Building an Agile Culture in a Regulated Environment

Michael Meissner, August 10th, 2011
Overview

• Omnyx – who we are & what we do

• Scrum Mechanics
  – Our Agile Adoption (Advantage)
  – Regulated Environments

• Culture Mechanics
  – Culture is Everything

• Organizational Heartbeat

• Lessons learned

• Things to tackle next

• Acknowledgements

• QA
OMNYX – WHO WE ARE & WHAT WE DO
Omnyx – Who we are & what we do

Established as an independent company Mar 2008

- Two locations in Pittsburgh, PA and Piscataway, NJ
- 105 employees

Joint-venture of GE Healthcare and UPMC

- Clinical insight of UPMC Pathologists with patented GE technology
- GE healthcare will be worldwide distributor of Omnyx products - provides customer service and support
- Outside those big parent companies, enabling Agility and not being slowed down by processes grown over generations

A GE Healthcare and UPMC Venture

$70 Million Research & Development Investment
Omynx – Who we are & what we do (2)

**United States**

- Educational: For conference / future educational reference
- Currently Reviewing
- Complete but not filed away

**United Kingdom**

- Signed out but waiting for follow up stains
- Incomplete: waiting for all slides and paperwork to come in.
- Need to review again with trainee or other pathologist

**France**
Omnyx – Who we are & what we do (3)

Today - Analog

This is really cool stuff that is a lot of fun to work on as it clearly impacts people’s lifes

Tomorrow - Digital
SCRUM MECHANICS

OUR AGILE ADOPTION (ADVANTAGE)
Scrum Mechanics – Our Agile Adoption

• Pretty much straight forward, fully embracing:

1. Visibility / Transparency
2. Predictability
3. Continuous delivery
4. Continuous learning \((\text{and thus improvement})\)
5. Be respectful of people’s time

• Do not compromise … otherwise you start eroding your potential.

⇒ We refer to this as Scrum Mechanics
Scrum Mechanics – Our Agile Adoption Advantage

Started from scratch:

• **Greenfield** environment

• Hired the **right people**
  *(CEHHS, no thanks to ScrumBut)*

• Everybody co-located *(one exception)*

• No historic people “baggage”

• Started with absolutely **no legacy code**

• Built out the **office space to foster collaboration**

• **Top-down** support for Agile and bottom-up effort

• Development, Test, Technical Writing, Implementation and Service all under one roof, Marketing its own group → **only very few silo issues**
Our Scrum Mechanics – Basics … done well

Sprint Planning

Sprint Review

Sprint Retro
Our Scrum Mechanics – Release Review
Scrum Mechanics – Release planning

“Forbidden City” Approach:

• **Avoid mad scramble** at release transition

• Plan next release during ongoing release

• “Guard” the scrum teams (*productivity*)

• Incremental maturing of release content
SCRUM MECHANICS
(Regulated Environments)
Regulated Environments
FDA: Design Input, Outputs, and Traceability

• Design Inputs:
  – Marketing’s Product Requirements Definitions (PRDs)

• Design Outputs:
  – Engineering’s Software Requirement Specifications (SRSs)
  – HCD’s UI specifications (drawings)
  – Engineering’s SDDs

• Design Verification and Design Validation
  – Test cases

• Design Traceability
  – Input to Outputs
  – Outputs to Test cases
  – Code / change sets to features / defects
PRD:
As a histologist, I must be able to manage patient records so that the pathologist is able to see details of the patient during diagnosis.

SRS:
- The system shall provide patient entry.
- The system shall allow to activate / inactive patients
- The user shall be able to update first name
- The user shall be able to update last name
- The user shall be able to update DoB
- Etc.

Sprints:
- Granularity of work items so that they can fit into a sprint
Regulated Environments – Key issues

“Dilemma”: Working software over comprehensive documentation:
- FDA is about patient safety: plan, document, assess risk, and execute
- We produce artifacts incrementally; formal Design Verification every release
- Export to “paper” artifacts which get managed in DHF (820 part 11 compliant)
- “Show stopper”: lack of revision control across multiple releases

Vendors: Agile Tooling is a real issue (gap in 820 Part 11 compliance)
- Dean Leffingwell’s blog: http://scalingsoftwareagility.wordpress.com/category/high-assurance-and-regulated-environments/
- Whitepaper by Dean and Craig Langenfeld (RALLY) to follow shortly
CULTURE MECHANICS
(CULTURE IS EVERYTHING)
Culture Mechanics – Culture is Everything

Observation:
• Scrum by itself is **not enough**
• Adding people into the mix is **not enough either**
• You will get good results but will you get great results?

What is missing?
• **It is people** we expect to work together, not robots
• People are rarely up-front about issues (**lack of trust**)  
• People like to use a backdoor to vent about something (**avoidance of conflict**)  
• Without trust and healthy conflict, commitment, accountability, and results are limited  
• We need a foundation to enable lasting high-performing teams

➔ We refer to this as **Culture Mechanics**

High Performing Teams(?)
Culture Mechanics – Culture is Everything

Lou Gerstner (former Chairman and CEO of IBM):

“Culture isn’t part of the game – it is the game”

Culture Mechanics:

• Think beyond coding and technical problems
• Help self-organizing to optimize beyond local maxima
• Foster the right atmosphere for a team / teams to become great
• Encourage constructive and honest peer-to-peer feedback (really hard)
• Tweak the team compositions (yes, for cultural reasons)
• There is a huge missed potential
Culture Mechanics – The 5 Dysfunctions of a Team

Books by Patrick Lencioni:

- The THREE SIGNS of a Miserable Job
- The FIVE Dysfunctions of a TEAM
- The FOUR OBSESSIONS of an EXTRAORDINARY EXECUTIVE
- DEATH by Meeting
- SILOS, POLITICS, and TURF WARS
- The FIVE TEMPTATIONS of a CEO
Culture Mechanics – Culture is Everything

What we did / do about it:

• Developed our own Core Values (team building event)
• Adopted an Excellence Credo (try to “nail it”)
• Actively celebrate contributions to above (Top3 / Bottom1 Monday’s Keynote)
• Focus on “The 5 Dysfunctions of a Team”
• Conduct one team building event per sprint
• Coach individuals on their team effectiveness
• Utilize instruments such as MBTI, StrengthFinder, Predictive Index, TKI, etc.
• Use SBI's to provide non-projecting mechanism to provide feedback
• Daily Brain Teaser (since 2+ years)

• Note: This is hard because Engineers are a bit “geeky”
Culture Mechanics – Culture is Everything

Team Building:

• Helps reduce BIBS syndrom / fatal attribution error
• Get people out of their day-to-day rhythm
• Mix people up across scrum teams and functions
• Challenge them in a playful way
• Don’t forget to have **fun**
• Make sure there is learning, too
• Teams to comment on what went well / not so good
• Managers to follow-up coaching individuals
• Everybody can host one
Culture Mechanics – Management Structure

Matrix organization with managers driving / facilitating:

- Architecture (incl. Tech Debt)
- Test (Exploratory, Regression, Automation, etc.)
- Implementation & Support
- External relation- and partnerships
- Scrum (release and sprint planning)
- Mentoring / Coaching (things just don’t happen because you have a process in place)
- Self-organizing (It takes effort)
- Continuously build culture (Excellence Credo + Core Values)

→ Management plays critically important role to grow the culture
ORGANIZATIONAL HEARTBEAT
Organizational Heartbeat

Need to combine **Scrum Mechanics** and **Culture Mechanics**:

- **Releases and sprints** execution
  - 3 month releases, 6 iterations (*commitment and results*)

- **One team building activity** per sprint
  - Get people together to interact in playful manner (*builds trust and enables coaching opportunities*)

- **One team meeting** per sprint
  - Celebrate individuals&teams (*Top3, Bottom1; Positivity*), provide bigger perspective, etc.

- **One manager session** per sprint
  - Coaching, check SBIs / peer feedback, follow-up on conflict situations that arose, etc.

- **Incremental release planning** for subsequent release
  - “Forbidden City” approach
Organizational Heartbeat

Scrum Mechanics

3 months release

Release Planning

Sprint #1
Sprint #2
Sprint #3
Sprint #4
Sprint #5
Sprint #6

Release Planning

Sprint #1
Sprint #2
Sprint #3
Sprint #4
Sprint #5
Sprint #6

Culture Mechanics

Team Building Activities, Team Meetings, and One-on-One Sessions

Culture

Execution Roadmap

1 2 3 4 5 6
1 2 3 4 5 6

3 months release

1 2 3 4 5 6
1 2 3 4 5 6

Team Meetings, One-on-One Sessions
LESSONS LEARNED
Lessons Learned

Scrum Mechanics:

• Agile is fragile, establish an Organizational Scrum Heartbeat

• Short term wins are easy

• Agile requires constant effort to keep and improve the beat

• Engage an external consultant / coach (really important)

• Educate on Regulated Environments (early and often to get broad buy-in)

• Use Checklists (release and sprint review, planning, etc.)

• Always over-communicate (you never communicate enough, this is not just e-Mail)

• Push metrics to internal retrospective meeting, not sprint review (pointless point questions and debate with external stakeholders take away from review)
Lessons Learned

Culture Mechanics:

• Agile is fragile, establish an Organizational Culture Heartbeat
• Short term wins are hard
• Agile requires a culture that enables & empowers it
• Culture needs to be actively fostered and that takes time
• Coaching is critical (not just on the process but day-to-day with individuals)
• Middle management layer is critical (need the right material and capacity)
• Manage poor performers out (Zero voluntary FTE turn-over in 3 years)
Lessons Learned

There are two pieces to building **high performing teams**:

- **Scrum Mechanics**
- **Culture Mechanics**

**Essential:**

- Work on “The 5 Dysfunctions of a Team” (*fundamental to Scrum*)
- Build an environment where any issue can be raised
- Get comfortable to be uncomfortable (*everybody, no exceptions*)
- Always encourage to “Pull the pain forward”
- “If you don’t add to the culture, you take away from it” (*everybody*)
THINGS TO TACKLE NEXT
Things to tackle next

Culture Mechanics:
• Tackle lack of passion for the customer (*most puzzling*)
• How to effectively persist and robust a culture? (*Build to Last*)
• Do great companies need a CCO / CAO? (*Chief Culture / Agile Officer*)

Scrum Mechanics:
• Increase investment in *Automation*
• Further strengthen *Architecture* (*Dean Leffingwell’s book: “Architectural Runway”*)
• Establish a *Release Management Team*
• Short release cycle to *6 weeks*
• Establish high-level *roadmap* beyond next 3 months (*some people need that*)
ACKNOWLEDGEMENTS
Acknowledgements

• **Pete Behrens**, Trail Ridge Consulting
• All scrum teams @ Omnyx *(having fun at work is a great thing)*
• Sam Pareso, Scott Ross, Raghavan Venugopal, and Jon Kriebel, Omnyx
• CCL (Center for Creative Leadership)
• Andrew Deitsch, Erik Preiss, and many more at GE Healthcare
• Craig Langenfeld, RALLY
• Dean Leffingwell
• Barbara L. Fredrickson *(Tuesday’s “fantastic” keynote)*

• Reminder: Please fill out and hand-in your feedback forms. Thank you!