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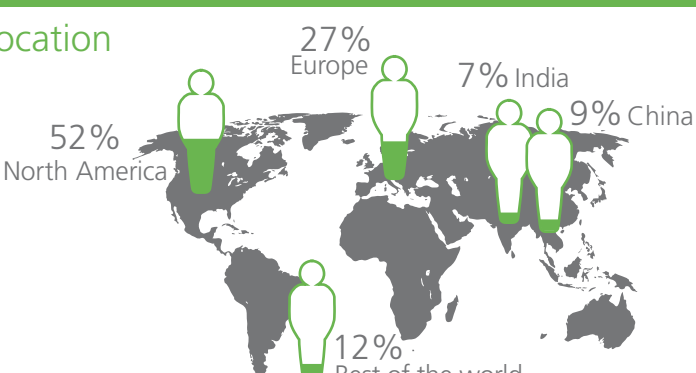
Waters

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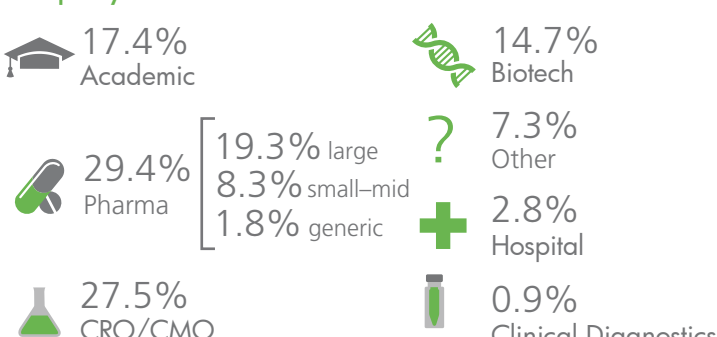
Antibody-drug conjugates (ADCs) are dynamic, heterogeneous mixtures typically comprising a cytotoxic drug covalently bound to an antibody via a synthetic linker. There is huge interest in ADCs as they have the potential to substantially improve efficacy and reduce toxicity compared with cytotoxic drugs. This interest is highlighted by a robust pipeline of ADCs in pre-clinical and clinical development. The heterogeneity and dynamic nature of ADCs raises unique bioanalytical challenges. During this Spotlight we have been exploring the analysis of ADCs and how these challenges are being addressed.

About the respondents

Location



Employer

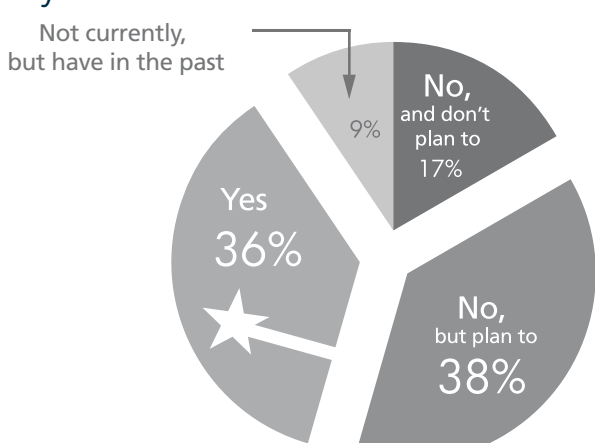


Role



ADC bioanalysis in your laboratory

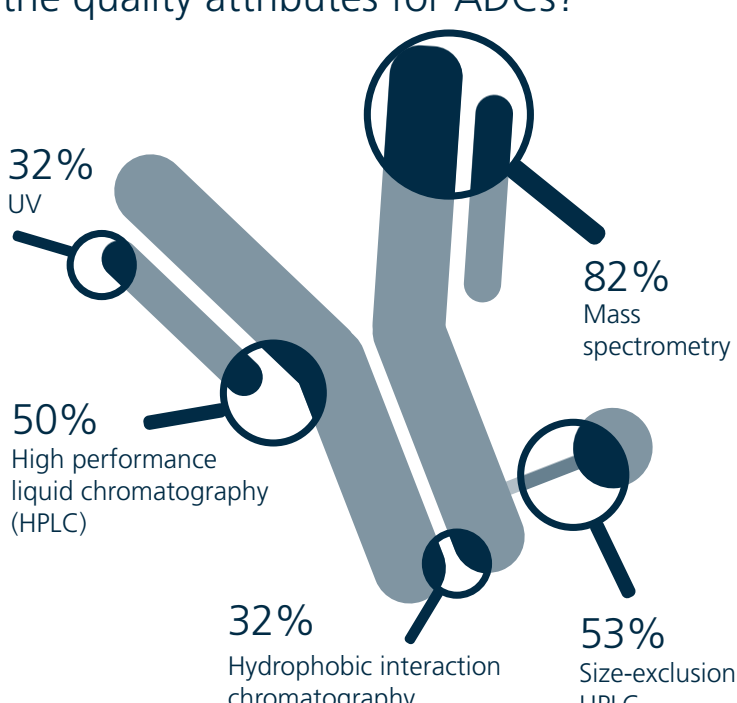
Do you work with ADCs?



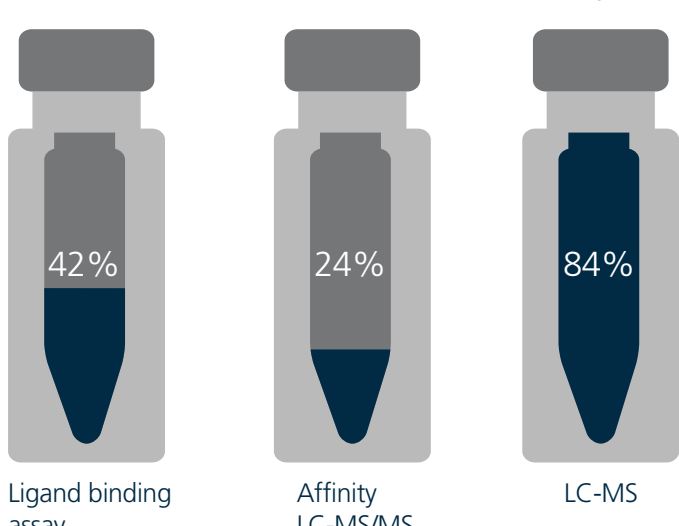
Phases of ADC development



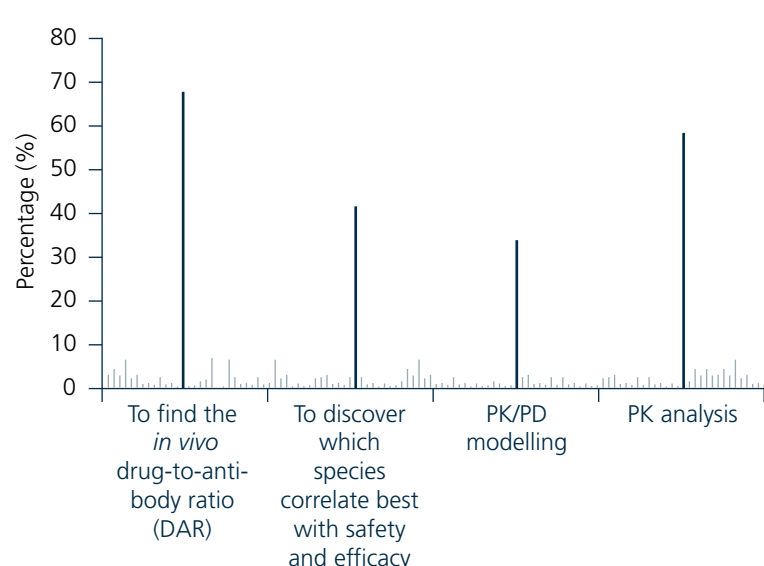
Techniques used to evaluate the quality attributes for ADCs?



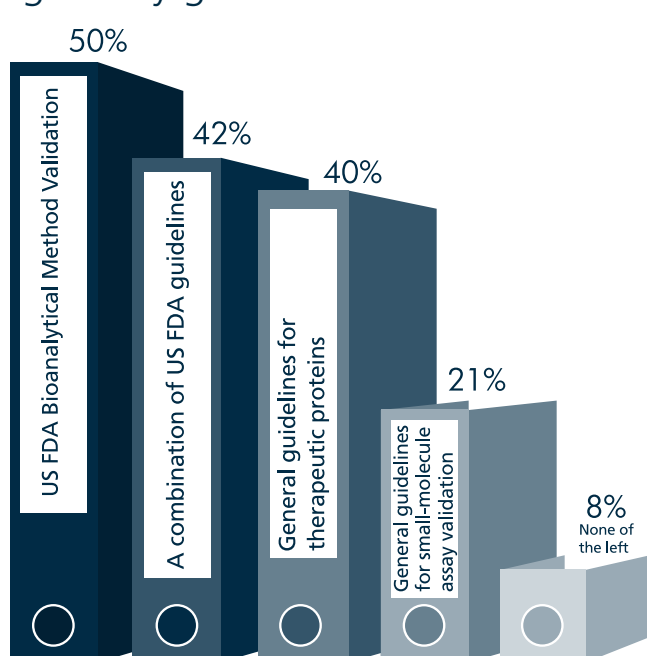
Techniques used for ADC bioanalysis



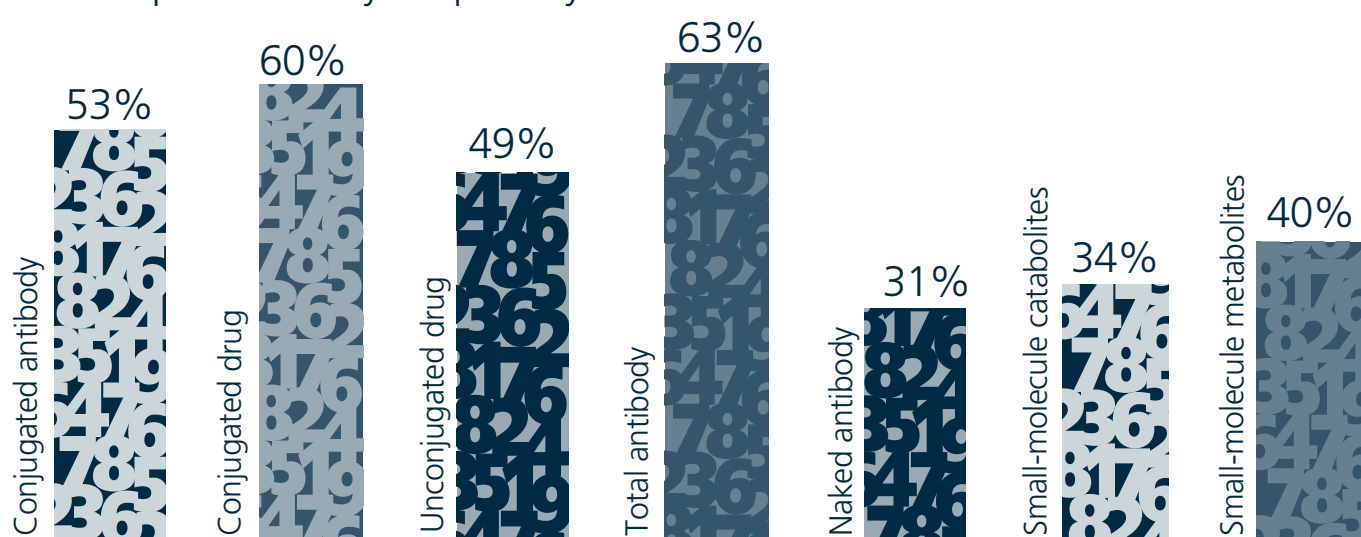
What do you use ADC bioanalytical data for?



Regulatory guidelines used...

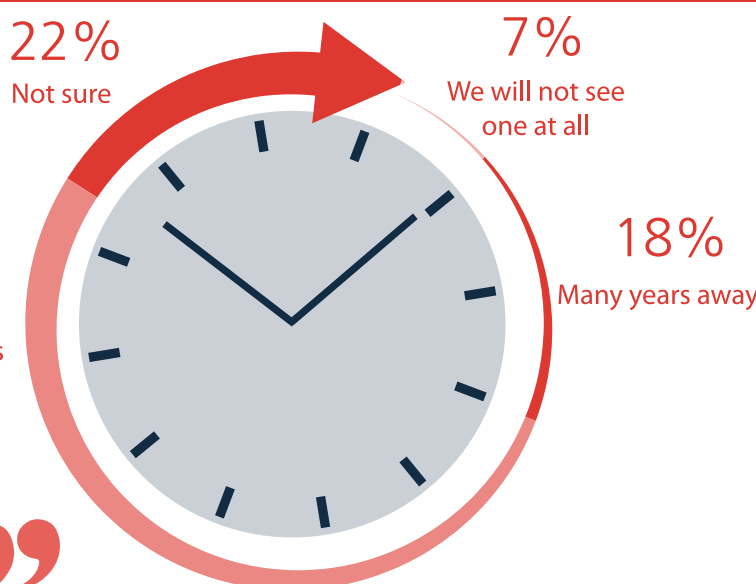


Which components do you quantify?



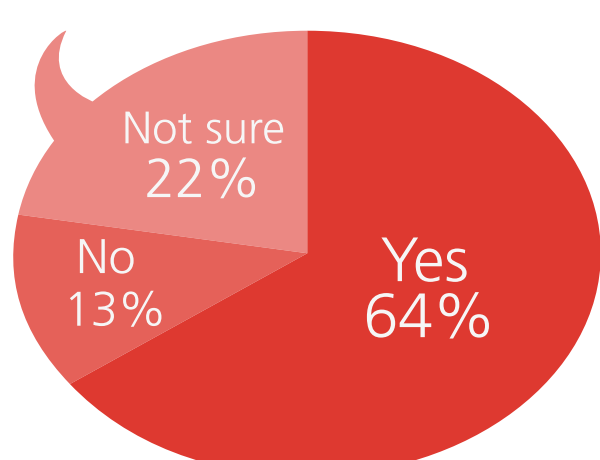
Opinions on issues

How far do you believe we are from a single assay that could describe the PK of an ADC?



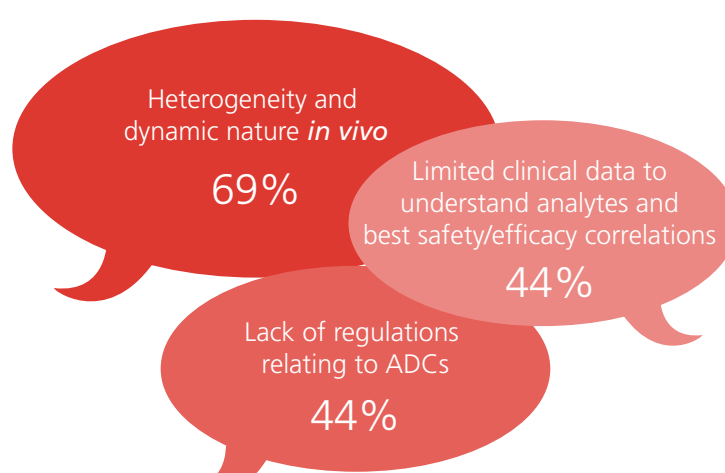
“The differences between the various components make me doubt whether the effort would be worthwhile. [It may be] better to develop reliable methods appropriate for each component than compromise for the sake of a single assay.”

Is it better to develop bioanalytical strategies for ADCs on a case-by-case basis?



“There should be a general strategy that applies to the 90%; there are always exceptions, but the industry should at least work to have a single strategy that works for a majority of ADCs. This could be broken down to cleavable and non-cleavable.”

What is the main issue in the bioanalysis of ADCs?



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at www.bioanalysis-zone.com

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