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ISO 9001 Online Consultation Center

ISO 9001:2015 clause 4 (Context of the organization, interested parties and scope)

Presenter: Carlos Pereira da Cruz

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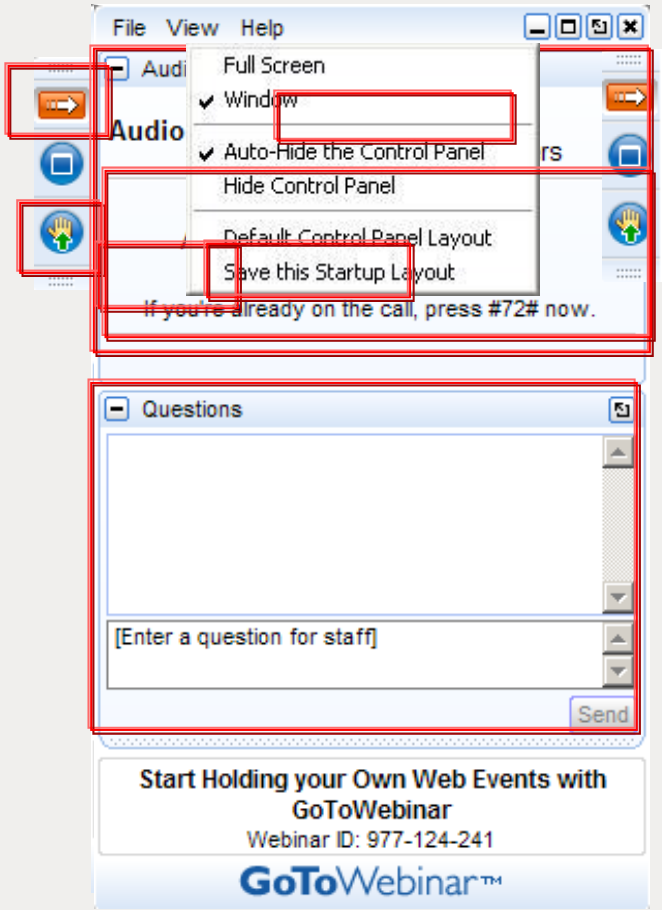

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How to deal with the context of the organization, interested parties and scope of the QMS

If you're starting to implement a QMS…

… these issues need to be addressed before you start implementing the rest.

An organization determines: what is relevant in the context, who the interested parties are, what their relevant requirements are, and the scope of the QMS.

Agenda

- Context – external issues
- Context – internal issues
- Relevant interested parties
- Relevant requirements of interested parties
- Scope of the QMS
- Exclusions

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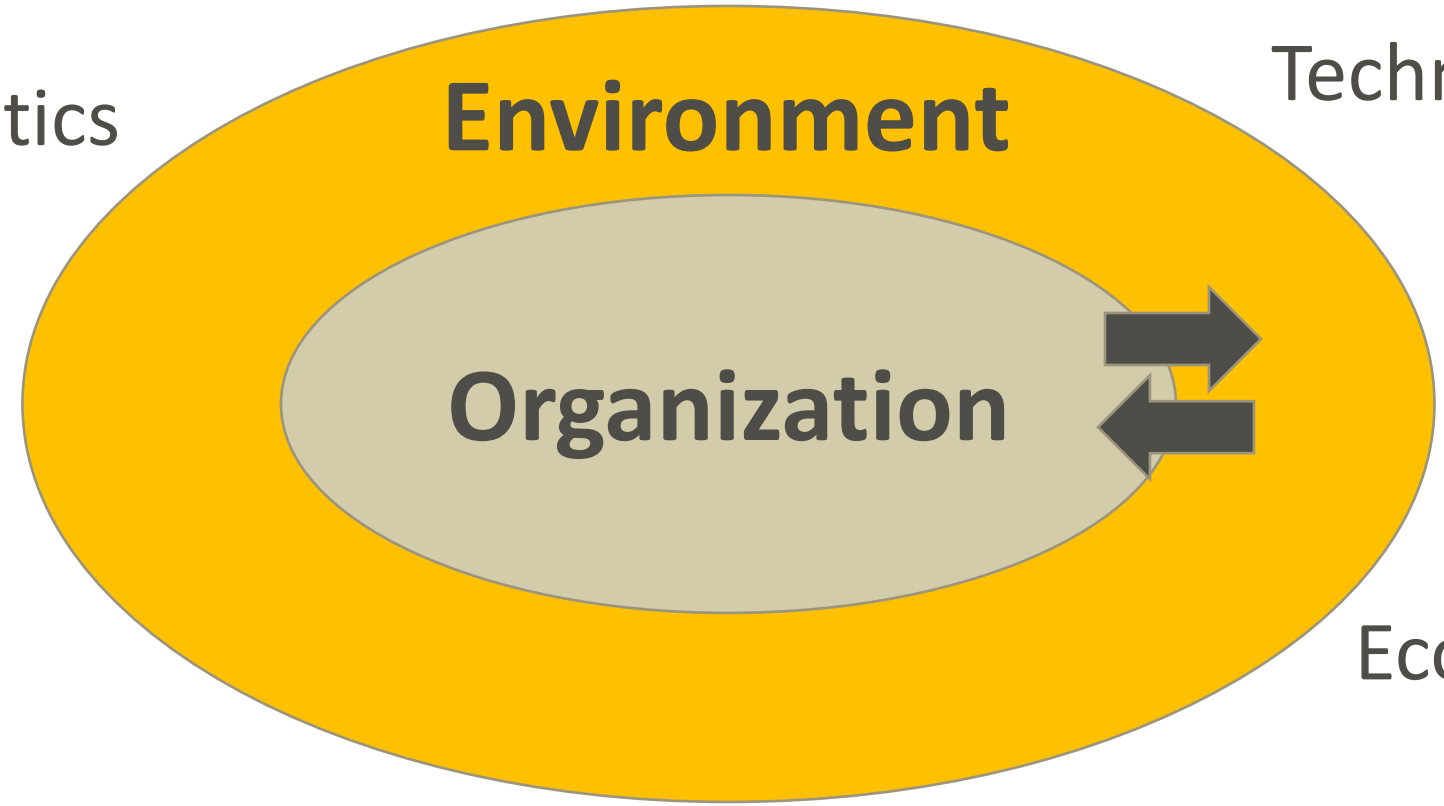
Context - external



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Context – internal

Employees

Performance

Product portfolio getting old

Breakdowns

Quality problems

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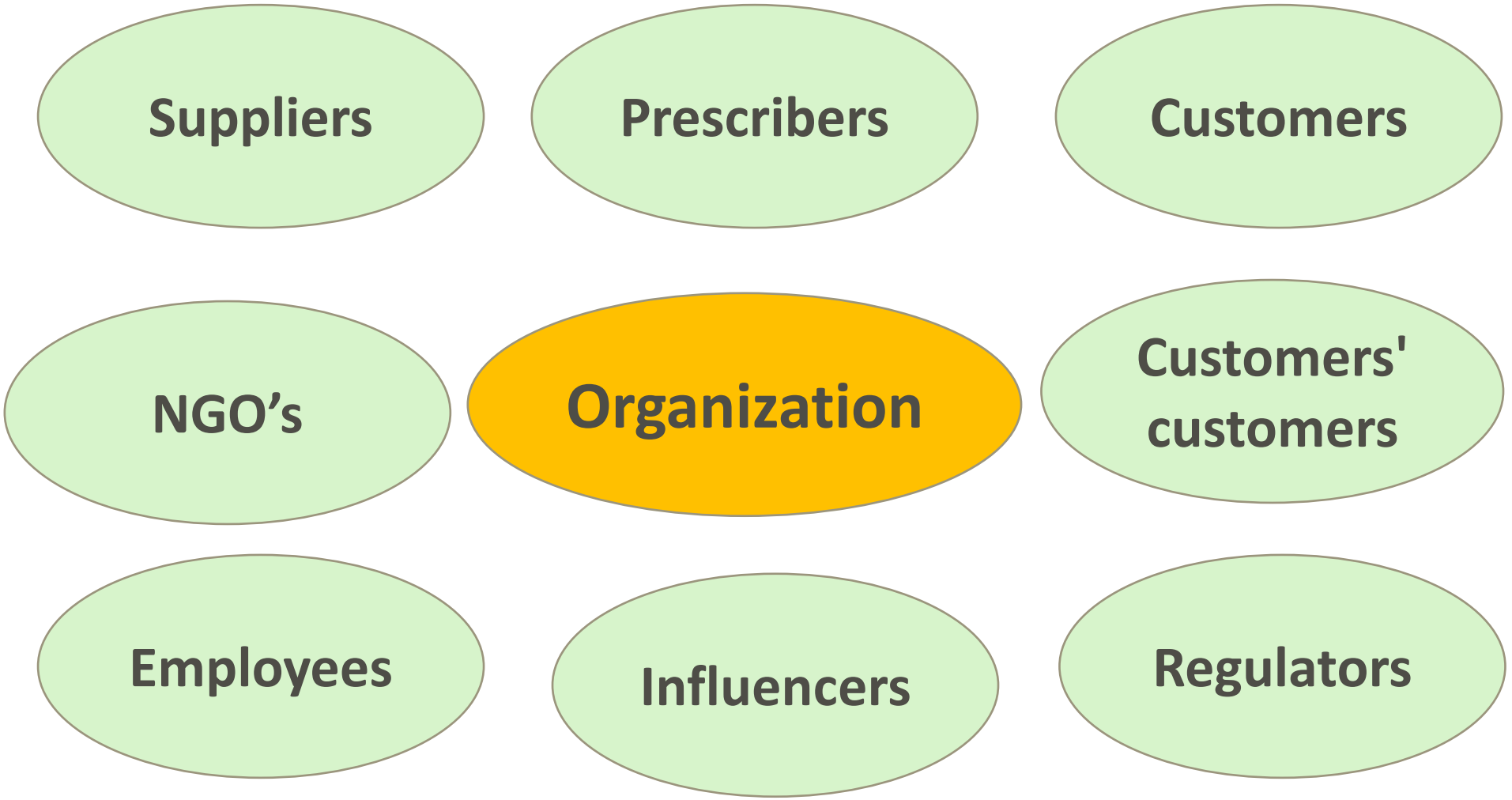
4.1 Understanding the organization and its context

- Determine the relevant issues
- Determination of relevant issues is a never ending activity

Potential interested parties



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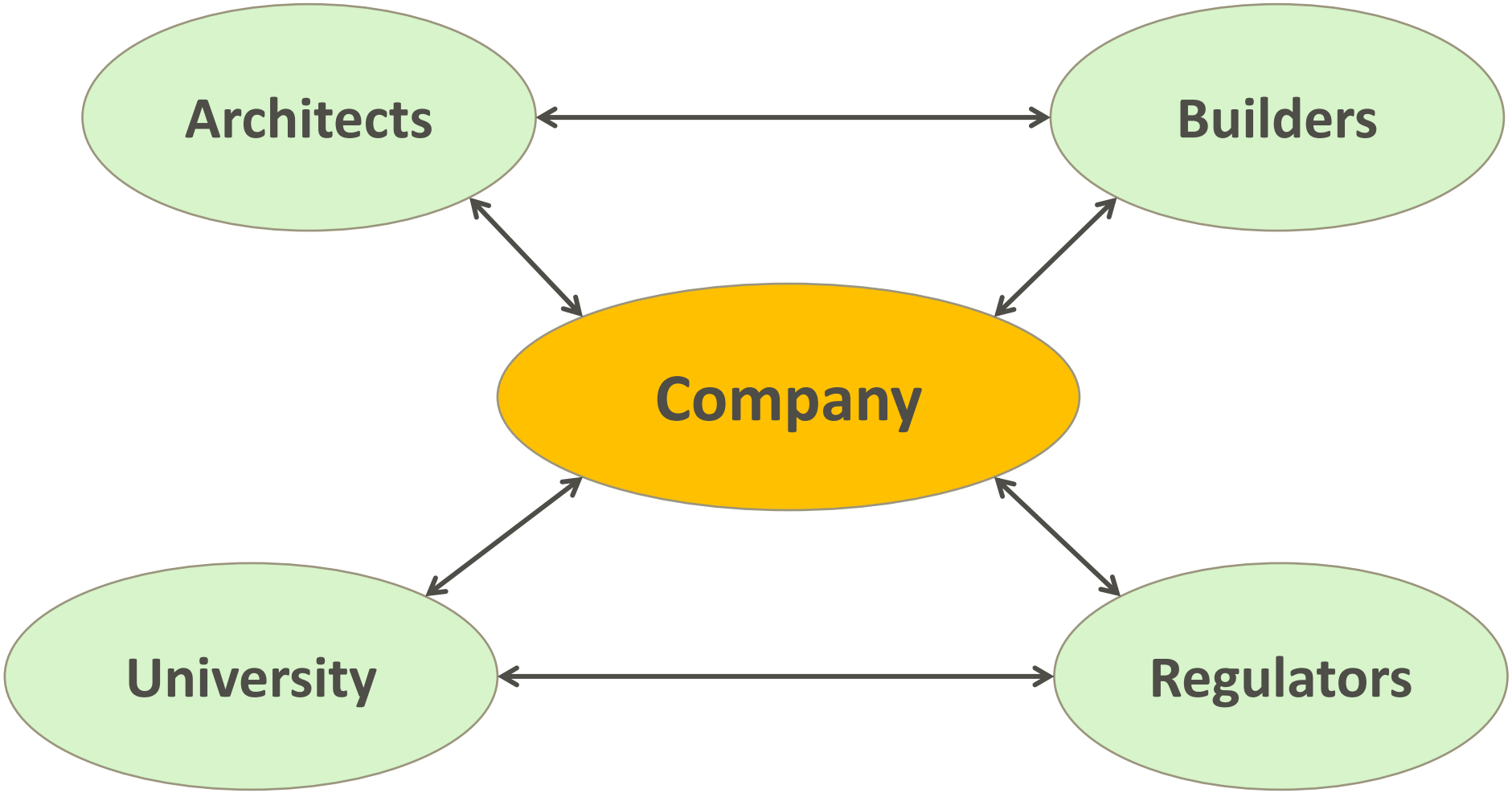
Relationships between interested parties



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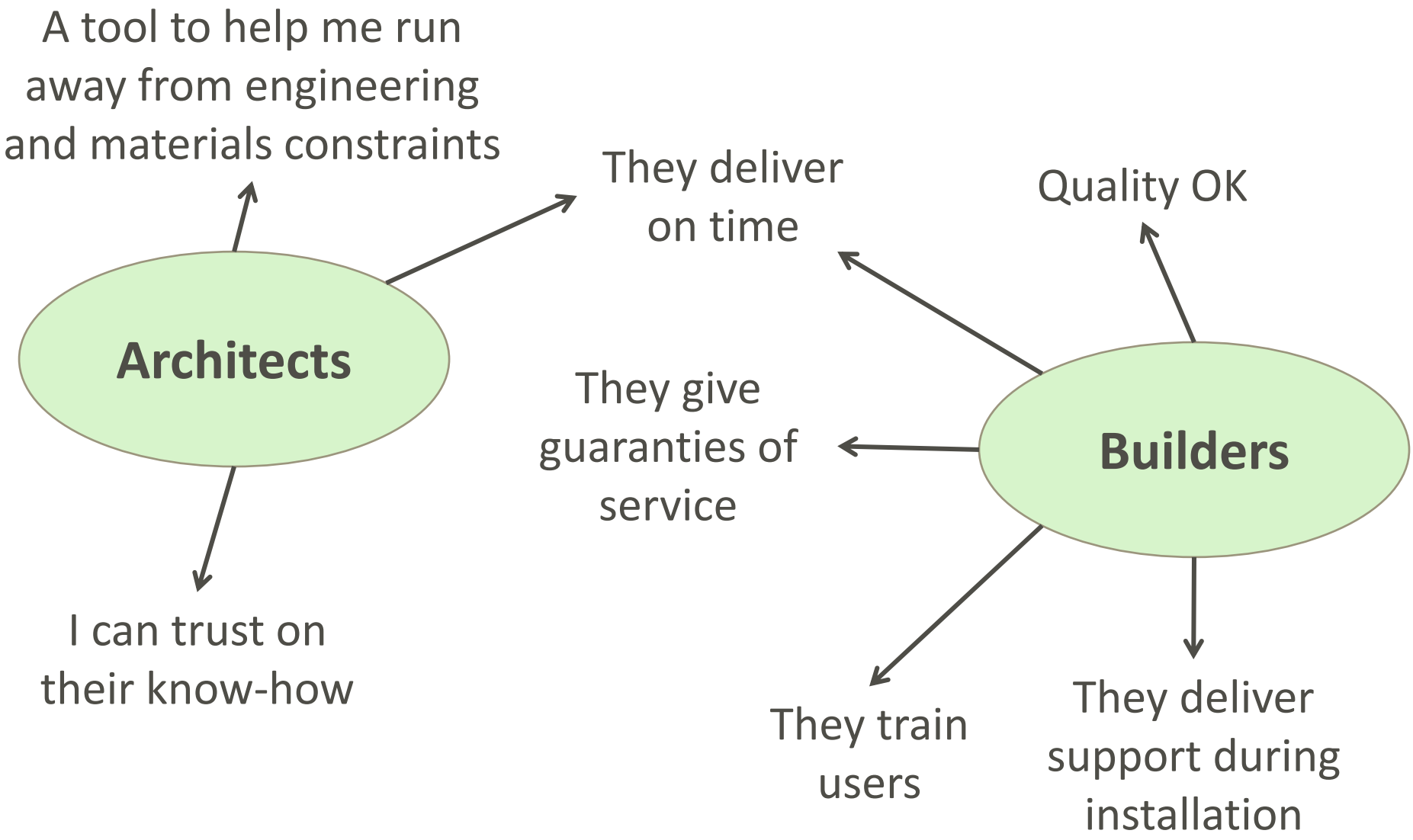
Requirements from interested parties



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4.2 Understanding the needs and expectations of interested parties

- Determination of relevant interested parties and their relevant requirements is a never ending activity

ISO 9001 clause 4.3 requirements for the scope

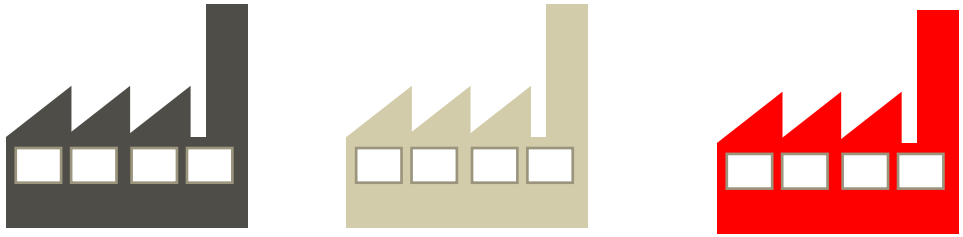
- An organization must determine the scope of the quality management system
- No exclusions are allowed, if a clause is applicable it must be considered in the QMS

Exclusions from the QMS scope

- An organization has the flexibility to apply the QMS to all products and services or part of it, to all locations or parts, provided that everything is very clear, and not misleading.

Example of making a scope decision and exclusion

Is clause **8.3 Design and development of products and services** applicable to a company?



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Applicable?	**NO**	**YES**	**?**

Main challenges

- Find the appropriate level of detail for internal and external factors
- Design an ecosystem of relevant interested parties
- Using the scope as a management decision
- Live without mandatory documentation

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Conclusion

Determine the context of your organization and the relevant interested parties

Determine the scope of your QMS that best suits your activity

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Q & A

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Thank you!

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