**UNCONFIRMED MINUTES**

**FEBRUARY 10, 2016**

**FACE-TO-FACE**

**ANAHEIM, CALIFORNIA, USA**

**These minutes are not final until confirmed by the MedAccred Management Council in writing or by vote at a subsequent meeting. Information herein does not constitute a communication or recommendation from the MedAccred Management Council and shall not be considered as such by any agency.**

**WEDNESDAY, FEBRUARY 10, 2016**

# OPENING COMMENTS

* + Call to Order / Quorum Check / Introductions
    - The MedAccred Management Council (MMC) Face-to-Face Meeting was called to order at 9:00 a.m. EST, 10-Feb-16, with the following representatives in attendance:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **NAME** |  | **TITLE** | **COMPANY NAME** |
|  | Robert | Berger | Vice President, Contract Manufacturing | Medtronic |
|  | Ken | Chesney | Senior Director, High Reliability Solutions Regulatory/Quality/Engineering | Flextronics |
|  | Ed | Engelhard | Corporate Quality Manager | Solar Atmospheres |
|  | Scott | Goolsbey | Supplier Controls Manager | Stryker |
|  | Wendy | Gould | Sr. Director, Global Quality & Regulatory Systems | Synergy Health (STERIS) |
|  | John | Hastings | Director, Supplier Quality Engineering - Plastics Category | Johnson & Johnson |
|  | Paul | Hugo | Director of Corporate Quality | Global Technologies |
|  | Jeff | Olds | CEO | Global Technologies |
|  | Ravi | Nabar | Head of Supplier Quality Assurance | Philips |
|  | Steve | Niedelman | Lead Quality System and Compliance Consultant | King & Spalding LLP |
|  | Mike | Piersol | Quality Manager | Kimball |

***PRI Staff Present***

|  |  |  |  |
| --- | --- | --- | --- |
| Connie | Conboy | Director, Strategy and Business Development | PRI |
| Hannah | Godfrey | Senior Specialist, Business Development Europe, MedAccred Co-Lead | PRI |
| Justin | McCabe | Senior Specialist, Business Development, MedAccred Co-Lead | PRI |

* + Code of Ethics, Anti-trust and Conflict of Interest
    - The PRI Code of Ethics, Anti-trust and Conflict of Interest policy was reviewed. For more information, please view the video via the following link: [PRI Code of Ethics, Anti-trust and Conflict of Interest Video](https://www.youtube.com/watch?v=skr4dB9YE8c&feature=youtu.be)
  + Approval of MMC Minutes
    - Addition: “PRI was invited and accepted to speak at an upcoming Q1Productions Supplier Quality conference on April 11-12”
    - All in favor of accepting addition and 13Jan16 minutes were approved.
  + Connie Conboy reviewed the meeting agenda.

# MedAccred PROGRAM HIGHLIGHTS

Connie Conboy reviewed the embedded slides giving a summary of recent MedAccred accomplishments.



* + Supplier Audits (Goal of 40)
    - Goal is not broken down by critical process area – MMC objective is to conduct 40 audits in 2016
    - Goal was decided during the Andover, MMC meeting in October 2015 and was based on what the MMC felt was achievable.
  + Subscriber Agreements
    - Audit observation:
      * Following a recent observation, Stryker was comfortable with the rigor of the audit and had only positive feedback
      * J&J found that the suppliers were more enthusiastic because it is a process-focused audit. It was more targeted to their core competencies and more interesting than a QMS-type audit. It was noted that the auditors need additional training in the medical device language used (i.e., DHR, MHR, etc.)
  + FDA
    - We might recommend FDA join us as a “fly on the wall” to observe one audit. We would need to get assurances from the FDA before doing this.
      * Start with sharing the audit criteria with the FDA – this may be sufficient.
      * Will need to ensure that Process Validation is fully incorporated into the audit criteria before sharing.
    - New Director at FDA Office of Compliance – this individual has no FDA experience. Will wait to approach this new individual so they can become familiar with their job. We will focus on Bill MacFarland and Vincent Vicente for now.
    - Connie proposed putting together a small work team to work with Steve on how to best work with the FDA, if they request joining us for a MedAccred audit.
      * If we do go in this direction, Wendy Gould, Ravi Nabar volunteered to participate.
  + Medmarc Insurance Incentive
    - Accredited suppliers will need to approach Medmarc directly to determine exact benefit they will receive and whether the discount is to be adjusted based on the number of sites they have accredited etc.
    - No other insurance companies have been approached for similar incentives at this point.

# Task Group Accomplishments

## Justin McCabe provided updates on the status for their respective Task Group activities and accomplishments.

## 

Discussion:

* + Sterilization Auditors – there is a need to source more auditors in this area which PRI is working to address.
  + Welding – require first audit in this area. OEMs are encouraged to work with any suppliers who may be interested.
  + Batteries
    - Is not at the top of the list of the participants in the room.
    - However, remains a priority issue for FDA. Agency is concerned about charged, re-charged, lithium ion
      * Affects defibrillator machines, external defibrillators, etc.
    - This might be more of a “system design” issue, not necessarily a battery issue. Difficult to differentiate.
    - Many people involved in batteries are in the “Design” group. A lot of this is being done overseas.

***ACTION: Ravi Nabar and Robert Berger are identifying individuals from their companies to participate in a sub-team. (31-Mar-16)***

***ACTION: PRI to ask BD and Baxter to see if there is any interest. (31-Mar-16)***

# Process Validation Sub-Team Update

Wendy Gould and Ken Chesney presented an update on Process Validation activity.



Discussion:

* + - Process validation must be fully implemented in all MedAccred audit criteria.
    - Task Groups have been asked to complete Gap Assessment by 31-Mar-16
    - GAP Assessment document validation
      * The document has not been validated, but if this is significant, we can print, sign, and date them. The printed copies can be scanned and stored in the system.
      * MedAccred Staff Engineers should sign and date them.

***ACTION: MedAccred Staff Engineers to sign printed copies of the Gap Assessment documents*** ***(after completed by Task Groups and approved by Process Validation sub-team) (31-Mar-16)***

* + - Validation Training
      * Training will be essential for all our stakeholders
      * There will be three Levels of training delivered
      * Level 2 – will include Software validation as part of the process validation training
      * Caution: FDA CDRH does not necessarily embrace the QbD (Quality by Design) approach. CDRH does like the GHTF document.
      * It is important that the auditors and auditees are well-trained in this area.
      * It is not necessary to tell FDA about our training program, but they need to be comfortable that we are addressing it sufficiently.

# MedAccred communications update

Hannah Godfrey provided a status update on recent communications activities.



Discussion:

* + Data from Nadcap on aerospace successes – this will be very helpful for the industry
    - MMC to agree on questions that we could use to survey Nadcap suppliers
    - Sub-team Objective: Develop list of survey questions for Nadcap accredited suppliers; questions cannot be subjective; what metrics do they have available that could be shared with the medical device industry

***ACTION ITEM: Form a sub-team to develop some questions that could be distributed to Nadcap accredited suppliers. Scott Goolsbey, John Hastings, Ravi Nabar, Wendy Gould (Chair), Ed Engelhard (31-Mar-16)***

# Next steps with fda

Ravi Nabar and Steven Niedelman provided an update on next steps with FDA.

Discussion:

* + What does FDA think of Nadcap?
    - Steve – Thinks they are being more considerate of what is going on in other industries. FDA sees aerospace as a “fail-safe” industry, and is the most closely aligned as a risk-averse industry.
  + Trying to schedule a call with Bill MacFarland and Vincent Vicente to follow-up. We will want individuals from MMC to participate in that meeting. What did the audits find? No confidential data will be shared. We will identify the significant improvements as a result of the MedAccred audits. Articulate who is involved.
    - Ask FDA if there are any particular projects that we can assist with
    - Audit observation
  + Three big areas:
    - 1. AdvaMed CtQ (Ravi) / MDIC (Steve) - PMA
      * Bill MacFarland wants to know how the FDA can use MedAccred to get confidence in their suppliers, and get confidence that our auditees are getting value from being audited. For example, PMA approvals for Class 3 suppliers. If they are a “MedAccred Supplier” then FDA might not have to look at that supplier.
      * This may take place on March 8, 2016, and we could possibly present on March 7th or 9th. We can ask Bill MacFarland to get a topic on the agenda. We cannot control the timing of this. There are no guarantees.
      * Next Steps: Steve and Ravi will keep the MMC up to date.
    - 2. “Batteries” is a big focus of the FDA
    - 3. “Inspectional Guidance” – Critical to Quality/Case for Quality – Top 5 things that affect the quality of the process or product.
      * What is the intersect between this and the MedAccred program?

***ACTION ITEM: After the 10-12 audits have been conducted, look at the top 5 CtQ attributes that were looked at during the audit and corrected as a result of the MedAccred audit. PRI will work with Ravi Nabar to summarize the document. (30-Jun-16)***

# overview of johnson & johnson medaccred supplier forums

John Hastings provided an overview of the Johnson & Johnson activities to involve their supply chain in MedAccred.

Discussion:

* + J&J has been socializing the MedAccred concept for some time via individual supplier visits and has now scheduled multiple on-line events to educate their key suppliers on the benefits of participation in MedAccred
  + The supplier forum invitations are co-signed by the global head of Procurement and Quality
  + J&J is planning to distribute a survey afterwards. They want to make sure the suppliers leave the event “knowing” what MedAccred is. After the event, they will speak to what the next steps are for the suppliers.
  + They are targeting specific suppliers and some are in the current MedAccred Task Groups.
  + The key expectation statement is to “participate and here is one of the things you can do to get a deeper relationship with J&J.”

# Supplier Best Practices in maximizing the value of accreditation

Ed Engelhard, Wendy Gould and Jeff Olds presented their methods/strategies for promoting their MedAccred accreditations.

* + Ed Engelhard – Solar Atmospheres – Heat Treating Accreditation
    - Ed shared a presentation that is given at invitation only customer seminars regarding the benefits of MedAccred to their operations.
    - As a result of MedAccred, Solar re-wrote their contract review process. Put in Solar’s default practices in the contract. Site sources for their practices. This defines their operation, and how they do it every time.

***ACTION: PRI to schedule a training to discuss flowdown and best practices for MedAccred stakeholders*. (30-Jun-16)**

***ACTION: PRI to share PPT with the MMC with the minutes (10-Mar-16)***

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* + Jeff Olds – Global Technologies – Cable & Wire Harness Accreditation
    - Showed the promotional video they produced.
    - The video can be viewed online [here](https://www.youtube.com/watch?v=FJDsVDfNWJU)
  + Wendy Gould – Synergy Health (STERIS) – Sterilization Accreditation
    - Contract sterilization is different from other MedAccred Task Groups. The value of accreditation is not necessarily more compliance – they are already there. The big value is realizing reduced audits from their customers.
    - Synergy is working on a long-term strategy to promote their accreditation.

# HIGHLIGHTS OF UPCOMING MEDACCRED MD&M PRESENTATION

Robert Berger provided an update on the MedAccred presentation being made on Thursday, 11 February during the MD&M Conference.

The title of the presentation: “MedAccred: Innovating critical process manufacturing oversight”

Confirmed Speakers:

* + Robert Berger, Vice President Contract Manufacturing - Minimally Invasive Therapies Group, **Medtronic**
  + Ravi Nabar, Head of Supplier Quality Assurance, **Philips**
  + Charlie Mason, Vice President, Medical Division, **Sanmina**

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# MedAccred TRAINING OPPORTUNITIES

Hannah Godfrey provided an overview of various training opportunities PRI offers to suppliers who have scheduled audits.



***ACTION: PRI set up a separate meeting to discuss MedAccred’s future training requirements with interested parties (30-Apr-16)***

# OTHER BUSINESS

Connie Conboy led a discussion on other business topics:



* + eAuditNet Software Validation
    - External consultant has finished their review and recommendations
    - PRI is addressing all recommendations
    - System validation should be complete by end of Q1 2016
    - Presentation will be made at April 06 MMC telecon
  + 2016 MMC Meeting Schedule
    - The 2016 MMC telecon and face to face meeting schedule was confirmed.
    - Synergy Health (STERIS) volunteered to hold the November 9, 2016 face to face meeting at their facility in Tampa, FL
    - Stryker volunteered to hold the June 8, 2016 face to face meeting at a US Stryker facility. Exact location TBD.

***ACTION ITEM: PRI to send Outlook appointments to MMC members for all 2016 meetings (31-Mar-16)***

# Rolling action item list (RAIL) review



The new action items assigned during this meeting were reviewed.

**ADJOURNMENT** – 10-Oct-2016 – Meeting was adjourned at 4:30 p.m.

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