Survey on: Perceptions and Barriers Regarding Advanced Modelling and Adaptive Control Strategies

Evaluation including responses from CMC Strategy Forum

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Goal of the Survey

This survey aims to better understand current perceptions, barriers, and regulatory considerations regarding advanced modelling approaches in biopharmaceutical process development and manufacturing, including end-to-end process models, hybrid models, digital twins, and adaptive control strategies.

The survey is anonymous and intended for exploratory discussion within the biopharmaceutical and regulatory community.

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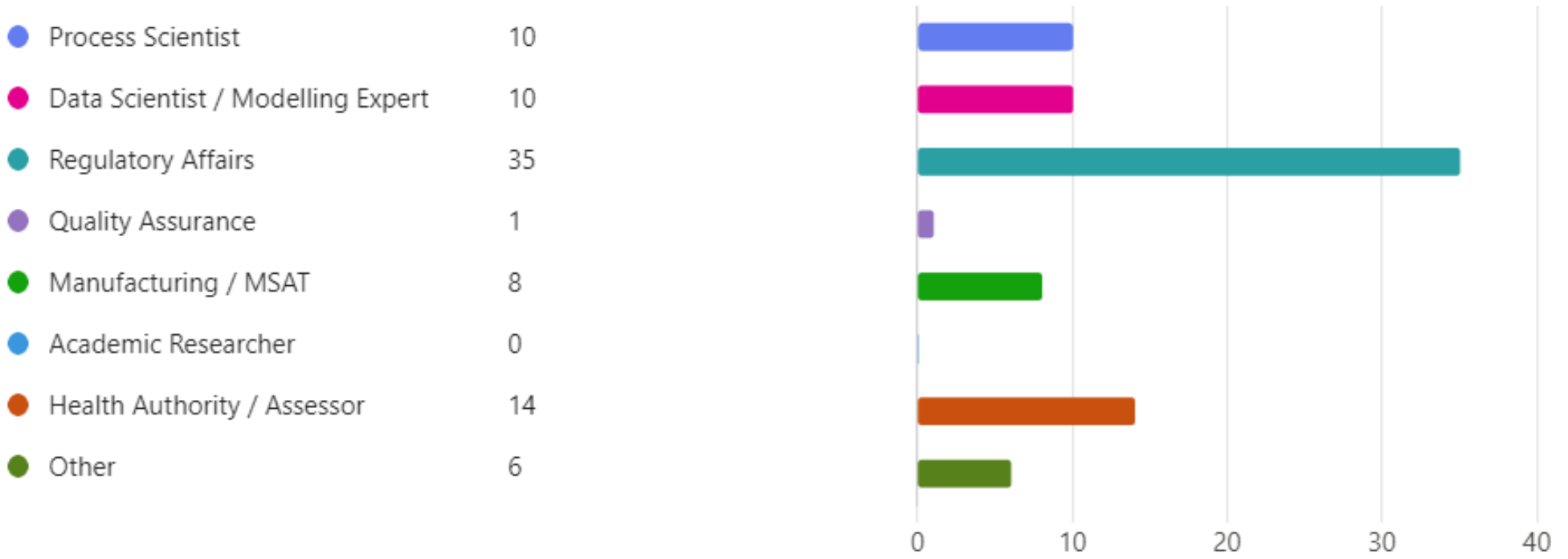
Role of Participants

84 participants (evaluation time 25th of June 16:52)

1. What best describes your primary role

More details

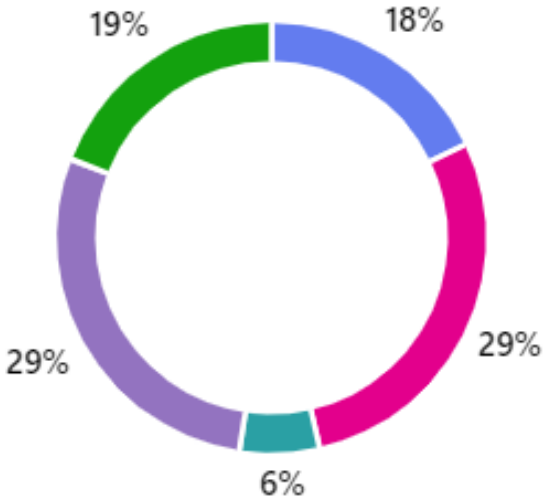


Primary Area of Participants

2. In which area do you primarily work?

More details

Early-stage CMC development	15
Late-stage/commercial CMC	24
GMP manufacturing operations	5
Regulatory submissions/review	24
Cross-functional/multiple areas	16

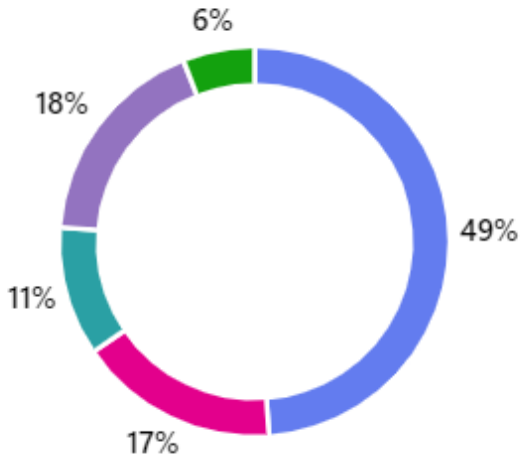


Level of Experience

3. What is your level of experience with advanced modelling approaches? E.g. end-to-end process models that concatenate models of multiple unit operations of drug substance and drug product manufacturing (statistical regression models, mechanistic and hybrid models). For more information see, e.g. https://www.koerber-pharma.com/en/blog/advantages-of-digital-twins-along-the-pharmaceutical-product-life-cycle or https://www.mdpi.com/2306-5354/4/4/86

More details

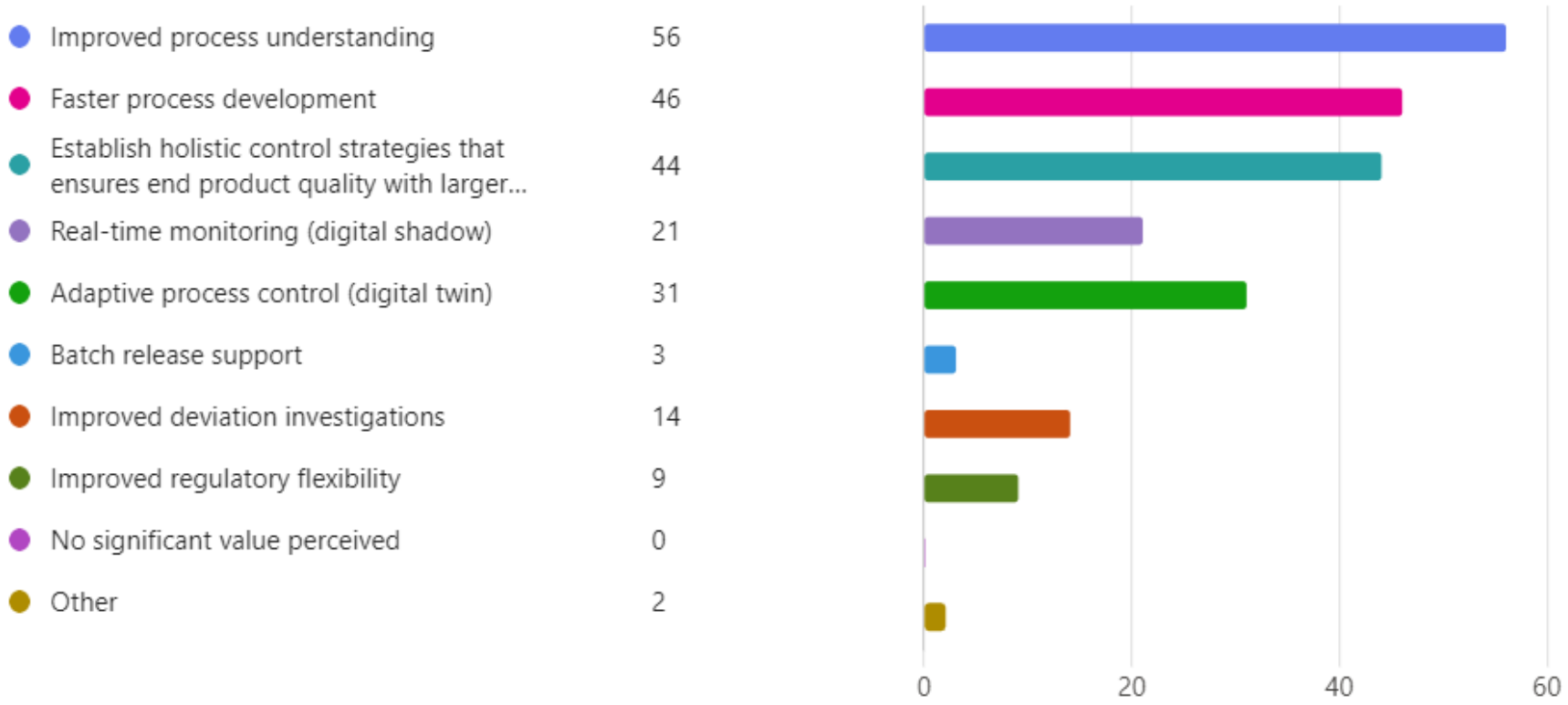
No direct experience	41
Evaluated but not implemented	14
Pilot implementation only	9
Used in process development	15
Used in GMP/commercial setting	5



Where Is the Perceived Greatest Benefit of End-to-End Process Models?

3 choices possible per participant

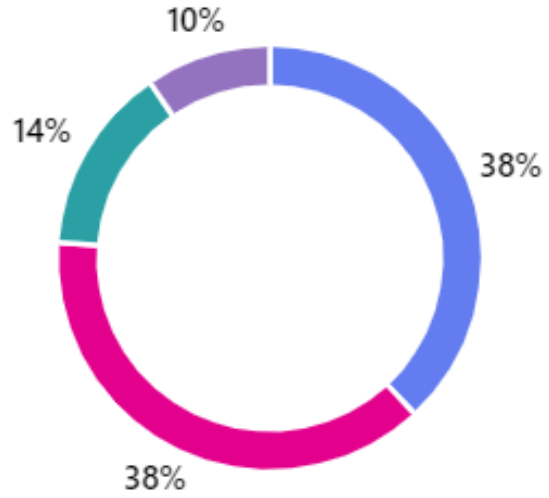
4. In which areas do you believe advanced integrated/end-to-end process models could provide the greatest value? More details



How Familiar Are You with Regulatory or Credibility Frameworks?

5. Are you familiar with regulatory or credibility frameworks relevant to advanced model validation?
Examples may include risk-informed credibility frameworks, model lifecycle approaches, or regulatory discussion paper s/guidance related to advanced modelling. More details

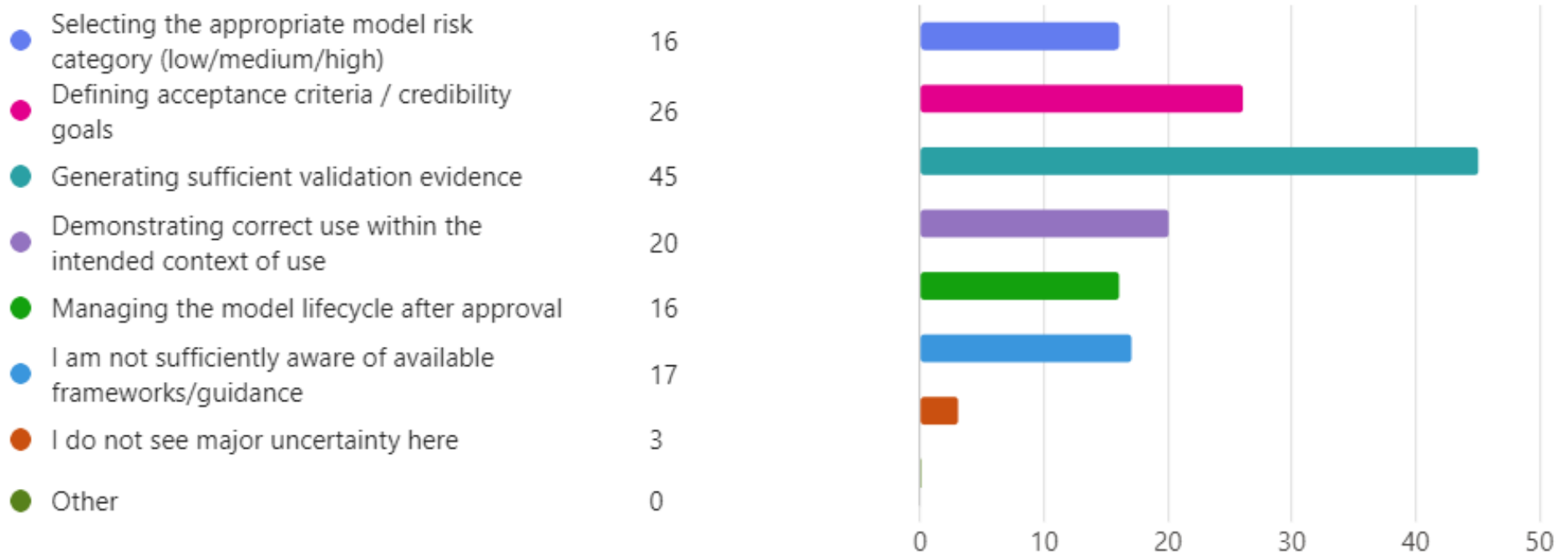
Not familiar	32
Aware, but not familiar with details	32
Familiar, but have not applied them	12
Applied them in practice	8



Model Validation: Where is the Largest Uncertainty?

6. For model validation/credibility, where do you see the greatest remaining uncertainty?

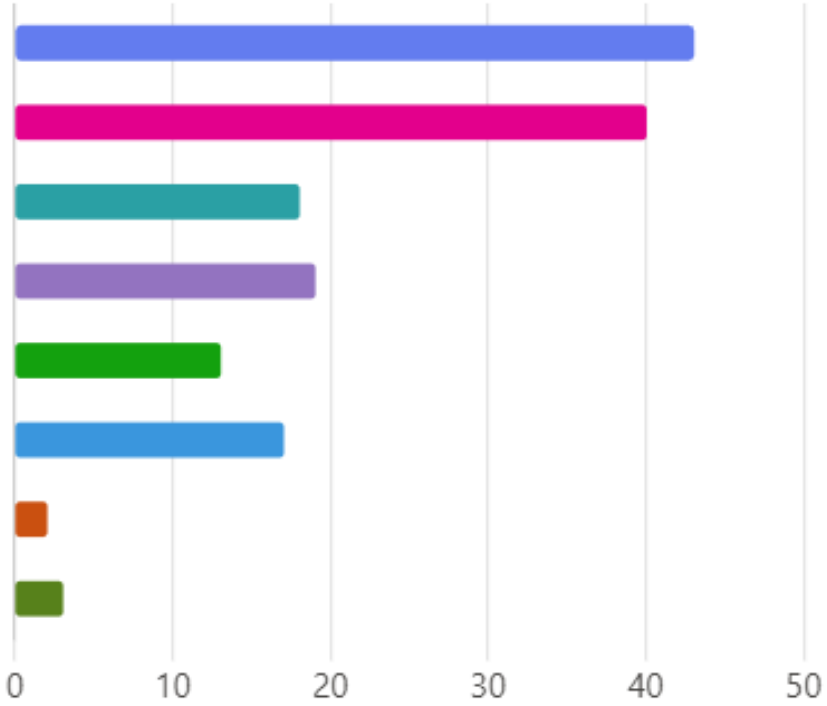
More details



7. What regulatory factors most limit use of advanced models in filings or GMP implementation?

More details

Unclear expectations from regulators	43
Limited public precedent/examples	40
Concern about inconsistent assessment	18
Concern that assessors may lack sufficient modelling expertise	19
Unclear post-approval change expectations	13
Difficulty explaining model impact on product quality	17
No major regulatory limitation perceived	2
Other	3



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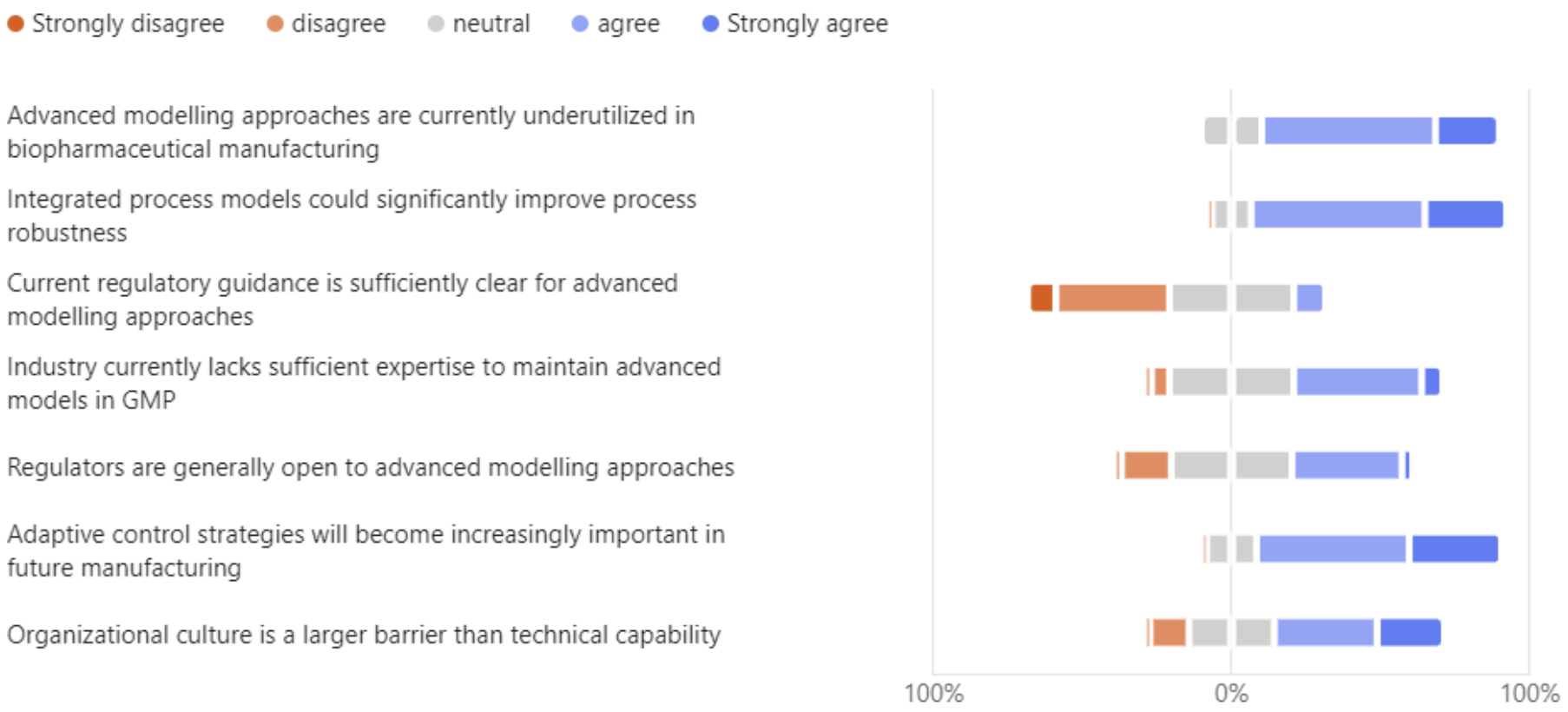
Add-On Questions

8. Question

More details



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What Would Accelerate the Adoption of Advanced Modelling & Control Strategy

Free text answer

9. What changes would most accelerate adoption of advanced modelling and adaptive control strategies? More details

31
Responses

9 respondents (29%) answered industry for this question.