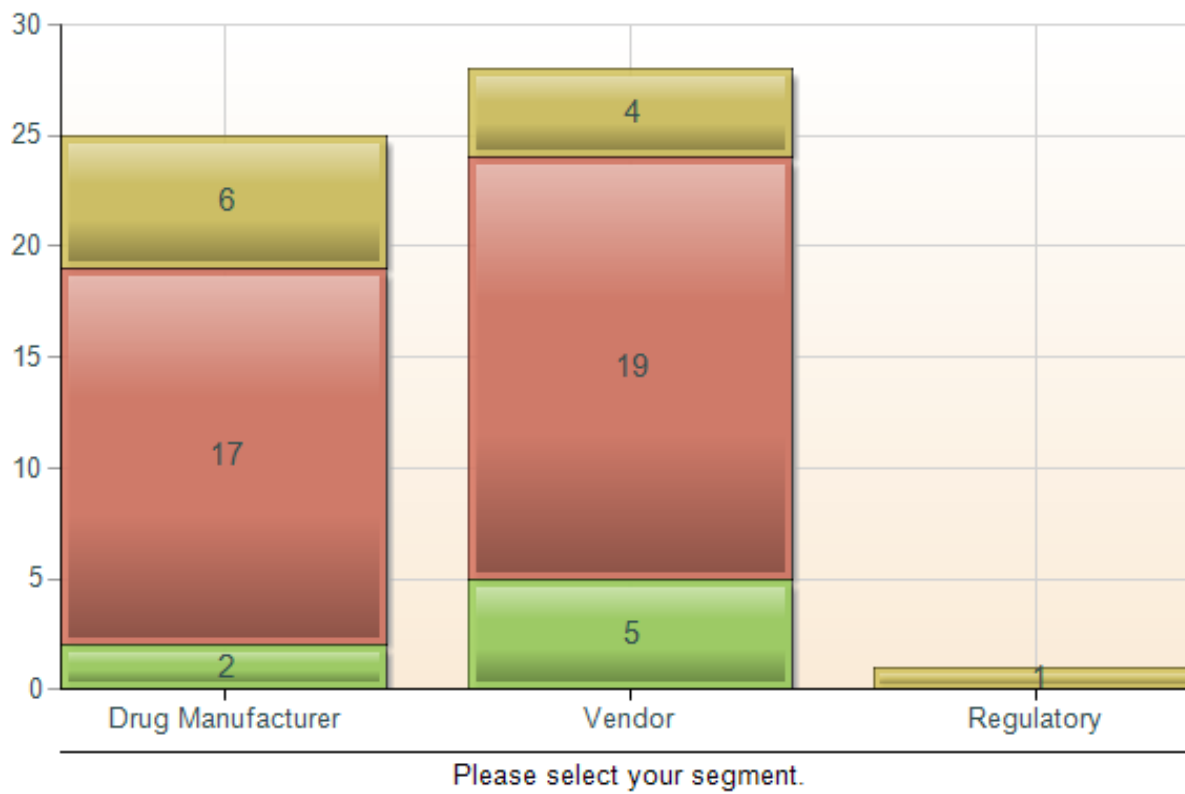
BUSTED PLASIBLE CONFIRMED



# Myth 3

The Process Validation Guidance will result in increased drug quality and lower regulatory risk for drug manufacturers.

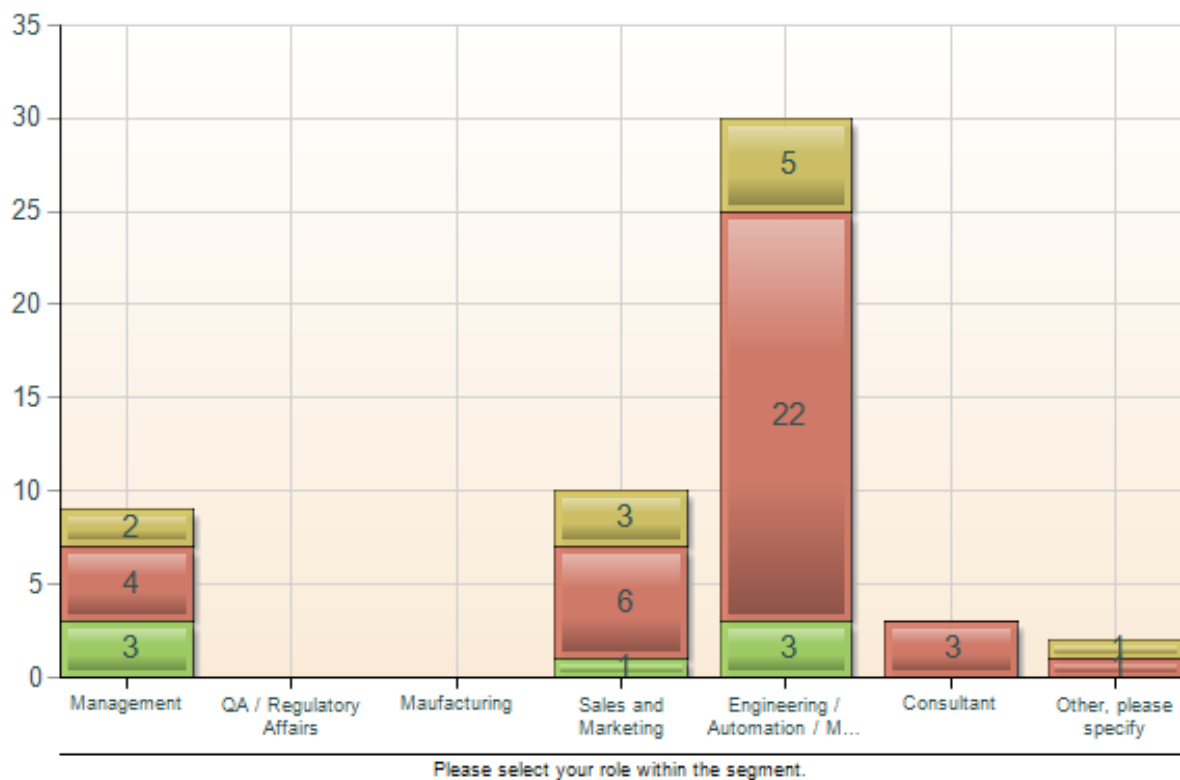
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BUSTED PLAUSIBLE CONFIRMED

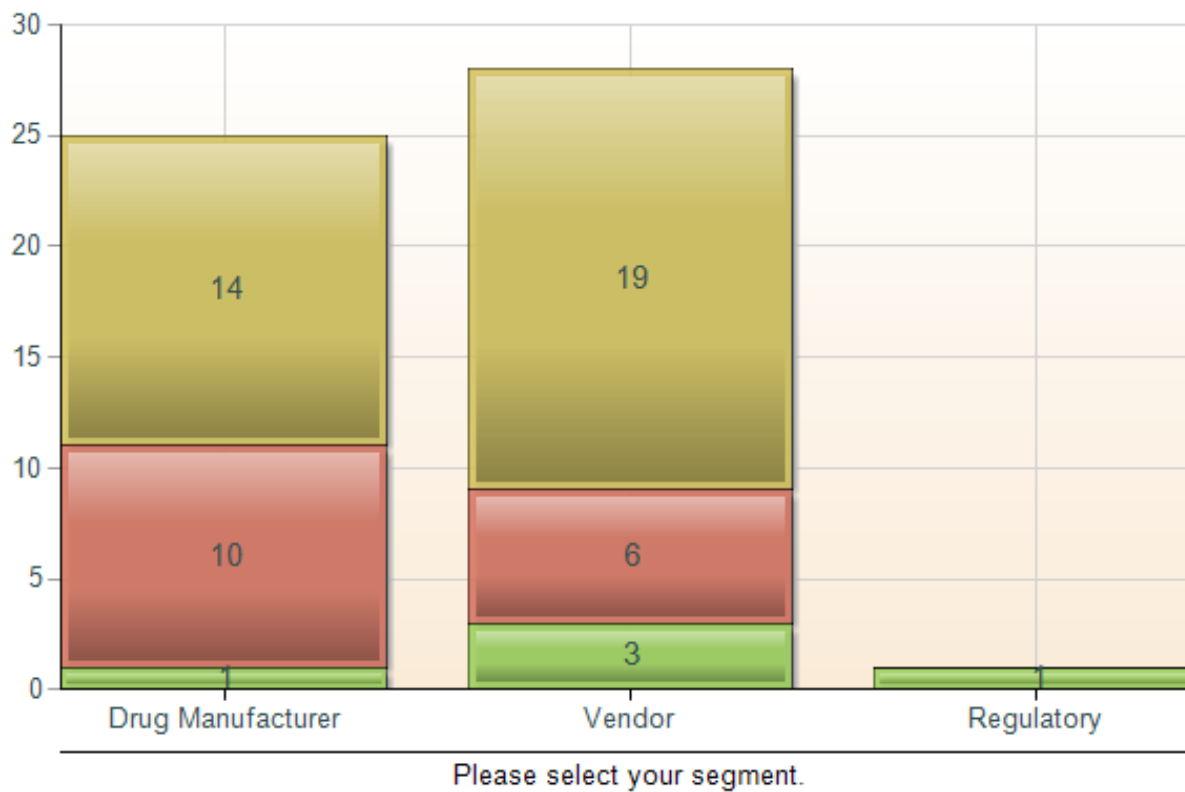




# Myth 4

Manufacturers are wary of FDA behavior regarding Process Validation and PAT. Without clear guidance and assurances from FDA, risk and cost are increased for the manufacturer.

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