

**Minutes of the MedAccred Management Council**

28 August 2013 at SAE International, Warrendale, PA (USA)

1. **Participants**

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| **Participants** | **Affiliation** |
| Ken Stopar | Baxter Healthcare |
| Dan Whalen | Baxter Healthcare |
| Simon Adam | DePuy |
| Steve Niedelman | King & Spalding |
| Ashley Goldberg | Merz Aesthetics/Rx-360 |
| Ravi Nabar | Philips Healthcare |
| Denise Caldwell | Philips Healthcare |
| Jim Ahle | Stryker Corp |
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| Mark Aubele | PRI |
| Rebekah Braun | PRI |
| Hannah Godfrey | PRI |
| Mike Graham | PRI |
| Jim Lewis | PRI |
| Justin McCabe | PRI |
| Joe Pinto | PRI |
| James Steady | PRI |

1. **Opening Address and Welcome**

* Joe Pinto welcomed participants to the meeting
* Participants were reminded of PRI’s guidelines for antitrust compliance
* Participants introduced themselves

1. **Task Group Activities: Recap and Discussion**

Mark Aubele presented an update on Sterilization, Electronics – PCBA and Cable and Harness activities



* + Sterilization (see embedded PPT)
    - Steve Niedelman spoke with Kathy Bardwell of STERIS who is planning to ramp this proposal up to their CEO. STERIS was earlier concerned that the FDA would be an impediment. Desire to see an example of Nadcap checklist. STERIS has auditors and people that can help to educate Mark. Steve will follow up with Kathy.
    - **ACTION:** PRI to share Nadcap checklists with Kathy Bardwell (Due: 13Sept13)
    - Mark Aubele requested to observe a Sterilization audit or witness the process
    - Ken Stopar is looking to receive internal clearance for Mark to observe an audit
    - MedAccred should not wait to conduct a Sterilization PoC audit before approaching the FDA
  + Electronic Circuits – PCBA (see embedded PPT)
  + Cable and Harness (see embedded PPT)

Justin McCabe presented an update on Heat Treating and Welding Task Group activities

* + Heat Treating (see embedded PPT)
  + Welding (see embedded PPT)

1. **MMC Sub-Team Activities: Recap and Discussion**

Rebekah Braun presented an update on MMC sub-team activities



* + Proof of Concept Audits Sub-team
    - Welding Proof of Concept Audit Report
      * What objective evidence can we include that can be shown to the FDA? The goal is for the FDA to see all of the science behind the process.
      * In Aerospace, each Task Group shares a different amount of information, and is dependent on ITAR restrictions, etc.
      * The minimum that should be included:
        + Aerospace Audit Checklist
        + Actual checklist that was used: strong areas, areas that did not flow right, types of questions to include/remove.
        + Equivalence between the Aerospace and Medical Device industries
        + Highlight how the checklists address QMS as related to the Critical Process.
        + Demonstrate that the checklist is robust enough
      * It is important to protect the participating companies.
      * **ACTION:** Welding Task Group to conduct a gap analysis between the Nadcap checklist and Welding Proof of Concept audit (**Due: 16Sept13**)
  + Program Documents Sub-team
    - Audit Failure Criteria
      * Suggestion was made to define failure as an index, e.g. 1-5 criteria
      * Roles & Responsibilities:
        + MedAccred will communicate audit failure to industry and will handle the supplier’s accreditation status
        + Subscriber OEMs react and decide on actions to take internally regarding that supplier
      * Rx-360 provides 2 different kinds of observation rankings: Information sharing and Certification/Accreditation
        + For now, Rx-360 has gone the “information sharing” route and not the “Certification/Accreditation” route, where objective 3rd party auditors share information and allow the manufacturer to make the decision about their respective suppliers
        + OEMs are still interested in supplier certification, so Rx-360 is looking at this as well.
      * The Key will be clearly defining the Program’s alerts, feedback loops, failure criteria, etc.
        + This group needs to define the roles that each participating segment of industry will play in this program. What will PRI do? What will OEMs do? What will suppliers do?
      * Concern: PRI provides the intelligence. What is PRI doing to risk-rank that intelligence?
        + The Program Document Sub-team is to define MedAccred roles and responsibilities, failure criteria, consequences for supplier failure, etc.,
    - FDA wants and needs:
      * The speed at which the industry would be advised of a failed audit (see Failure discussion above)
      * The efficiency of the MedAccred process
    - Question: Is there a conflict of interest if suppliers pay for their own audits?
      * Answer: Steve Niedelman does not think this would be considered a conflict of interest, as there is a new focus on using 3rd party accreditation in order to reduce the number of audits through FDASIA. The FDA does not have the internal resources available.
    - Combo products – Medical Devices and Pharma are starting to converge and the lines are being blurred between them. We may need to consider how this program would meet the needs of Pharma as well.
      * Joe Pinto Response: MedAccred is “process” specific and it would not matter whether it was pharma or devices.
      * Steve Niedelman Response: FDA will like that the supplier is responsible for paying for a portion of the audit.
      * Industry participants will pay a subscription fee. The supplier will not pay to participate in the program, but pay only for the audit.
    - **ACTION**: PRI to create a 1-page document (i.e. FAQ doc) that explains how MedAccred will be structured so that it can be easily explained to industry and can be included in the report to the FDA. Relationships between industry participants. Device Manufacturers roles and responsibilities, Supplier roles and responsibilities, contributions to the program, etc. (Due: prior to FDA meetings)
    - Question: Do suppliers participate in MMC?
      * Answer: Yes, each Task Group nominates a supplier to participate on the MMC. Subscriber members represent their individual company. A supplier member does not represent their individual company, but represents the technology group that they participate in.
    - Question: Can problem suppliers participate in MMC?
      * Answer: Currently, audit performance is not considered for participation in Task Groups and the Management Council.
  + External Communications & Strategy Sub-team
    - The sub-team is planning a meeting with the FDA in mid to late October 2013
    - Steve Silverman and Jeff Shurin are the current FDA targets

1. **Subscriber OEM Definition**



* + Question: Do we want contract manufacturers (CMs) to be subscribers to the program?
    - Answer: Joe Pinto thinks they would bring expertise and could contribute to the program.
  + Everything ties into who holds the responsibility for “product clearance” – ie a specification developer
  + However, there are a lot of devices that do not require 510K, so we would need to be careful
  + The term “Legal Manufacturer” is not applicable in the USA
  + Participants decided to remove the following from the previous definition: “internal engineering and supplier quality management organizations”, because there are now many “virtual” companies in existence.
  + Question: How do we involve “virtual” companies? Virtual companies contract out for everything, though they are ultimately responsible for the final product.
    - Answer: Steve Niedelman thinks they will be involved in the program, as it will take some of the pressure off of them.
    - Jim Ahle disagreed.
  + There are CMs who are also OEMs. There are other CMs who are told what to do by the OEMs, and are not OEMs themselves.
  + By definition, a CM would not own the design.
  + Discussion Summary:
    - MedAccred Subscribers = OEMs
    - MedAccred Subscribers = CMs of a finished device and OEM
    - Non-subscribers = CMs of a finished device and not OEM
    - Non-subscribers = CMs of components (no “clearance”)
  + Jim Ahle Question: If CM has a supplier, wouldn’t they be expected to control that supply chain? Wouldn’t we want them to be up to date on the process, since they are responsible?
    - Answer: Jim Ahle and Simon Adam could not think of a downside for including CMs.
  + Question: Should there be information sharing between OEM and CMs?
    - Answer: Depends on what information. If process specs, then it is not a problem. Risk mitigation information would be problematic.
  + Tier 1 and Tier 2 Definition
    - Steve Niedelman’s perspective: Expect pushback from the FDA if Tier 2 subscribers do not have access to the full program. FDA will see Tier 2s as “lower class citizens” who should be given a financial break to receive the same benefits of Tier 1s
    - Caution is required since a large section of industry is smaller mom and pops, and we do not want to create an elitist organization of the heavy weights.
    - Question: Do we want to say that those who qualify under SBA also to receive full benefits?
    - Ravi Nabar wondered if it is necessary to define two separate Tiers at this stage. It might be too complex to try and figure out right now.
    - Jim Ahle likes the idea of allowing the small guys to participate. However, Stryker is currently at the table spending a lot of time, money and resource and it would not be equitable for a company of 12 employees to have the same voting rights as a company of 2400 employees.
    - Joe Pinto suggestion: Companies do not have to subscribe and participate in the program, but MedAccred can encourage smaller companies who do not subscribe to still have the ability to mandate MedAccred to their supply chain and receive an accreditation in order to be their supplier
    - Rx-360 has 4 types of participation on their Board (large and small OEMs, large and small Suppliers)
  + Steve Niedelman suggested that it needs to be made clear to FDA that MedAccred is not being controlled by Aerospace representatives at the highest level

1. **Rx-360 Presentation and Discussion**

Ashley Goldberg of Merz Aesthetics presented an overview of medical device activity within Rx-360



1. **Marketing Activities (Branding and new Webpages)**

Hannah Godfrey provided an overview of recent marketing activities

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* + Participants decided on which tagline to use for the program:
    - **6 votes – “Advancing Medical Device Quality Through Supply Chain Process Accreditation”**
    - 1 vote – “Advancing Medical Device Quality Through Critical Process Supply Chain Accreditation”
    - 1 vote – “Advancing Medical Device Quality Through Critical Process Accreditation”
  + MedAccred webpage on the PRI website
    - The MedAccred webpage was unveiled to participants
    - It was recommended to include web releases and marketing that has occurred recently on the webpage. For example, the Silversheet, Medical Device Quality Congress, Medmarc PPT, future presentations, conferences, etc.

1. **Next Steps/ Program Development Timeline Discussion**

Justin McCabe and Bekah Braun presented the embedded program development timeline for discussion



* + Letters of Intent (LOI)
    - Baxter is having difficulty getting it signed, but will keep working on it.
    - Stryker is pushing to have it signed and sees it as a good opportunity to communicate the program higher up in the company.
  + Budgeting process –
    - Aiming for end of Q1 2014 for Program Development agreements ($90,000 for <15 OEMs). The Program Subscription fees would not be charged until 2015.
    - If 15 OEMS sign subscriber agreements by end of 2014, they will receive a refund of $30k each.
  + Question: Is there anything we can do to help companies to sell this internally?
    - Hannah has been working with Siemens to create a PPT for internal promotion.
    - **ACTION:** PRI to ask Siemens of we can share redacted Siemens PPT with MMC members. Participants want to see Internal Rates of Return. **(action complete 30Aug13)**
    - **ACTION:** Participating OEMs to share with each other how they are selling this internally (Due: Ongoing)
    - Jim Ahle – The Value Proposition was a good first step, but each OEM will have to go beyond this to pitch it internally. Each OEM will sell this differently.
    - Stryker is pitching that this will be a higher level of audit. He will not focus on reducing cost, as this will not be the most effective argument. Baxter will probably do the same.
    - Baxter requested some data so that OEMs can coordinate to better sell the concept internally (i.e. Bombardier example from 5Dec12)
    - **ACTION** – PRI to provide participants with data that can be used to better sell concept internally **(action complete 30Aug13)**
    - Philips – Sold the program concept internally four different ways and achieved buy-in. Quality, Reduction in the number of audits, increasing number of process audits, frees up SQEs’ time for supplier development.
  + Question: Would having a PRI staff person present to OEMs Q&R departments be helpful?
    - Baxter doesn’t think that having PRI present would be that helpful at this point and thinks that real numbers will be most helpful, both current and future value.
  + Rx-360 uses 3rd party auditors (ie SQA) to conduct audits. Auditors then have to meet the criteria that the OEMs define for each audit. This removes overhead of Rx-360. Independent.
    - Ravi Nabar thinks that this could be a good short term solution.
    - Steve Niedelman knows that in the Medical Device industry, SQA has provided inconsistent results to multiple clients. However, SQA does have locations all over the world.
    - Most SQA auditors have QMS experience, but not for specific processes.
  + Request was made for participating OEMs to identify the number of supplier site locations and names (if possible) within their respective supply bases. Suppliers, whether Tier 1 or 2, who are performing the process.
    - PRI needs this information to know how many auditors to hire, resources to allocate, etc.
    - **ACTION**: MMC members to volunteer with PRI the number of supplier site locations and names (if possible) they think that will be participating in this program, per technology, per region. (Due: 19Sept13)
    - **ACTION:** PRI to reach out to GE Healthcare (Jose Luis Estrada) to request this information (Due: 6Sept13)
  + Ravi Nabar proposed conducting a “Drive” between now and year end 2013 to push the program forward.
    - **ACTION**: PRI to work with MMC participating companies to divide up and call interested companies to push selling the program internally within the next few months. Ask, “Are you in or are you out?” We need a head count. (**Due: 11Sept13**)
  + Jim Ahle requested to know the costs of a mature program (ie Nadcap at 50+ subscribers with fees of $28k) so their companies can appreciate the comparison of new program with a small number of subscribers vs. an established program with 50+ subscribers)).
  + **ACTION**: PRI to provide the MMC with a breakdown of activities that contribute to costs as the program matures (**Due: 13Sept13**)
  + **ACTION** – Steve Niedelman to touch base with new Abbott contact
  + Stryker SMEs are anxious to get involved in Cable & Harness TG. Stryker has suppliers who can get involved right away.
  + Supplier mandates will take a while to roll-out, as there will be a good amount of preparation that an OEM will have to do to educate the suppliers, etc.
  + **ACTION**: Each company to look at their 2014 audit plans, and identify an audit plan between now and the end of 2014 so that MedAccred audits can be tailored to this schedule. This would require preparing suppliers now. Start with currently participating Suppliers (Sanmina, Flextronics, Plexus, Symmetry, etc.)
    - OEMs could then take that information and sell the program to higher level mgmt.
    - Jim Ahle sees 2014 as a development year and 2015 as an active program.
    - Ravi Nabar wants to conduct audits in Q1 2014 and wants to see ROI right away.
    - OEMs could announce this at their respective “Supplier Days”
  + Question: How are participating OEMs changing their current systems to accommodate the new process audits? How does it roll into Quality System program?
  + Baxter only has PCBAs and Sterilization, so thinks it would be a hard sell to get approved for $90,000 to conduct a few PCBA audits. Sterilization will be huge later on. Baxter would also be interested in disposables and extrusions
  + DePuy also has extrusions
  + Ravi Nabar raised interest in castings
  + Medcon - 6 or 7 May 2014
    - Supplier Quality is the #1 issue to be discussed during the Quality track
    - 1.5 hours dedicated to supplier quality – STERIS to drive case study.
    - End of the day – 15 minutes for PRI and Rx-360 to discuss programs – Recommended that Joe Pinto presents. The goal is to present the concept to as many people as possible.
    - There may be a Case for Quality session the day before.
  + MD&M Minneapolis
    - **ACTION**: Ravi will share the Quality Congress overview with Ken
  + Other Conferences
    - Ravi Nabar is presenting at the 5th Annual Pharmaceutical & Medical Device Manufacturing & Quality Assurance Forum (San Antonio, TX – 10-11Oct13)
    - Enterprise Ireland (October 2013)
    - **ACTION**: Simon Adam to determine if there is any value in attending Enterprise Ireland

1. **Other Business**
   * None to report
2. **RAIL Review**
   * Justin McCabe reviewed open actions in the RAIL
3. **Closing Remarks**



* + Next MMC teleconference: 11Sept13 – 11:00am – 12:00pm EDT
  + Next face to face MMC meeting: 31Oct13 – Minneapolis, Minnesota (Millennium Hotel Minneapolis)
  + Joe Pinto thanked participants for their attendance and participation in the continued development of MedAccred