



Survey

Rapid Microbiological Methods

ECA Masterclass „PAT in Microbial QC“ + ECA Internet Survey

Results

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37 Replies

Represented Pharmaceutical Companies:

Novo Nordisk, DK	Roche Diagnostics, GER
Genentech, E	Valeant Pharmaceuticals, CH
Bayer Healthcare, GER	Pliva Lachema, CZ
Schering, GER	Janssen Pharmaceutica, B
AstraZeneca, S	Vetter Pharma-Fertigung, GER
Organon, NL	Genzyme, DK
Serono, CH	Merck, GER
MSD, IRL	Sanofi-Aventis, GER
Eli Lilly & Company, USA/I	Berlin-Chemie, GER
F. Hofmann-La Roche, CH	Sanochemia Pharmazeutika, A
Nycomed, A	Cytos Biotechnology, CH
Jadran, HR	Weleda, GER

(i)	What are your company's plans to introduce Rapid Microbiology technology ?	ECA Masterclass & Internet Survey
(a)	Within 1-3 years.	26
(b)	Within 3-5 years.	5
(c)	More than 5 years.	1
(d)	No plans at present to introduce Rapid Microbiology methods.	4

(ii)	If applicable, what factors would accelerate you company's plans to adopt Rapid Microbiology?	ECA Masterclass & Internet Survey
(a)	Clearer regulatory guidance.	19
(b)	Inclusion as an alternative compendial method.	13
(c)	Lower cost of purchasing a system.	4
(d)	Easier and hence less costly system validation.	11
(e)	Lower routine costs to use Rapid Microbiology.	7

(iii)	If applicable, on which general area(s) are your plans for Rapid Microbiology focused? Please tick all that apply:	ECA Masterclass & Internet Survey
(a)	Non-sterile product	21
(b)	Sterile product	16
(c)	Environmental monitoring	24
(d)	Raw materials	17
(e)	Other (if possible, please state briefly what this is).	Water (4), Identification, BI, IPC

(iv)	If applicable, in which Rapid Microbiology area (as defined by EP 5.1.6) is your focus?	ECA Masterclass & Internet Survey
(a)	Quantitative methods	27
(b)	Qualitative methods	11
(c)	Identification-based methods	13

(v)	If applicable, what factors are delaying/could delay your company's decision to adopt Rapid Microbiology?	ECA Masterclass & Internet Survey
(a)	Perceived complexity of obtaining regulatory approval.	21
(b)	Lack of apparent support from regulatory and pharmacopoeial bodies.	10
(c)	High cost of usage.	10
(d)	Limited return on investment for some or most applications.	5
(e)	Other (please state briefly).	No single comparability-type protocol to satisfy all local regulatory authorities.

(vi)	What is your perception of the regulatory views on Rapid Microbiology?	ECA Masterclass & Internet Survey
(a)	There is little real evidence of regulatory support of new methods and hence no motivation to adopt new methods.	3
(b)	There is some regulatory support of new methods but not enough to drive a change quickly.	17
(c)	There is regulatory support of new methods but real regulatory pressure to move to these methods is long term.	13
(d)	My company does not operate in an area where regulatory opinion is driving new technology.	1

(vii)	To what extent would a clear regulatory expectation to adopt Rapid Microbiology influence your company's thinking on adoption of Rapid Microbiology?	ECA Masterclass & Internet Survey
(a)	Strongly	22
(b)	Some influence	11
(c)	Little influence	1
(d)	No immediate influence.	0

Summary

Many companies plan to introduce RMMs within the next 1-3 years.

Clearer regulatory guidance would accelerate introduction.

Most companies plan to apply RMMs for Environmental Monitoring.

Most companies focus on quantitative methods.

Introduction of RMMs often delayed by perceived complexity of regulatory approval.

Not enough regulatory support to drive a change quickly.

A clear regulatory expectation to adopt RMMs would strongly influence many companies' thinking.