## Tidepool FDA Pre-submission Meeting Minutes

June 2, 2015, 10:30am EDT
Food and Drug Administration, 10903 New Hampshire Ave., WO 66, Silver Spring, MD 20993
Pre-submission Document ID: Q150777

Attached: Presentation and pre-submission agenda.
Note: [Comments in brackets have been added after the meeting to provide additional clarity.]

## Attendees

Tidepool

- (in person) Howard Look, President and CEO
- (by phone) Brandon Arbiter, VP Product and Business Development
- (by phone) Sheila Ramerman,  SJR Associates, software quality system consultant

FDA

- Stayce Beck, Branch Chief
- Joshua Balsam, Reviewer
- Alain Silk, Review
- Seth Carmody, Reviewer

## Overview

Howard:

- We're moving quickly. We built a quality system. We're proud of it. We're going to publish it openly.
- Tidepool is non-profit, open source.
- Received grant from JDRF for Uploader.
- Received grant from Helmsley Charitable Trust for Tidepool Platform.
- Goal today: Feedback on our quality system. It likely won't look like what you've seen before; but we do think it's conformant to 820.30 and ISO 13485.
- Inspired by Bakul Patel's writings, AAMI TIR45.

Stayce:

- Comment re: Quality System: "Lots of folks wish they'd done that [build a quality system from the beginning of the project] to start with. It may not be required now [for any given project], but it may be in the future."
- Regarding decision by Tidepool to limit to age 13 and up: On our end, we're not concerned with age (under 13) but understand you have COPA (children online protection act) to address as well.

## Brief overview and Demo of Blip

Howard:

- Brief Blip demo.
- We've done tons of usability testing, gotten great feedback. For example, parents of kids said they want to see M,W,F for soccer practice, so we build a filter to allow selection of days.
- Can hover over a BG to data value.
- Click into a BG and see data from CGM and pump, too.
- Fourth device is mobile phone for contextual notes.

## Overview of Tidepool Platform

Howard:
Tidepool platform is usable by other application developers to store diabetes-related data. Example of diabetes application ecosystem: Doug Kanter's application, Meal Memory.

FDA: Is there a hosted solution [for application developers]?
HL: Yes, developers can use a hosted version of the platform and treat it like their own database. Or they can leverage the existing, hosted Tidepool Platform, one patient at a time for free, as authorized by the patient.

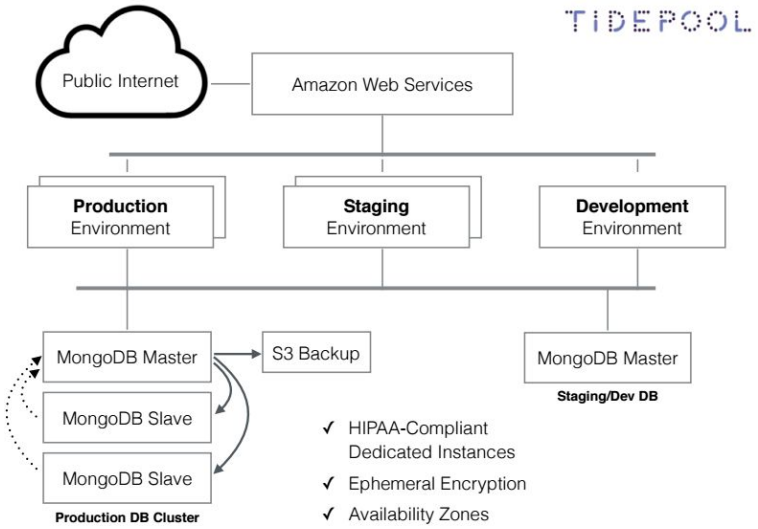
FDA: Is there T1D Exchange Registry integration?
HL: Yes. [In the near future we will be asking all users of the Tidepool Platform if they would like to donate their data to the T1D Exchange.]
FDA: We're interested in having patients donate data to us as well.
[Tidepool - we are certainly open to that. Would need the FDA sets up a web or mobile application that can gather data and uses Oauth and APIs to allow the Tidepool user to connect with the FDA application. In all cases we believe that the patient owns their own data, so it would be at their discretion.]

## Architecture Overview

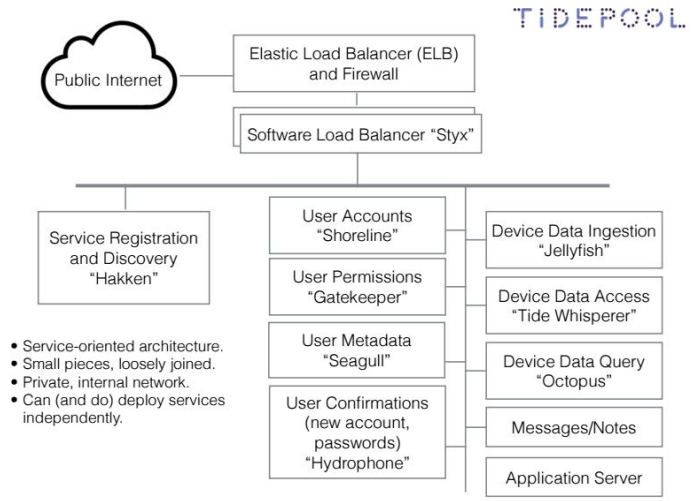
Howard:

- We use AWS. [Amazon Web Services]
- Have multiple testing environments [Dev and Staging, as well as developers local environments]
- Redundant Mongo databases [Master and two slaves], plus daily backups.
- HIPAA compliant
- We maintain no physical hardware

FDA: This is what RackSpace does?
HL: Yes, similar. They are a competitor to Amazon [Web Services].




We have a service oriented architecture where we can deploy small, modular pieces with very limited risk to the whole system.




## Security Overview

HL:

- Data is encrypted, can't be physically stolen.
- Each user has their own key. If you managed to crack one user's key, it would only work with that user.

FDA: Unlike [large retail examples], who got their entire DB cracked?

HL: Exactly. [Discovering the encryption key for one user only works for that user, not the whole database.]

## Tools

Howard:

- We use modern tools. And we apply them to an 21 CFR 820 regulated environment.
- **Google Docs** - Enterprise version. Two-factor auth. Docs in quality system are under change control. For example, for some documents, only Brandon and Howard can make changes to docs; engineers can only view and comment.
- Folders 00 - 99 are under document control, in the quality system
- Folders 900+ are not in the quality system, not under change control.
- Revision history is provided by Google for all changes. We control who get to make changes.

FDA: You mentioned 2 factor auth, is that just for logging in or for editing? What happens if someone steals your laptop?
HL: Policy for timeout on laptop screensaver is 5 minutes.
BA: All new employees and new equipment goes through a security audit.
[All Tidepool employee and contractor laptops use encrypted filesystems and strong passwords. All accounts used for Tidepool systems use 2-factor authentication.]

HL: **Trello**

- Great for collaborating on bugs, features, etc.
- It's part of our quality system.
- Work is split into sprints.
- Work flows left to right, starting with Epics, the big goals of the sprint. On the right, the software deployments we've made. Trello cards include the requirement, the GitHub pull request. Every change is peer reviewed. Each Trello card has a test preocess associated with it.

**Design History File**: Data from Trello cards is consolidated in Google Sheets, comprises the DHF for each major functionality area.

**GitHub** - our code repository
Tags: version numbers indicate the latest release and pre-release versions
Click on the tag and you can see all the source code. Reproducing this deployment of code is a requirement of 820, this does it.

**Verification and Validation -**

- We do a ton of automated testing
- We also do manual testing for UI/UX

- For automated testing, we use TravisCI
- Anytime code is added to GitHub, a large suite of automated tests are run
- If a bug isn't caught, we will attempt to write a new test to catch it. This way the number of tests keeps going up.
- Data ingestion ("Jellyfish") for example has over 700 automated tests.
- For things that can't be caught in an automated way, we have manual tests.

FDA: How do you keep track of what requirement or risk control is covered by this test in terms of traceability?
HL: The Trello card with the requirement links back to the test.
FDA: Do you stress test this by trying to break the system?
HL: Yes, that's what many of the automated tests do, they test invalid values and see what happens.

**Standard Operating Procedures**
All documents are stored under change control in Google Docs

We hope others find helpful: in the SOP document we took the language from the CFR so it's clear exactly what we're implementing.

FDA: As open source, can people contribute code to Tidepool's software?
HL: Yes they can, but we curate the code. We review, test it, then consider it to be under our oversight. Only after it goes through that do we consider it part of our code base. We curate all of the code. We ultimately review and test everything [and take responsibility for all deployed code].

**Conclusion**
We are planning to release this openly. It will be available as Google Docs and on GitHub.

**FDA: That's great. The way to incorporate the tenets behind 820 into the modern world is great. This will help more companies around the world incorporate these practices.**

HL: In many cases, software developers are already doing the work [of building process that ensure quality]. It's just a matter of translating that into a documented quality system.

**FDA: "If Tidepool is willing to go out and talk about this to people, it would be a big benefit to the community."**

HL: Definitely open to that as time allows.

FDA: It looks like you've got all of the pieces [of a quality system] they are just in disparate places; you're familiar with flow. If you got inspected, if inspector said "hey where is this?" as long as you could pull it up, it will pass.

**FDA: Sheila, great work. This is awesome.**

Sheila: I kept asking how can we give a human readable version of this, and that's where the DHF table came from.

**FDA: Traceability table is key. The inspector will need a map. This table provides a map.**

FDA: Tidepool is on a better path than most.

HL: Look through the documents in the pre-sub. If you want to see more documents, let us know and we'll send you more.

**Stayce: Everything I've seen here is outstanding. It's good for you as company and will benefit a lot of people.**

---

**Additional clarification between Stayce Beck and Howard Look**
Later that week on June 7, 2015, Stayce and Howard had an additional in-person conversation at the ADA Conference in Boston. Howard showed Stayce the application prototype screen shots below showing the use of **real-time Continuous Glucose Monitor data in a secondary display via mobile applications. Stayce confirmed that applications such as these would be considered Class 2/Exempt.**