

BEBPA's 7<sup>th</sup> Annual

# Host Cell Protein Conference

May 15-17, 2019

San Pedro, CA, USA

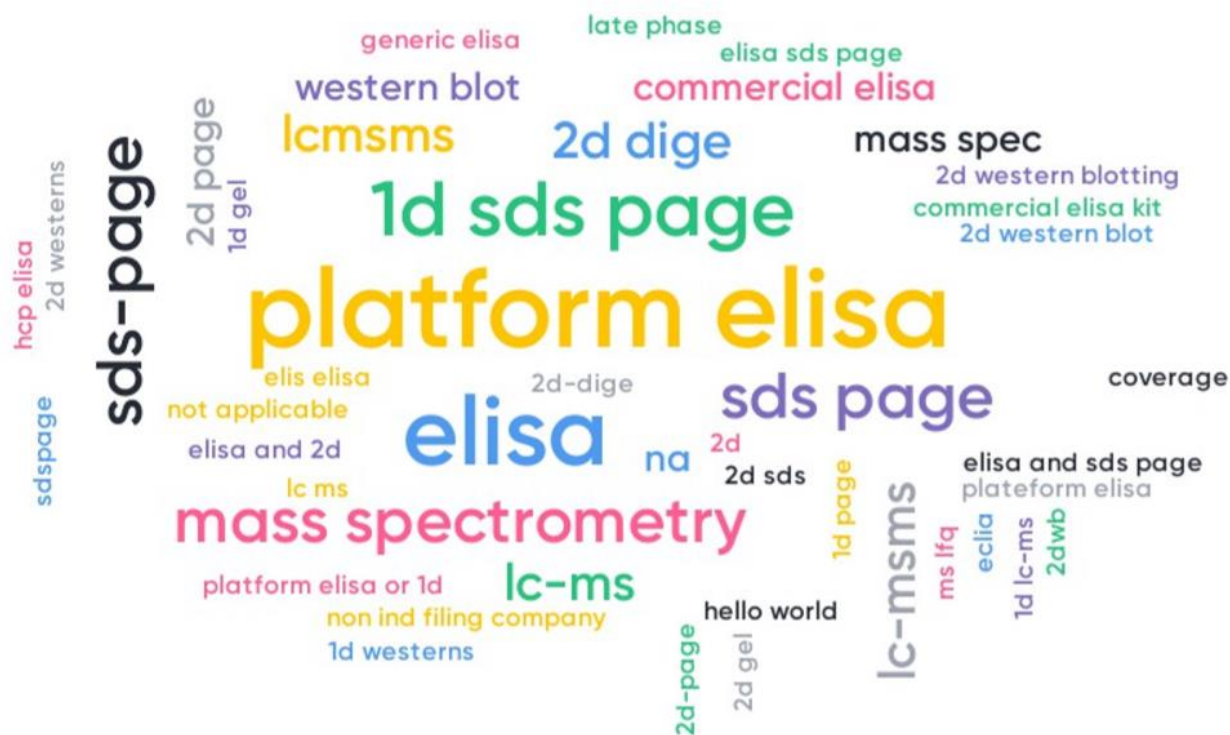
## Survey Results



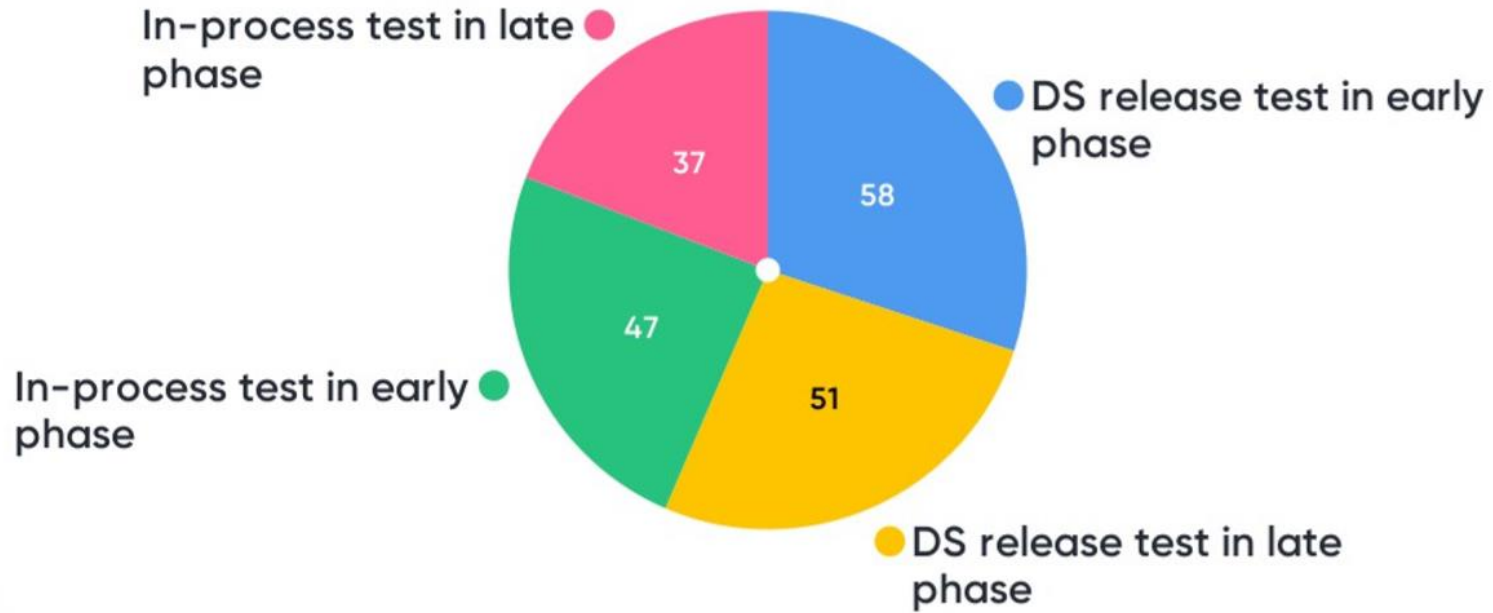
# Session 1

Which HCP Assay is Most Suitable

Which test methods for monitoring HCP levels are included in your organization's Phase I IND filings? (e.g. platform ELISA, 1D SDS PAGE)



What is your go-to strategy for HCP control in clinical products during early vs. late-stage process development? (Select any/all)

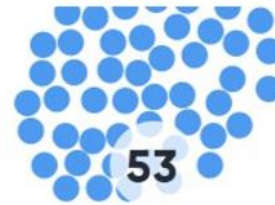


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# When does your organization perform qualification for assay reagent lots? (Select any/all)



Triggered by trending data



For every new batch/lot



Dedicated experiments on a specified timeline



As needed for IND/MAA reporting

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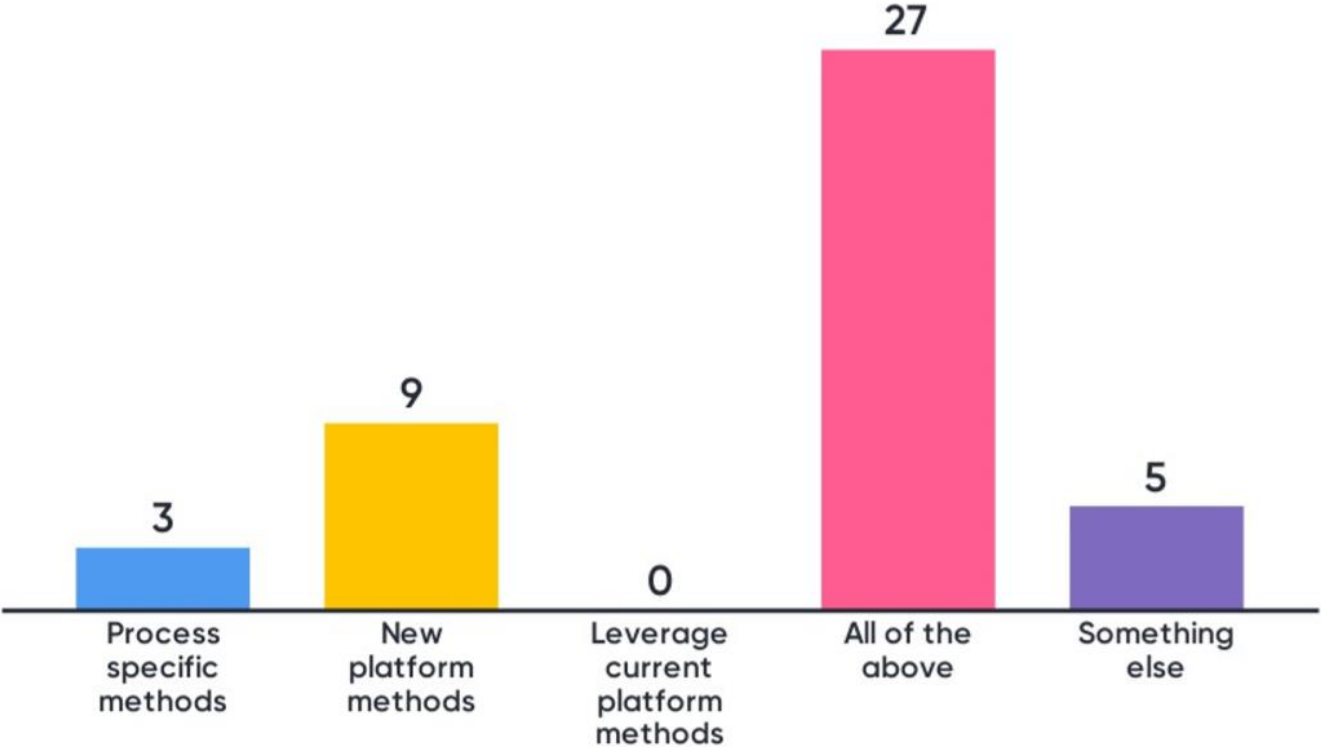
# Session 2

Analysis of HCP's for Gene Therapy  
and Viral Vaccines

What types of cell lines are used for clinical production of gene therapy and/or viral vaccines? (e.g. PER.C6, Yeast, HEK293)



What methods are needed to effectively monitor and control HCPs from gene, viral and cell-based therapies? (Select any/all)



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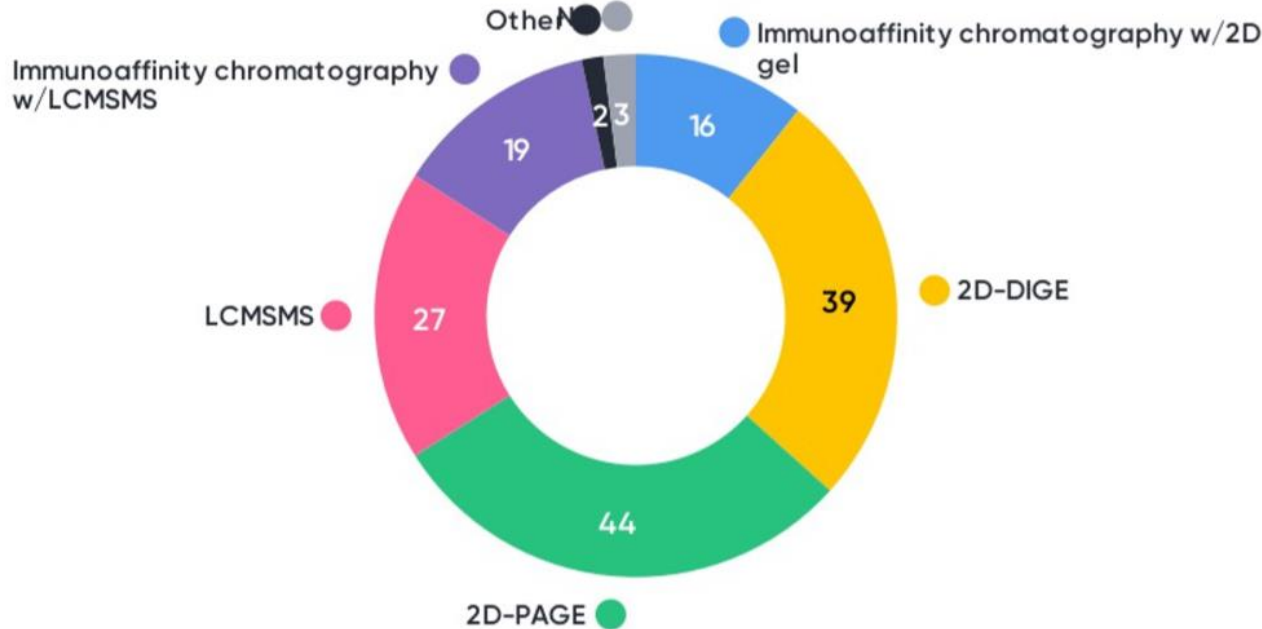


The background features a light blue globe with a grid pattern, centered behind the text. Overlaid on the globe is the acronym 'BEBPA' in large, light blue, semi-transparent letters.

# Session 3

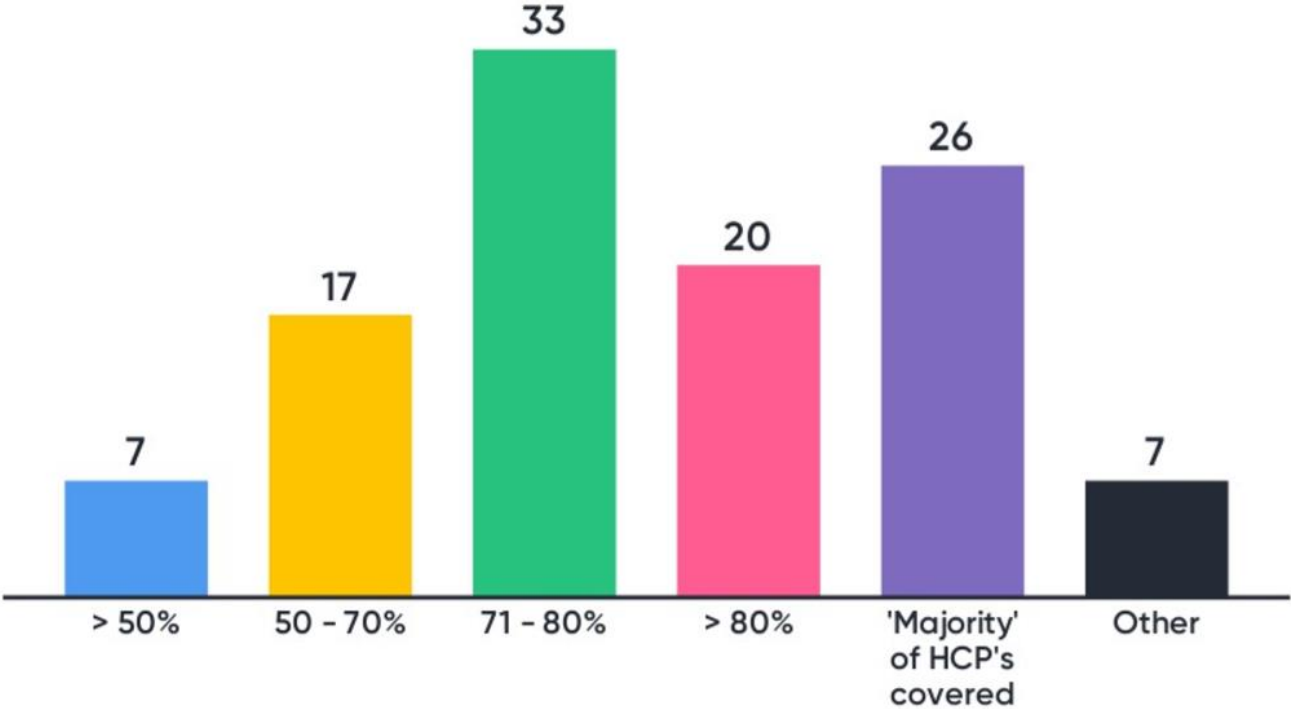
Improved Methods for HCP Antibody  
Coverage Determination

Which method(s) are routinely used for comparing an immunoassay standard with process or mock harvest? (Select any/all)



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What HCP coverage is considered acceptable for reporting (e.g. BLA) at your organization? (Select any/all)

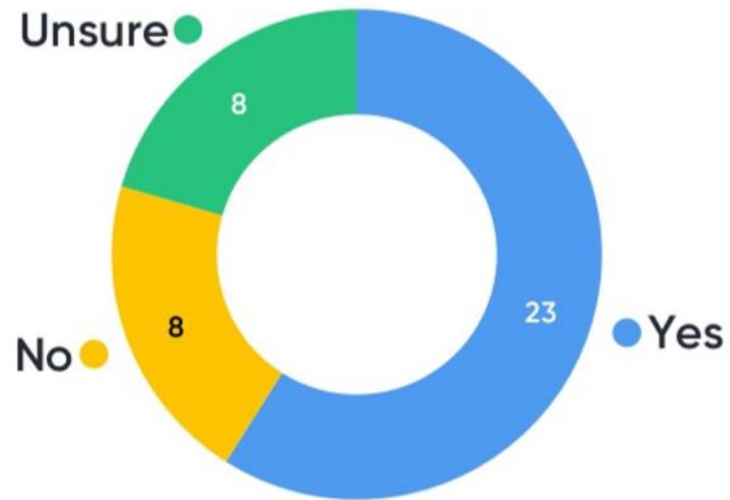




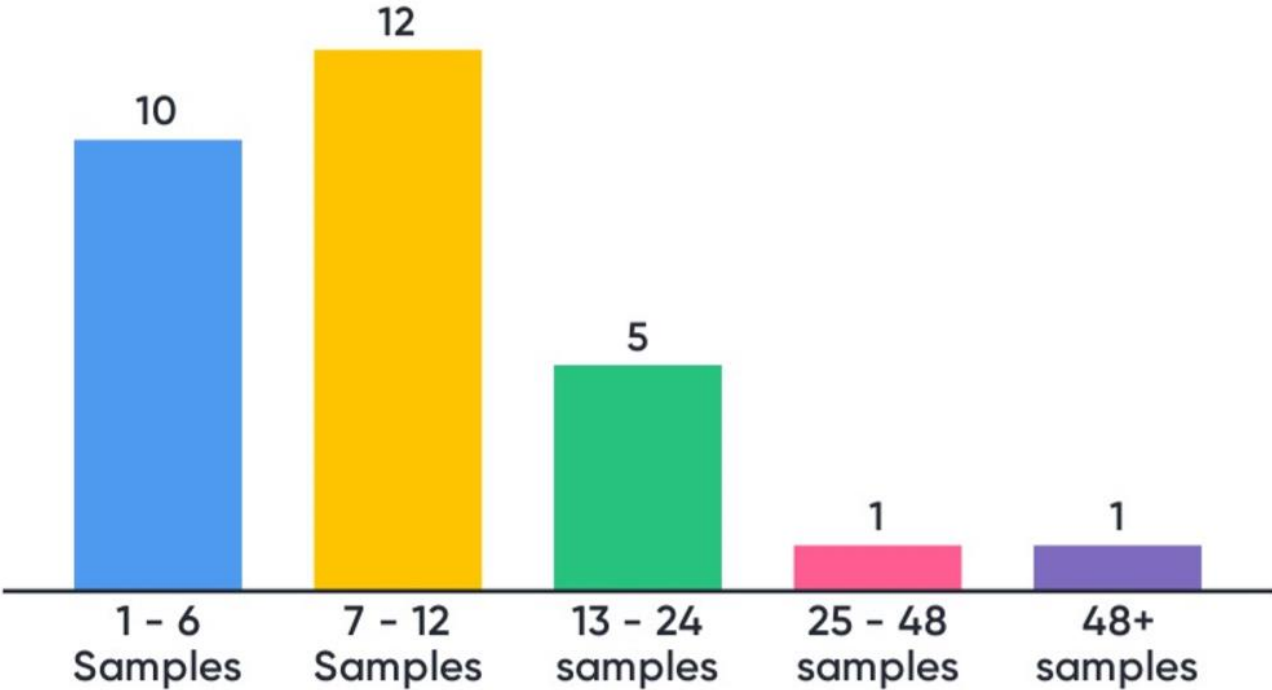
# Session 4

Application of Mass Spectrometry to Identify  
and Quantify HCPs

Does your organization routinely use LC-MS/MS methods with ~10ppm sensitivity or better?

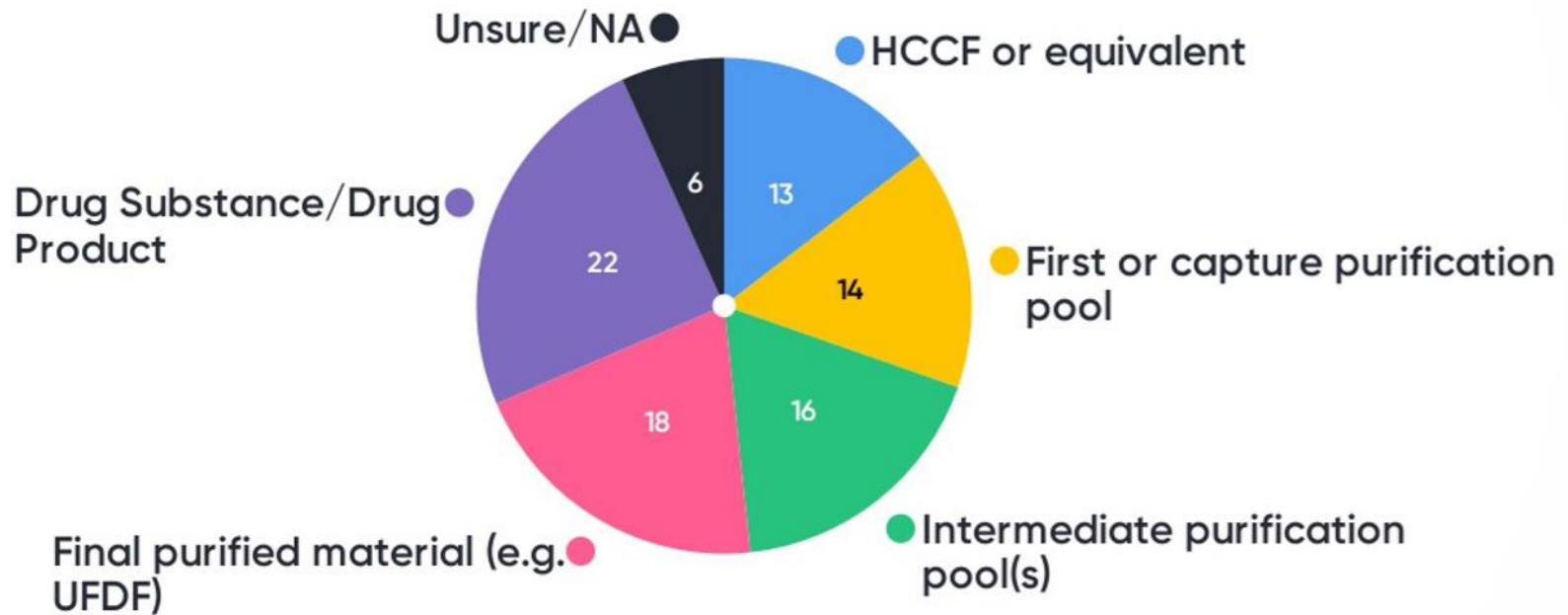


For HCP identification, what is the typical throughput for 1 testing run using your routine LC-MS/MS method?



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# Which sample type(s) do you routinely evaluate by LC-MS/MS methods for HCP identification? (Select any/all)



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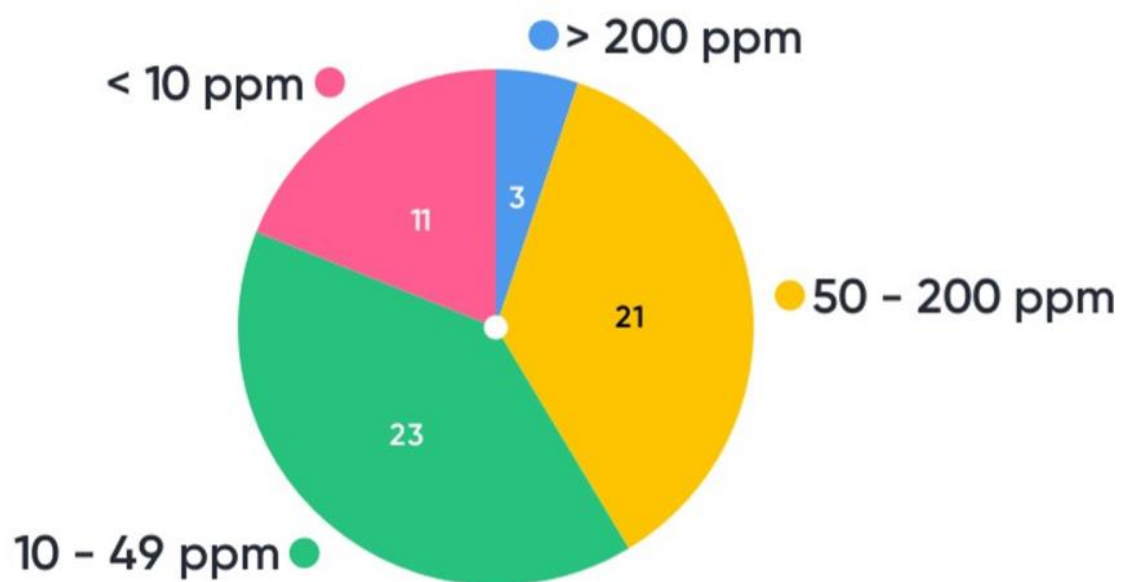


# Session 5

Safety and Tox Risks Associated with  
Host Cell Protein Impurities

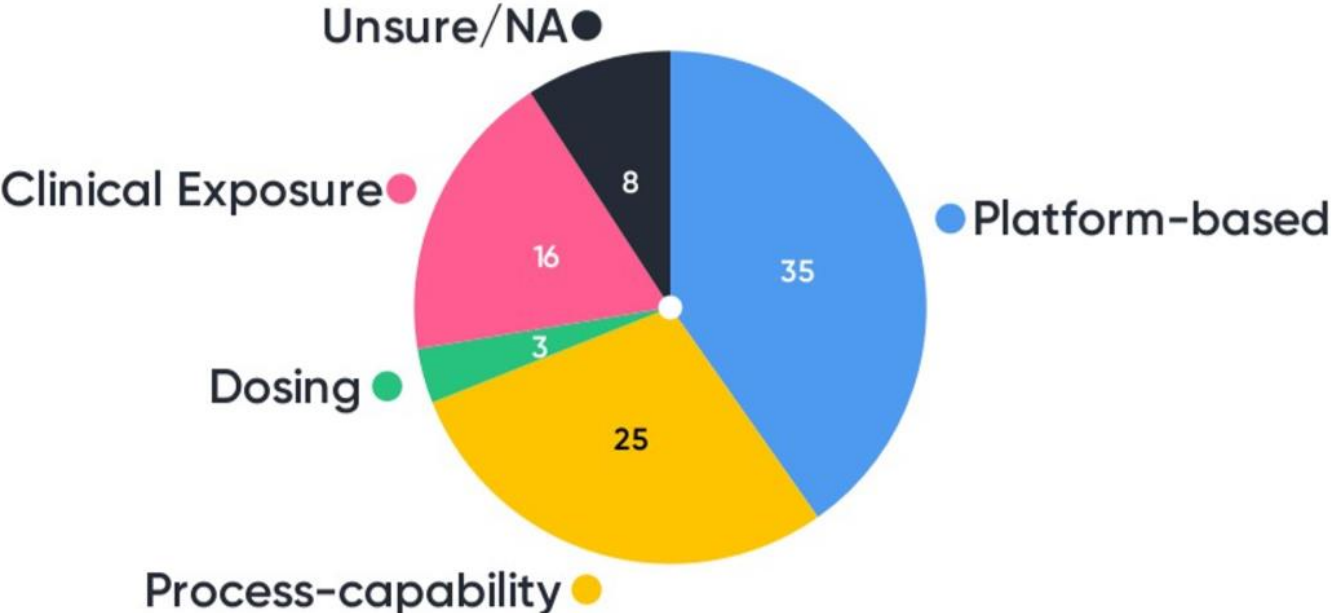


What numerical limits does your organization typically have around total HCP levels by ELISA In BLA/MAA for MAb products?



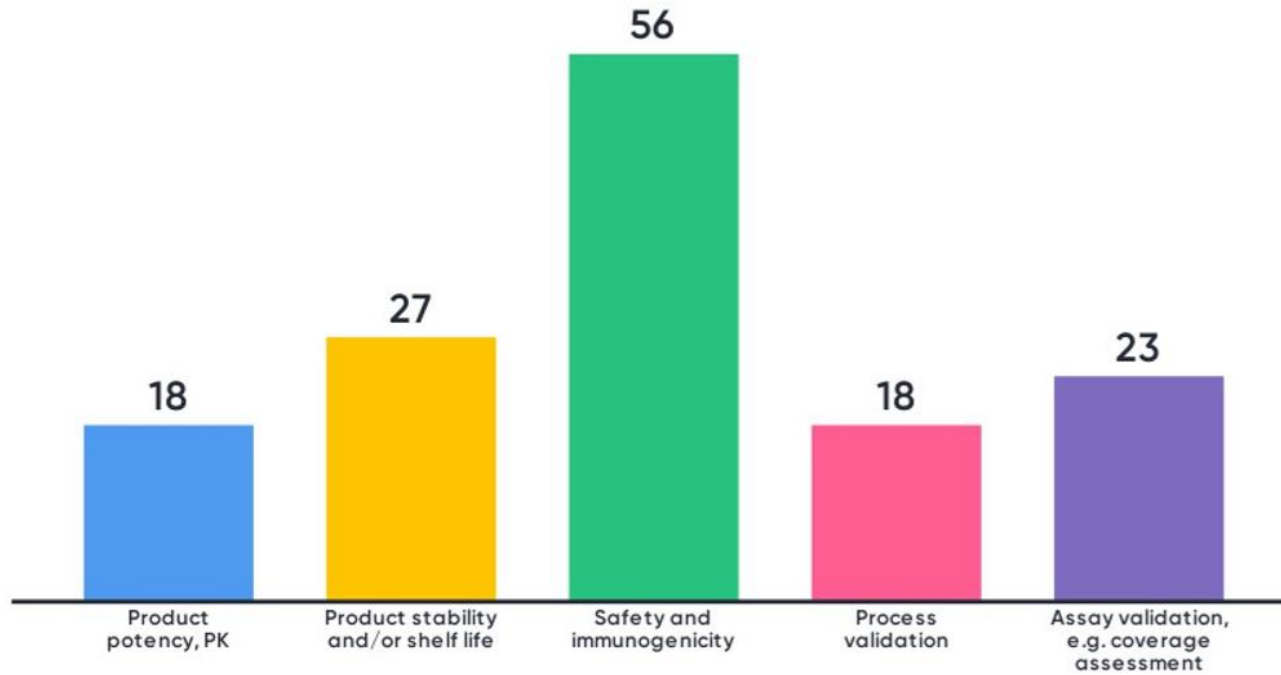
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What is the general strategy your organization uses to determine the HCP acceptance criteria by ELISA for BLA/MAA?



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What are the primary impact considerations for risk assessment of specific/individual HCP's? (Select any/all)



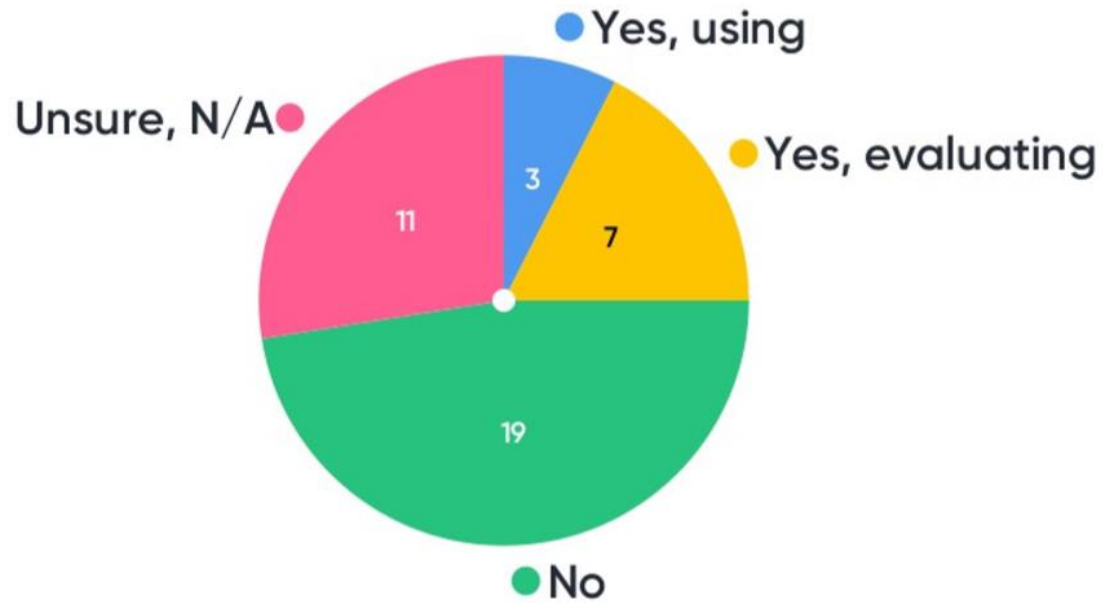
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The logo for BEBPA (Business Enterprise Business Process Association) features the letters 'B', 'E', 'B', 'P', and 'A' in a light blue, outlined font. A globe is positioned behind the letters 'E' and 'B', showing the Americas in light blue and the rest of the world in white.

# Session 6

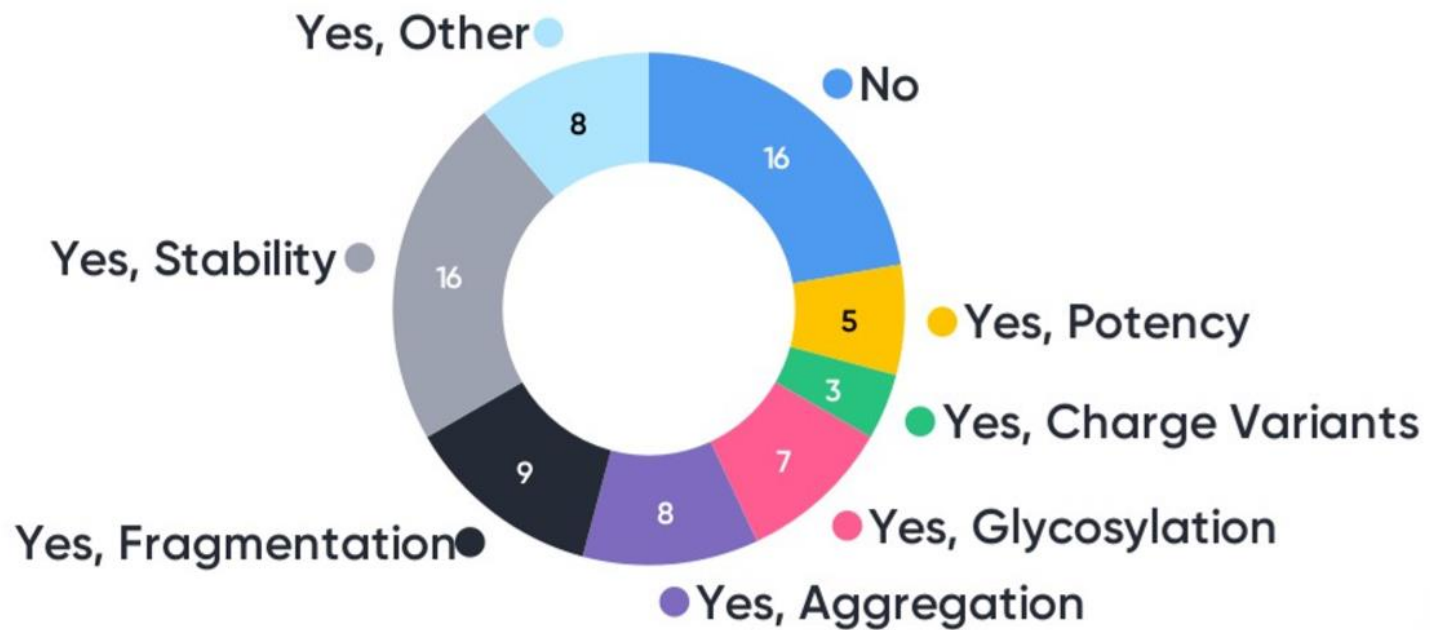
## Process Impacts on HCP Profile

# Is your organization currently using or evaluating knockout cell lines for reduction of HCP load?



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Is your organization currently tracking correlations between specific HCP's and product quality attributes? (Select any/all)



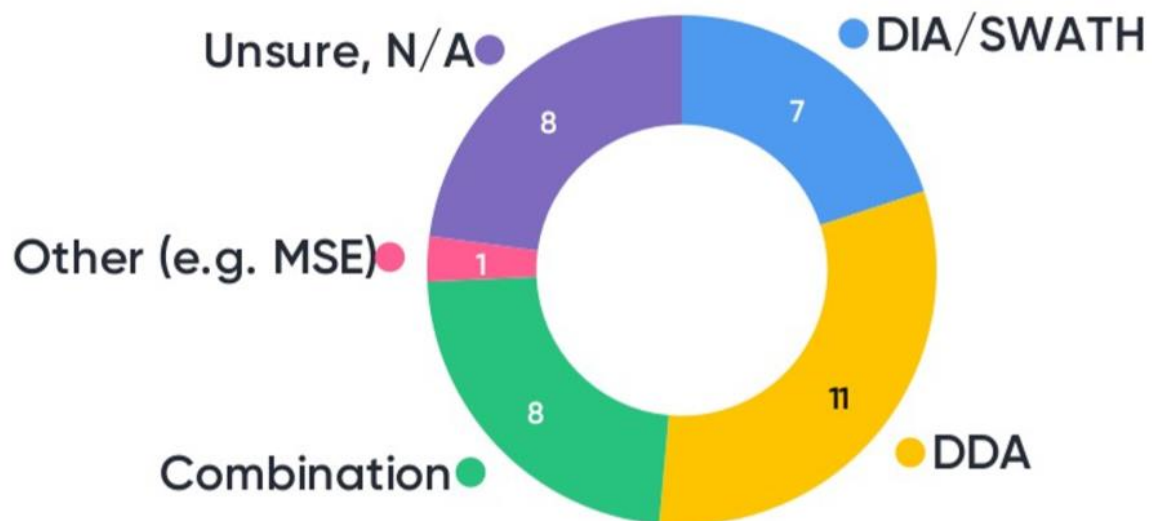
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# Session 7

Innovations in Mass Spectrometry  
for HCP Analysis

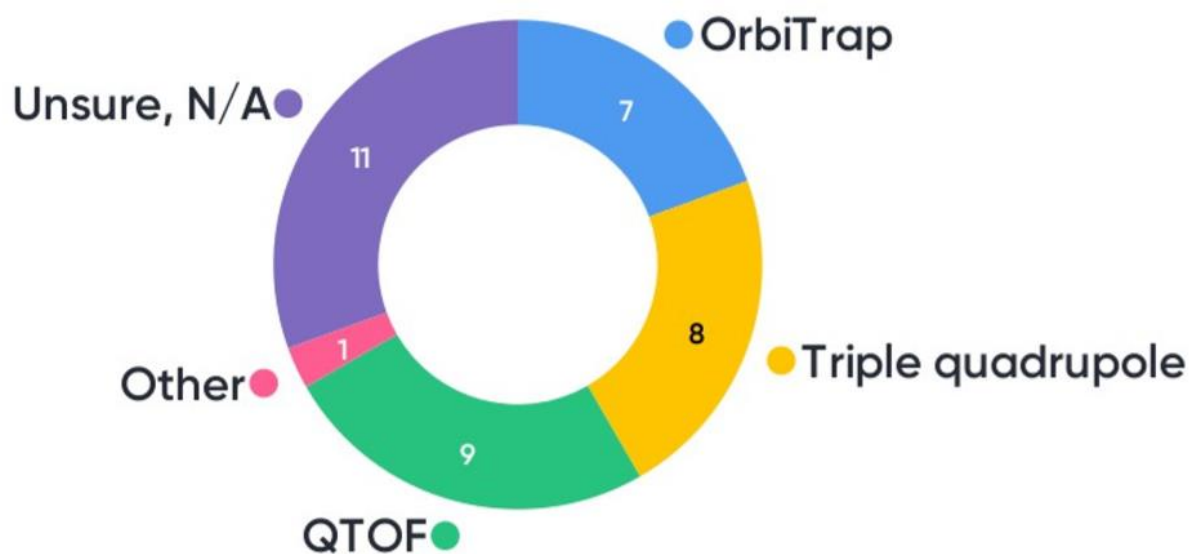
Does your organization routinely use DIA, DDA, or a combination of acquisition methods for HCP identification?



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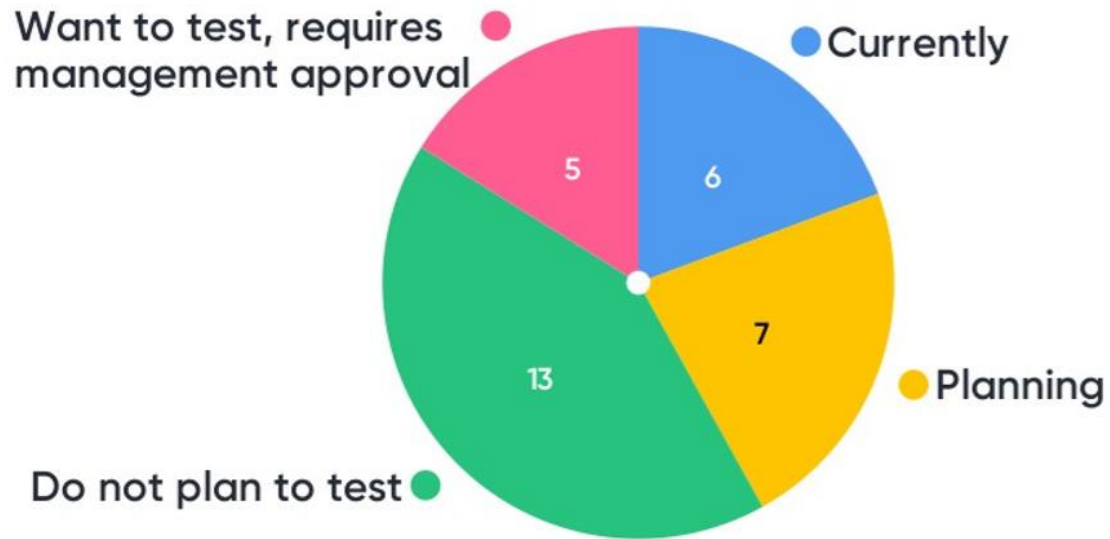


# Which MS instrument is preferred for HCP quantification?



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Do you currently or are you planning to test marketed products using high sensitivity (< 10 ppm) LC-MS/MS methods?



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