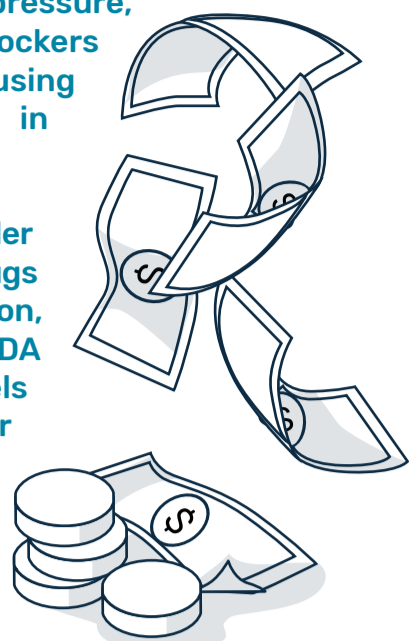


# Current trends in nitrosamine analysis



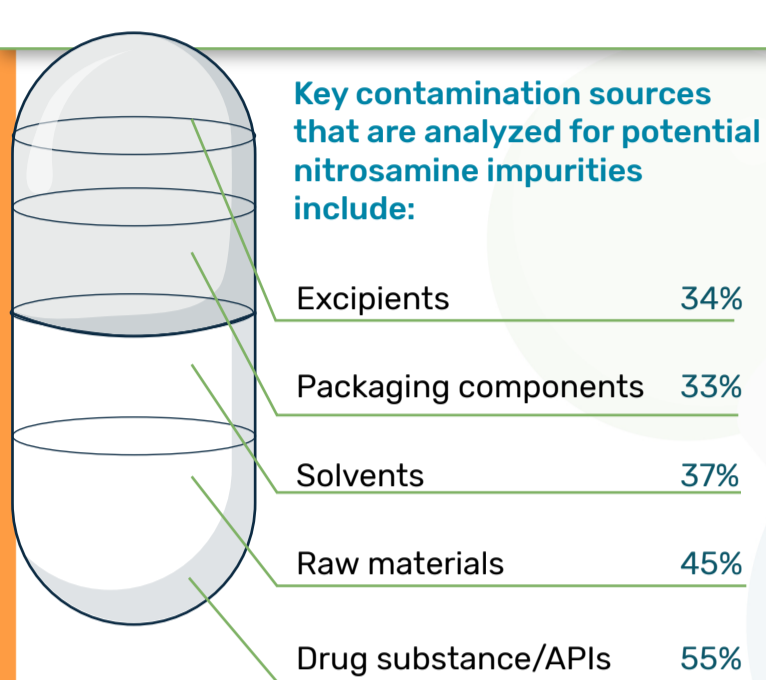
The pharmaceutical industry is facing an ongoing issue with genotoxic impurities. Since 2018, genotoxic impurities have affected several drugs, including those used to treat elevated blood pressure, heartburn and acid reflux. Some angiotensin II receptor blockers were recalled to investigate several potentially cancer-causing substances, called nitrosamines. This issue has resulted in regulatory actions and loss of revenue for the manufacturers.

Amid this crisis, companies realized the need to address the wider issue of active pharmaceutical ingredient (APIs) quality for drugs currently on the market including the accurate identification, quantification and monitoring of impurity levels. Both the FDA and EMA have issued guidance for the impurity detection level based on daily dosage. But regulators plan to enforce lower allowable daily exposure limits, challenging the quantitative limit of detection of the analytical methods. The ability to reach that level of detection requires the highest levels of sensitivity, to help ensure that manufacturers can verify final products before they go to market.

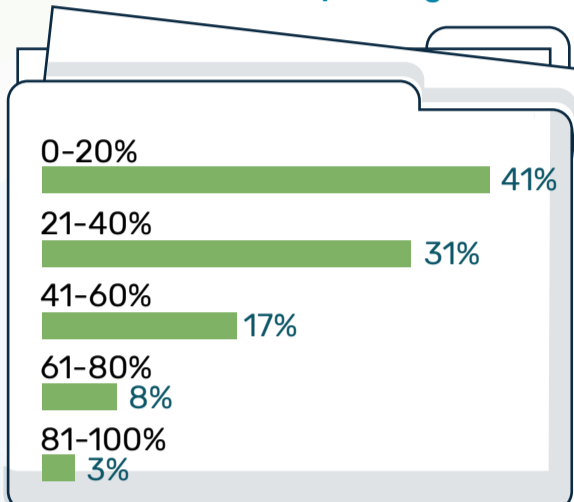


The below infographic was created upon results from the Bioanalysis Zone survey 'Current trends in nitrosamine analysis' [January 2022]. In total 177 respondents participated in the survey.

## Nitrosamine contamination sources

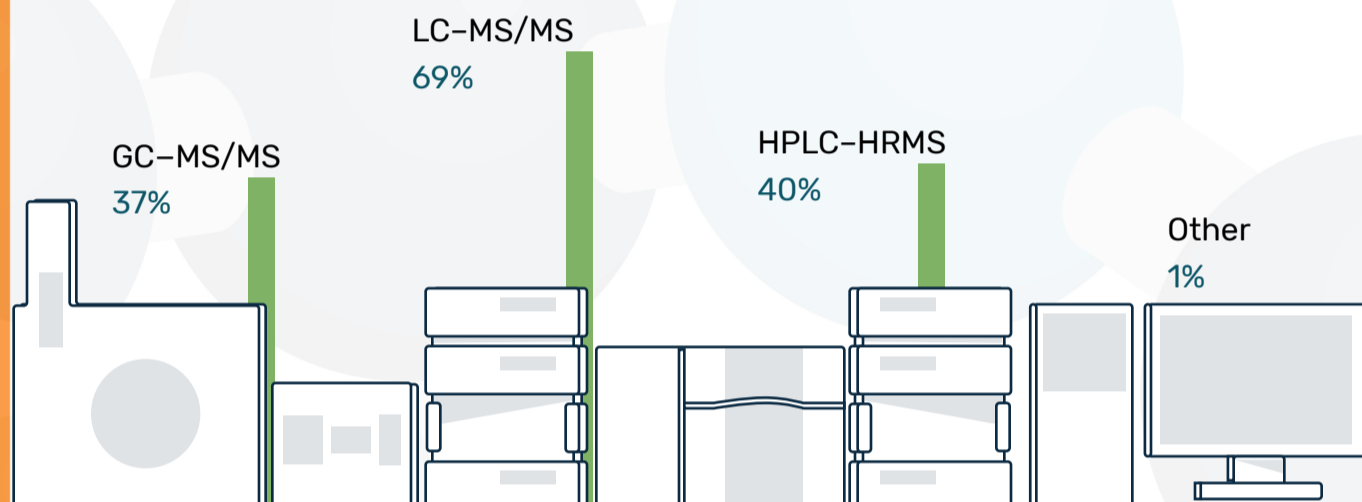


The proportion of an average company's portfolio that has been identified with potential nitrosamine risk and needs confirmatory testing is quite significant:

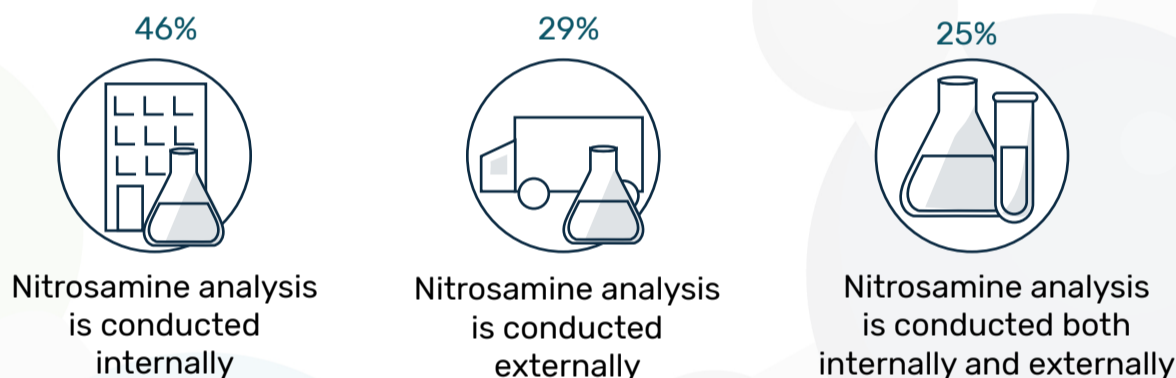


## Analytical detection methods

Analytical techniques that are used to detect nitrosamine impurities include:

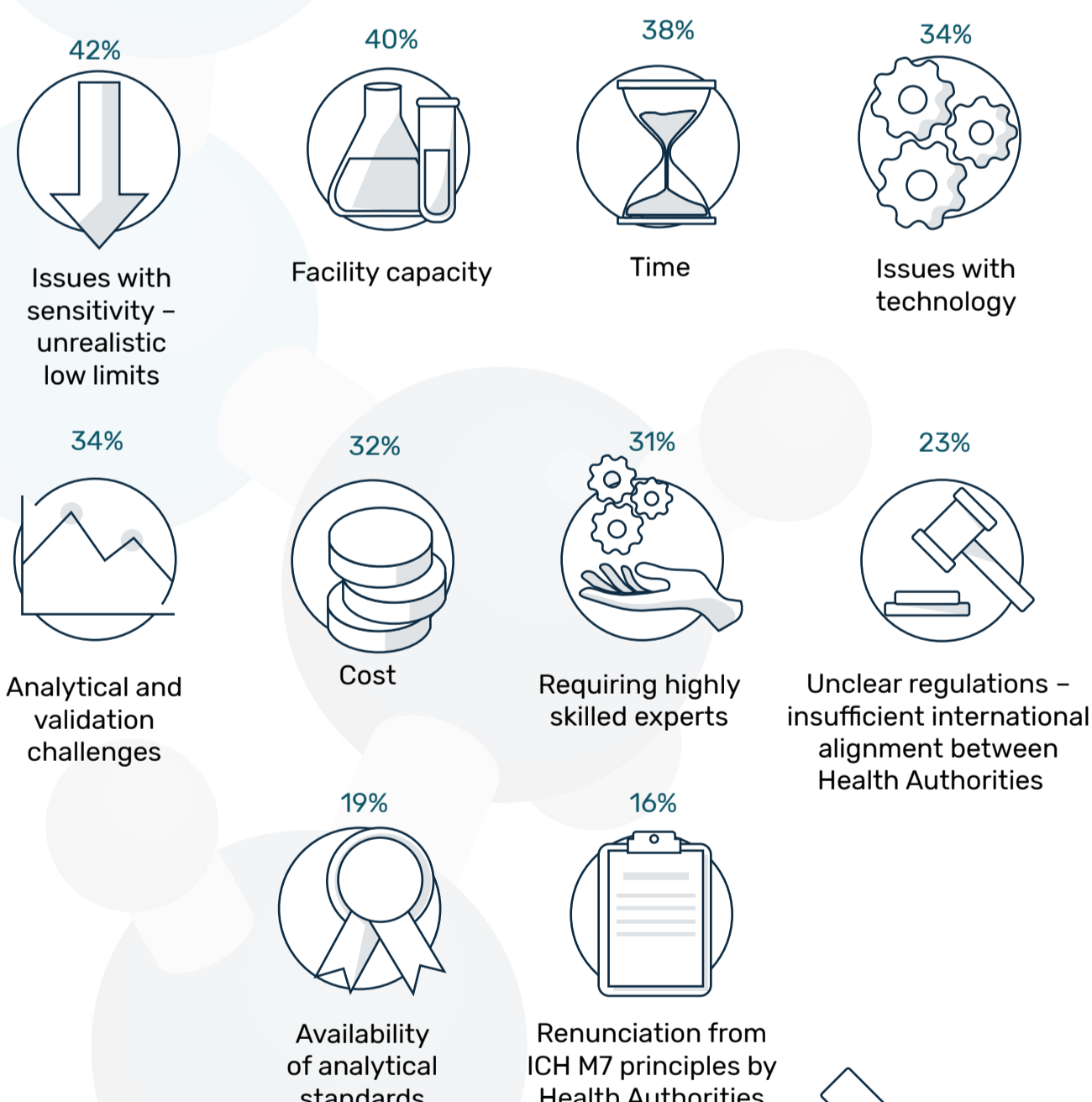


Most respondents internally conduct and perform nitrosamine analysis:



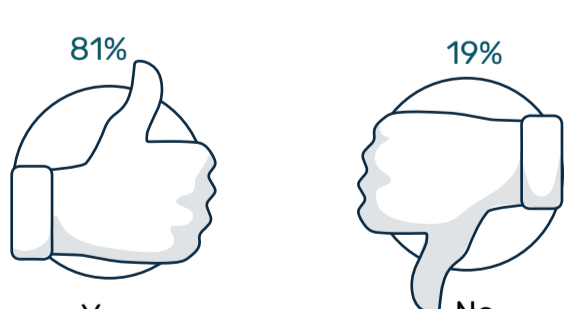
## Challenges of nitrosamine analysis

The main challenges of analyzing nitrosamines include:



## Regulations

Most respondents believe that current regulatory guidance's are satisfactory for the analysis of nitrosamines:



## Demographic of respondents

Organization	Percentage	Location	Percentage
CRO/CMO	12%	Asia	9%
Biotechnology	24%	Europe	13%
Generic pharma	12%	Africa	4%
Large pharma	10%	South and Central America	4%
Small/mid-size pharma	8%	North America	68%
Diagnostics	6%	Australia and Oceania	2%
Bioinformatics	6%		
Equipment vendor	6%	<b>Job title</b>	
Healthcare practitioner	7%	Chemist/Scientist	36%
Academia	7%	Director/CEO/VP	15%
Other	2%	Manager/Group Leader	15%
		Technician	17%
		Healthcare provider	16%
		Other	1%

This infographic has been created as part of a Bioanalysis Zone feature in association with SCIEX.