FDA/MDIC Symposium on Computational Modeling and Simulation

Generating Regulatory In Silico Evidence

Symposium Review

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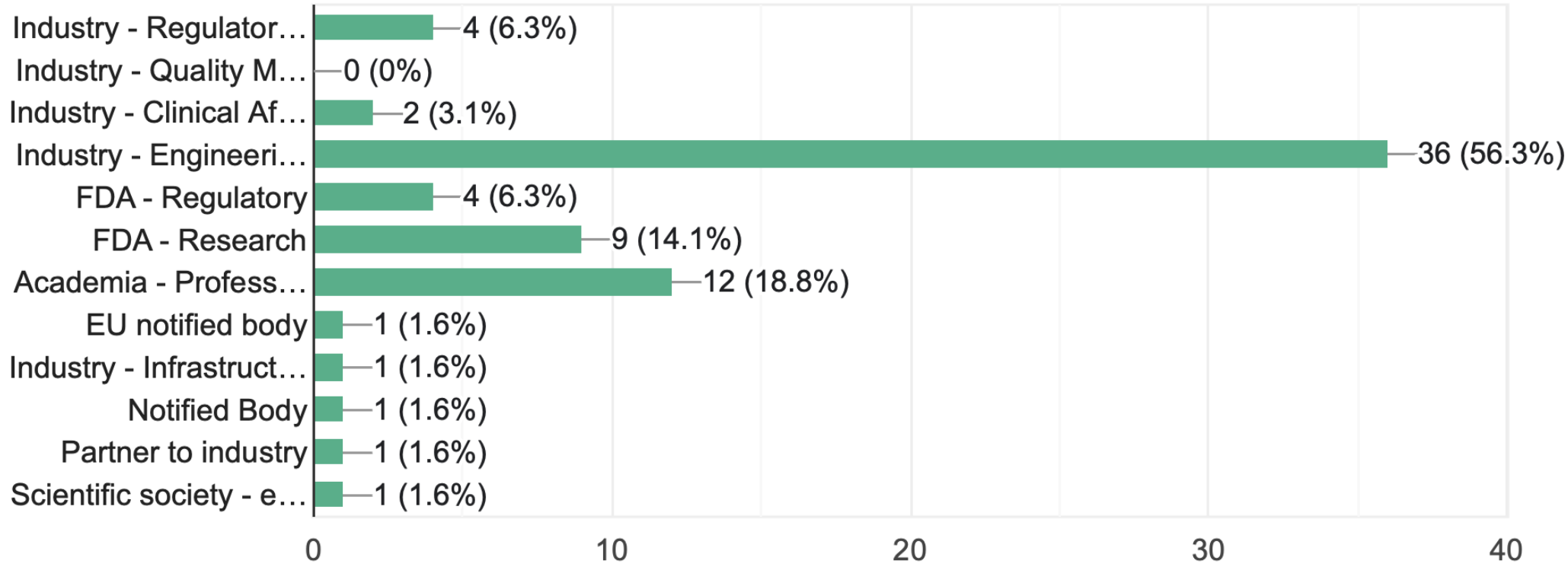
Preliminary Polling Responses

Question 1

What is your functional role? (check all that apply)

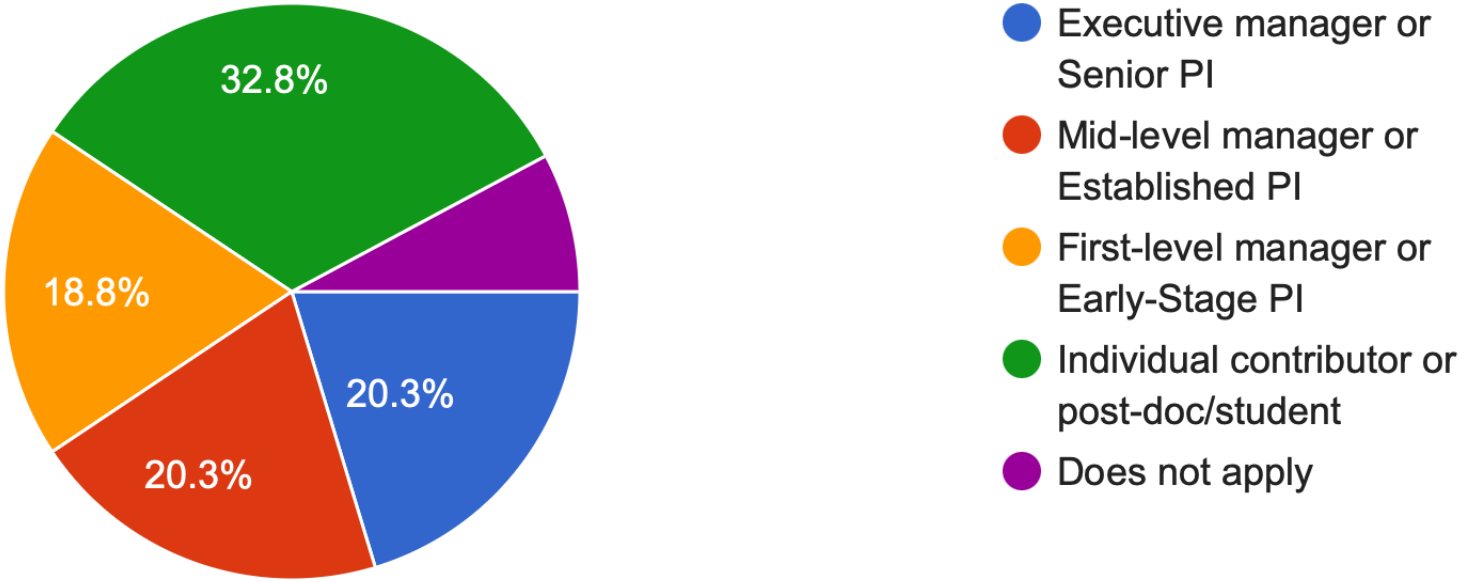
64 responses



Question 2

What is your managerial role? (choose one)

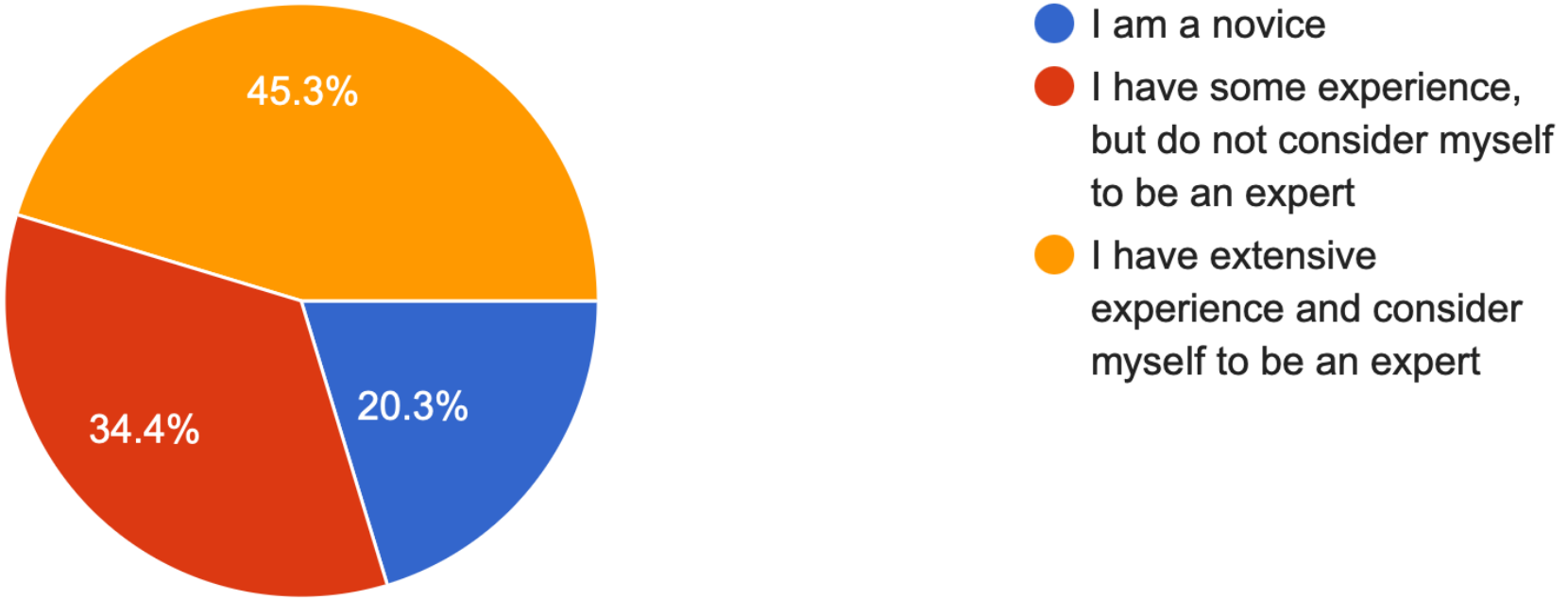
64 responses



Question 3

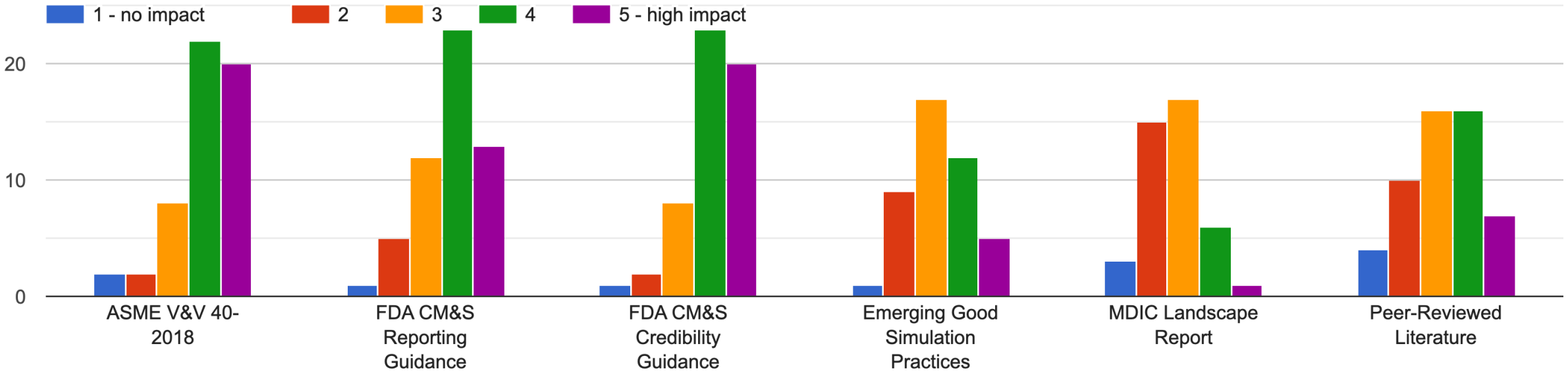
What is your technical or regulatory experience with CM&S? (choose one)

64 responses



Question 4

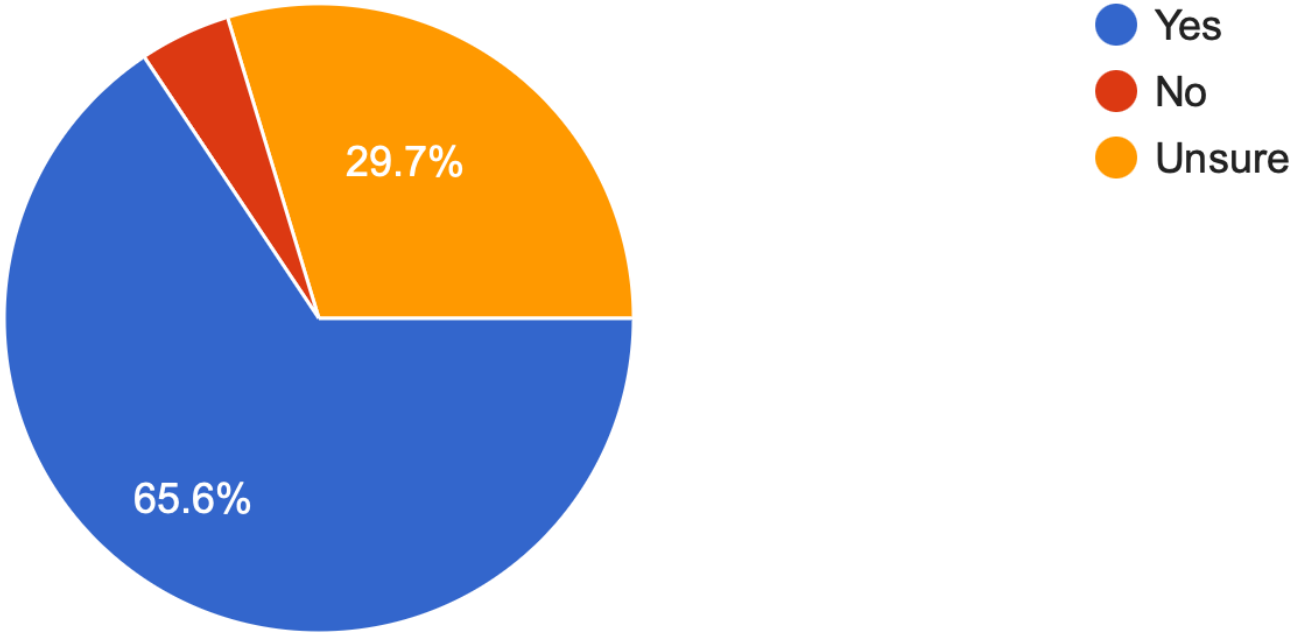
What community initiatives do you believe have been most impactful for advancing the use of CM&S for medical device regulatory applications? (provide a rating of 1-5; 1=no impact; 5=high impact; if unsure for an initiative, do not check)



Question 5

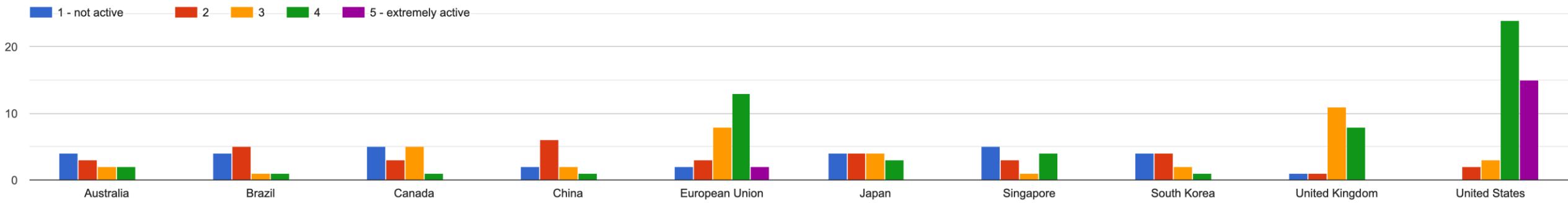
Over the past 5 years, do you believe CM&S has become more widely adopted for use in medical device regulatory submissions? (choose one)

64 responses



Question 6

What geographic areas are most active at advancing the use of CM&S? (provide a rating of 1-5; 1=not active; 5=extremely active; if unsure for a geographic area, do not check)



Question 7:

What do you believe are impediments to broader use of CM&S in regulatory submissions?

- Top Result:
  - Uncertainty in CM&S expectations by Regulatory bodies

- Runners Up:
  - Uncertainty regarding CM&S in regulatory affairs within my organization
  - Lack of model credibility assessment best practices or examples
  - Lack of understanding of the system being modeled

Open Forum Discussion Points

- What symposium information was impactful?
- What challenges should we tackle?
- What credibility strategies have worked well?

Symposium Goals

- Exemplify *in silico* data as valid scientific evidence that is applicable across the medical device total product lifecycle
- Provide examples of model credibility assessments
- Form community consensus on model credibility strategies
- Identify challenges that the community must face
- Collect information that can be used as a referenceable resource for the future

Symposium Next Steps

- Look for a peer-reviewed journal article summarizing the opinions and recommendations from the symposium content and attendees
- The intent is for the article to be referenceable for future work and establish some fundamental community knowledge on the state of the field
- Look for ways to get involved within the different industry wide working groups

Thank You

Save the Date

Stay tuned for another in-person symposium Fall 2025