2004 Pharmaceutical Process Analytics Roundtable

Benchmarking Survey

Organization		2001 total	2001 # responses	2001%	2003 total	2003 # responses	2003%	2004 total	2004 # responses	2004%
O1	Does your organization have a group of scientists dedicated specifically to PAC?									
	If YES, enter "1" here.	7	9	78%	7	9	78%	9	12	75%
	If NO, enter "1" here and go on to question O9.	2	9	22%	2	9	22%	3	12	25%
O2	How many full-time PAC practitioners?									
	1-5, enter "1" here.	2	7	29%	1	7	14%	2	9	22%
	6-10, enter "1" here.	3	7	43%	1	7	14%	2	9	22%
	11-15, enter "1" here.	2	7	29%	2	7	29%	4	9	44%
	More than 15, enter "1" here.	2	7	29%	3	7	43%	1	9	11%
O3	In which function(s) are they principally operating?									
	Process R&D, enter "1" here.	7	7	100%	5	7	71%	5	9	56%
	Commercial manufacturing, enter "1" here.	7	7	100%	5	7	71%	4	9	44%
	QA, enter "1" here.	2	7	29%	0	7	0%	2	9	22%
	Technical Services, enter "1" here.	1	7	14%	4	7	57%	4	9	44%
	Pharmaceutical Development, enter "1" here.	1	7	14%	5	7	71%	4	9	44%
	Other, enter "1" here.	0	7	0%	0	7	0%	0	9	0%
O4	Does your organization also have chemists and engineers routinely performing PAC outside of the formally structured PAC group?									
	If YES, enter "1" here.				4	7	57%	8	9	89%
	If NO, enter "1" here and go on to question O6.				3	7	43%	1	9	11%
O5	What best describes the interaction between the groups?									
	PAC group involved as team members on projects, , enter "1" here.				3	4	75%	7	8	88%
	PAC group serves as consultants/reviewers, enter "1" here.				2	4	50%	3	8	38%
	PAC group provides equipment, enter "1" here.				2	4	50%	3	8	38%
	PAC group does not interact with the engineers/chemists, enter "1" here.				0	4	0%	0	8	0%
O6	Which of the following are the PAC scientists aligned with?									
	An analytical group, enter "1" here.	8	7	114%	4	7	57%	5	9	56%
	A chemistry group, enter "1" here.	2	7	29%	2	7	29%	1	9	11%
	An engineering group, enter "1" here.	7	7	100%	3	7	43%	2	9	22%
	Technical Services, enter "1" here.	1	7	14%	3	7	43%	3	9	33%
	Other, enter "1" here.	0	7	0%	1	7	14%	1	9	11%
O7	How does the PAC group become involved in projects?									
	Service organization responding to customer requests, enter "1" here.	5	7	71%	3	7	43%	4	9	44%
	Assigned by management to solve specific problem, enter "1" here.	3	7	43%	4	7	57%	5	9	56%
	As members of development teams, enter "1" here.	9	7	129%	4	7	57%	5	9	56%
	Other, enter "1" here.	0	7	0%	0	7	0%	0	9	0%

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O8	What is the source of funding for PAC projects?									
	Corporate-wide funding (as overhead), enter "1" here.				2	7	29%	4	9	44%
	Included in project development budgets, enter "1" here.				5	7	71%	6	9	67%
	Recharge system, enter "1" here.				0	7	0%	1	9	11%
	Fee for services (negotiate project contracts), enter "1" here.				1	7	14%	1	9	11%
O9	Where do you believe that PAC can have the most economic impact?									
	Process R&D, enter "1" here.	5	9	56%	5	9	56%	7	12	58%
	Commercial process support, enter "1" here.	9	9	100%	3	9	33%	9	12	75%
	QA, enter "1" here.	0	9	0%	1	9	11%	0	12	0%
	Other, enter "1" here.	0	9	0%	0	9	0%	0	12	0%
O10	Do you or someone in your company participate on any of the following PAC regulatory compliance initiatives?									
	NIRVWoG, enter "1" here.	8	9	89%	3	9	33%	1	12	8%
	Process Analytical Technologies Subcommittee, enter "1" here.	8	9	89%	4	9	44%	3	12	25%
	PhRMA PAT team, enter "1" here.	0	9	0%	3	9	33%	4	12	33%
	Other, enter "1" here.	0	9	0%	2	9	22%	4	12	33%
O11	Do you or someone in your company participate on any of the following PAC technology development consortia or initiatives?									
	Center for Process Analytical Chemistry (CPAC), enter "1" here.	6	9	67%	2	9	22%	3	12	25%
	Center for Pharmaceutical Process Research (CPPR), enter "1" here.	2	9	22%	1	9	11%	2	12	17%
	Measurement and Control Engineering Center (MCEC), enter "1" here.	0	9	0%	1	9	11%	2	12	17%
	Centre for Process Analytics and Control technology (CPACT), enter "1" here.	1	9	11%	1	9	11%	0	12	0%
	Other, enter "1" here.	0	9	0%	2	9	22%	4	12	33%
O12	Is your company crafting a formal response to the FDA Draft Guidance on PAT?									
	If YES, enter "1" here.				5	9	56%	6	12	50%
	If NO, enter "1" here and go on to question M1.				1	9	11%	4	12	33%
	If DON'T KNOW, enter "1" here and go on to question M1.				3	9	33%	2	12	17%
O13	Has the PAC group been involved in discussions directed at that response?									
	If YES, enter "1" here.				5	5	100%	6	6	100%
	If NO, enter "1" here.				1	5	20%	0	6	0%

Manufacturing		2001 total	2001 # responses	2001%	2003 total	2003 # responses	2003%	2004 total	2004 # responses	2004%
M1	Does your company use PAC technology in commercial manufacturing processes (see question M3 for definition of PAC technology)?									
	If YES, enter "1" here.	9	10	90%	7	9	78%	10	12	83%
	If NO, enter "1" here and go on to question M10.	1	10	10%	2	9	22%	2	12	17%
M2	If yes, where does your company use PAC technology?									
	Tech transfers -- for optimization and information purposes, enter "1" here.	4	9	44%	7	7	100%	5	10	50%
	Improvement and repair of existing processes, enter "1" here.	6	9	67%	4	7	57%	7	10	70%
	In-process checks (IPCs) for process control, enter "1" here.	7	9	78%	7	7	100%	10	10	100%
	QA release testing for raw materials, enter "1" here.	6	9	67%	4	7	57%	5	10	50%
	Final product assays and release testing, enter "1" here.	3	9	33%	2	7	29%	3	10	30%
	Other, enter "1" here.	0	9	0%	0	7	0%	0	10	0%
M3a	Other than temperature, pressure, and flow, what PAC technologies are currently used in dedicated commercial manufacturing applications?									
	pH, enter "1" here.	7	9	78%	7	7	100%	9	10	90%
	Conductivity, enter "1" here.	4	9	44%	6	7	86%	8	10	80%
	NIR, enter "1" here.	8	9	89%	6	7	86%	9	10	90%
	Mid-IR, enter "1" here.	4	9	44%	5	7	71%	5	10	50%
	UV-Vis, enter "1" here.	4	9	44%	5	7	71%	7	10	70%
	Raman, enter "1" here.	2	9	22%	3	7	43%	0	10	0%
	Microwave, enter "1" here.	0	9	0%	0	7	0%	0	10	0%
	Mass spectrometry, enter "1" here.	3	9	33%	2	7	29%	4	10	40%
	GC, enter "1" here.	4	9	44%	2	7	29%	2	10	20%
	LC, enter "1" here.	4	9	44%	4	7	57%	3	10	30%
	Hyphenated, enter "1" here.	0	9	0%	0	7	0%	1	10	10%
	Imaging systems, enter "1" here.	0	9	0%	2	7	29%	1	10	10%
M3b	Other than temperature, pressure, and flow, what PAC technologies are currently used in dedicated commercial manufacturing applications for closed-loop control?									
	pH, enter "1" here.				4	7	57%	8	10	80%
	Conductivity, enter "1" here.				5	7	71%	5	10	50%
	NIR, enter "1" here.				2	7	29%	3	10	30%
	Mid-IR, enter "1" here.				0	7	0%	0	10	0%
	UV-Vis, enter "1" here.				2	7	29%	5	10	50%
	Raman, enter "1" here.				0	7	0%	0	10	0%
	Microwave, enter "1" here.				0	7	0%	0	10	0%
	Mass spectrometry, enter "1" here.				1	7	14%	1	10	10%
	GC, enter "1" here.				0	7	0%	1	10	10%
	LC, enter "1" here.				2	7	29%	2	10	20%
	Hyphenated, enter "1" here.				0	7	0%	0	10	0%
	Imaging systems, enter "1" here.				0	7	0%	0	10	0%

Manufacturing		2001 total	2001 # responses	2001%	2003 total	2003 # responses	2003%	2004 total	2004 # responses	2004%
M4	In total, how many of these analyzers do you estimate are currently operating in your manufacturing plant?									
	Fewer than 10, enter "1" here.	3	9	33%	0	7	0%	2	10	20%
	10-50, enter "1" here.	3	9	33%	3	7	43%	3	10	30%
	51-100, enter "1" here.	1	9	11%	0	7	0%	2	10	20%
	Greater than 100, enter "1" here.	1	9	11%	4	7	57%	3	10	30%
M5	What best describes your opinions about the current status of your on-line analytical technology?									
	We are about where we should be, enter "1" here.	0	9	0%	0	7	0%	0	10	0%
	There is much value that can still be captured in a select few processes and product, enter "1" here.	1	9	11%	3	7	43%	2	10	20%
	We have barely scratched the surface, enter "1" here.	8	9	89%	4	7	57%	8	10	80%
	We have too many analyzers returning too little value, enter "1" here.	0	9	0%	0	7	0%	0	10	0%
M6	Who provides the major support and maintenance of your PAC technology in your manufacturing facilities?									
	PAC group, enter "1" here.	4	9	44%	4	7	57%	4	10	40%
	Plant operators/engineers, enter "1" here.	2	9	22%	1	7	14%	5	10	50%
	I&E group, enter "1" here.	0	9	0%	2	7	29%	1	10	10%
	Vendors, enter "1" here.	0	9	0%	0	7	0%	2	10	20%
	Site Champion, enter "1" here.	1	9	11%	3	7	43%	2	10	20%
	Other, enter "1" here.	0	9	0%	1	7	14%	2	10	20%
M7	For chemometric applications, who owns/maintains the calibration?									
	Plant champion, enter "1" here.				2	7	29%	3	10	30%
	Vendor, enter "1" here.				0	7	0%	1	10	10%
	PAC group, enter "1" here.				3	7	43%	5	10	50%
M8	For plant installations, who provides the documentation package for PAC installations?									
	Plant Champion/project team, enter "1" here.				6	7	86%	4	10	40%
	Vendor/contractor (e.g. S2I), enter "1" here.				1	7	14%	2	10	20%
	PAC group, enter "1" here.				5	7	71%	7	10	70%
M9	For plant applications, what sort of analyzer reliability data is being collected?									
	No analyzer reliability data is collected, enter "1" here.				2	7	29%	2	10	20%
	Analyzer uptime is tracked and charted, enter "1" here.				1	7	14%	1	10	10%
	Failure data is documented and shared (w/ vendor or inter-company), enter "1" here.				2	7	29%	3	10	30%
	All instruments have PM plans in place, enter "1" here.				4	7	57%	8	10	80%

Manufacturing		2001 total	2001 # responses	2001%	2003 total	2003 # responses	2003%	2004 total	2004 # responses	2004%
M10	What do you see as the greatest barriers to implementing PAC technology in manufacturing facilities? (pick two)									
	FDA regulations, enter "1" here.	1	9	11%	3	9	33%	2	12	17%
	Lack of robust technology, enter "1" here.	0	9	0%	3	9	33%	3	12	25%
	Lack of scientists developing & transferring PAC technology, enter "1" here.	2	9	22%	1	9	11%	2	12	17%
	PAC technology not part of process development efforts, enter "1" here.	3	9	33%	3	9	33%	4	12	33%
	Lack of long-term support for PAC technology, enter "1" here.	3	9	33%	2	9	22%	3	12	25%
	Manufacturing site leadership, enter "1" here.	3	9	33%	1	9	11%	1	12	8%
	QA/internal regulatory group, enter "1" here.	5	9	56%	3	9	33%	1	12	8%
	Other, enter "1" here.	0	9	0%	0	9	0%	3	12	25%
M11	What do you see is the most time-consuming component in implementation of PAC technology?									
	Developing sampling technology, enter "1" here.	3	9	33%	2	9	22%	2	12	17%
	Developing the analytical method, enter "1" here.	1	9	11%	2	9	22%	4	12	33%
	Data analysis and presentation, enter "1" here.	0	9	0%	0	9	0%	0	12	0%
	Meeting instrument classification requirements, enter "1" here.	0	9	0%	1	9	11%	0	12	0%
	IQ/OQ/PQ, enter "1" here.	4	9	44%	3	9	33%	5	12	42%
	Documentation, enter "1" here.	5	9	56%	5	9	56%	4	12	33%
	Procuring/ensuring trained owner and infrastructure, enter "1" here.	1	9	11%	0	9	0%	0	12	0%
	Other, enter "1" here.	0	9	0%	0	9	0%	1	12	8%
M12	Where do you see the greatest need for future developments in PAC applied to commercial manufacturing?									
	Vendor certification/audits to simplify documentation, enter "1" here.							3	12	25%
	Data management technology development, enter "1" here.							2	12	17%
	Analyzer technology development (smaller, simpler, more robust, etc.), enter "1" here.							5	12	42%
	Analyzer cost decrease, enter "1" here.							1	12	8%
	Organizational commitment to PAC, enter "1" here.							6	12	50%
	Other, enter "1" here.							1	12	8%

Research & Development		2001 total	2001 # responses	2001%	2003 total	2003 # responses	2003%	2004 total	2004 # responses	2004%
R1	Does your company use PAC technology in process R&D?									
	If YES, enter "1" here.	9	9	100%	7	9	78%	10	12	83%
	If NO, enter "1" here.	1	9	11%	2	9	22%	2	12	17%
R2	Which of the following does your company commonly use real-time analytical technology to generate data for?									
	Route selection, enter "1" here.	3	9	33%	3	9	33%	2	12	17%
	Process characterization and identifying CPP's, enter "1" here.	8	9	89%	5	9	56%	9	12	75%
	Developing control strategies, enter "1" here.	4	9	44%	2	9	22%	6	12	50%
	Scale-down of existing processes for improvement and maintenance, enter "1" here.	1	9	11%	2	9	22%	2	12	17%
	Reaction engineering and safety determinations, enter "1" here.	5	9	56%	4	9	44%	5	12	42%
	Optimization of particular units operations (e.g. drying), enter "1" here.	0	9	0%	5	9	56%	7	12	58%
	Crystallization studies, enter "1" here.	0	9	0%	5	9	56%	5	12	42%
	Other, enter "1" here.	0	9	0%	0	9	0%	1	12	8%
R3	At what scale do you commonly employ real-time data collection? (can be more than one)									
	Less than 500-cc, enter "1" here.	3	9	33%	4	9	44%	5	12	42%
	500-cc to 2-L, enter "1" here.	7	9	78%	7	9	78%	7	12	58%
	2-L to 100-L (kilo lab, mini-plant), enter "1" here.	6	9	67%	6	9	67%	7	12	58%
	>100-L (pilot plant or demonstration/validation runs), enter "1" here.	0	9	0%	4	9	44%	5	12	42%
R4	Do you have real-time or automated analytical coupled with the following?									
	Automated parallel synthesis workstations, enter "1" here.	3	9	33%	1	9	11%	2	12	17%
	Automated reactors (RC-1, LabMax, CLARK etc.), enter "1" here.	7	9	78%	6	9	67%	4	12	33%

Research & Development		2001 total	2001 # responses	2001%	2003 total	2003 # responses	2003%	2004 total	2004 # responses	2004%
R5	Other than temperature, pressure, and flow, what technologies are currently used in R&D?									
	pH, enter "1" here.	7	9	78%	6	9	67%	10	12	83%
	Conductivity, enter "1" here.	3	9	33%	4	9	44%	4	12	33%
	NIR, enter "1" here.	5	9	56%	5	9	56%	7	12	58%
	Mid-IR, enter "1" here.	7	9	78%	6	9	67%	6	12	50%
	UV-Vis, enter "1" here.	3	9	33%	5	9	56%	4	12	33%
	Raman, enter "1" here.	5	9	56%	3	9	33%	4	12	33%
	Microwave, enter "1" here.	1	9	11%	0	9	0%	1	12	8%
	Mass spectrometry, enter "1" here.	4	9	44%	4	9	44%	3	12	25%
	GC, enter "1" here.	2	9	22%	3	9	33%	1	12	8%
	LC, enter "1" here.	3	9	33%	2	9	22%	2	12	17%
	Hyphenated, enter "1" here.	0	9	0%	3	9	33%	0	12	0%
	Turbidity, enter "1" here.	1	9	11%	4	9	44%	6	12	50%
	Microscopy, enter "1" here.	1	9	11%	4	9	44%	3	12	25%
	LIF, enter "1" here.	1	9	11%	1	9	11%	1	12	8%
	Particle Size, enter "1" here.	1	9	11%	5	9	56%	7	12	58%
	Other, enter "1" here.	0	9	0%	0	9	0%	2	12	17%
R6	In total, how many of these analyzers do you estimate are currently operating in your laboratories?									
	Fewer than 10, enter "1" here.	4	9	44%	2	9	22%	3	12	25%
	11-50, enter "1" here.	4	9	44%	3	9	33%	3	12	25%
	51-100, enter "1" here.	0	9	0%	0	9	0%	5	12	42%
	Greater than 100, enter "1" here.	1	9	11%	1	9	11%	0	12	0%
R7	For chemometric applications, who performs the chemometric modeling or evaluation?									
	The instrument user, with vendor software, enter "1" here.				5	9	56%	7	12	58%
	A staff chemometrician, using semi-custom software, enter "1" here.				3	9	33%	7	12	58%

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R8	What do you see as the greatest barrier to implementing PAC technology in process R&D facilities?									
	Lack of reliable, user-friendly technology, enter "1" here.	1	9	11%	3	9	33%	3	12	25%
	Lack of scientists developing & supporting PAC technology, enter "1" here.	6	9	67%	4	9	44%	6	12	50%
	Lack of support for installed PAC technology, enter "1" here.	0	9	0%	0	9	0%	1	12	8%
	Development chemist's & engineer's reluctance to try new approach, enter "1" here.	7	9	78%	4	9	44%	4	12	33%
	Process development leadership, enter "1" here.	2	9	22%	1	9	11%	2	12	17%
	QA/internal regulations, enter "1" here.	0	9	0%	1	9	11%	0	12	0%
R9	Where do you see the greatest need for future developments in PAC for process R&D applications?									
	Vendor certification/audits to simplify documentation, enter "1" here.							1	12	8%
	Data management technology development, enter "1" here.							1	12	8%
	Analyzer technology development (smaller, simpler, more robust, etc.), enter "1" here.							5	12	42%
	Analyzer cost decrease, enter "1" here.							0	12	0%
	Organizational commitment to PAC, enter "1" here.							9	12	75%
	Other, enter "1" here.							0	12	0%