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Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

To whom it may concern, Dr. Stayce Beck, et al.

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Minutes to Q141084/S002 follow

Sincerely,

Ben West

Meeting Minutes Q141084/S002

On January 27th, 2015, Nightscout contributors met with FDA at 12pm EST to discuss progress updates, and begin to address open questions from previous discussion Q141084.

Summary

- FDA provides updates on de novo classification
- Projects like Nightscout encouraged to document quality controls and fulfill regulations.
- FDA is waiting on the `#wewearenotwaiting` community to finish the pending documentation in order to become eligible, expresses frustration that the documentation is not ready yet.
- Guidance on designing and documenting controls
- Quality controls as tool for community
- Editorial tips
- Future work

Attendees

Nightscout contributors Dana Lewis, John Costik, Kevin Lee, Ken Stack, Stephen Black, Ben West

FDA

- Alberto Gutierrez, Director, OIR
- Katie Serrano, Acting Division Director, OIR/DCTD
- Scott McFarland, Regulatory Counsel, OIR
- Ariel Seeley, Attorney, OCC
- Rob Sauer, Policy Analyst, OIR/DPOM
- Steve Tjoe, Regulatory Counsel, OIR
- Ryan Lubert, Regulatory Counsel, OIR
- Beth Stephen, Lead Reviewer, OIR/DCTD

Discussion Topics

Introduction FDA led the discussion, beginning with updates on how `de novo` classification with special controls can provide a pathway for secondary display.

`de-novo` regulatory pathway FDA highlighted the existence of a new pathway, designed to lessen regulatory burdens and foster innovation in the market, for devices like Nightscout to:

- register with FDA
- meet special controls
- meet appropriate validations
- document quality controls

Meeting these controls and other FDA guidelines provides a way for sponsors to access the market without requiring pre-market approval. FDA observed special controls related to the new de novo process include preventing unauthorized access to data, properly display warning against using for dosing, and labeling to emphasize that it's not intended to replace self-monitoring.

> There's a question in the press about whether Nightscout could meet this. Yes, you could - but you don't meet requirements yet and you're not listed with FDA. But this gives you a path forward, and hopefully you would do so, so you could offer your product in a legally marketable way.

While there is now a clear regulatory pathway, FDA notes disappointment in the readiness of the prepared documentation. FDA relies on snapshots of prepared material for rigorous review. While the prepared documentation loosely outlines the process, a much more thorough explanation of how each part of the process works is required along with how that process relates to the regulations. FDA is hoping Nightscout will prioritize documentation needed to review eligibility for this process.

FDA outlined special controls for Nightscout would include the following:

- Devices must protect against unauthorized access to and modification of data.
- Device labeling must display the following warning "Dosing decisions should not be made based on this device. The user should follow instructions on the continuous glucose monitoring system."
- Device labeling must include the following limitation "This device is not intended to replace self-monitoring practices advised by a physician."

Guidance on designing and documenting controls

> This is for the Nightscout community to use – its not for the FDA specifically – this needs to be a tool the Nightscout community is using.

The group discussed the role of quality controls, and their relationship to the community and to reguators. Establishing a quality system registered with the FDA is a foundation which can be augmented to support additional projects. The point of establishing quality controls is to provide the community with a tool to help ensure safety. As risk increases, additional controls such as IDE and IRB are used to ensure oversight.

Editorial tips The group discussed FDA need to refer to submitted materials that have been reviewed in order to discuss them, links to live or changing documents make it difficult to identify, what if anything, has changed, increasing the burden on reviewers. The group discussed how to iterate through regulations as a rough guide. However, the beauty of the way the regulations are written allows you to address your community's needs in whatever way best suits your community. The FDA explained that they look to see that the information and documentation created are being used to ensure safety.

FDA suggested focusing on practical questions, and documenting how different parts of the system, such as Github issues, or Facebook groups work as well as how they are used by the community. Nightscout asked about potential relevance of several linked resourced to regulations. While README's and summary of issues may be useful, the FDA is looking for a clearer explanation of how these resources are used by the community, and how they relate to the regulations.

Future work The group discussed the need to prepare documentation that is ready for review as a tool for the community and regulators. While there eventually does need to be a single resource for a reviewer to evaluate compliance against all regulations, FDA recommends starting by thoroughly answering a few questions to help break up the work. When these documents are available for review, the resulting quality control system serves as foundation which can be used to help facilitate additional work with the FDA.

The group discussed the existence of projects often accompanying Nightscout that are higher risk. The FDA outlined additional controls such as IDE and IRB that are needed in addition to the quality system controls discussed, especially as risk increases. In particular when Nightscout's quality control system is properly documented and registered with the FDA, while Nightscout could become eligible for the `de novo` application, the elements of that system can be re-used to help augment the controls for the advanced projects as well.