2019 Summer Meeting Minutes

Location: The Brown Palace Hotel & Spa (Central City) · Denver, Colorado

Date: Wednesday, July 24th, 2019

Time: 12:45pm – 5:30pm EST

Attendees: (See Attachment 3)

Agenda Topic	Presenter
Welcome, Introductions, Reading of Meeting Guidelines & Meeting Logistics	Stacey Bonnell

Stacey called the meeting to order and welcomed attendees. Stacey read the meeting guidelines verbatim and reviewed the meeting and dinner logistics, and attendees (both OSMA members and guests) introduced themselves. Stacey introduced Lisa Boyle to present the guest speakers.

FDA Conference Call	Ronald Jean, Ph.D.

Officially under the OPEQ structure.

OHT6 Staffing
-New leadership moving forward.
-Interviewing for 3 divisional directors (Joint, Spine and Restorative/Stereotactic and Fracture Fixation)
-2 assistant directors (Joint Arthroplasty – both knee and shoulder).
-CAPT Peat should make selections by the end of this month.

Future Activities
November 6,2019 OrthoCRN meeting
(Started out as spine focus but has expanded to include joint and trauma)

March 24, 2020 Orthopedics Town Hall Meeting (AAOS and FDA hosting)

QUESTIONS

To what extent does the agency expect companies to police the personal social media sites of their employees? If an employee of a company were to share / like on their personal social media site third party user-generated content which is not part of any marketing campaign, and it contained inaccurate or misleading information, is the agency likely to hold the company accountable?

Example: Bob sees a Facebook post with a TV News story about a device his company manufactures. During the TV news story, an individual makes unsubstantiated claims. Bob "likes" the story and shares it on his LinkedIn and Facebook pages. Is the company obligated to monitor this content or will they be held liable for promoting misleading information?

The Food, Drug and Cosmetic Act provides that a device is misbranded or adulterated if the device advertising or labeling are false or misleading, or if it changes the product's intended use/indications for use. The example described in the question above pertains to personal social media site visits of a manufacturer's employees, and FDA does not have particular statutory authority over a company's role with regard to the personal social media sites of its employees. The relationship between a company and its employees in this area, as in many others, can raise issues better addressed on a case-by-case basis. With this said, it may be helpful to have training and education offered to employees to make them aware of how to identify and handle inaccurate or misleading information that they come across; although not final, FDA has published a draft guidance, Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices, that outlines our recent consideration on this topic, and provides some guidelines that might be helpful if a manufacturer elects to correct independent third-party misinformation.

Which priority list is the draft Guidance document in?
Not sure. However, it represents our best, current thinking.

We are aware the 510(k) reviewers are searching the MAUDE database while conducting premarket reviews. How are these searches being done – by predicate brand name or by more broadly by FDA Product Code?

How does the agency reconcile this use of the database when the MAUDE website states:
"…this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data" and
"Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated."

There are a variety of methods that reviewers use to conduct MDR searches, including by trade name, generic name, product code and typographical variants. We do take into account the limitations of passive surveillance, but there have been valuable safety signals identified through this type of analysis both in orthopedics as well as other OPEQ product areas.

Reach out to team leads or assistant directors in each group for additional questions. Post market safety signals are more routine. There are a variety of uses on the premarket side.

Are there cursory searches on the premarket side?
Instruction has been given but likely need additional training. It is more cursory reviews. This is not truly new. Sometimes directed to new things through these searches.

There is an instance of an AI letter issued in response to a safety signal. Would that safety signal have been confirmed with the post market folk's evaluation?
Not sure about that specific example. The expectation would be that it has been verified with SME's.

The safety signal program was eliminated and now with OPEQ, it has formally been opened again. This program is run by OPEQ's front office. I would expect that if something is flagged, there would be some

communication with that party as well. Great feedback. If you have experiences like this and can share a specific example, I will take that back to CAPT Peat.

Please be patient with us. It's a new process. There have been rough expectations on how this should have rolled out. Definitely could be some misinterpretations. It is best to bring these to our attention.

What is the connection with the safety signal program?
If a safety signal is initiated on the post market side, (maybe via a FR or on the website), there is a formal process for this. They will take the info back, discuss with OPEQ management and determine if it's a truly a safety signal or not.

For premarket activities/ad hoc reviews that are not directly tied to a specific signal, could results from MDR database searches lead to an NSE?
Not sure. Hypothetically, it could be possible. It would need to be a product area event that would have impact. In 99% of cases, it is likely that type of action would not be expected. The intent is to make reviewers more aware. It should serve as a vigilance activity. Not expecting those to escalate.

Does FDA feel it will need to review summary of safety and clinical performance (SSCP) documents for Class II devices?
The SSCP is a requirement for the European Medical Device Regulations (MDR) and apply to Class III and implantable devices under their system and is not a requirement imposed by FDA. With this said, if the SSCP is included as part of a pre-market submission, such as a 510(k), the Lead Reviewer may look at this information.

If it is value added, submit. If it's not value added, recommend you not submit it.

Will labeling modifications that are required for MDR (e.g. patient implant card and CMR labeling) require submission of a 510(k) to the FDA or can it be documented internally?
It is recommended that you consult the document, Deciding When to Submit a 510(k) for a Change to an Existing Device - Guidance for Industry and FDA Staff, to determine whether or not a 510(k) submission is needed for any labeling modifications that are required for MDR (e.g., patient implant card and CMR labeling), as the extent of changes made from the existing labeling within a cleared 510(k) will likely dictate the need for a new premarket submission. When the interpretation is unclear, we are available to provide input on the proposed modifications.

FDA District Office Update — Lauren Priest

Safety signals can initiate a for cause or directed audit.
ORA has aligned so that investigators are more specialized now.
OMDRHO – Office of Medical Device and Radiological Health Operations

For Routine Inspections, is that scheduled at headquarters or how is it determined? Who makes that inspection schedule?
There is a risk formula that is used to determine the list annually. There is a list of criteria that firms must meet, and the criteria changes somewhat each year. CDRH and ORA work collaboratively to determine the work plan and then ORA does most of the scheduling. If it's a directed inspection from CDRH, it may have a more specific timeline, such as, audit the firm within the year or quarter.

For slide 17, it states not on 483 - "Registration & Listing". Why?
Registration and Listing SME's are located within CDRH, therefore ORA does not put R&L on 483s.

Post-inspection activities, best method of correspondence with ORA?
Respond via email (responses are only electronic now). The email address will be provided on a handout sheet from the investigator during your inspection. The email box is division-specific.

Is there a limitation on email size?
There likely is but I'm not certain what it is.

Is there guidance online for the desired format for the response?
No official format for the response.

Received a response that said, "could not review because was not provided". Could this be because the email reached the file limit size and was not received? How do we know?
There should be an auto response from the automated inbox stating, 'it was received'. If you did not receive the automated response, reach out to your Division to ensure it was received.

For post-inspection activities, is the review happening at ORA or CDRH?
It depends on the inspection. Typically review begins at ORA and CDRH may participate depending on the findings.

Does CDRH participate in it?
It depends on the issues found during the inspection.

Critical Quality Program – how much influence does that have in the field?
They haven't come out with it for all product types.

How many of those QSIT elements and findings connect with the scorecard?
Not sure.

For a regulatory meeting, should we bring legal counsel?
If it's at CDRH, you can talk to the review team in advance and ask who will be present. If they bring a lawyer, you can also bring a lawyer if you choose. If it's a meeting with ORA, you may ask the Compliance Officer that is involved. Generally, it is not necessary to bring counsel for a Reg Mtg.

Comment:
You don't need to include every supporting document in your response to a 483; use your best judgement. Also, don't just reference, "I opened a CAPA" in your response. Elaborate on the measures that you are doing. Especially if you still have product in the field. Assess the risk mitigation efforts and include this information within your response.

First warning letter with UDI just went out recently (within the last 2 weeks).

In developing a schedule for inspections, ORA makes the plan and CDRH might be able to provide suggestions (criteria), how often do you listen to them?
Always. Not sure how work planning goes. If CDRH requested an audit of a firm, that was audited within the last year, ORA would bring that up. Again, the criteria for selection changes slightly every year. ORA typically schedule inspections. It is a multi-factorial decision process in developing the annual inspection plan.

Pre-certificate Program for software medical device?
Podcasts available.

When all of the elements of the Warning Letter are satisfied, what's the process in making this public?
FOIA office makes the Warning Letters public and they are posted online. Companies can highlight to the public when a warning letter is lifted.

Regarding 510(k) premarket inspections (in response to De Novo guidance doc requiring "pre-grant inspections": Do we anticipate this happening in the future?
Lauren was unsure at this point; handled by CDRH.

Regarding inspections post-MDSAP audits: Can we expect inspections based on findings?
CDRH reviews all findings and can possibly send out FDA investigators if there are significant concerns, however, that's not Lauren's area so it's unclear what to expect at this point.