

Agile meets Regulations

Clash or Synergy: Agility and Regulatory Demands in Pharma & Medtech companies

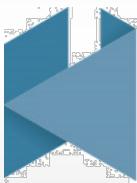
Basel

September 27, 2017
Prof. Dr. Ayelt Komus

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ayelt@komus.de

 www.twitter.com/AyeltKomus
www.process-and-project.net



HEUPEL
CONSULTANTS

Wissen.Wege.Wirkung



Process and Project

Prof. Dr. Ayelt Komus

- Professor of Organization and Information Systems
- 15+ relevant international studies, 50+ publications, 100+ keynotes/ lectures, 150+ interviews/ media reports
- Co-Initiator of „**Modellfabrik Koblenz**“ (Model factory Koblenz)
- Scientific director of **data center - University of appl. Sc. Koblenz**
- **Certified Scrum Master** (3 organizations)
- Scientific advisory board Heupel Consultants
- Advisory board member „Projektmagazin“



Further information www.komus.de

Current Initiatives (sorry, mostly German)



Process and Project

Studien www.process-and-project.net/studien

- Mein Digital Profil www.mein-digital-profil.de
- Stacey Portfolio Analyse www.process-and-project.net/spa
- Status Quo Agile www.status-quo-agile.net
- Agile Procurement Survey www.process-and-project.net/agile-procurement-survey
- Multitasking im Projektmanagement
- Agiles PMO
- Erfolgsfaktoren im Projektmanagement –
Studie zum evidenzbasierten Projektmanagement
- Metastudie BPM-Quintessenz
- Prozess-/IT-Management in Chemie/Life Science
- IT-Radar für BPM und ERP
- ...

www.process-and-project.net

Workshops

www.process-and-project.net/workshops

- Agile Methoden im PM (7. November 2017)
- Agiles PMO (8. November 2017)
- BPM-Compass (28. September und 17. Oktober 2017)
- Projektmanagement Erfolgsfaktoren (Inhouse)
- Agiler Einkauf (29. September und 8. November 2017)
- Interactive Web-Seminar: Fundamentals Of Agile Methods And Scrum (10. Nov.)

11. Praxisforum Prozess- und IT-Management (12. Juni 2018) www.praxisforum.eu

3. Praxiswerkstatt Digitalisierung und Agilität (13. Juni 2018) www.praxiswerkstatt.eu

Projektumfeld-Studie

Was macht Ihnen im Projekt das Leben schwer?

Was läuft gut?

Wo sollten Organisationen und PMOs ansetzen?

Studie mit dem Projektmagazin - ab 25. September.



Ökosystem Projekt:

Prof. Ayelt Komus & ProjektMagazin

Wie gut ist der Nährboden für Ihren Projekterfolg?

www.projektmagazin.de/oekosystem-projekt

Was läuft gut – was stört Ihre Projektarbeit?

Teilnehmer profitieren von Studienbericht und Workshop-Verlosung.

www.projektmagazin.de/oekosystem-projekt

My Digital Profile

Mein Digital Profil

Sehr geehrte Teilnehmerin, sehr geehrter Teilnehmer,

wir freuen uns über Ihr Interesse am Digitalisierungs-Profil: „Mein Digital Profil“.

Bitte beantworten Sie die folgenden Fragen. Einige Fragen müssen beantwortet werden, andere Fragen können bedarfswise übersprungen werden. Wenn Sie sich bei der Beantwortung einer Frage nicht sicher sind, wählen Sie bitte die Antwort, die Ihrer Meinung nach den Sachverhalt am besten beschreibt. Sollten Sie in einem Konzern oder größeren Unternehmen tätig sein, so beantworten Sie die Fragen bitte für Ihren Unternehmensbereich.

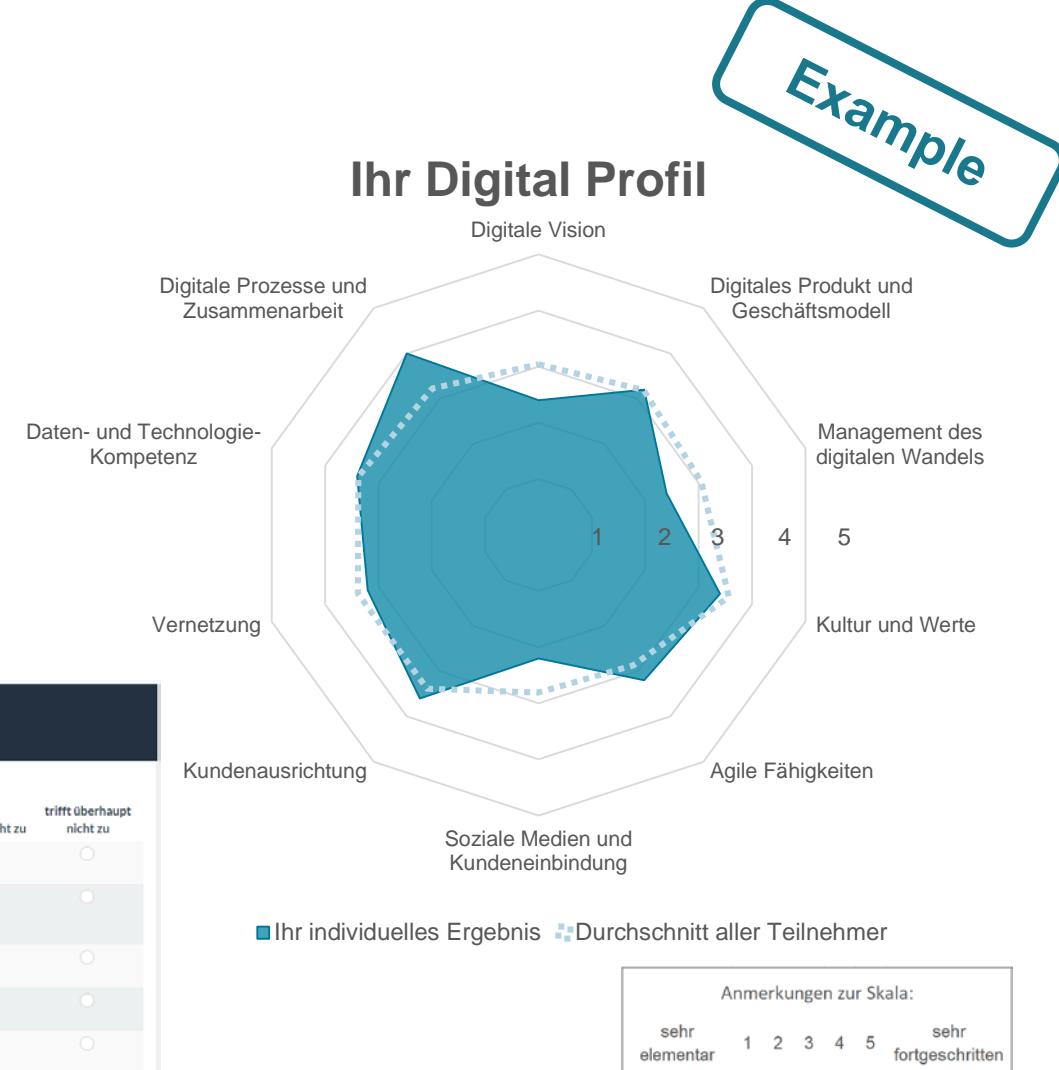
Für Rückfragen stehen wir Ihnen gerne zur Verfügung: per Mail an info@process-and-project.net

Viel Erfolg und freundliche Grüße
Prof. Dr. Ayelt Komus und Team

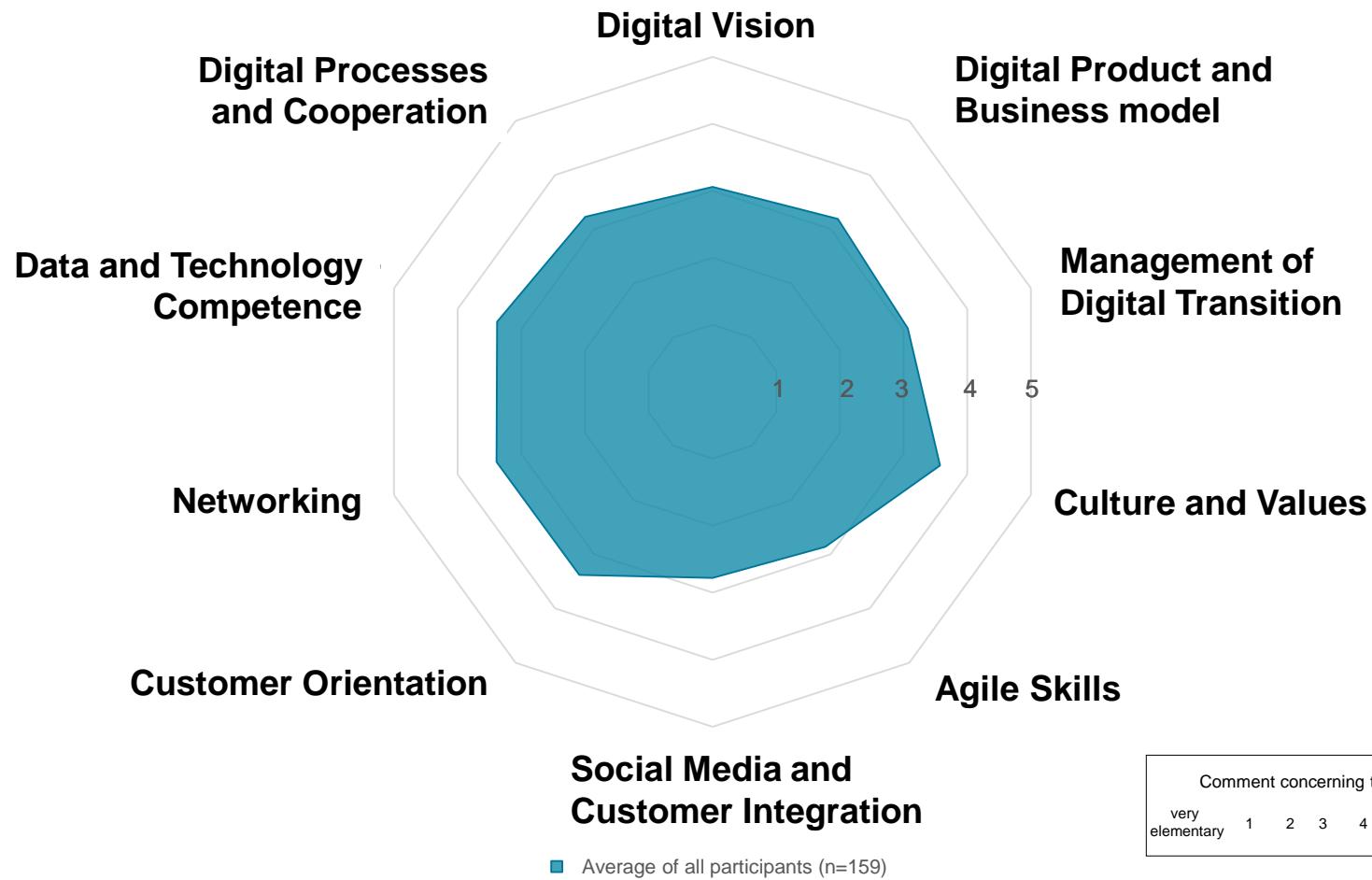
 

***Digitale Vision**

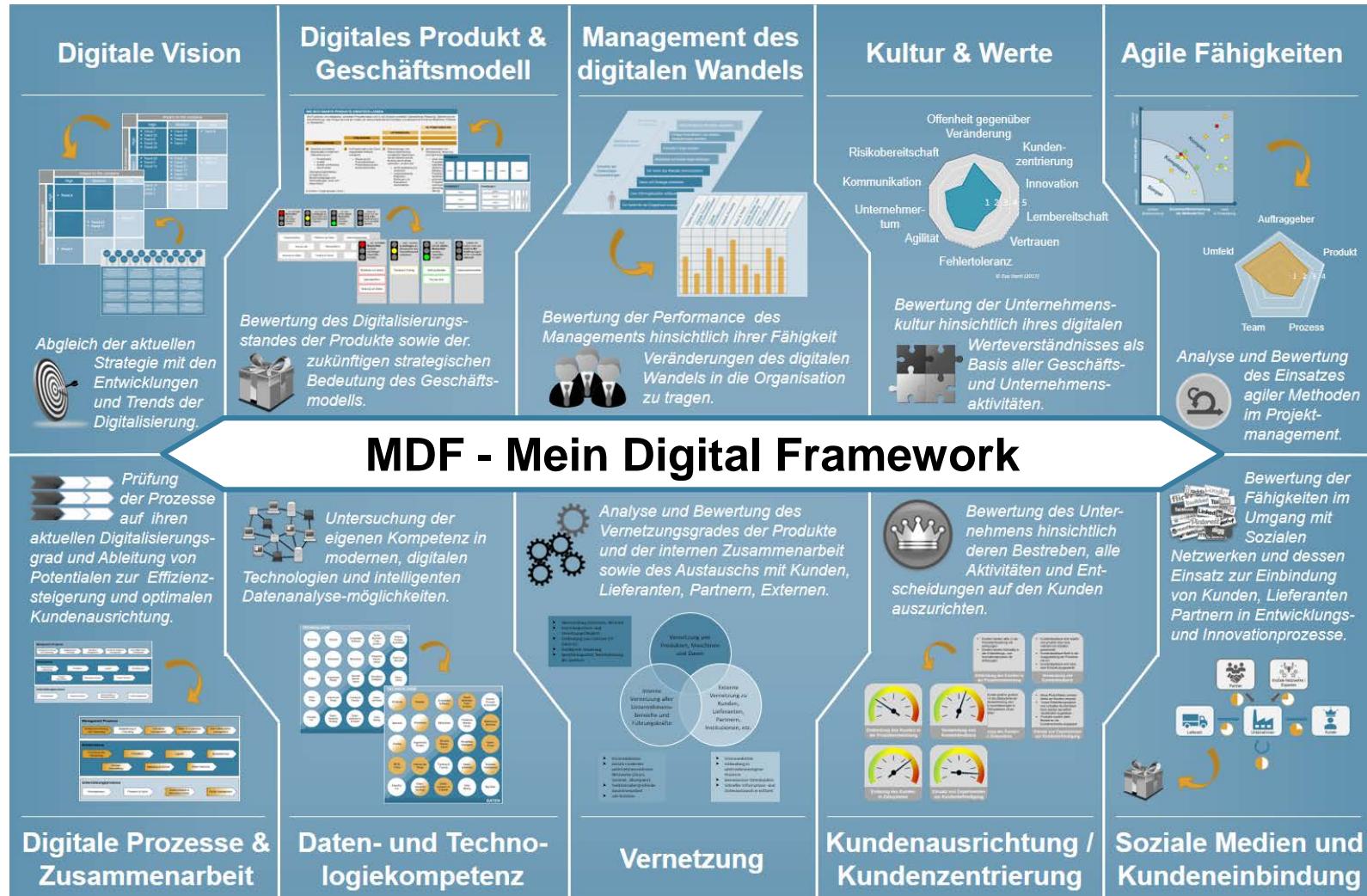
	trifft voll zu	trifft teilweise zu	teils-teils	trifft eher nicht zu	trifft überhaupt nicht zu
Es gibt ein gemeinsames Bild wie die digitale Zukunft unseres Unternehmens aussehen wird.	<input type="radio"/>				
Die Vision von der Zukunft unseres Unternehmens ist sehr weitreichend vom Gedanken einer digitalen und vernetzten Zukunft geprägt.	<input type="radio"/>				
Digitalisierung wird in unserem Unternehmen als entscheidender Entwicklungsprozess verstanden, an dem sich alle beteiligen.	<input type="radio"/>				
Wir werden von unseren Kunden als digitales Unternehmen wahrgenommen.	<input type="radio"/>				
Unsere Unternehmensstrategie ist hochgradig harmonisiert mit unseren digitalen Zielen.	<input type="radio"/>				



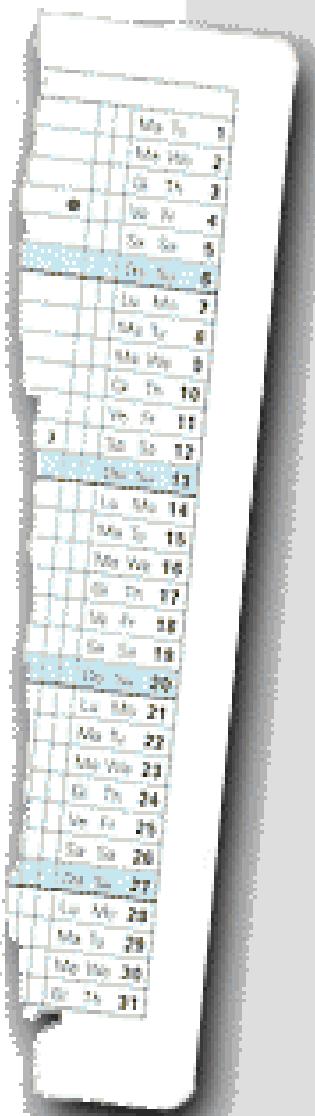
My Digital Profile – 10 Dimensions of Skills



My Digital Framework



Agenda



- Limitations And Problems With Classic Project Management
- Agility As An Answer
- Agile = Poor Quality And Documentation?
- Hybrid Practices
- Agile And Regulated

Limitations And Problems With Classic Project Management

3 Assumptions....

3 things we wish were true...

- The customer knows what he wants
- The developers know how to build it
- Nothing will change along the way

3 things we have to live with...

- The customer discovers what he wants
- The developers discover how to build it
- Things change along the way

<http://commons.wikimedia.org/wiki/File:Change.jpg?uselang=de>



Planning Horizon And Level Of Detail (1/3)

*Uncertainty of
knowledge/
prediction*

increasing vagueness

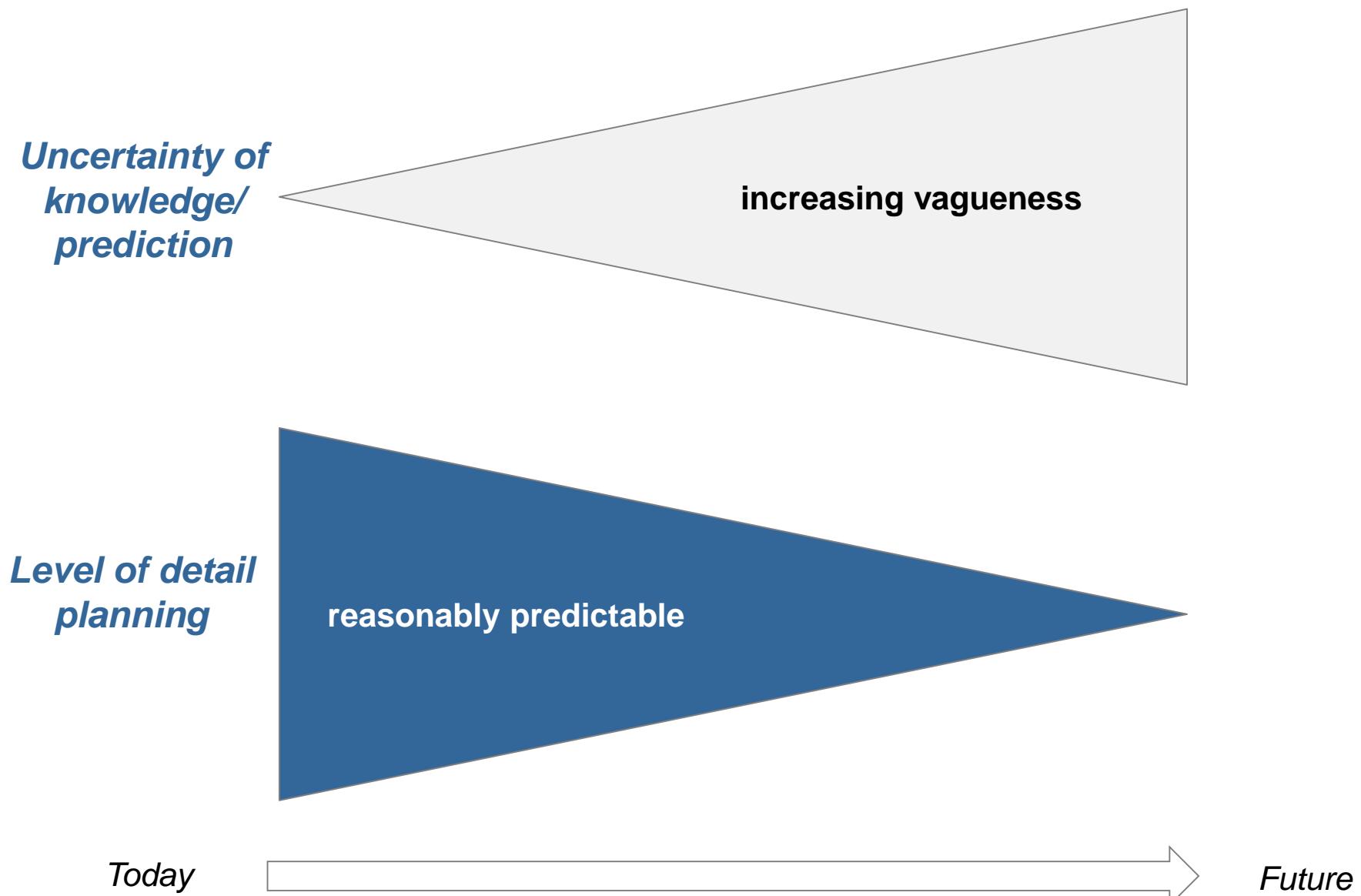
Today



Future

Based on idea of Schlereth, CanDo

Planning Horizon And Level Of Detail (2/3)



Based on idea of Schlereth, CanDo

Planning Horizon And Level Of Detail (3/3)

Uncertainty of knowledge/prediction

increasing vagueness

Level of detail planning

reasonably predictable

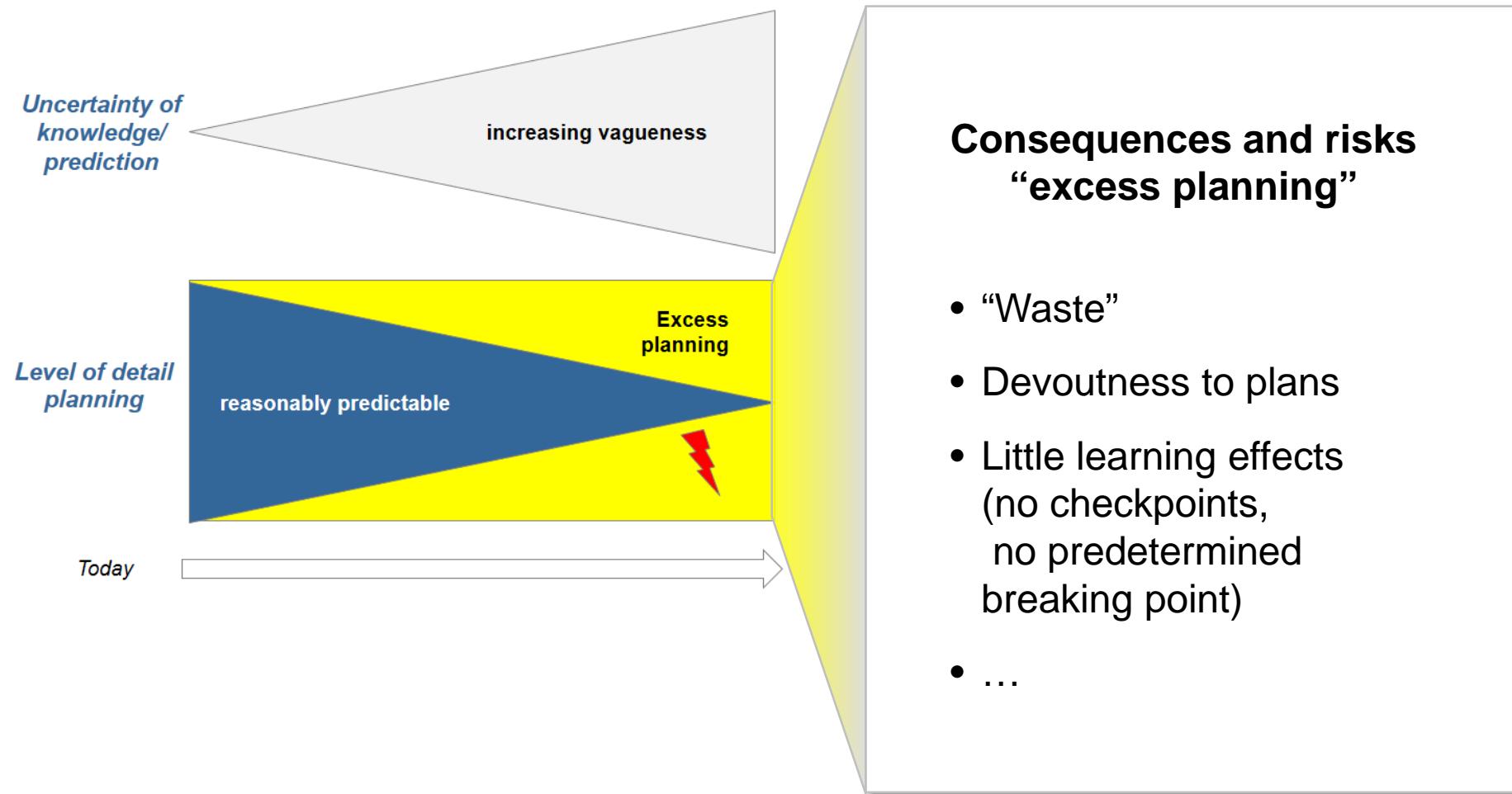
Excess planning

Today

Future

Based on idea of Schlereth, CanDo

Consequences – Excess Planning



Based on idea of Schlereth, CanDo

Typical Waterfall Symptoms

- Unsatisfying and changing quality, documentation, ...
- PM-Process is perceived as a burden
- Problem of underestimation / unrealistic plannings
- Watermelon effect
- 90%- Syndrome
- Inevitable changes are delayed
- Low acceptance for results
- “loosing” the sponsors
- ...



Agility As An Answer

Manifesto for Agile Software Development

We are uncovering better ways of developing software by doing it and helping others do it.

Through this work we have come to value:

Individuals and interactions over processes and tools

Working software over comprehensive documentation

Customer collaboration over contract negotiation

Responding to change over following a plan

That is, while there is value in the items on the right, we value the items on the left more.

Kent Beck

Mike Beedle

Arie van Bennekum

Alistair Cockburn

Ward Cunningham

Martin Fowler

James Grenning

Jim Highsmith

Andrew Hunt

Ron Jeffries

Jon Kern

Brian Marick

Robert C. Martin

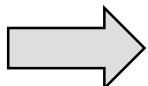
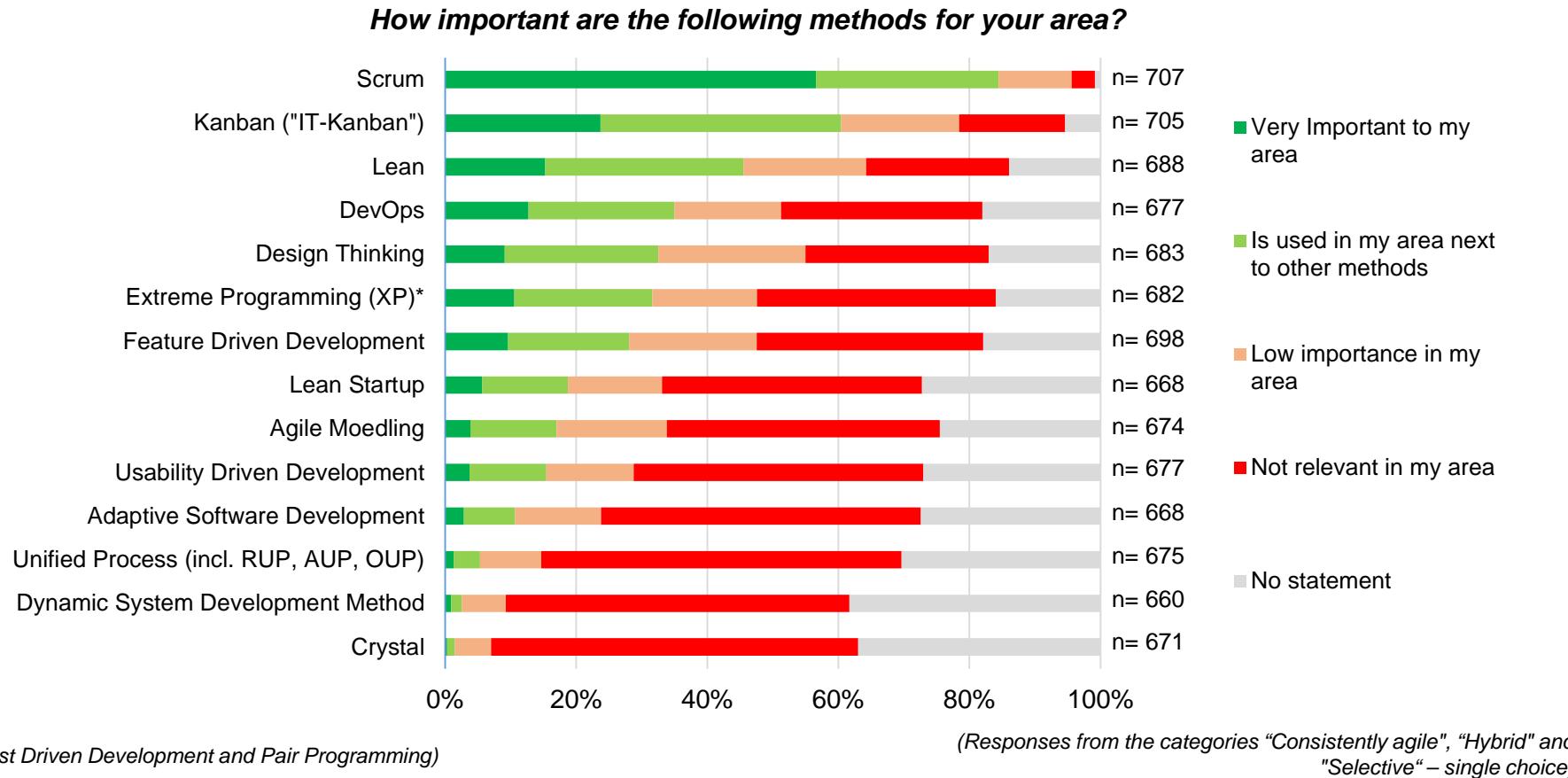
Steve Mellor

Ken Schwaber

Jeff Sutherland

Dave Thomas

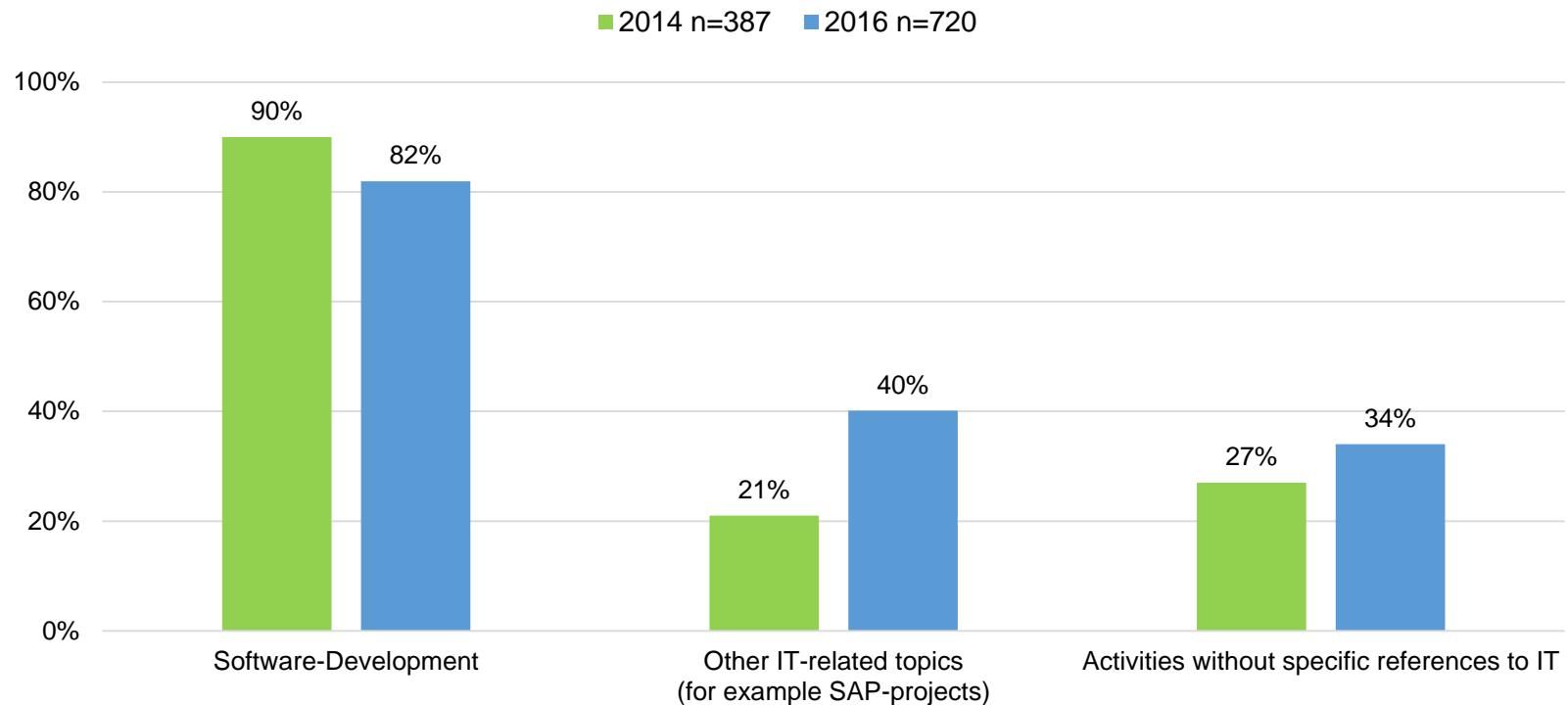
Importance Of Agile Methods



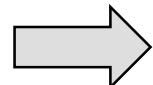
**Scrum is still the most common method.
DevOps is gaining in importance.**

Fields Of Application And Usage

In which areas do you use agile methods/ project management?



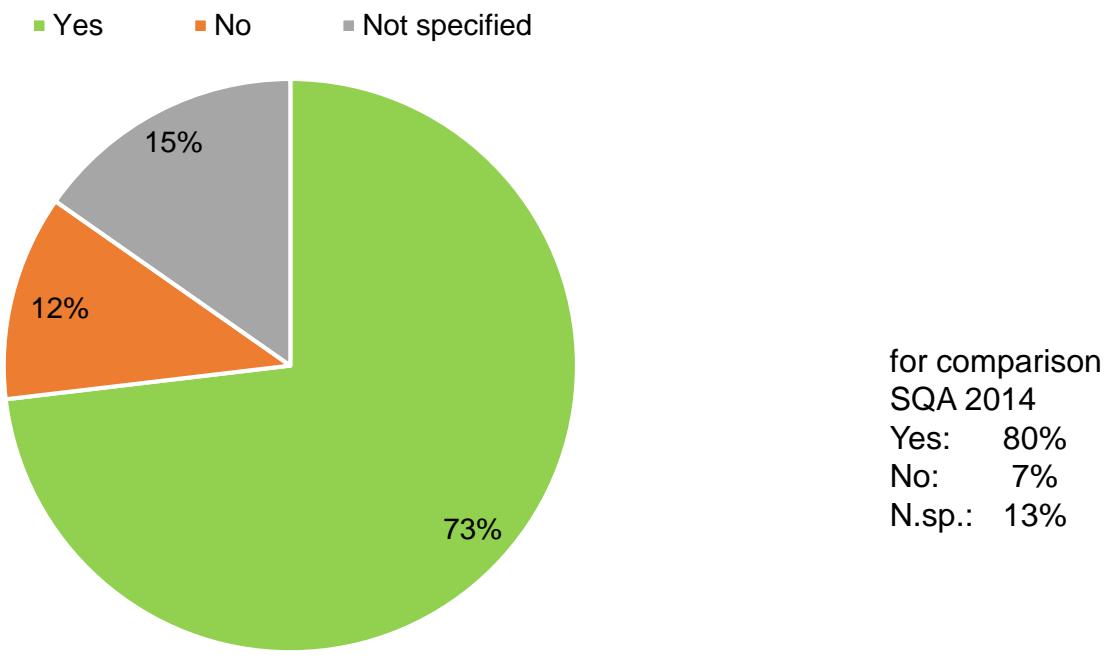
(Responses from the categories "Consistently agile", "Hybrid" and "Selective" – multiple choice)



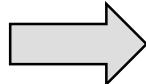
Agile methods are no longer used only in software development

Improvement Of Results And Efficiency Due To Agile Methods

Did the usage of agile methods lead to improved results and efficiency?



(Responses from the categories "Consistently agile", "Hybrid" and "Selective" – single choice)

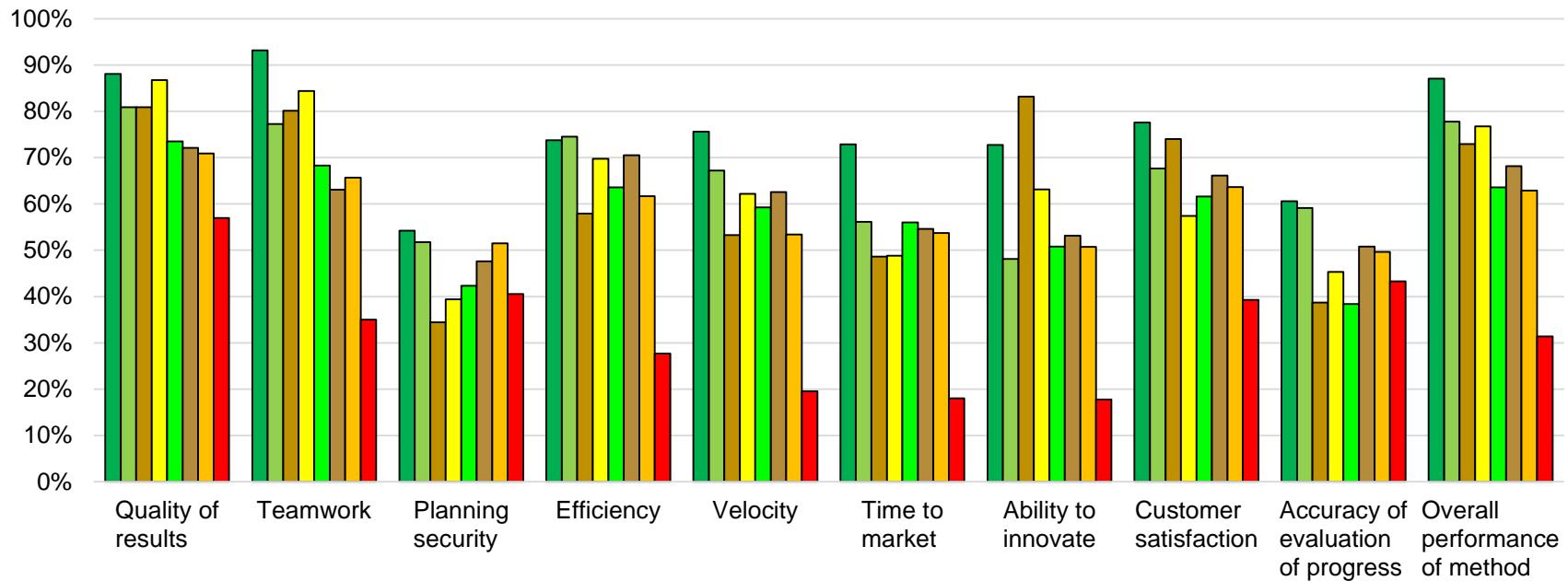


Again the vast majority of respondents see improvements through agile methods.

Success Rates Agile Versus Classic PM

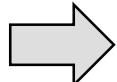
Sum of the "very good" and "good" ratings

■ Scrum ■ Kanban ■ Design Thinking ■ Extreme Programming ■ DevOps ■ Lean ■ Feature Driven Development ■ Classic Project Management



n: see individual evaluations*

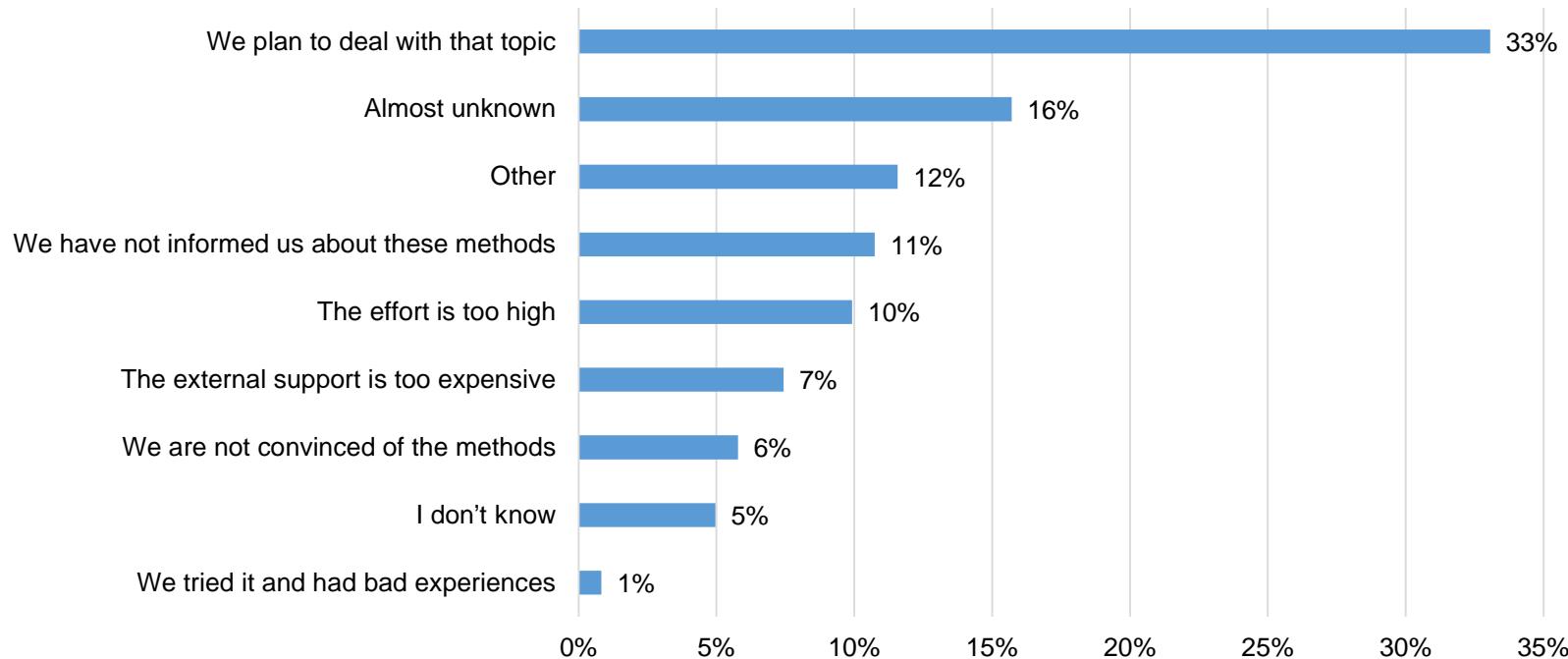
(Responses from the categories "Consistently agile", "Hybrid", "Selective" and "Consistently classic project management" – single choice)



Agile methods are also clearly superior regarding Quality of results, Customer satisfaction, and Accuracy of evaluation of progress

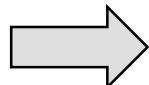
Reasons For Not Using Agile Methods

Why do you not use agile methods?



n=121

(Responses from the category "Consistently classic project management" – single choice)

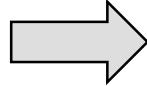
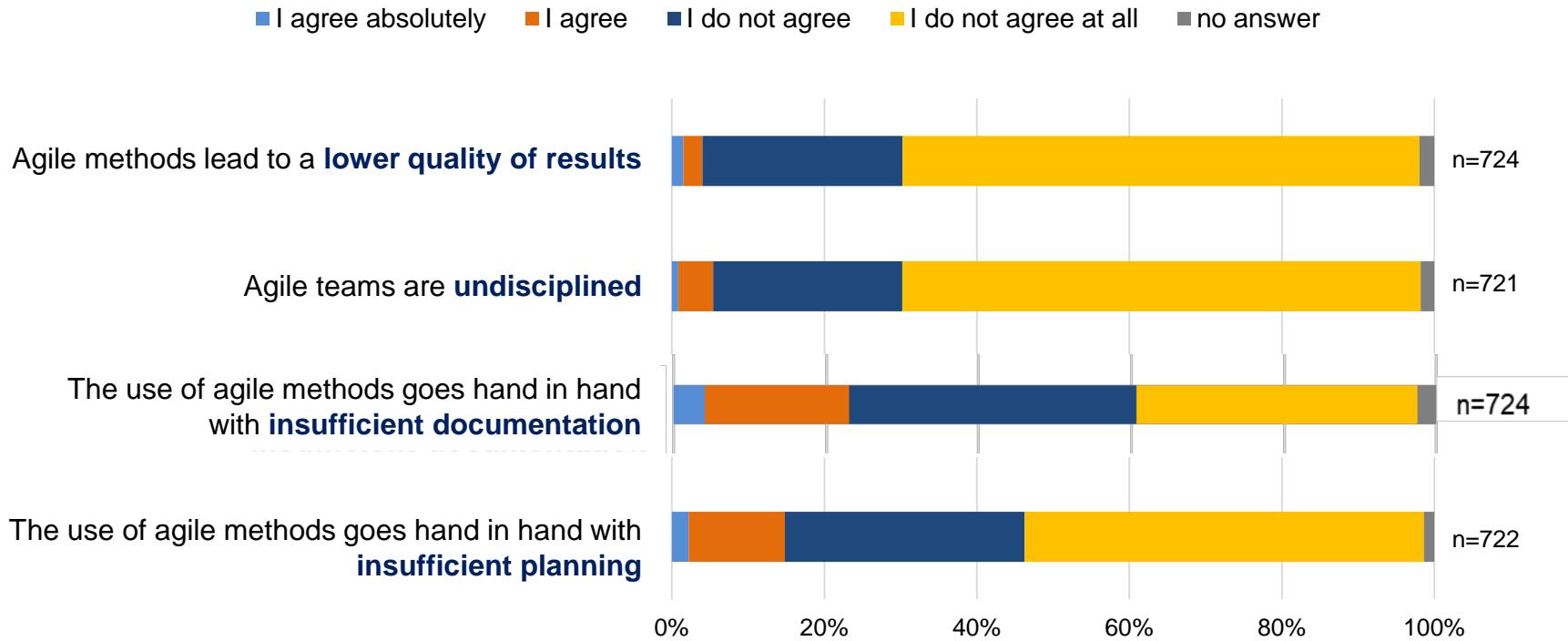


Often, there is no know-how or initiative to tackle the issue

Agile = Poor Quality And Documentation?

Agile Methods And Quality, Documentation

How much do the following statements correspond to your opinion?



Quality, Discipline, Insufficient Documentation and Planning are hardly an issue

DoD – Definition of Done

Sprint Review: Done means Done!

1. Code produced (all ‘to do’ items in code completed)
2. Code commented, checked in and run against current version in source control
3. Peer reviewed (or produced with pair programming) and meeting development standards
4. Builds without errors
5. Unit tests written and passing
6. Deployed to system test environment and passed system tests
7. Passed UAT (User Acceptance Testing) and signed off as meeting requirements
8. Any build/deployment/configuration changes implemented/document/documented/communicated
9. Relevant documentation/diagrams produced and/or updated
10. Remaining hours for task set to zero and task closed



Reasons To Use Or Not To Use Agile Methods

Why did your organization decide to work with agile methods?

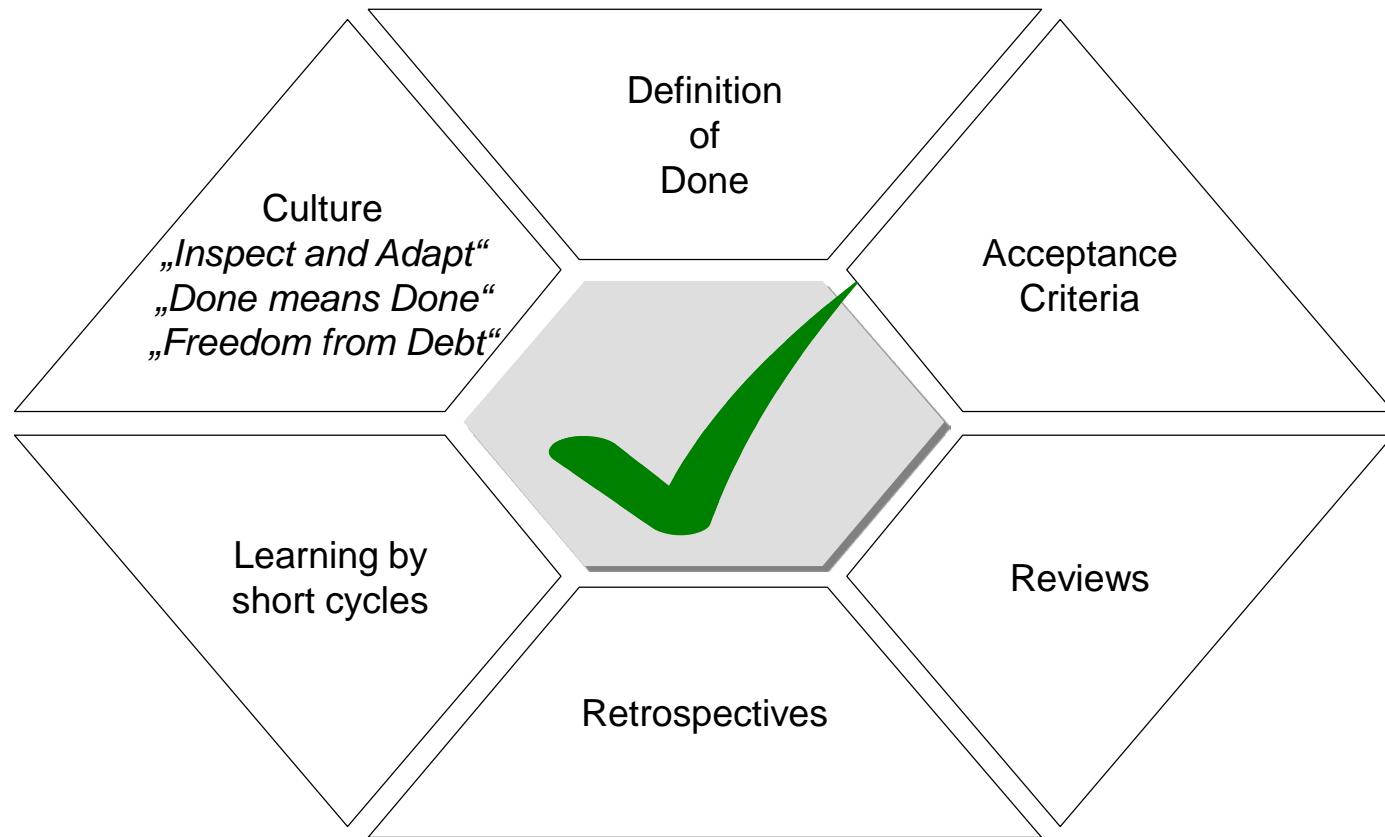


(Responses from the categories "Consistently agile", "Hybrid" and "Selective" – multiple choice)



Quality, Risk minimization and predictability are often the motives for using agile methods

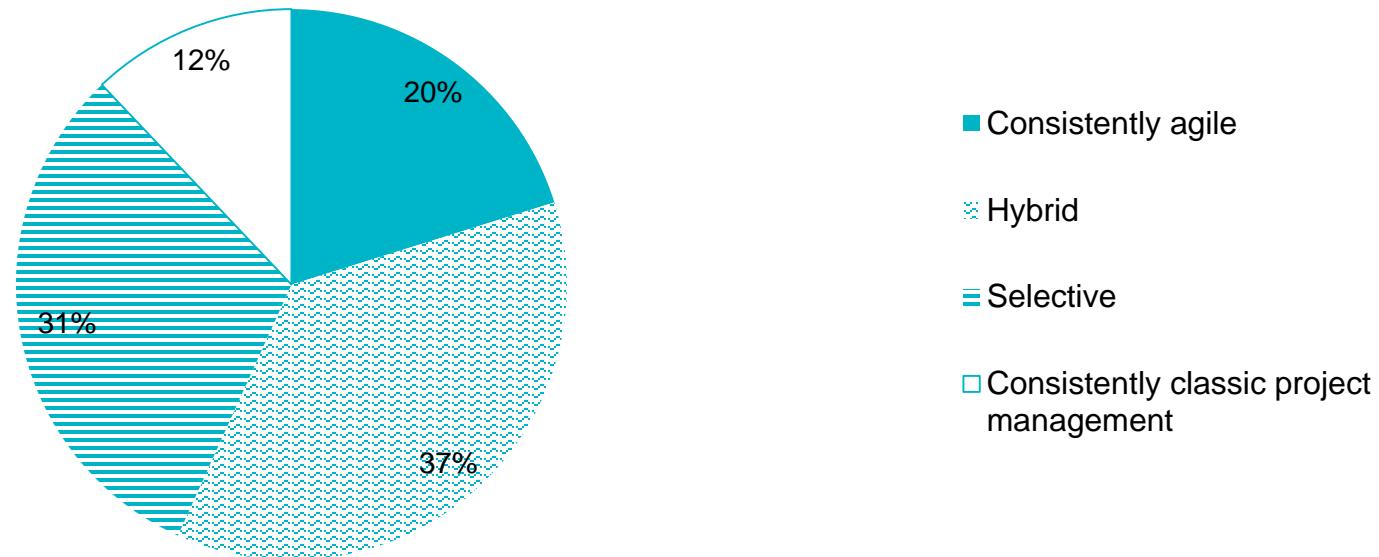
Quality in Agile Methods



Hybrid Practices

Fields Of Application And Usage

In which form do you use agile methods in your area to plan and execute projects/ development processes?



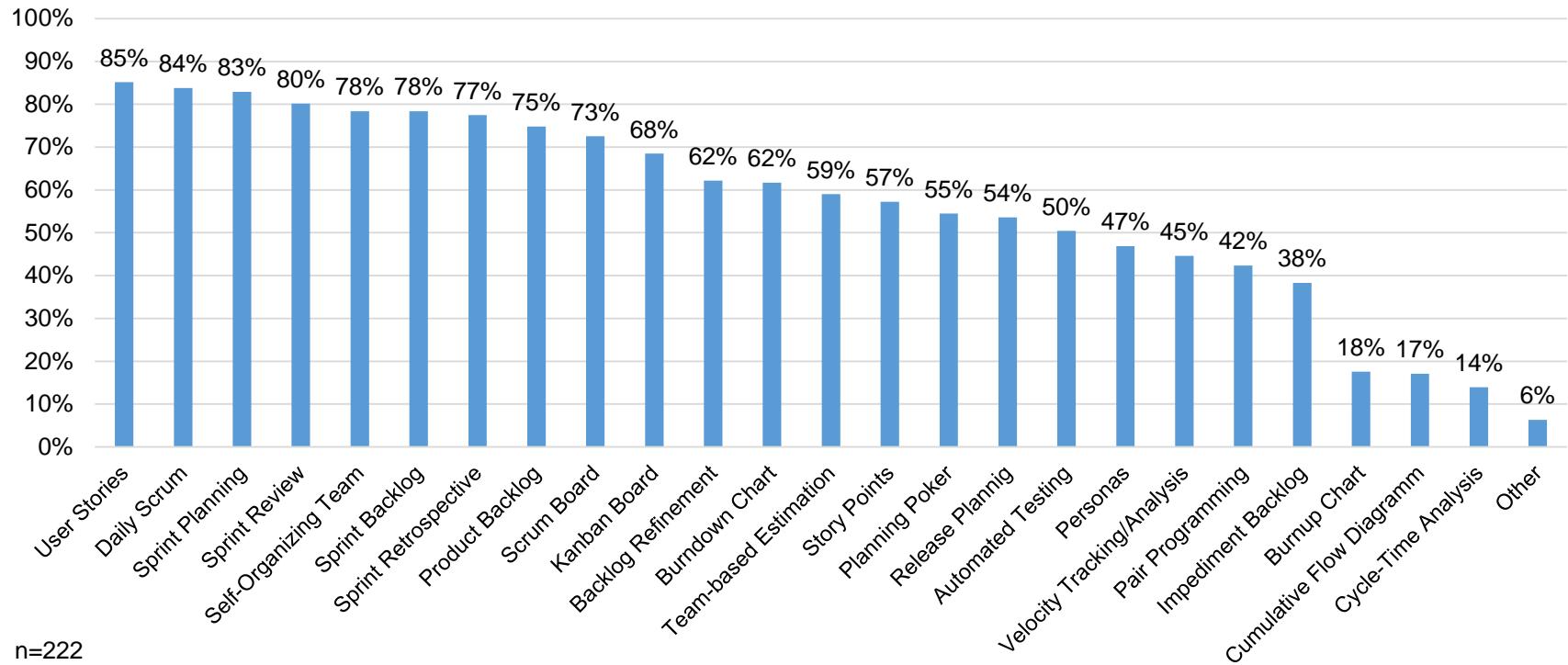
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(Responses from the categories "Consistently agile", "Hybrid", "Selective" and "Consistently classic project management" – single choice)

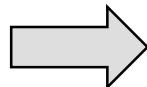
**Only a minority uses agile methods consistently
“by the book”.**

Usage Of Agile Techniques

Which agile practices do you use?

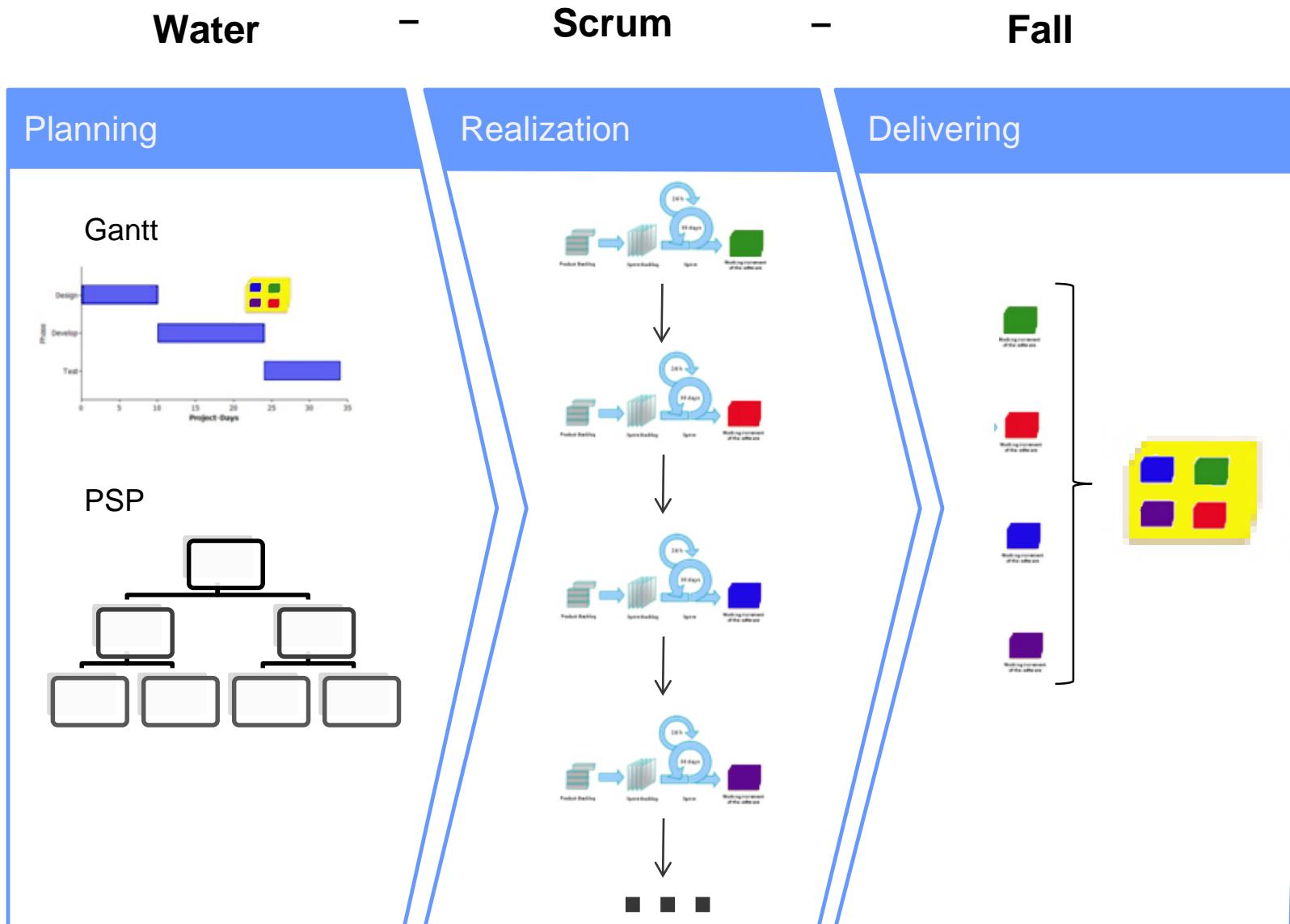


(Responses from the categories “Consistently agile”, “Hybrid” and “Selective” – multiple choice)



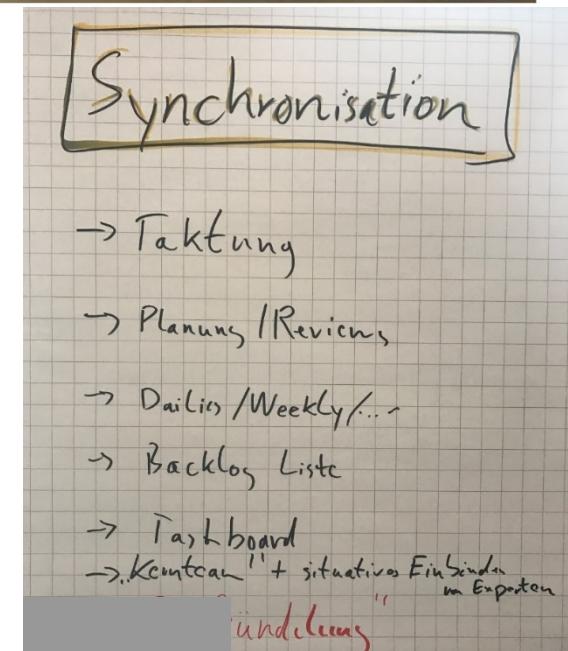
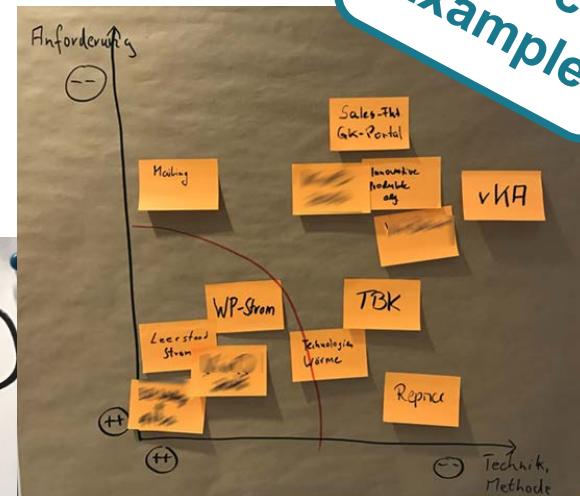
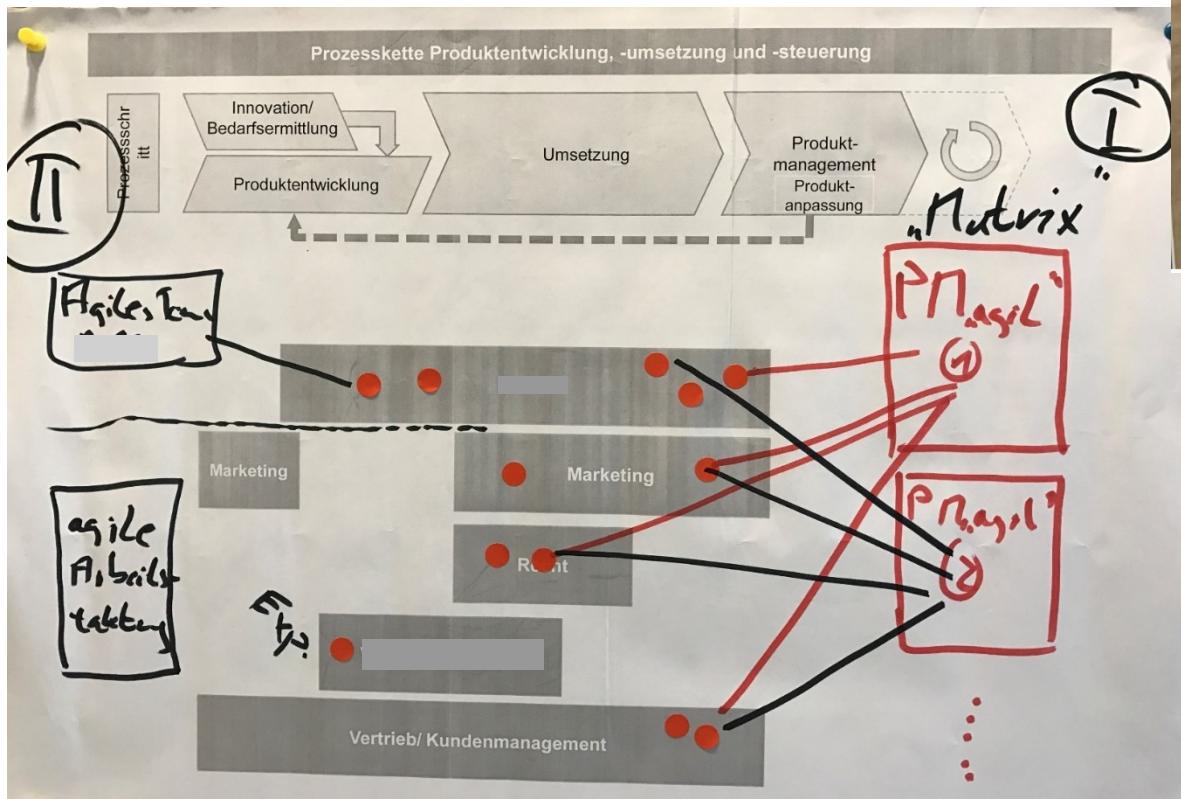
Many very common techniques can also be used in classic project management

“Water–Scrum–Fall”



Combining Agile And Classical Processes

Project Example

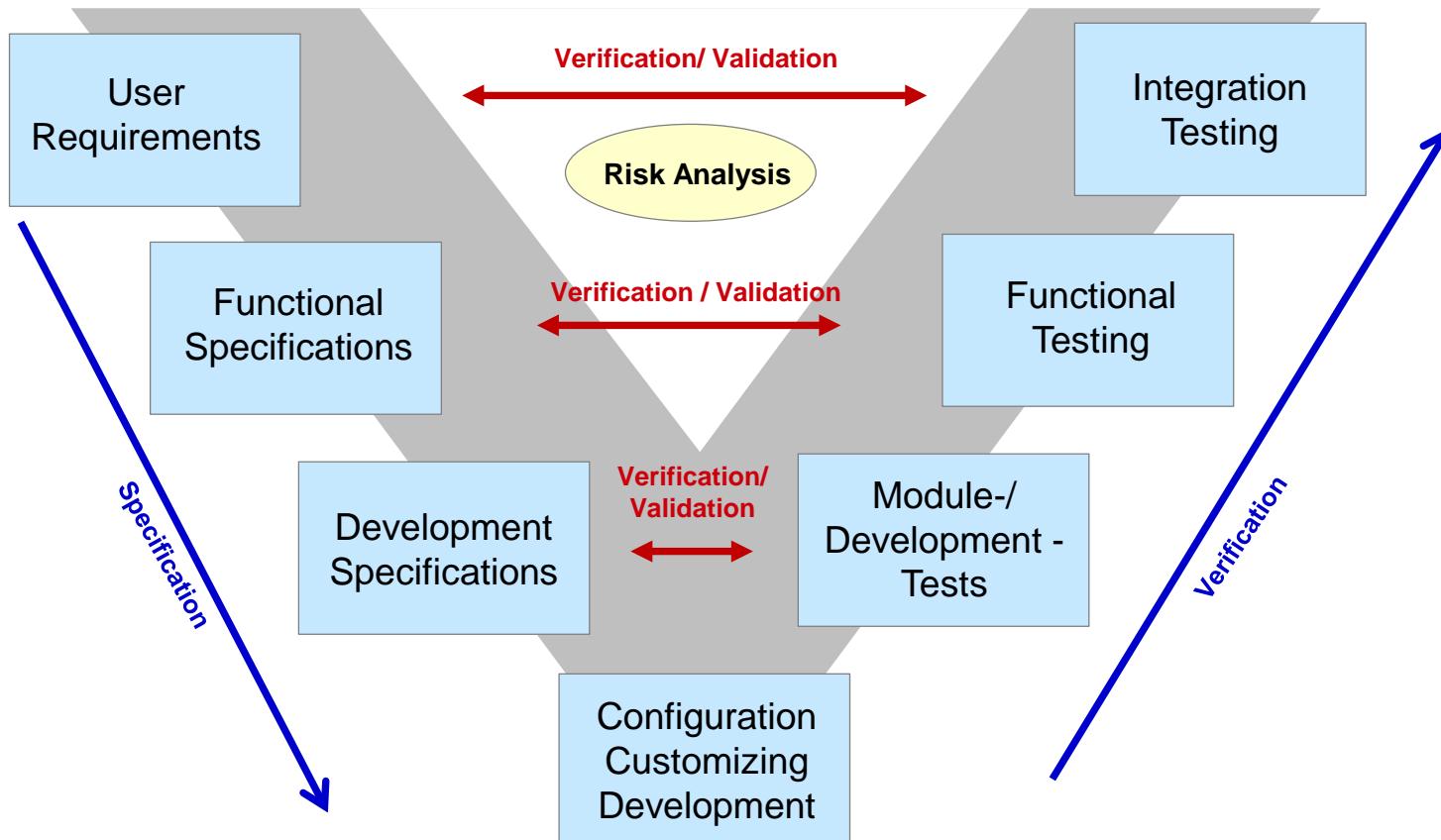


Quelle: Heupel Consultants

Agile And Regulated

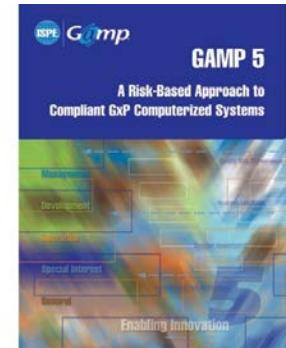
Classical Approach

**V-Model for prospective validation -
Sequential approach, each phase completed**



Requirements from GAMP 5

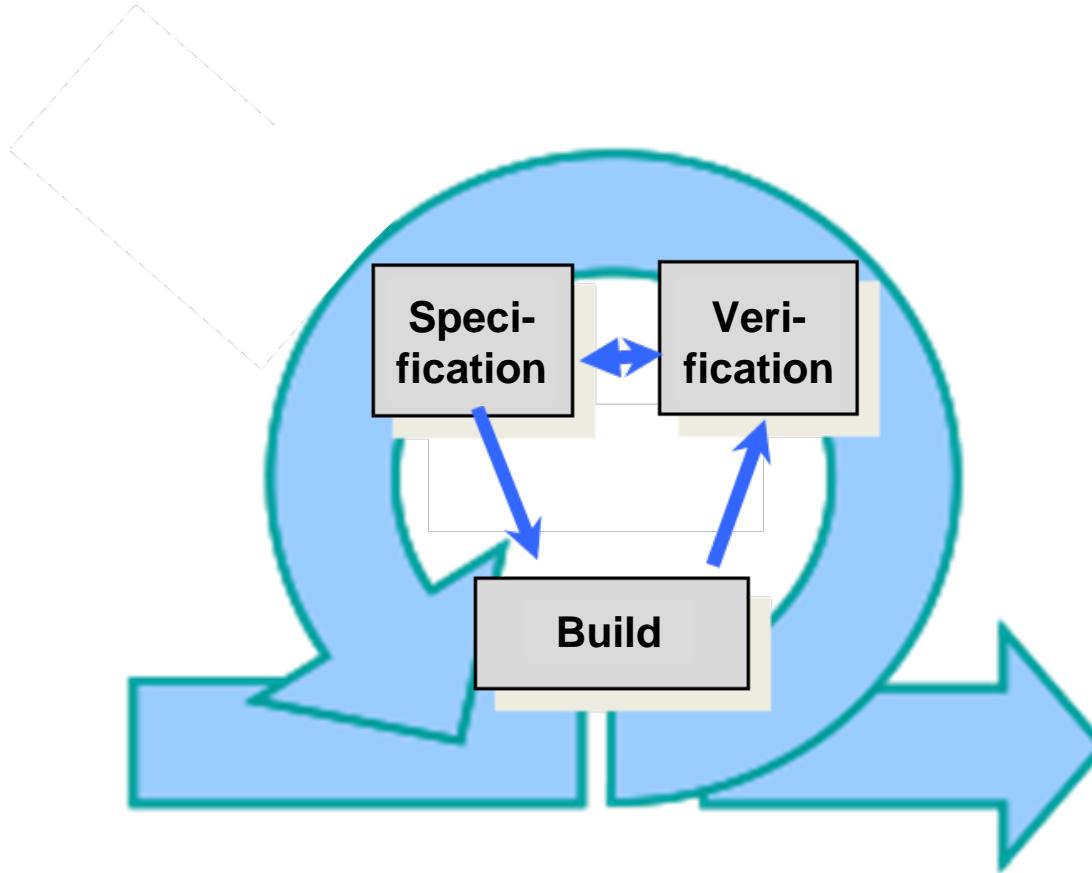
Quotes from GAMP 5 regarding Agile



- "Formal (change) control should **not be introduced too early** during development in order to minimize non-productive work during what are naturally iterative or evolutionary processes."
- "At the **end** of the development **phase** document review and approval should act as the **formal verification** that the document content is complete, accurate, and fit for intended use."
- "Changes made during approved prototyping work are **exempt** and should be subject to these controls **only** when they become **documented design proposals**."

Sprint As A Small Waterfall („V“)

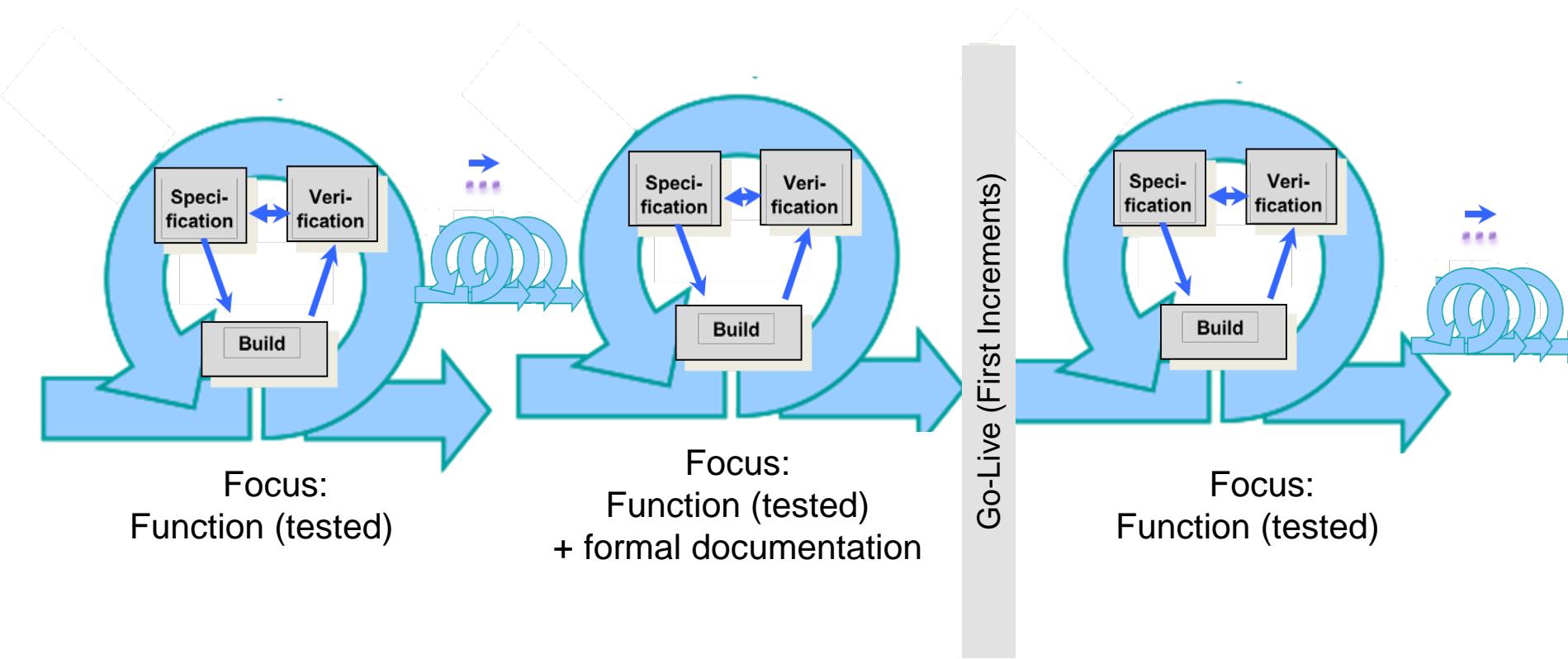
Sprint



Quelle: Komus/Komus, CHEManager

Possible Adapted Validation Procedure

Scrum cycle with sprint for formal proof in regulated environment



Quelle: Komus/Komus, CHEManager:

<http://www.chemanager-online.com/en/topics/pharma-biotech-processing/scrum-regulated-environment>

Good Arguments For Using Scrum

Close contact with people involved in the projects

- Direct user input for the formulation and prioritization of user requirements
- Testing of the product at the end of each sprint cycle
- Early user involvement and knowledge transfer

No accumulation of incomplete documentation

- With the end of the sprint all tasks have to be completely finished (for example with documentation and approval)
- No postponing of documentation

Accordance of documentation and **actual** updated technical and organizational system !



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Study Reports, Events
(mostly German)

www.process-and-project.net



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LinkedIn: <http://de.linkedin.com/in/komus>

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