**CONFIRMED MINUTES**

**JUNE 2, 2014**

**WEBEX / TELECONFERENCE CALL**

**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.**

**TUESDAY, JUNE 2, 2014**

# OPENING COMMENTS

## Call to Order / Quorum Check

The MedAccred Management Council (MMC) WebEx & Teleconference Meeting was called to order at 10:00 a.m., 02-Jun-2014, with the following representatives in attendance:

***Subscriber Participants Present***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | NAME |  | COMPANY NAME |  |
|  |  |  |  |  |
|  | Thomas | Karimpanal | Philips Healthcare |  |
|  | Vance | Kyle | DePuy |  |
|  | Amy | Sousa | DePuy |  |

***Other Participants Present***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | NAME |  | COMPANY NAME |  |
|  |  |  |  |  |
|  | Jim | Ahle | Stryker Corporation |  |
|  | Robert | Berger | Covidien |  |
|  | Edward | Engelhard | Solar Atmospheres Inc. |  |
|  | Karen | Meck | Zimmer, Inc. |  |
|  | Steven | Niedelman | King & Spalding |  |

***PRI Staff Present***

|  |  |
| --- | --- |
| Jerry | Aston |
| Mark | Aubele |
| Bill | Dumas |
| Bekah | Gondek |
| Justin | McCabe |
| Kellie | O’Connor |
| Christine | Sanz |
| Ian | Simpson |

## Anti-trust and Code of Ethics

Justin McCabe reviewed the Anti-trust and Code of Ethics policy. For more information, please see the attached presentation.



## The agenda was reviewed. Minutes from the 02-May-2014 face-to-face meeting were discussed.

## Motion made by Steve Niedelman and seconded by Ed Engelhard to approve and confirm the May 2014 MMC Minutes. Motion passed and the May 2014 MMC Minutes are now confirmed.

# Rolling Action Item List (RAIL)

The current RAIL was reviewed. Item #131 is in currently in discussion. Mark Aubele echoed Ian Simpson’s request from the last several meetings that MedAccred may want to consider a NonDestructive Testing (NDT) Task Group. Bill Dumas also considered that there may be a need for a Printed Boards Task Group in the future.

# MMC Sub-Team Activities: Recap and Discussion



## External Communications and Strategy

Justin McCabe gave an update of this team’s activities. It was noted that Joe Pinto and Simon Adam are in Stuttgart, Germany this week presenting at MedTec.

## Program Documents

It was noted that the Program Governing Document, PD 1300, is nearing completion.

## MMC Face-to-Face Meetings

To date, we have had two face-to-face meetings of the MedAccred Management Council. The next meeting is scheduled at PRI Headquarters in the fall of 2014. A registration has been created, so all participants (whether attending in person or via WebEx) are highly encouraged to pre-register for this meeting by using the following link: <http://events.constantcontact.com/register/event?llr=t4cxmocab&oeidk=a07e9bcf3ww6ecd9e00>

*Important Note:* The meeting date has been changed to **October 1, 2014**.

# TASk group activities



## Electronics – Cable & Harness (C&H)

This Task Group is holding regular meeting and are making steady progress. They currently expect to have Audit Checklists completed by early November, and plan to contract their first auditor in that same time frame.

## Electronics – Printed Circuit Board Assembly (PCBA)

The PCBA group has completed their first pass of the checklist. A meeting is scheduled this week to develop a go-forward plan. Current estimated completion date is August 2014, however it will depend on readiness for audit scheduling.

## Heat Treating (HT)

The HT Task Group is gaining participation, and they have elected a Chairperson, Bruce Dall from Stryker. Estimated date of completion for the checklist is late June. Additionally, there are plans to take AMS 2750, and possibly also 2759, to the FDA for inclusion on the list of approved standards once the Task Group is functioning in an official capacity.

It was noted that the process to get a standard approved by the FDA could be a lengthy one, and therefore the group may want to consider putting AMS 2750 forward sooner than originally planned to avoid a work stoppage.

## Sterilization (STN)

The STN Group had a face-to-face meeting in mid-May, and good progress was made during this meeting. The Task Group’s next meeting is a teleconference call scheduled for tomorrow, 03-Jun-2014. Their estimated completion date at this time is October.

## Welding (WLD)

The WLD Task Group has completed three checklist drafts and they are planning for a test audit to be conducted. Estimated completion date is late July. Two auditor candidates are in the review process.

# Other business and open discussion

## The completion dates within the Task Groups are approaching very rapidly. There is some concern with losing momentum during the period of time between completion of the audit criteria and the commencement of supplier audits. OEMs and Subscribers may want to begin thinking about what MedAccred will look like within their companies. Additionally, if anyone knows of any Suppliers who would be good candidates to conduct some of the first audits, please contact Justin or Bekah so those Suppliers can begin the education process on how to prepare for an audit.

## DePuy has become MedAccred’s second official program Subscriber. Thank you and welcome to the DePuy team.

# Rolling Action Item List (RAIL) Review

There were no additional actions recorded during this meeting. Please find the current RAIL attached below.

ADJOURNMENT – 02-Jun-2014 – Meeting was adjourned at 10:45 a.m.

Minutes Prepared by: Kellie O’Connor, koconnor@p-r-i.org

RAIL:

