



Perception and Application of the Concept “Quality by Design” (QbD) by the Pharmaceutical Industry in Portugal

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Introduction

Quality by Design (QbD) is an emerging driving force and multi-process approach that is becoming a priority for both regulators and the pharmaceutical industry. It is integrated in the entire chain of a product lifecycle, since design, passing through development and ending only at discontinuation of the product. It states that in order to ensure predefined product quality, improve manufacturing quality performance and serve customers' needs, one must fully understand the processes behind it^{1,2}.

The International Conference on Harmonisation (ICH) guidelines Q8, Q9 and Q10, and more recently Q11, provide a solid foundation and guidance for better understanding and applying this new paradigm.

Aim

To assess the Portuguese pharmaceutical companies' perception about the usefulness of a strategy of development, production optimization and control/quality management according to the QbD concept and its level of implementation.

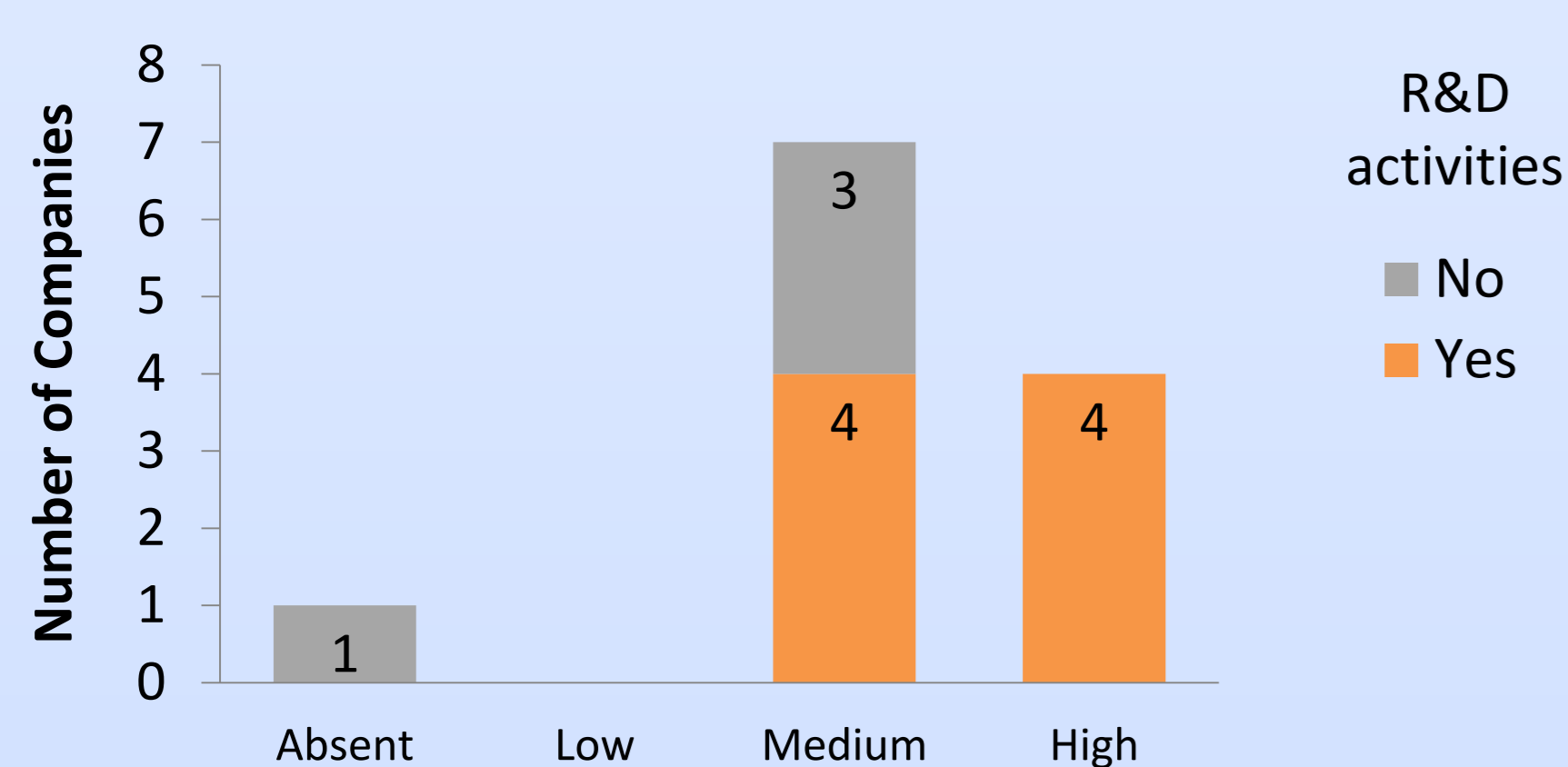
Methodology & Methods

Survey to 28 licensed entities listed by INFARMED for the production of drug substances and products (excluding medicinal gases). Answers were collected between 16/12/2014 and 1/06/2014. It had 2 groups of questions: the first one intended to characterize the industries and the second one to give answers to the study aim. SPSS (v.21) was used for data analysis. Inferential analysis (association between variables) used Fisher's exact test.

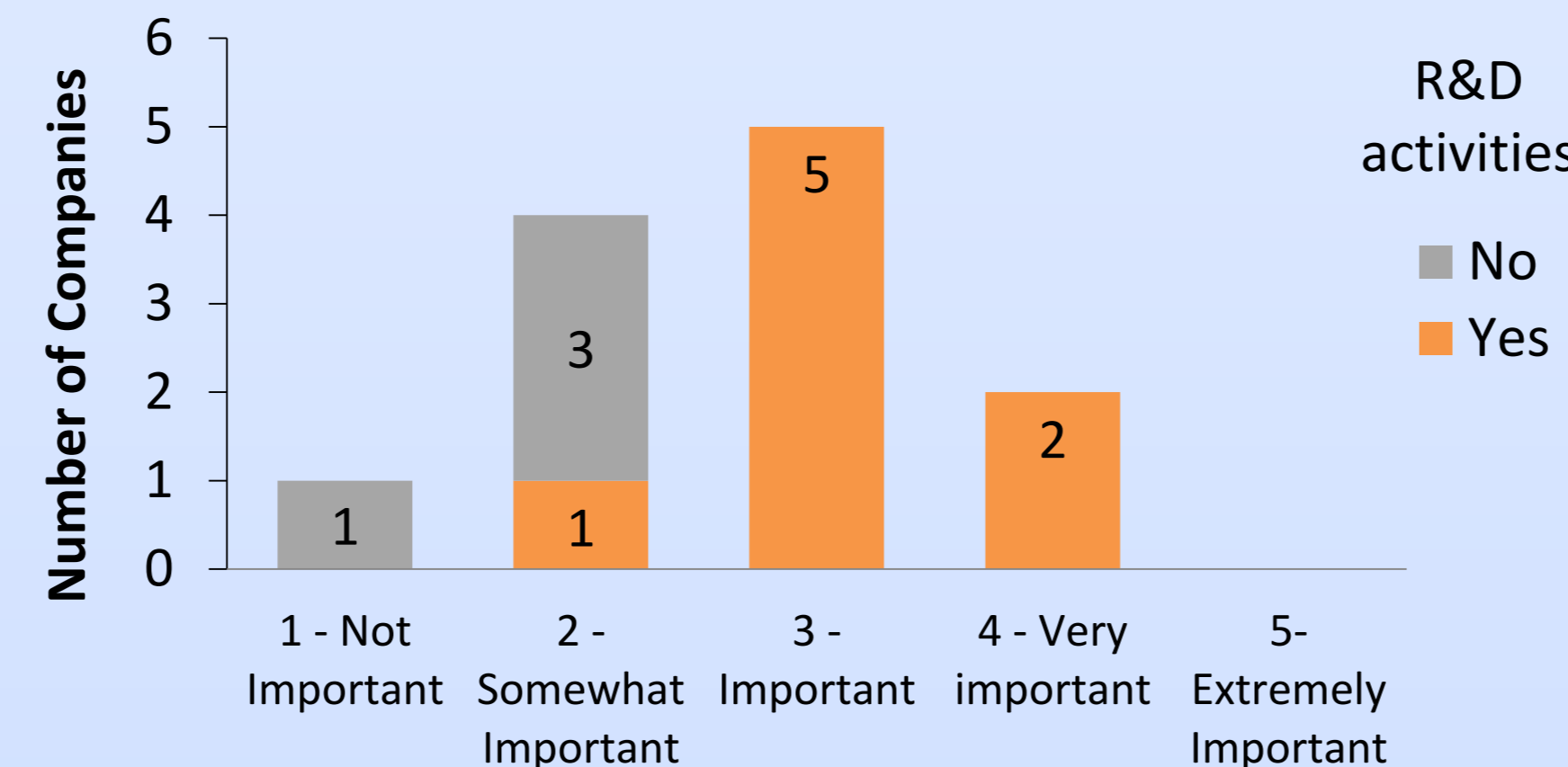
Results

1. 12 companies answered the survey. All of them knew the QbD concept in the context of the ICH quality guidelines.

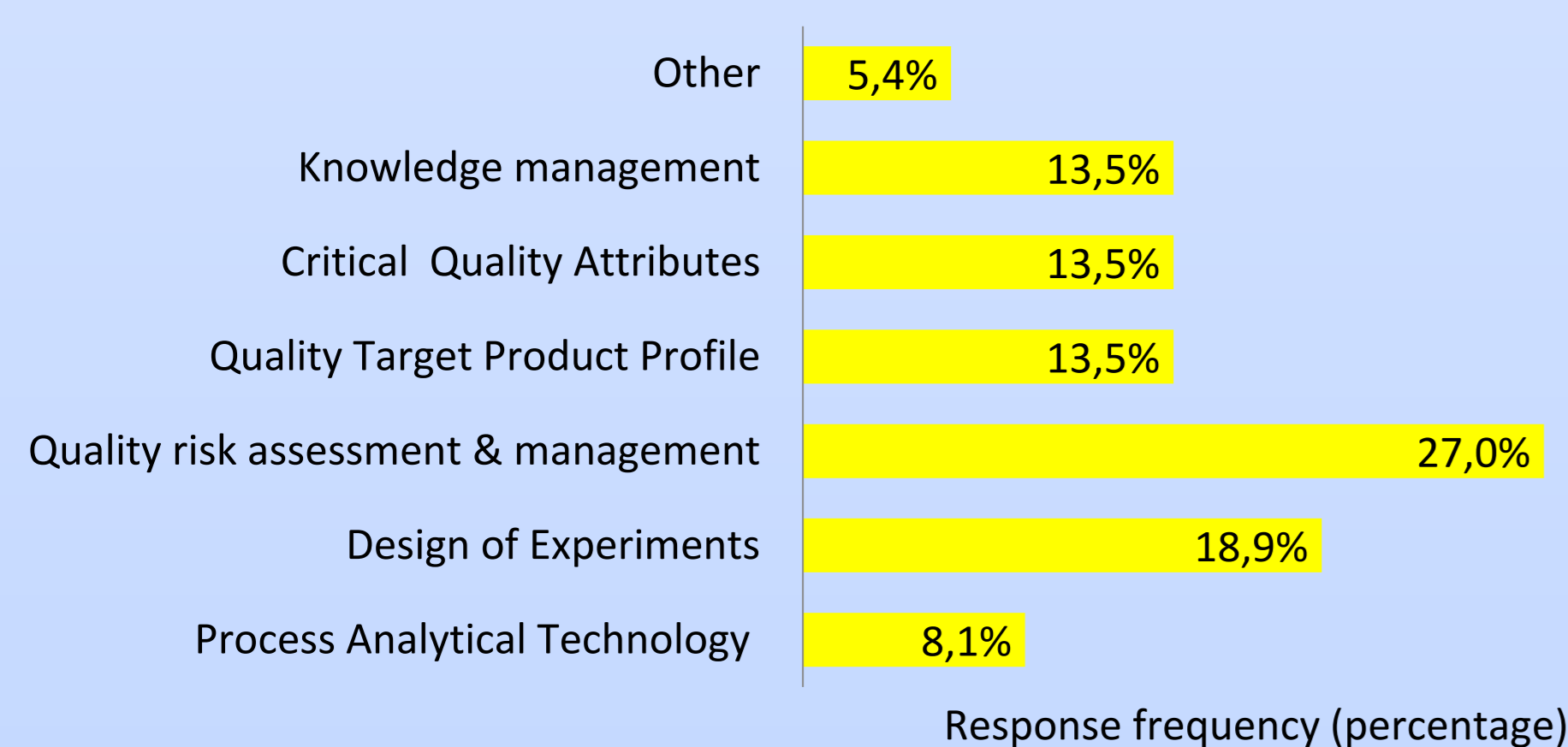
2. Level of QbD implementation in companies having or not R&D



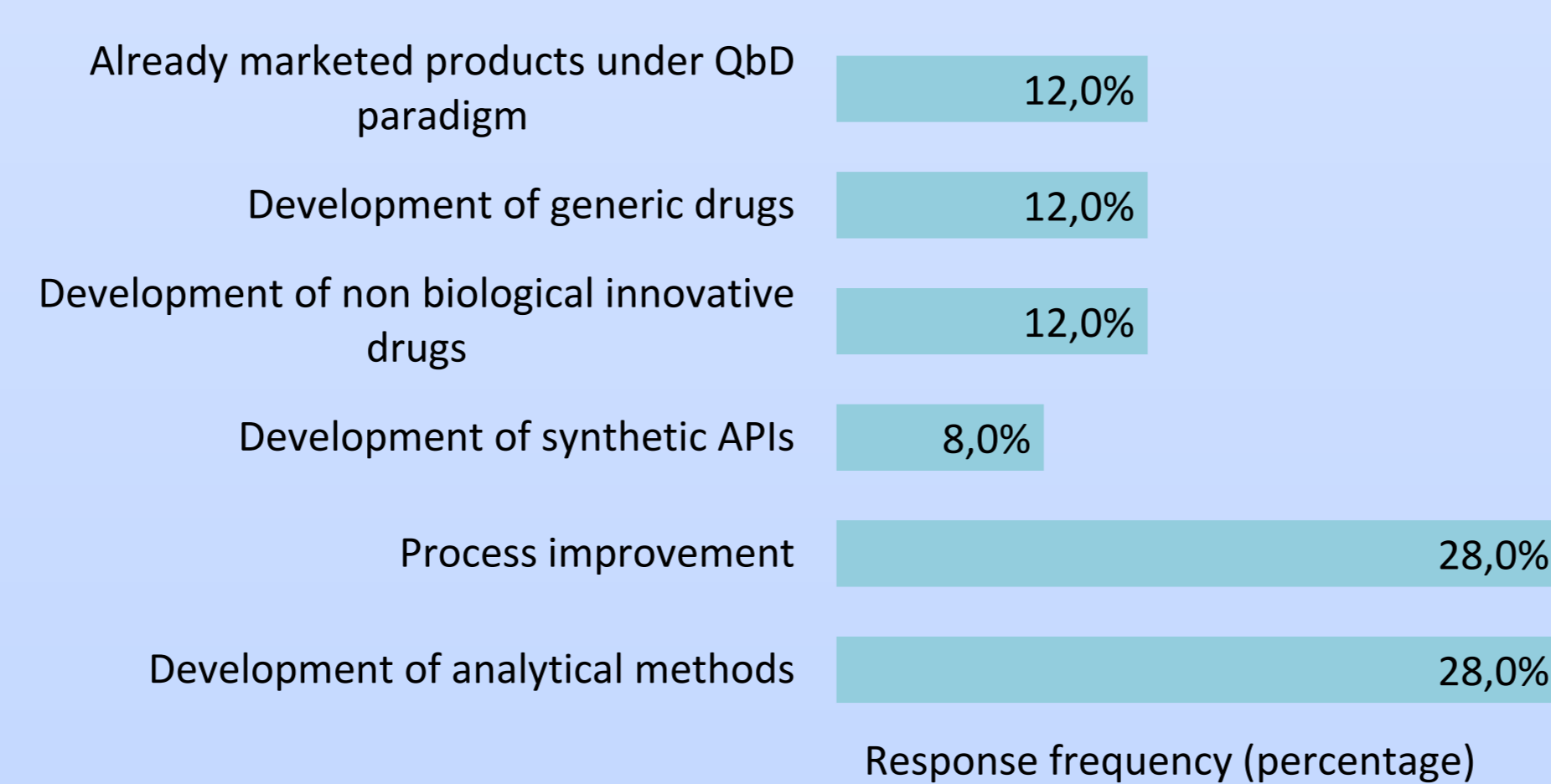
3. Perception of QbD importance in companies having or not R&D



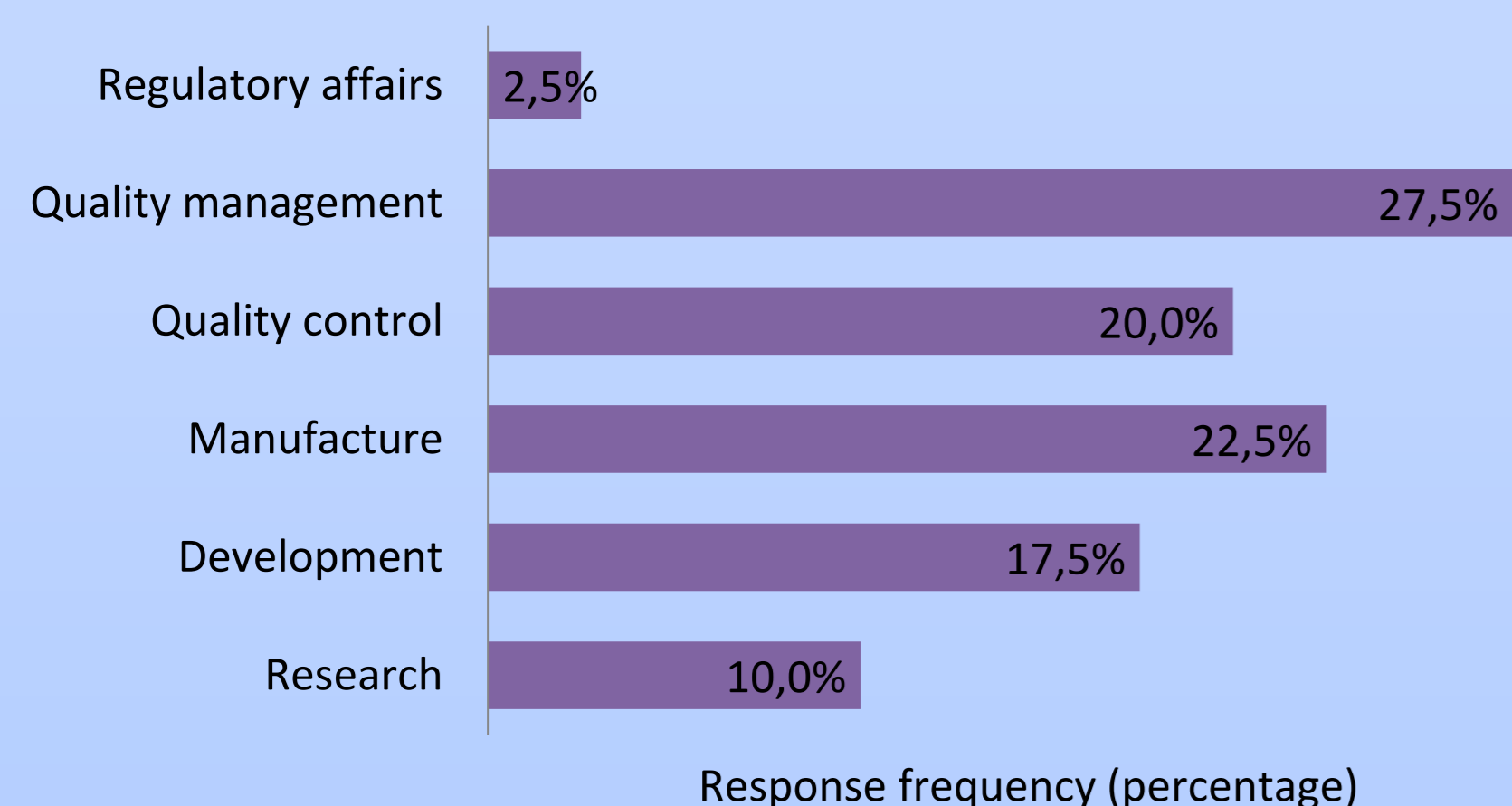
4. QbD tools/aspects in use or in implementation



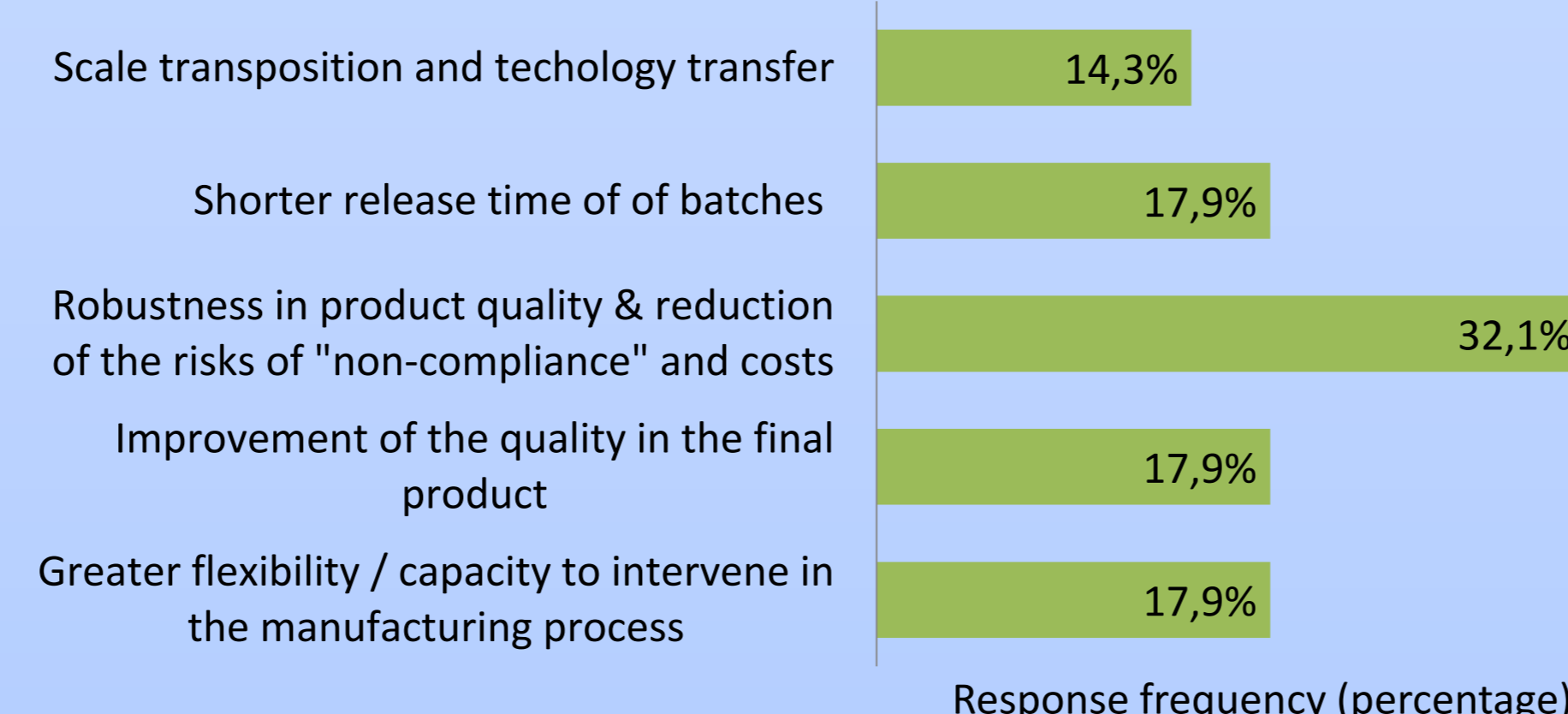
5. Scope of use and implementation of QbD



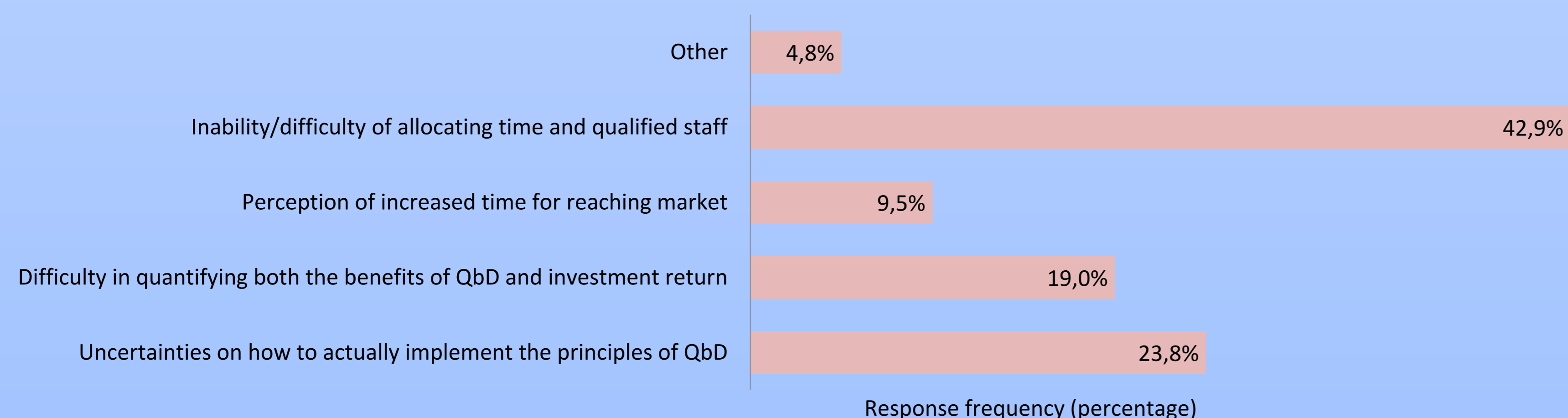
6. Industry sectors under QbD influence



7. Benefits indicated as possibly achieved through QbD



8. Obstacles towards implementation of QbD



Discussion & Conclusion

- Portuguese industries are aware of regulatory proceedings and are keeping pace towards global regulatory harmonisation. QbD has importance among the industries having R&D activities (p -value=0,024, assuming a significance level of 5%)*.
- In spite of industries ambition to succeed throughout this integrative strategy, there is still the need to better learn the “know how” and master the skills underlying QbD.
- To invest time and manpower might be essential to go beyond theoretical knowledge and to acquire the tools and competences for approaching more efficiently this concept.

Portuguese industries still have a long path ahead of them towards full adoption of QbD and proving its benefits.

Might be done with straight cooperation of regulatory agencies (ICH, EMA, FDA) and experts of this field.

We propose that the Portuguese academy should also participate, giving pharmacy students the awareness and competences in the use of QbD tools and concepts.

Acknowledgments

We would like to acknowledge the panel of experts that revised the survey: Cláudia Silva, PharmD, PhD Head of Research Bluepharma (pharmaceutical company); Bruno Gago, PharmD, PhD Invited Assistant Professor and Deputy Director of the training programme in Pharmaceutical Medicine, University of Aveiro; and Paula Correia, PharmD, Regulatory Affairs professional at GlaxoSmithKline (pharmaceutical company).

References

1. Berridge, J. Overview: Quality By Design (QbD). *ISPE Knowledge Brief*(2008).
2. Rathore, A. S. & Winkle, H. Quality by design for biopharmaceuticals. *Nat. Biotechnol.* 27, 26–34 (2009).

* Fisher's exact test was made grouping data “having or not R&D “ and “low or medium/high importance” on a 2x2 contingency table.