



The National Institute for Innovation in Manufacturing Biopharmaceuticals

AMERICAN INNOVATION AT WORK

Technical Survey Results

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Technical Survey Project

- Assess interest in biopharmaceutical **product types**
- Assess interest in technical **project categories**
- Determine level of interest in **project sub-topics**

General outline of the survey:

- What type of biopharmaceutical **product type** was of greatest interest?
- What **project category** was of most interest?
 - Host Cell Line Development for Manufacturability
 - Process Development / Process Intensification / Platform Development
 - Analytical Methods / Process Control
 - Reference Standards / Regulatory Science
 - Supply Chain Management / IT Solutions
- Within each project category, which **project sub-topic** was of greatest interest?

Where the polling was done

Both real-time and on-line polling

R

Regional Meeting Polling

Real-time polling done at 5 regional meetings

- Mix of large and small companies, academia, government, non-profits
- Meeting 1: single session
- Meetings 2-5: separate 'Industry' and 'Academic' sessions

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Qualtrics Industry Survey

On-line survey sent to 207 industry representatives

- Mix of small and large companies (responses anonymous, so final composition unknown)
- Regional Meeting attendees, companies who had provided letters of support for application, and/or who had been recently contacted for outreach (n=49 respondents)

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Combined Survey Data

Pooled data from some Regional Meeting sessions and Qualtrics survey

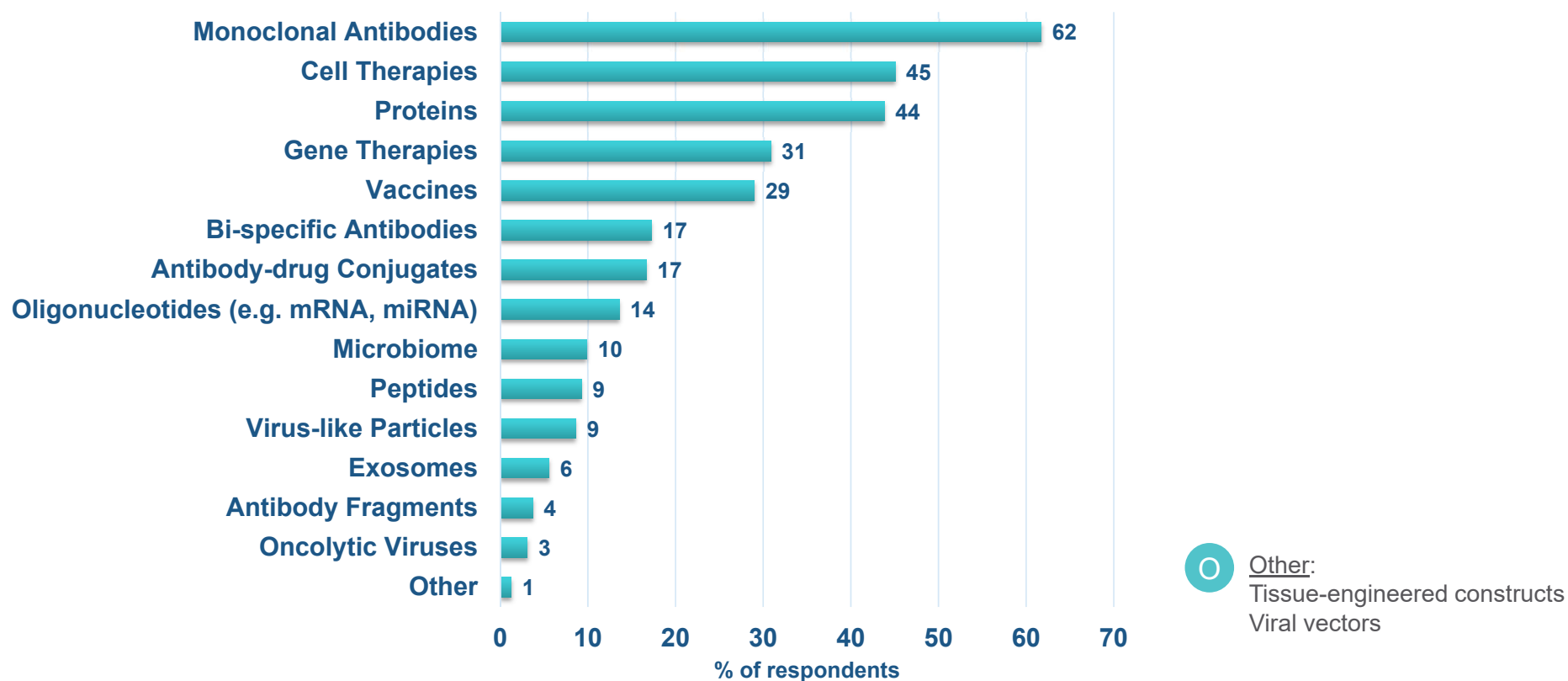
- Regional Meeting 1 and Meetings 2-5 'Industry' session data included

Profile of survey respondents

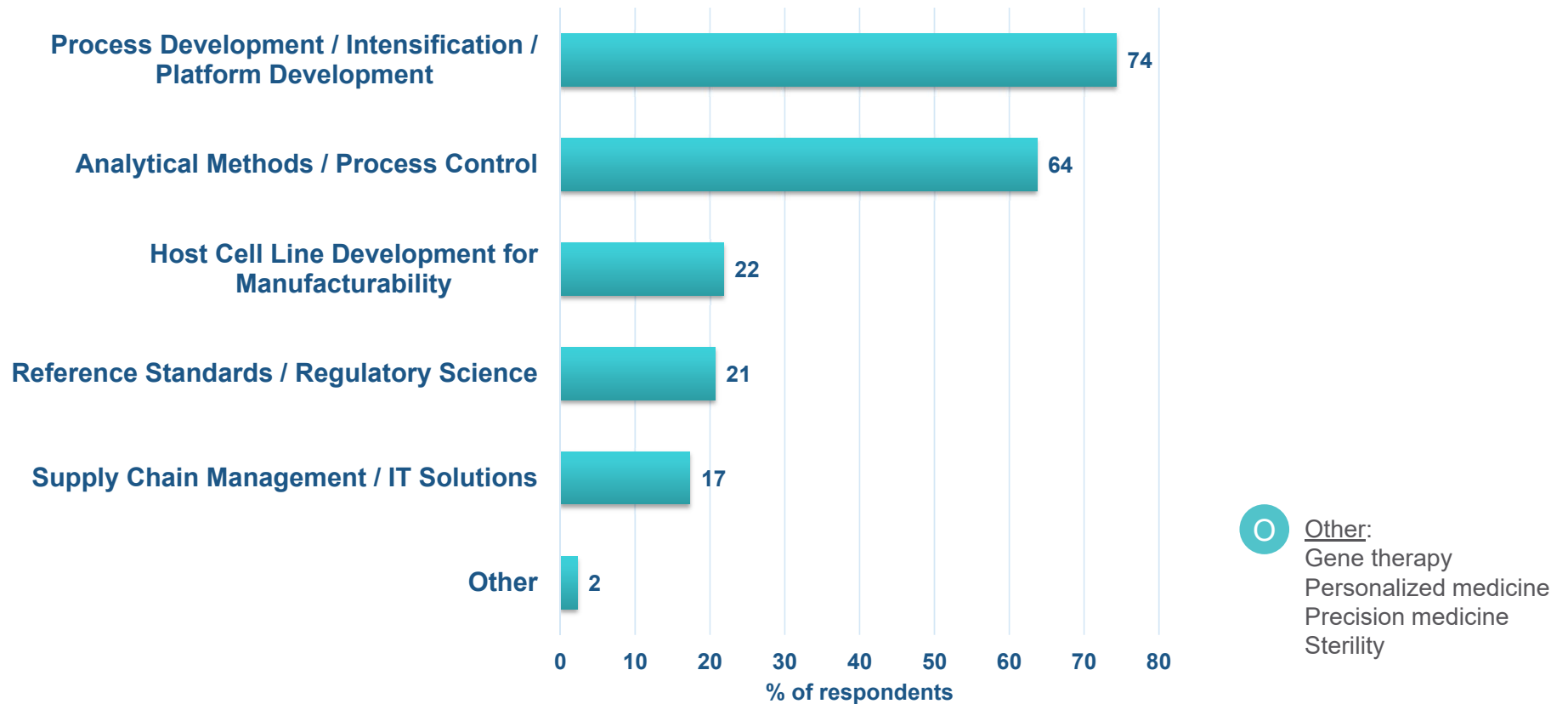
Poll	Industry	Academia	Government / Non-profit	Total
Regional Meeting	73	24	25	122
Qualtrics*	49	0	0	49
Total	122	24	25	171
Total (%)	71.3%	14.0%	14.6%	99.9%

*Note: the Qualtrics survey was sent to 207 industry contacts, 143 (69.1%) of these were industrial Regional Meeting attendees; remaining were contacts from NIIMBL application/outreach efforts

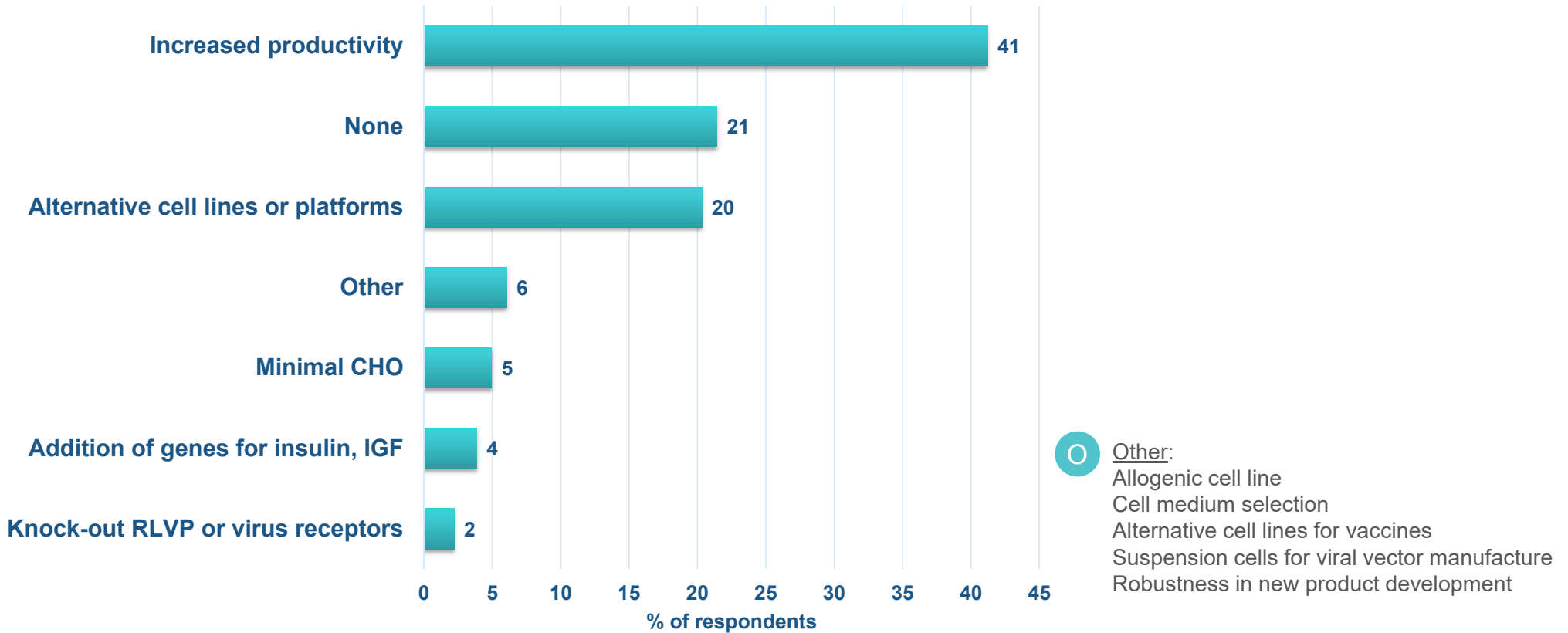
What product type is of greatest interest to your organization? (choose 3)



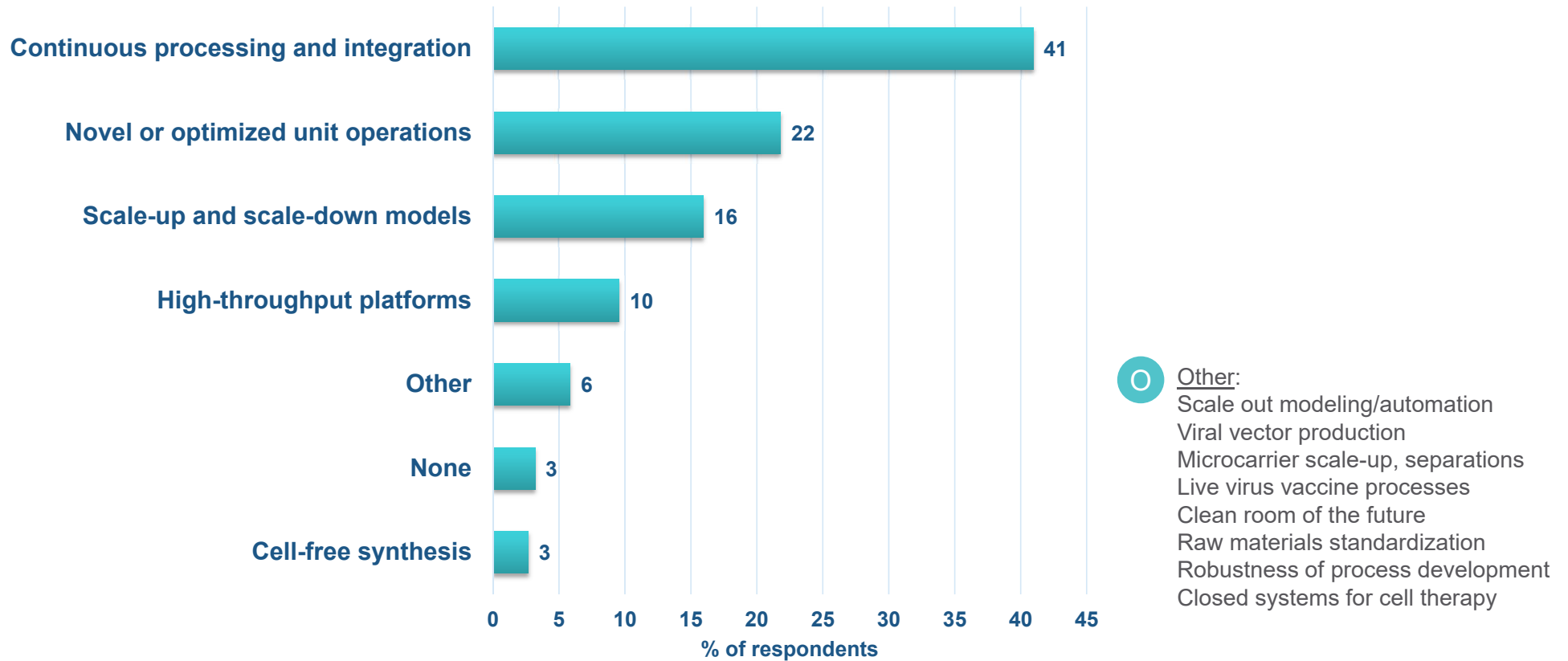
Which project category is of most interest to your organization? (choose 2)



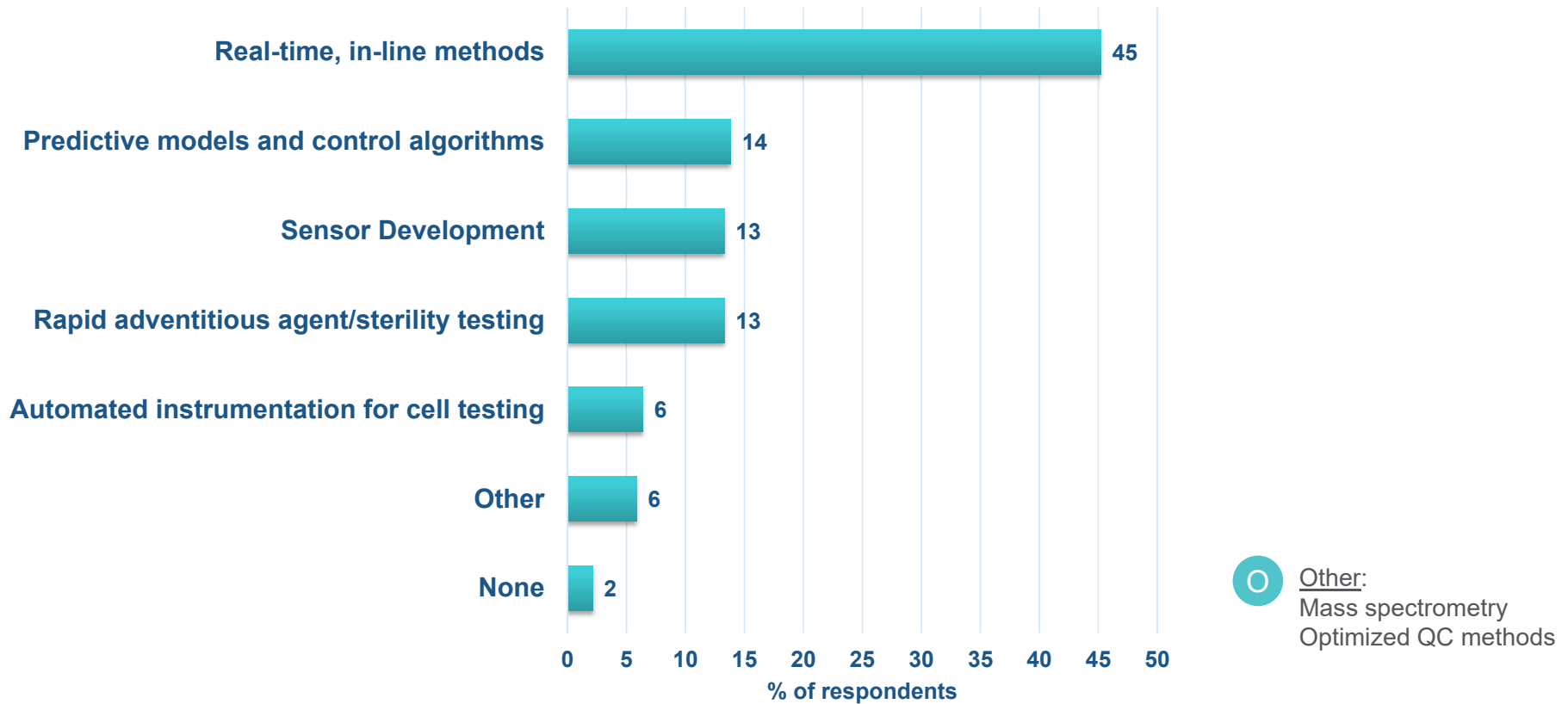
Which Host Cell Line Development sub-topic is of most interest to your organization?



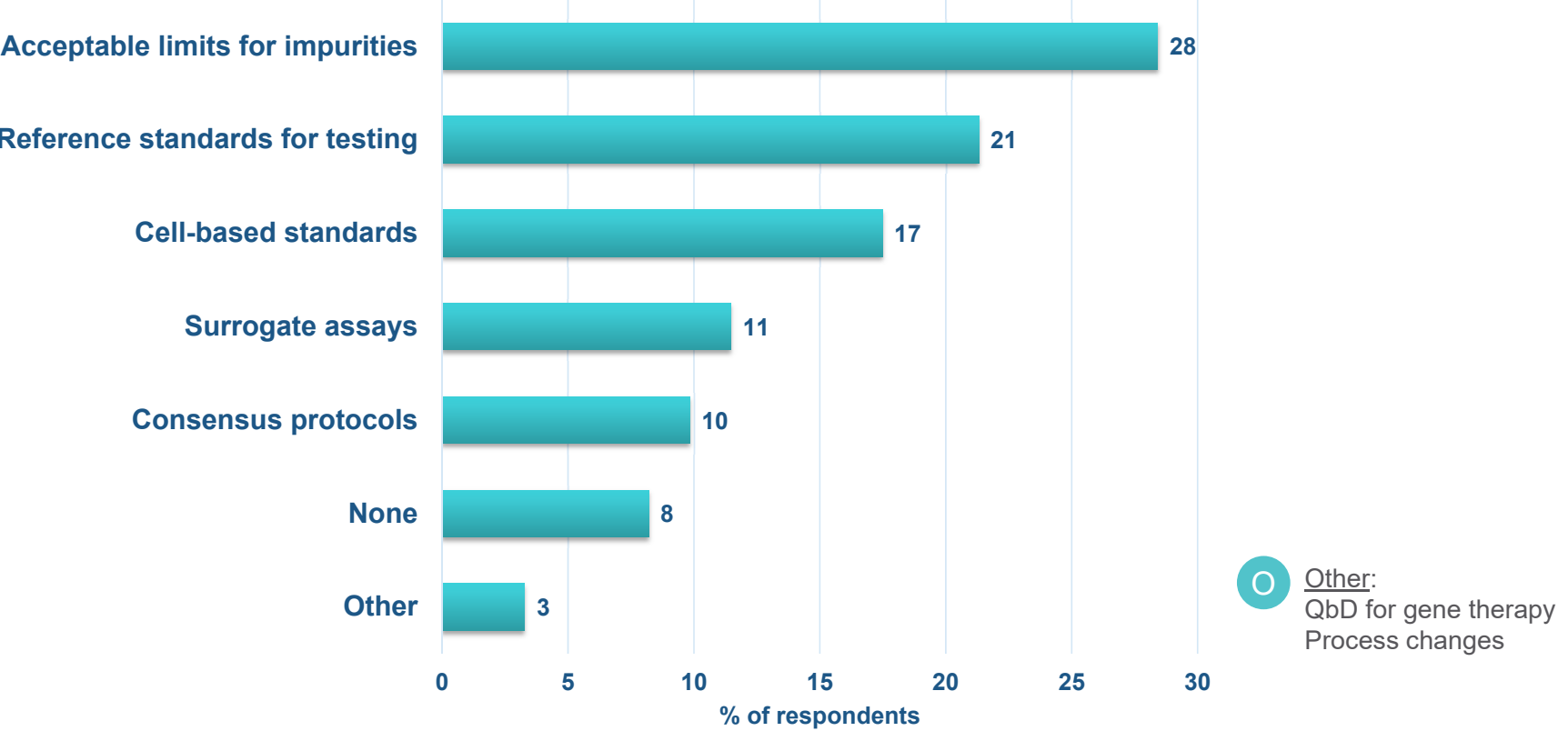
Which **Process Development** sub-topic is of most interest to your organization?



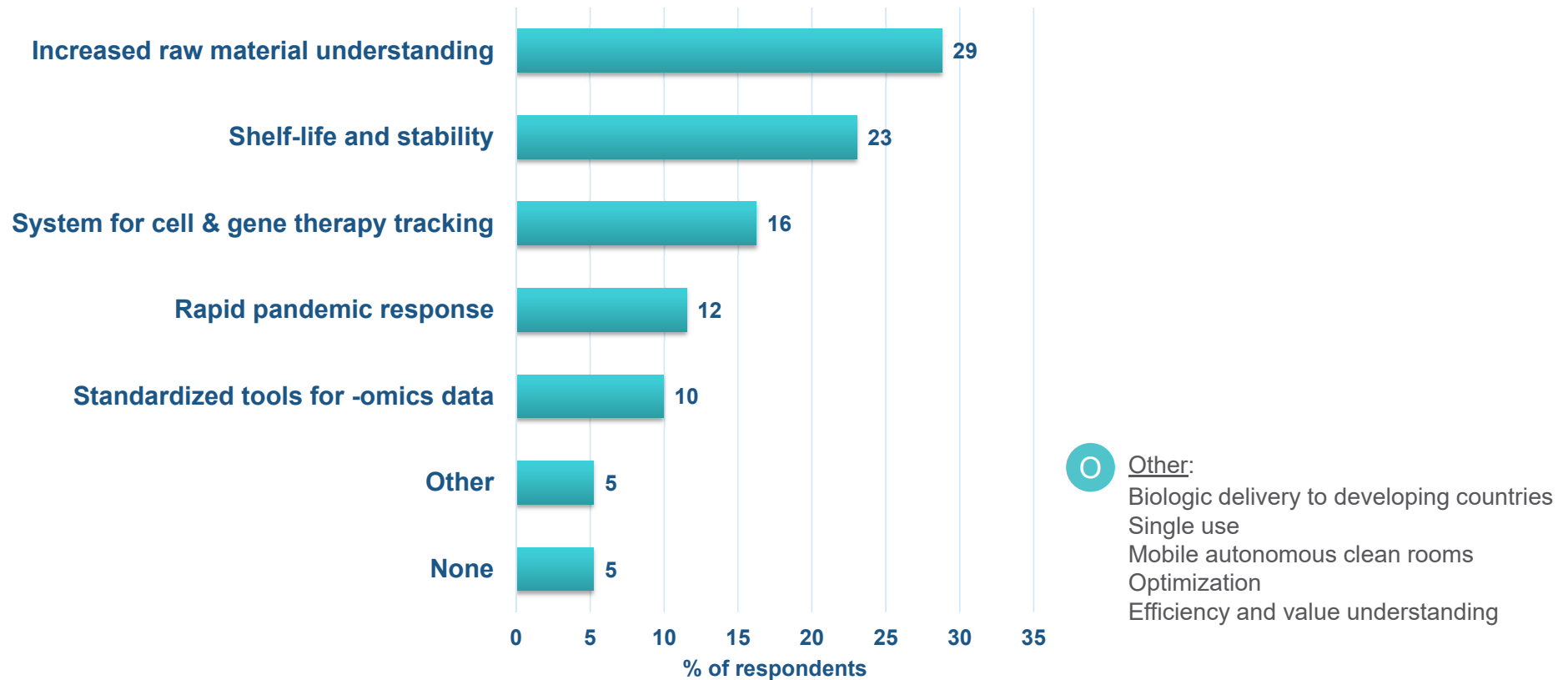
Which Analytical Methods/Process Control sub-topic is of most interest to your organization?



Which Reference Standards / Regulatory Science sub-topic is of most interest to your organization?



Which **Supply Chain Management / IT Solutions** sub-topic is of most interest to your organization?



Conclusions

- **Product type**
Existing products such as **monoclonal antibodies, proteins, and vaccines** and emerging product such as **cell and gene therapies** are both important.
- **Project type**
Process development and **Analytical methods/process control** projects are of most interest.
- **Cell Line Development**
Increased productivity and **alternative cell lines** are of the most interest.
- **Process Development**
Continuous manufacturing and process integration is by far of the most interest, followed by **new or optimized unit operations**.
- **Analytical Methods/Process Control**
Real-time, in-line methods is by far of the most interest.
- **Reference Standards / Regulatory Science**
Broad interest in a number of different sub-topics, with **acceptable limits for impurities** being most often mentioned.
- **Supply Chain Management / IT Solutions**
Most interest in **increased raw material understanding** and **shelf life and stability**.