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# Validation Bingo

**Is your company gambling with analytical methods and with your product's future? Play validation bingo and find out.**

by **John E. McEntire**

**M**ethod validation is no joke. It's serious business and is key to successful product development. Validation is driven by careful planning, science-based strategy, and documentation — not excuses. If you regularly hear these phrases at work, then it's

time to make a choice: Speak up and burn a few bridges, or embrace your stupidity and go down with the ship. Companies making these excuses probably invest their employees' 401k money in stocks like Enron, too. **BP**



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	<b>B</b>	<b>I</b>	<b>N</b>	<b>G</b>	<b>O</b>
<b>1</b>	The agency knows how important our product is!	So it may not make sense scientifically; it's still valid!	It's validated; I ran it three times!	. . . intended purpose?	. . . in the spirit of GMP. . .
<b>2</b>	I wanted it to be a "flexible" document.	Of course it was reviewed. Look at these 16 signatures!	It's not my product; it must be the assay!	Give me a break! That's a question only QA would ask!	So it failed acceptance criteria; just change them!
<b>3</b>	We don't use protocols; we have a Level 2 guidance.	Acceptance criteria reflect historical performance.	That doesn't apply to me: I'm in biotech!	Next you'll want to see my training records!	Didn't address column temperature: we don't control that.
<b>4</b>	It's just easier to validate everything for each method.	It's stability indicating. My product just doesn't degrade!	It's not my assay; it must be their product.	No need for a report; it's compendial.	Written method?
<b>5</b>	But the statisticians don't understand our assay!	We've been doing it this way for years.	Of course it's a good assay. It has an $r^2$ of 0.99!	Sure I run it differently in the QC lab. This is the validation!	I can't set acceptance criteria there. We'd never meet them!

**How to Play.** Take this card with you to all meetings of the group responsible for analytical methods validation. When you hear someone utter one of these phrases, mark it off. When you have completed a vertical, horizontal, or diagonal line . . . then holler "BINGO!" (or your favorite expletive) and run out of the room — then straight down to the human resources department to be the first to hand in that resignation. Fill the card, and win a warning letter! Fill it with statements made by senior management, and win a consent decree!