



**TERUMOBCT**

Unlocking the Potential of Blood

# TERUMOBCT'S AGILE JOURNEY

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# Introductions

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Megan Morgan – Certified Scrum Master with Project Management experience.

Scott Phillips – Certified Scrum Master with 7 + years in agile project management.

# COMPANY PROFILE



<b>Established:</b>	1964 as COBE Laboratories
<b>Mission:</b>	We improve lives through innovation, quality and services enabled by our technologies
<b>Customers:</b>	Throughout 130 countries, with average relationships spanning 20 years
<b>Associates:</b>	More than 6,000 globally
<b>Innovations:</b>	700 granted patents and 100 pending patent applications
<b>Global Headquarters:</b>	Lakewood, Colorado
<b>Regional Headquarters:</b>	Brussels, Buenos Aires, Singapore, Tokyo
<b>Manufacturing Facilities:</b>	Belgium, India, Japan, Northern Ireland, United States, Vietnam
<b>President and CEO:</b>	David Perez
<b>Parent Company:</b>	Terumo Corporation, founded in 1921, Tokyo Stock Exchange (4543)

# Challenges

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- Predictability
- Transparency
- Scheduling
- Collaboration
- Process gaps

# Comparison of Concepts

*How does it compare?*

## Traditional Methods

- Project focused
- Plan driven
- People brought to the work
  - Task-switching, multi-project
  - Team changed as necessary
- Scope is locked
  - Change is difficult

## Agile Methods

- Product Focused
- Value driven
- Work brought to the Team
  - Focused
  - Team remains intact
- Scope is dynamic
  - Responsive to change

# Role Based Approach

- Agile Teams are role-based with 3 primary roles
  - Product Owner
  - Scrum Master
  - Development Team
- Agile teams work with support from the larger product team
  - Including PMO, Quality, Regulatory, Commercial

# What does FDA and Design Quality think of Agile?

- “Based on the intended use and the safety risk associated with the software to be developed, the software developer should determine the specific approach, the combination of techniques to be used, and the level of effort to be applied. While this guidance does not recommend any specific technique or method, it does recommend that software validation and verification activities be conducted throughout the entire software lifecycle.”

## **GPSV: Page 1 – General Principles of Software Validation: Final Guidance for Industry and FDA Staff**

- The quality system requirements do not dictate the types of design process that a manufacturer must use. Manufacturers should use processes best suited to their needs. However, whatever the processes may be, it is important that the design controls are applied in an appropriate manner.”

## **Design Control Guidance for Medical Device Manufacturers**

- **What does Terumo Design Quality Team think of Agile?**



# How Does Agile Align with Design Controls?

- **Definition of Done**
  - Defined in WINs (Work Instructions) and SDQAPs (Software Development and Quality Assurance Plan)
  - Tasks considered for every story:
    - user needs and PRDs, software arch. updates, lower level requirements, detailed design docs, mitigations coordinated with risk management owners, coding and testing and impact analysis
- **Increment Review Ceremony**
  - All stake holders invited
  - Requirements reviewed
  - Functionality demonstrated
  - Design control artifacts reviewed
  - Project status updated
  - Dependencies reviewed



# How Terumo Benefited from Agile

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- Improved predictability
- Better responsiveness to change
- Improved team health
- Increased collaboration
- Enhanced philosophy

# Next Steps

*What Opportunities and Challenges do we still have?*

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- Introduce SAFe (Scaled Agile Framework)
- Organization alignment
- Continue reflecting and adapting



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**Thank you for attending!**  
**Share your experiences at**  
**#HWGSEC**

**Questions?**