



Agile meets Regulations

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

Expert Meeting in Basel | Wednesday 27. September 2017, 3 pm to 7pm

Principles of agile project methods like “Welcome changing requirements, even late in development” and “Deliver working software frequently” have strikingly proven their benefits over classic project management methods and, in times of globalization, are becoming more and more relevant far beyond IT-projects. Nevertheless using these methods in regulated business environments inevitably results in conflicts with common CSV procedures, as regulations and inspectors still expect documentation according to classic waterfall models as an documen-

ted evidence that systems are under control. The actual question is no longer if we need agile methods but how to bridge the gap between two worlds/convictions/beliefs!

This event will describe the current regulatory view on agile approaches and present possible solutions to close the gap. A vivid combination of presentations, discussions and networking will open up new perspectives to the participants and provide them insight into prior experiences of different companies in the pharmaceutical sector/ in regulated industry.

Target audience

Leaders and Specialists in the area of Software and/or Medical Device Development - Quality Assurance Managers, IT Planning & Strategy, Program and Project Management, Responsible persons for Project Methodologies and CSV, Heads of Project Portfolio Management and PSO

Location

Unternehmen Mitte - Salon Belle Etage, Gerbergasse 30, CH-4001 Basel

Due to the interactive nature of the event and in order to allow targeted discussions the number of participants is limited to a maximum of 30.

Contribution

CHF 195 / 180 €

Agenda

- 15:00 h Get Started - Coffee and Welcome**
- 15:15 h Keynote: The Future belongs to Agile Organisations**
Prof. Dr. Ayelt Komus, University of Applied Sciences in Koblenz
- Agility is not a choice – it's just the question how
 - Why agility is a substantial way to high quality and compliance
 - Benefits, spread and variety of agile methodologies
- 15:45 h Transition to an agile product development process for medical devices - an interim report**
Dr. Nicolas Schwenck, Technology Platform Leader, PARI GmbH
- Background: regulations and goals in the development process of inhalation devices
 - The small „V“ in the big „V“: concepts and measures to use agile methods in the regulated environment
 - First experiences: expected and unexpected challenges and wins
- 16:15 h Bridging the gap between Regulations and Agility**
Christoph Piller, Business Unit Manager Life Science & Healthcare, msg industry advisors
- Short overview on regulations, including new MDR
 - Conflict areas between agile methods and regulatory requirements
 - Solution approaches, risk management
- 16:45 h Get Connected - Break with Networking and Collection of Open Points & Questions**
- 17:15 h The right combination is the key: Realizing the advantages of Scrum in a regulated project environment with given constraints**
Claus-Peter Koch, CEO, Heupel Consultants Schweiz
- Learn about specific hybrid and scaled solution approaches with integrated documentation and review needs
 - Benefit from experiences and useful suggestions
- 17:45 h Open Panel Discussion: Agile meets Regulations - Clash or Synergy**
Interactive format (fishbow-elements); including questions from the participants collect during the break and in the process
- 18:30 h Get Connected – Apéro and Networking**
with experts from different companies and the speakers

Prof. Dr. Ayelt Komus is author of many well-known publications to agile method, agile PMO and initiator of many scientific studies in this field. This year he published the results of „Status Quo Agile (2016/17)“ – a study with more than 1000 participants in cooperation with Scrum.org and GPM.

▼ Complete this form and send it via email to info@msg-advisors.com or via Telefax to +49 89 96101-1113 ▼
Use our online-registration alternatively: www.msg-advisors.com/agile-meets-regulations

Yes, i will attend: 27. September 2017 | Unternehmen Mitte - Salon Belle Etage, Gerbergasse 30, CH-4001 Basel

Attendance fee: CHF 195 / 180 €

Name	Email
Company	Street
Position	ZIP City
Telephone	VAT Number

ATTENTION: This registration is mandatory. In case of absence, we will charge the full attendance fee. The substitution of an registered attendee with someone else is possible without charging an additional fee. All information is obligatory and only used by the event presenter.