

### MANUFACTURING

# PAT Survey Reflects Optimism, Uncertainty

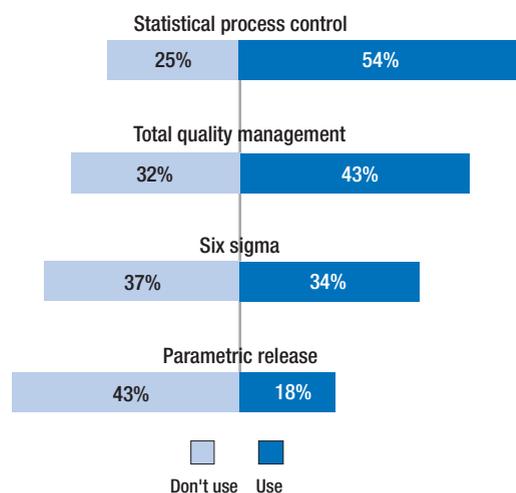
**D**uring the summer, Stelex (Bensalem, PA, consultants to regulated industries) and *Pharmaceutical Technology* posted a brief on-line survey, probing visitors' awareness of and attitudes towards process analytical technology (PAT) and the US Food and Drug Administration's guidance, *PAT—A Framework for Innov-*

*ative Pharmaceutical Development, Manufacturing, and Quality Assurance*. Sixty-five respondents registered and completed the survey.

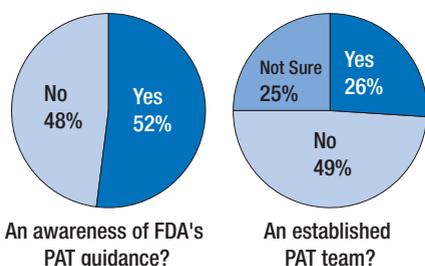
Overall, this small cross-section—self-selected for interest in PAT—claimed only a modest understanding of process analytical technology, its implementation, and its implications. Barely half said their organizations were aware of the PAT guidance, and more than half rated their own PAT understanding as low.

Fourteen percent said that their companies' quality assurance or regulatory affairs departments were currently preparing PAT-based new-product release strategies and SOPs. Just 6% said their companies were preparing PAT-based submissions.

**Does your organization already use any of the following engineering tools?**



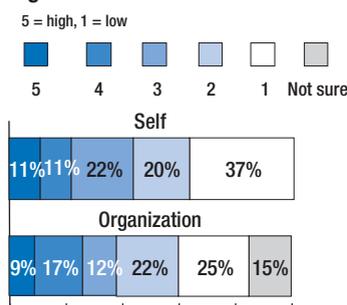
**Does your organization have...**



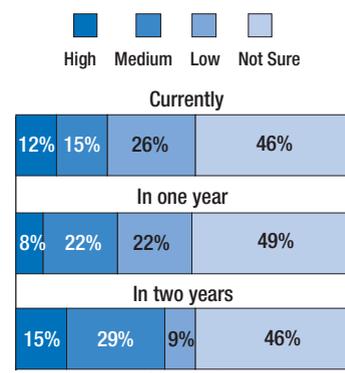
**Of the following, what do you believe would yield the most valuable data for your PAT program?**

Historical incidents	38%
Out-of-specification in-process samples	25%
Product recalls	8%
Equipment downtime	6%
Calibration records	6%
Training records	3%
Regulation changes	2%
Other	12%

**How well do you and your organization understand PAT?**



**How much of an effect do you see PAT having on your quality assurance and regulatory affairs departments?**



**Do you agree that the following can be improved through PAT?**

	Agree	Disagree	Not sure
Identifying critical sources of variability	65%	0%	35%
Using feedback to control processes and manage variability	63%	2%	35%
Facilitating continuous processing and improving efficiency by reducing downtime	62%	3%	35%
Preventing rejects, scrap, and re-processing	60%	0%	40%
Increasing automation to improve operator safety and reduce human errors	60%	3%	37%

Many answered "not sure" to questions about PAT's ultimate impact, while an even larger group expects PAT—with its improved process understanding and positive feedback controls—to yield improvements in quality, reduce rejects, and even improve usage of capital equipment. The graphs and tables provides a sample of the responses.

—Douglas McCormick