DevOps Culture in Life Science Implementing DevOps in a Regulated Traditionally Waterfall Environment



Peter Lega & Jason Victor, Merck

December 4–9, 2016 | Boston, MA www.usenix.org/lisa16 #lisa16







Introductions and About Us



Merck & Co., Inc

Healthcare Company

125 Year old healthcare company, in the Fortune 100, operating in 140+ countries, part of a highlyregulated industry



Applied Technology

Innovation Group

Bringing new technologies to speed up IT, creating new products and markets, enabling platformbased technical ecosystems.



Who we are



Peter Lega Director, Architecture

Applied Technology, former Web/ Content Management lead at Merck. 12 years in Health Science. Ancient Unix Kernel Hacker, Silicon Valley 1.0 (c|net), Middleware geek on Wall St, European commission. Automation dweeb.



Jason Victor

Assoc. Director, DevOps

Architect at Merck, DevOps Lead, 15yrs in Health Science, 17yrs in IT, 6 sigma greenbelt, ITIL Practitioner, Software Developer, Support Lead, Masters from Drexel University, Moravian College Mentor



Intro What we'll cover today



There is hope

It **is** possible to implement DevOps at a regulated company.



There is opportunity

DevOps presents an unprecedented opportunity to accelerate the science and practice of healthcare.



There are still challenges

Highly-regulated companies present unique challenges when introducing a technology culture like DevOps.





Our Appoach

Our multi-year journey to augment our traditional, waterfall methodology with DevOps/Agile culture and methodology



Tool Chain

You still need technology to support DevOps. We'll show you what we're working on.

Cultural Shifts

How we went from "that will never work" to "that's the new way to work."





Highly Regulated Industries

Definition: "a type of business that is controlled by government rules" ^[2] Regulations keep consumers/patients/populations safe.







LISA16







[2] Cambridge English Dictionary











"[Y]ounger baby boomers held an average of 11.7 jobs from ages 18 to 48." ^[1]

Exploding Sources of Data & Methods

- Longitudinal / IoT
- Genomic
- Historical
- Personalized Medicine
- Data-driven invention
- Open Data

usenix

LISA16

^[1] Bureau of Labor Statistics

the states

Why Now? It's the Perfect Storm



Talent & Culture

- Agile career mindset
- Cross-functional Organizations
- CrowdSourcing

• DEVOPS

The Growing Arsenal of Technology

- Big Data tooling and infrastructure
- Mainstream Platform-driven ecosystems & economies
- Collaborative-based tooling
- Quantum
- Open Source



Impact







^[3] J. A. DiMasi "Metrics on Technical Risks, Clinical Development Times, and Approval Times for Cancer Drugs"







Community

Foster a community - Bottom up w/ Key Decision-Makers

DevOps Platform

Co-Create an IT standard DevOps platform



How? Our 4 Key Strategies





Improve

Iterate, improve, & Publish KPIs

Over-communicate





usenıx

Foster a Community

Key executive sponsors in word, wallet and deed.

Delivery-proven SW experts from both traditional and emerging sides.

(regulatory waterfall and agile/DevOps/tech)

The authoritative approvers (quality, compliance)

An effective training and communications group

Key senior SMEs/leaders willing to facilitate crossorganizationally

A set of first-follower business partners.





Software Development Extremes



Traditional Regulated MindsetRisk AverseDeliver complete solutionSpecialization and hand-offsGet it right / lock it downFocused on Quality of Output





VS

Innovation Mindset (Agile) Fail Fast Minimum Viable Product (MVP) Cross-disciplinary teams Continuous Improvement Focused on Quality of Output



Bridging Understanding With "Why"



Traditional Regulated Mindset

Decrease Failure -Risk Averse -Fail Fast Deliver Right Product-Minimum Viable Product (MVP) Deliver complete solution Specialization and hand-offs-Increase Efficiency -Cross-disciplinary teams Get it right / lock it down Continuous Improvement Focused on Quality of Output — Increase Quality — Focused on Quality of Output







Innovation Mindset (Agile)













From Conflict to Synergy

Traditional

Established Support and Operations at Scale

Global Coverage

Global Communications Services

Mature Regulatory Services

Deep Regulatory Knowledge



DevOps

Viral Collaboration Ecosystems

Increased Transparency

Accelerated Software Delivery

Culture of Innovation & Invention

Industry Edge Sensing















From Conflict to Synergy Traditional AND DevOps



- Established Support and Operations at Scale
 - Viral Collaboration Ecosystems
 - Global Coverage
 - Increased Transparency
 - **Global Communications Services**
 - Accelerated Software Delivery
 - Mature Regulatory Services
 - Culture of Innovation & Invention
 - Deep Regulatory Knowledge
 - Industry Edge Sensing





Our 4 Key Strategies











Improve

Iterate, improve, & Publish KPIs

Over-communicate



Our DevOps Toolchain



usenix LISA16



Our 4 Key Strategies

Community

Foster a community - Bottom up w/ Key Decision-Makers

DevOps Platform

Co-Create an IT standard DevOps platform







Improve

Iterate, improve, & Publish KPIs

Over-communicate



Iterate, Improve & Gather Insights

Process that grows over time

Start with the **basic** code check in Wiki, Issue Tracking

CI / CD Suite

Git Repo

Collaboration Suite

Automate



Partly Qualified

Regulated processes can use pieces of the DevOps Stack

Fully Qualified

Regulated processes can fully utilize the DevOps Stack



Acceleration of Dev Tools Usage

Active Projects



usenix LISA16

Active User Count

JIRA 1,300

Confluence Bitbucket 3,300 500





Acceleration of APIs

API Usage



API Costs per user CENTS





Iterate, Improve & Gather Insights Rinse & Repeat

-2	Own search in	and it does not depice	3				
-	Environ benefit	ter Seatter a		-	-		
T.	10.0	e terrachiera	There is shown	81.545	Hint. Real-		
3	(Auto-auto-						
	The State of Contract of States and States						
		A LAND THE AND A LAND		A Table Preserve	A strat management		
		R retre to A Transforming to Constant integral		A property and	Lands and S		
		A Statistics		Tanta Setantiski Setantiski	A STATUS		
		A Loss IN Loss and		A State	Antonio a Antonio Antonio antonio Antonio Antonio antonio Antonio antonio		
		B constant		A second	States and States		
		A PanAm - Advance the		HPORT-38 A Paccard - Portfolo	A Snowman - AT Brandin Do you need b		
0		HPORT230 APT Government		HPORT-37 Syttx - Healthcare IT Platform	HPORT40 Glas - Massive and/or Sparse data set Visualization		

Inform the portfolio

Cross project insight & improvement



Working MVP in 2 months





÷		The second	0- 8-
2		The second strength of the second sec	0 m
-	Treesing of	-	0-
1		10-1 Standa presed waters in tables in case of Recordspine	0-
		() 	0.4
		2m 00	America and and a
-12		() And a first star	
		Their Road	-
	Clir	nical Trials Ap	р
	6 m	onths instead of 18	}

Our 4 Key Strategies



Community

Foster a community - Bottom up w/ Key Decision-Makers

DevOps Platform

Co-Create an IT standard DevOps platform







Over-communicate



Over Communicate

















In the Spirit of Over Communicating... Our 4 Key Strategies



Community

Foster a community - Bottom up w/ Key Decision-Makers

DevOps Platform

Co-Create an IT standard DevOps platform









Iterate, improve, & Publish KPIs

Over-communicate







Impact







Remember - It's Personal



Impact









