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

Peter Lega & Jason Victor, Merck
Who we are

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 highly-regulated industry

Applied Technology
Innovation Group

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

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
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 Approach
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.

Why Now?
It’s the **Perfect Storm**

“[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

**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

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Impact

- Reducing cycle time
- Discovering things faster
- Health - Improving lives

Cycle Time

- Launch
- Phase IV
- Clinical
- Pre-clinical
- Discovery

J. A. DiMasi “Metrics on Technical Risks, Clinical Development Times, and Approval Times for Cancer Drugs”
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
Over-communicate
Over-communicate
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 cross-organizationally

A set of first-follower business partners.
Software Development Extremes

Traditional Regulated Mindset
- Risk Averse
- Deliver complete solution
- Specialization and hand-offs
- Get it right / lock it down
- Focused 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”

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**Innovation Mindset (Agile)**
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- Decrease Failure
- Deliver Right Product
- Increase Efficiency
- Increase Quality
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

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Iterate, Improve & Gather Insights

Process that grows over time

- Git Repo
- Collaboration Suite
- Automate
- CI / CD Suite
- Wiki, Issue Tracking

Start with the basic code check in

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

<table>
<thead>
<tr>
<th>Quarter</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>150</td>
<td>300</td>
</tr>
<tr>
<td>Q2</td>
<td>150</td>
<td>450</td>
</tr>
<tr>
<td>Q3</td>
<td>150</td>
<td>600</td>
</tr>
</tbody>
</table>

Active User Count

- JIRA: 1,300
- Bitbucket: 500
- Confluence: 3,300
Acceleration of APIs

API Usage

API Costs per user

Requests/Month (thousands)
GBs/Month

CENTS

2015 2016

Jan 2016
Feb Mar Apr May Jun Jul Aug Sep

0.8
0.6
0.4
0.2
0

Public
Iterate, Improve & Gather Insights

Rinse & Repeat

Inform the portfolio
Cross project insight & improvement

Sales App
Working MVP in 2 months

Clinical Trials App
6 months instead of 18
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Over Communicate

- Telling stories
- Sharing success
- Showing data
- Plain English, please

"Is there such a thing as over communicating?"
In the Spirit of Over Communicating…

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Remember - It's Personal
Any
Questions?