

# ANP 8 Mars 2023

## Transformation numérique dans l'industrie



# Liens d'Intérêts

- **Jean François Duliere**
- ISPE : Non for Profit Organisation
- OMS : Formations, Audits

# Pourquoi l'industrie s'oriente-t-elle vers la transformation numérique

## Meilleure maîtrise des procédés - Vérification continue des procédés

- Permet le développement des procédés continus
- La nouvelle Annexe 1 pour les procédés aseptiques augmente les exigences en terme de monitoring
- PAT (Process Analytical technologies) Guidance for Industry FDA 2004

## Position de certaines agences réglementaires

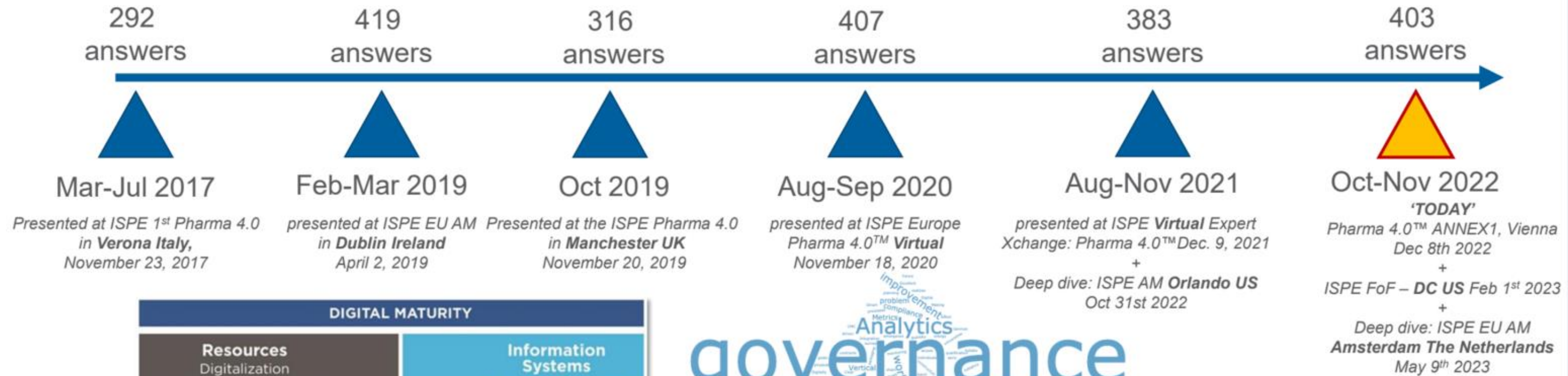
- FDA donne des délais plus courts pour l'approbation de dossier en procédés continus vs procédés en lots

## Les industriels

- Nombreux projets d'unités en procédés continus pour des produits existants ou nouveaux.
- Certains génériqueurs les mettent en place.

# Pharma 4.0™ 6th survey: latest results and trends

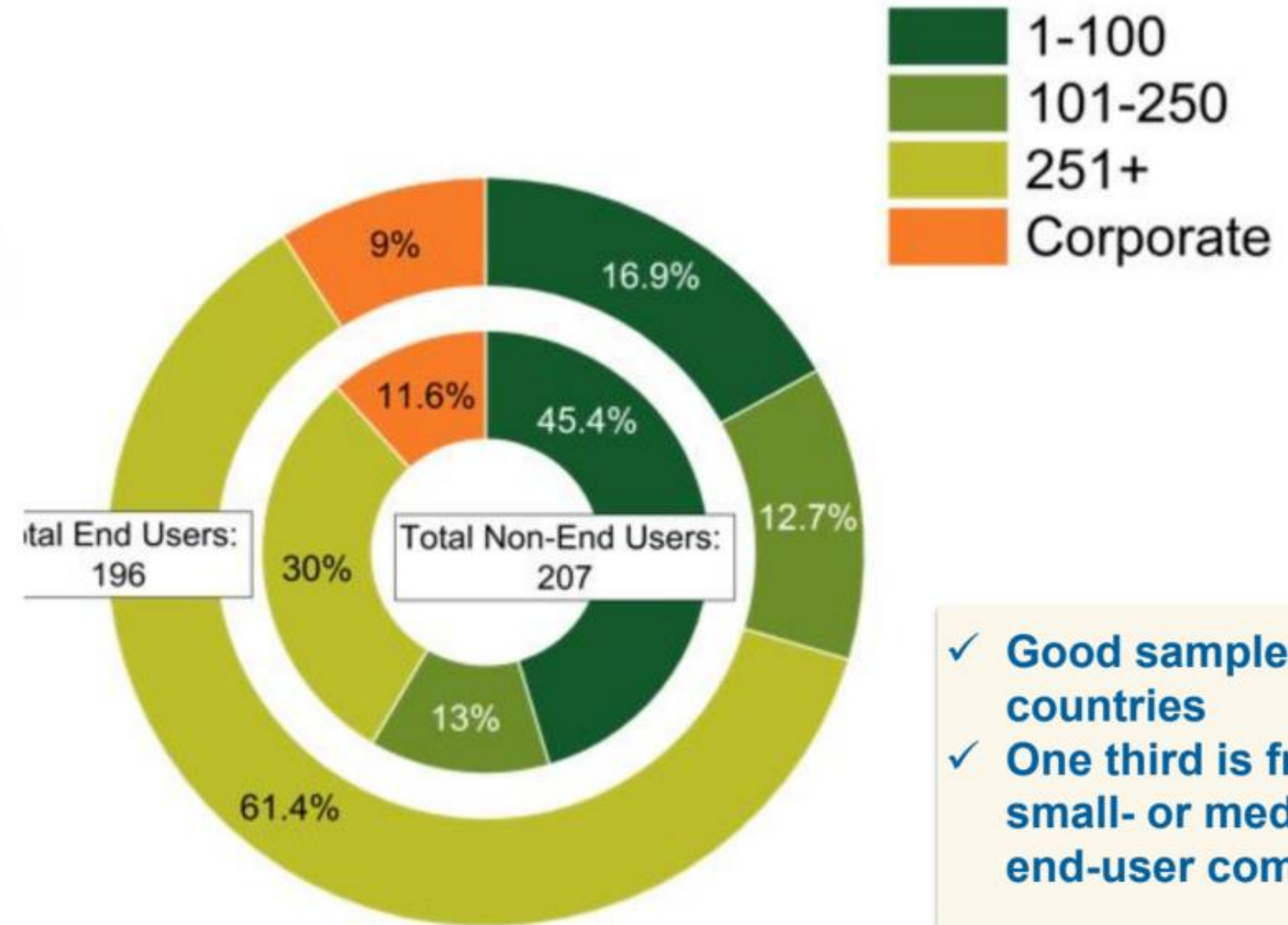
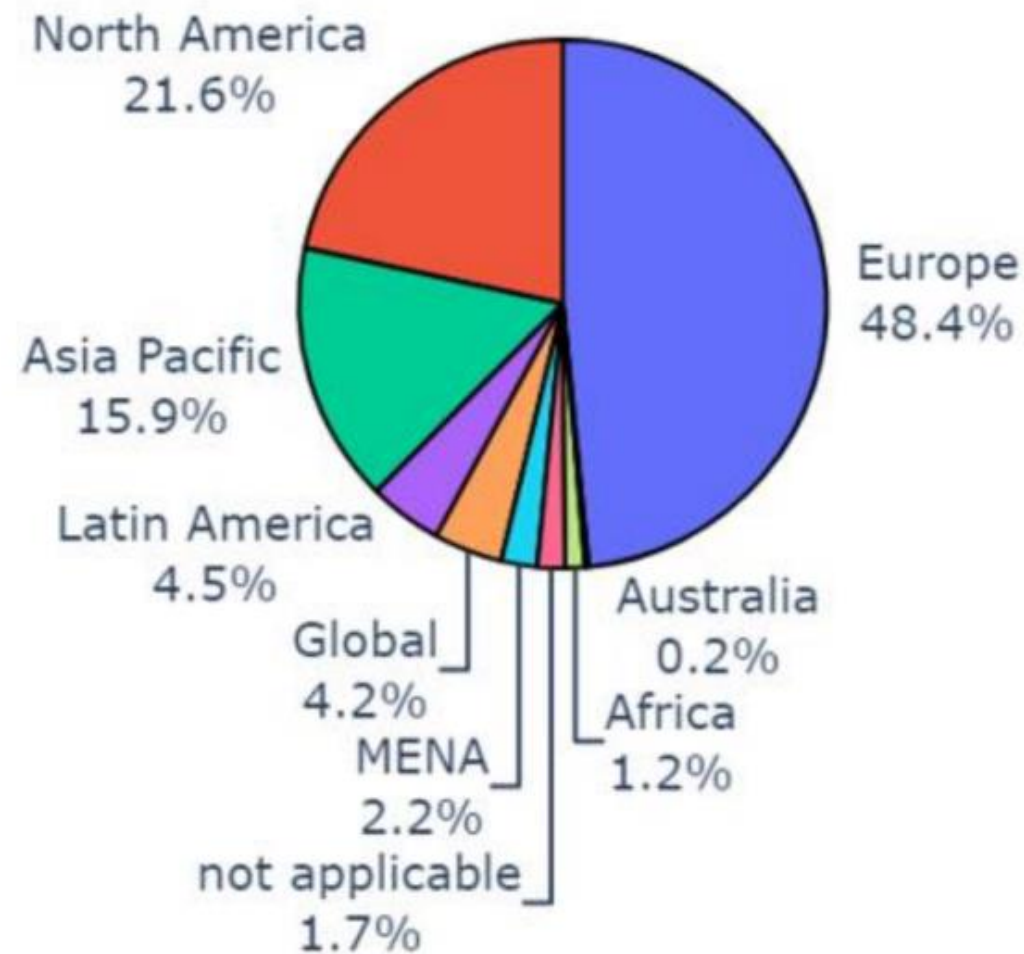
## ... some history



\*the '2020' edition likely trends ...

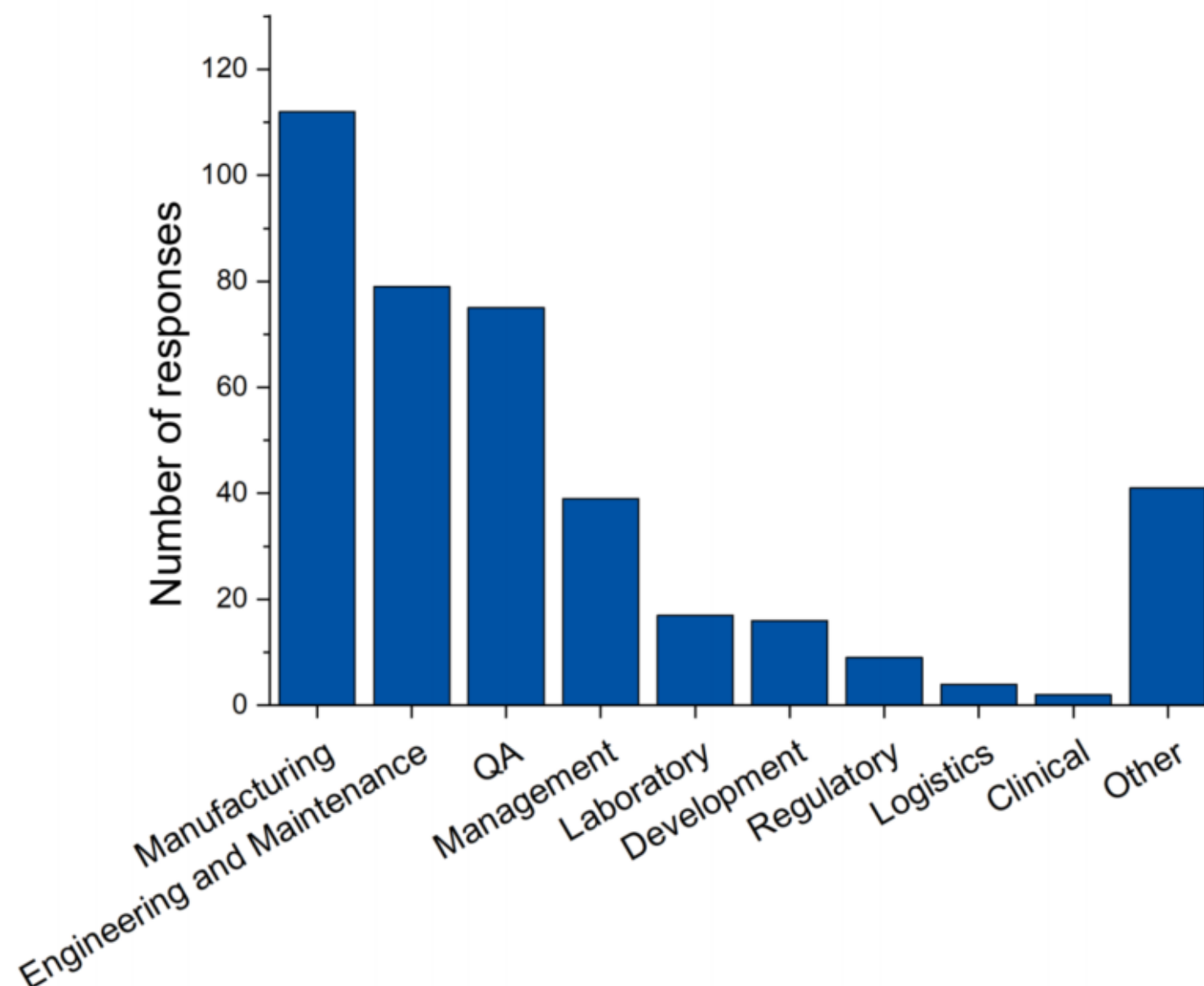


# 1. Demographics: territory, company size, end/non-end user



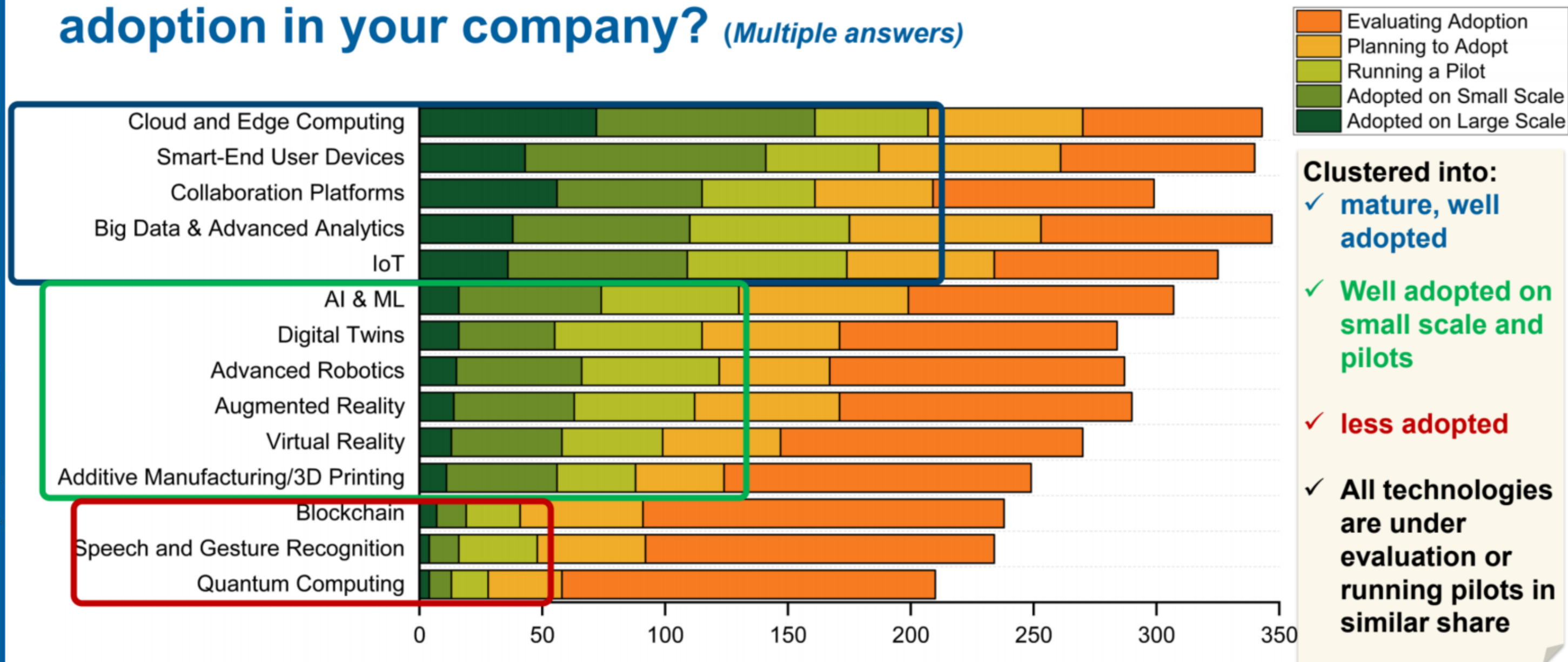
- ✓ Good sample with 57 countries
- ✓ One third is from small- or medium size end-user companies

# 1. Demographics: Area of activities



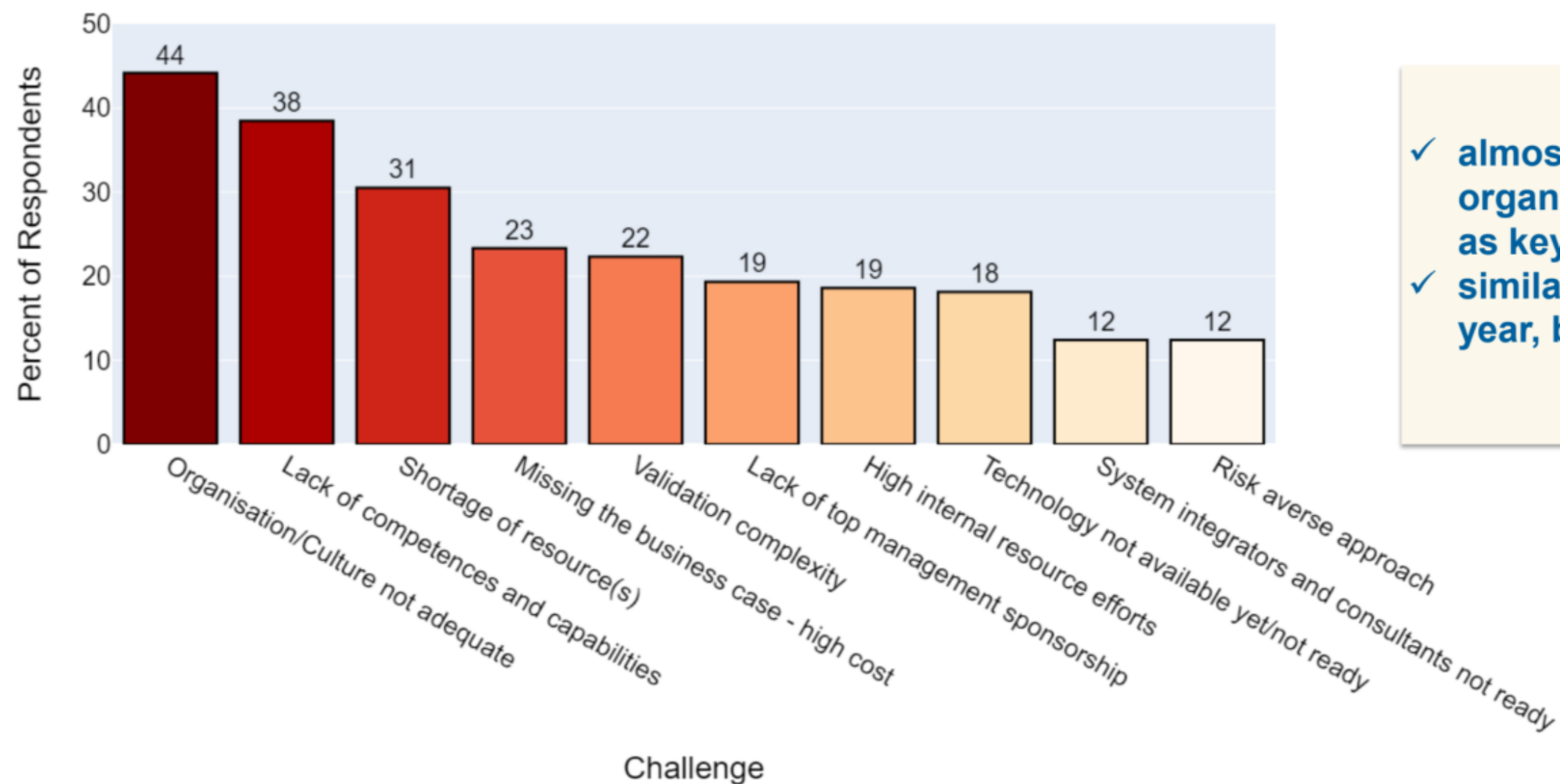
- ✓ representative sample of ISPE target group
- ✓ also good outreach to QA, management and lab

### 3. Which 4.0 enabling technologies are the focus of adoption in your company? *(Multiple answers)*





## 7a. Which are the key challenges on your Pharma 4.0™ programs?



- ✓ almost 50% experience organization and culture as key challenge
- ✓ similar ranking as last year, but ...



## 9. What's next?

Briefly specify and describe the projects you are planning to implement the next two years.



- ✓ majority of the projects of the next two years are from manufacturing
- ✓ predictive and AI-based projects are on the verge of being implemented

# What is the conclusion of the sith survey?

## our personal view concerning the main points:

- ✓ *It is a first round of analysis: deep dives and further correlations are still to be completed. Stay tuned for ISPE EU AM 8-10 May 2023!*
- ✓ *Good sample in term of geographical coverage and diversity of responses, clearly inside the ISPE reach and network.*
- ✓ *A general movement towards higher maturity level*
- ✓ *Quality & compliance improvements are experienced as the major benefits of adopting Pharma 4.0™*
- ✓ *Cultural and resource challenges are still the obstacle*

