## 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.











TO .









## Pharma 4.0<sup>™</sup> 6th survey: latest results and trends

#### ... some history

Resources

Digitalization Workforce of the Future Available and Qualified

Organization

and Processes



Mar-Jul 2017

Presented at ISPE 1st Pharma 4.0

in Verona Italy,

November 23, 2017







Oct 2019

316

answers



Aug-Sep 2020

presented at ISPE Europe

Pharma 4.0TM Virtual

November 18, 2020

407

answers

Aug-Nov 2021



Deep dive: ISPE AM Orlando US Oct 31st 2022



383

answers

Oct-Nov 2022 'TODAY'

403

answers

Pharma 4.0™ ANNEX1, Vienna Dec 8th 2022

ISPE FoF - DC US Feb 1st 2023

Deep dive: ISPE EU AM Amsterdam The Netherlands May 9th 2023

Feb-Mar 2019

419

answers

in Dublin Ireland April 2, 2019

**DIGITAL MATURITY** 

PHARMA 4.0

**DATA INTEGRITY BY DESIGN** 

presented at ISPE EU AM Presented at the ISPE Pharma 4.0 in Manchester UK November 20, 2019







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



















YYY

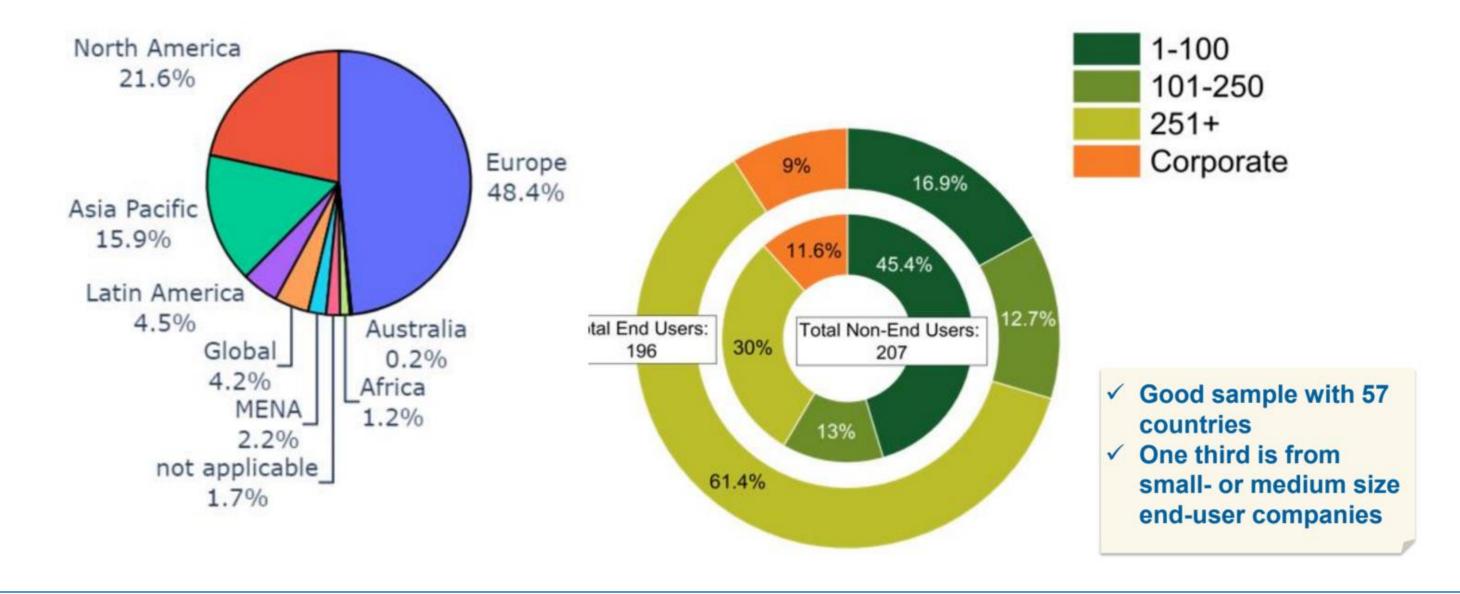




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**(1)** 

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

















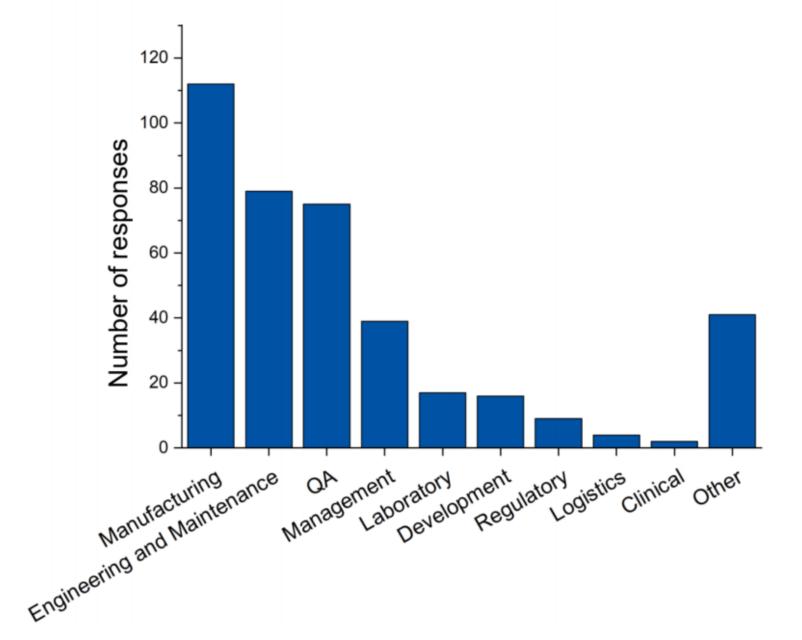






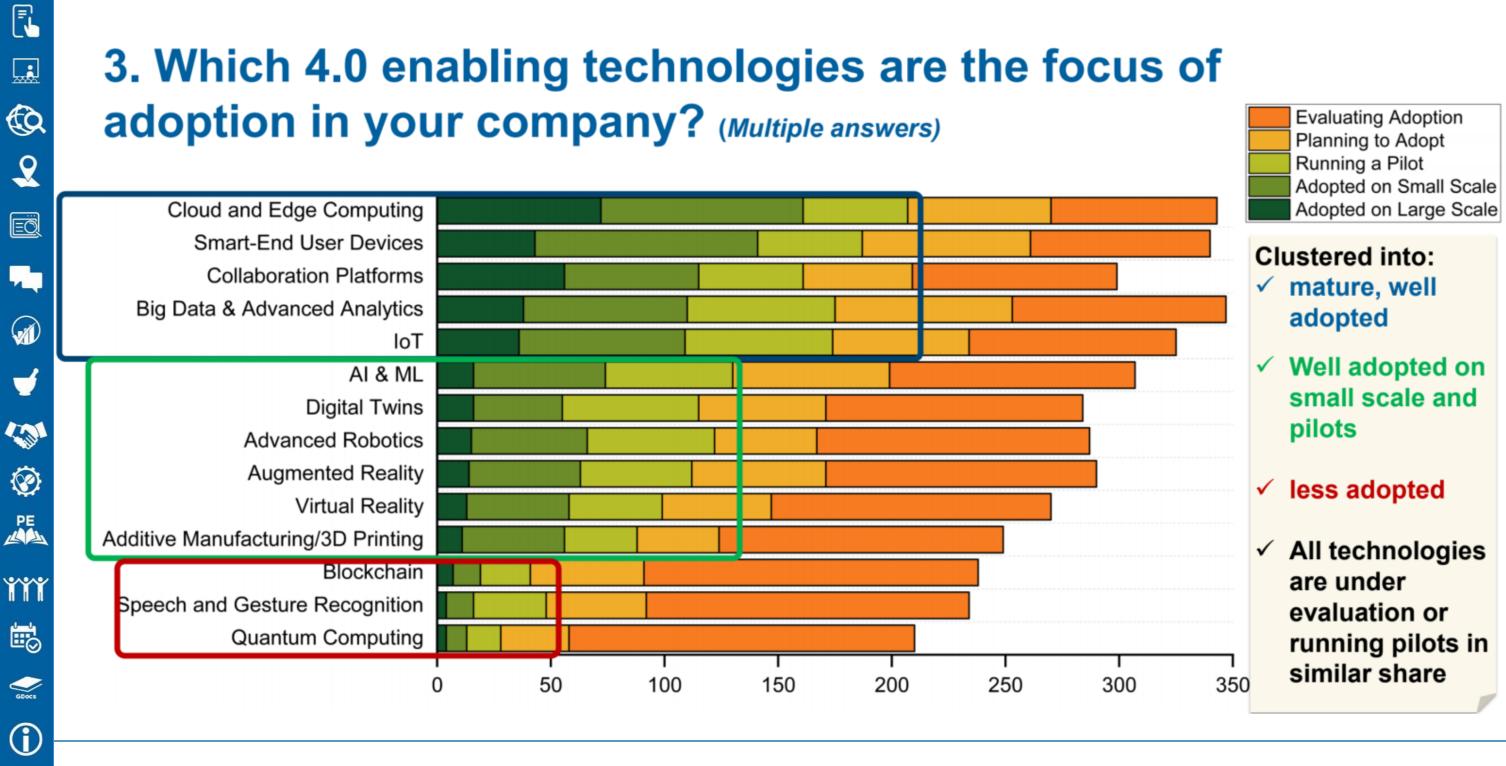


### 1. Demographics: Area of activities



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





















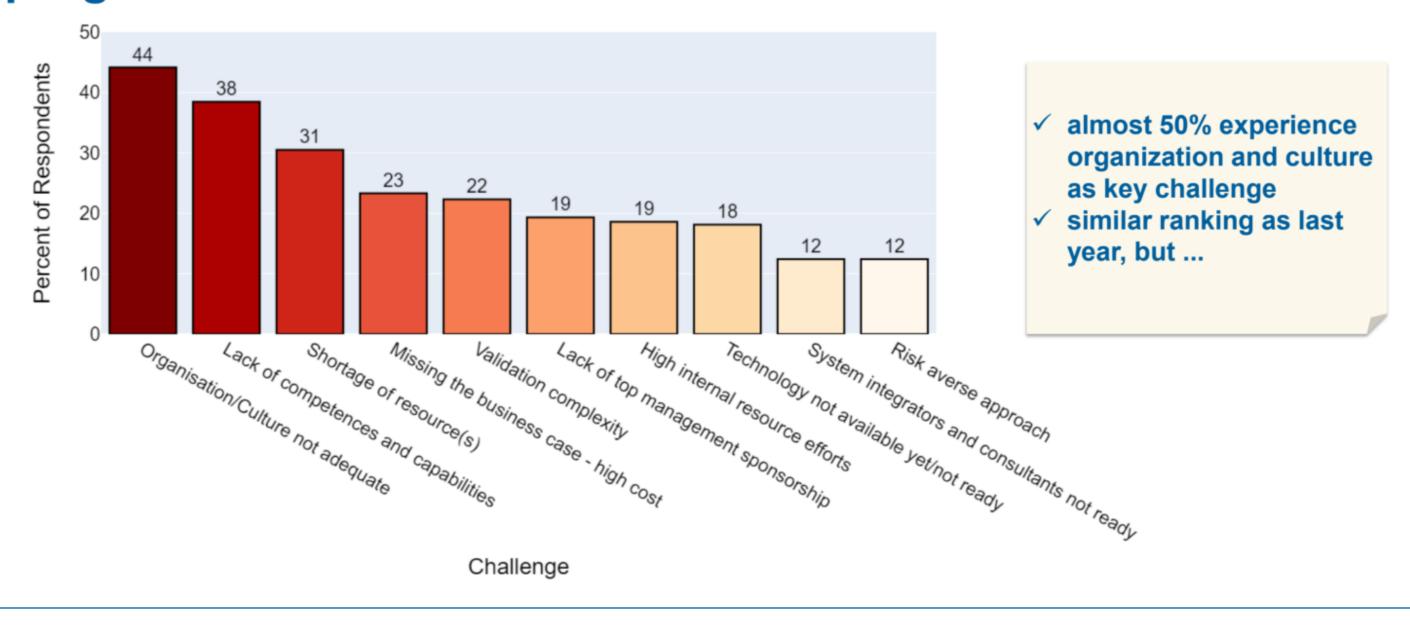






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# 7a. Which are the key challenges on your Pharma 4.0<sup>TM</sup> programs?



























#### 9. What's next?

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

Process integrationEBR Simulate MES

Automation Connectivity Cloud systems

Application Implementation

Supply chain Regulatory

Continuous manufacturing Digital Twins

Manufacturing A

Models Paperless I IA 40

Digital control Robotic Validation VR

Predictive maintenance

Real-time release Management

Electronic batch records

- ✓ majority of the projects of the next two years are from manufacturing
- ✓ predictive and Al-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 experiened as the major benefits of adopting Pharma 4.0™
- ✓ Cultural and resource challenges are still the obstacle

























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