**CONFIRMED MINUTES**

**JUNE 11, 2015**

**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.**

**THURSDAY, JUNE 11, 2015**

# OPENING COMMENTS

## Call to Order / Quorum Check

The MedAccred Management Council (MMC) WebEx & Teleconference Meeting was called to order at 10:30 a.m., 11-Jun-2015, with the following representatives in attendance:

***Participants Present***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | NAME |  | COMPANY NAME |  |
|  |  |  |  |  |
|  | Andrew | Bauermeister | Medtronic, Inc |  |
|  | Scott | Goolsbey | Stryker Corporation |  |
|  | Robert | Hayden | Industrial Metal Finishing, Inc. |  |
|  | Acelio | Hernandez | Nypro Healthcare |  |
|  | Steve | Niedelman | King & Spalding LLC |  |

***PRI Staff Present***

|  |  |
| --- | --- |
| Jerry | Aston |
| Mark | Aubele |
| Connie | Conboy |
| Susan | Frailey |
| Hannah | Godfrey |
| Bob | Lizewski |
| Joanna | Kennedy |
| Julia | Markardt |
| Justin | McCabe |
| Joe | Pinto |
| Ian | Simpson |
|  |  |

## Anti-trust and Code of Ethics

A video was shown on this topic. To view it, please use the following link:

<https://www.youtube.com/watch?v=skr4dB9YE8c&feature=youtu.be>

## Approval of Minutes

Motion made by Steve Niedelman and seconded by Joe Pinto to approve the May MMC Face-to-Face Meeting Minutes with minor changes to participant information. Motion passed and the minutes from the 13-May-2015 meeting were approved as revised.

# ROLLING ACTION ITEM LIST (RAIL)



Justin McCabe reviewed the key open action items per the attached presentation and provided updates.

The full RAIL is as attached:



# Task Group Activities

## 

## A new format has been introduced for the Task Group reports. Objective is to make the information more concise, highlighting achievements since the previous meeting, ongoing activities and any issues requiring input from the MMC.

## Electronics - Printed Circuit Board Assemblies (PCBA)

Two suppliers have committed to schedule audits (Flextronics and Sanmina). Participation is very good with a new supplier (Kimball Electronics) increasing the number of companies involved to 10. Two meetings were held in June with the group working on auditor training, the auditor handbook and the program structure. Auditor status is excellent with two auditor trained, 2 in training and a further auditor currently being interviewed. The Task Group has several resumes on hold. Task Group requests support from MMC to encourage supplier audit uptake. MMC participants do not have to be MedAccred Subscribers to work with their suppliers to get audits scheduled. However, non-subscribers would not be permitted access to supplier audit data in eAuditNet. Companies would have to obtain the data directly from their supplier.

## Electronics - Cable & Wire Harness (CWH)

Global Technologies has committed to scheduling the first audit. Two meetings were held in June with the group working on auditor training, the auditor handbook and the program structure. Auditor status is excellent with two auditor trained, 2 in training and a further auditor currently being interviewed. The Task Group has several resumes on hold. Task Group requests support from MMC to encourage supplier audit uptake.

## Heat Treating (HT)

Two further ‘slash sheet’ audit criteria have been balloted (Brazing and Aluminum). Task Group is targeted to conduct 10 audits in 2015 (1 is complete). Noted that Task Group members require training on balloting documents and audits in eAuditNet. Task Group requests support from MMC to encourage supplier audit uptake.

## Plastics

Two new suppliers have joined (GW Plastics and Mack Molding), bringing total number of participating companies to four. Follow-up work is also ongoing with two further companies who have expressed interest in participating (Plastikos and Kintz). Participation and engagement at the most recent meeting (04-Jun-2015) was excellent. Good progress is being made on the Injection Molding audit criteria. The Task Group will begin work on selecting a Chair and Vice Chair. Participation is improving but additional support would be beneficial. The next teleconference cannot be held until 22-Jul-2015 so the group is considering the viability of a face to face meeting in August.

## MedAccred Quality Systems (MQS)

The audit criteria, AC8004 is out for ballot. Task Group has decided to accept Nadcap Aerospace Quality Systems auditors for MQS audits and determined that MQS will be a one day audit conjoined with the critical process audit. The Task Group is currently being created in eAuditNet and support is required to get all the Members enrolled.

## Sterilization (STN)

Task Group completed draft audit criteria to be used during a Test/Pilot audit in August. Decision is being made on whether this will be Test or Pilot audit (Test audits are run to check the audit criteria whereas Pilot audits could lead to formal accreditation). Task Group requests support from MMC to encourage supplier audit uptake.

**ACTION: Subscribers are asked to each nominate one Sterilization supplier for audit (15-Jul-15)**

## Welding (WLD)

Task Group is currently working on the Laser Welding handbook. Participation has recently been an issue with two meetings being cancelled due to lack of attendance. However, at the last meeting for this group there was some improvement with all Subscribers and OEMs present as well as a new supplier (Paragon Medical). Task Group requests support from MMC to encourage supplier audit uptake.

# Sub-team updates

## Process Validation



Two meetings have been held over the past month with Philips Healthtech and Global Technologies joining the team. The Sub-team has received process validation questions from Medtronic (in addition to DePuy and Solar Atmospheres) and is implementing a short versus long-term approach to question development. As requested, the team has been communicating activity regularly with all Task Groups.

The team is now finalizing the general focus question and incorporating feedback from the Task Groups. Steve Niedelman advised that the team should be following GHTF guidance as part of this process.

Future objectives for the team are to develop a process validation case study and tie it to IQ/OQ/PQ and to develop content for the MedAccred auditor training package.

1. **2015 Supplier Audit Scheduling - Strategy**



Connie Conboy gave the attached presentation on MedAccred’s supplier audit strategy for 2015. Suppliers who have committed to audits this year are shown as well as a number of suppliers who the MMC, with support from PRI, will be encouraging to participate in the program.

If any company would like to suggest additional suppliers for audits, please contact a member of the PRI MedAccred team with information.

# Conferences / Publications – Update

Hannah Godfrey provided an update as follows:

6.1 Medical Product Outsourcing – Utah – September

Ken Stopar (Baxter Healthcare) and Joe Pinto will be presenting a general overview of MedAccred at the MPO Conference on September 29 2015. Objective is to raise awareness of the program and encourage participation from potential Subscribers and Suppliers.

6.2 1st MedAccred Audit – Heat Treating

Solar Atmospheres (recipients of the first MedAccred accreditation) and PRI have both recently issued press releases which have been re-published multiple times online. Publications that have featured this information include: *Today’s Medical Developments*, *Today’s Energy Solutions, The Monty, The Fabricator* and *Industrial Heating*. PRI Marketing department monitors and tracks where MedAccred is mentioned in the media on an ongoing basis.

6.3 FDA News

Steve Niedelman is working with FDA News on an article which will feature an interview with a MedAccred Subscriber and suppliers.

6.4 MPO / Medical Device Outsourcing

Steve Niedelman is coordinating an article on MedAccred progress. MPO have two publications one of which has an orthopedic focus which will be particularly relevant for the Heat Treating and Welding Task Groups.

6.5 Silversheet/Graysheet

PRI Marketing Department is producing a MedAccred update article including an interview with Solar Atmpsheres about the first MedAccred audit. It will also detail progress in areas such as Process Validation and Medical Device Quality Systems.

6.6 PRI MedAccred Newsletter

PRI Marketing Department is producing an e-newlsetter which will be distributed to all MedAccred contacts. The objective is to keep those company representatives who cannot attend all the teleconferences and meetings updated on the progress of the program therefore keeping MedAccred front of mind and hopefully encouraging future participation.

6.7 Advamed Virtual Quality Conference

Steve Niedeleman will be reference the MedAccred program during a presentation he is deliverying on supply chain quality.

# Other Business

7.1 eAuditNet – “Participating Manufacturer” Role

PRI requested permission from the MMC to create a new ‘participating manufacturer’ role in eAuditNet. This will be a temporary addition to allow manufacturers who are not yet Subscribers limited privileges in eAuditNet such as the ability to vote on program documents and audit criteria. Please note that this access will not include the ability to view supplier audit data.

There were no objections and the role will be created.

7.2 AMS 2750

This is an aerospace standard on pyrometric controls which is used extensively in MedAccred Heat Treating checklists. Led by Elizabeth George (Vice President Global Regulations & Standards at Philips Healthtech), a team is in the process of submitting the standard to the FDA Speciality Task Group for their review. It is hoped that the standard will be formally recognized. It was noted that the standard is copyrighted by SAE and must be purchased by any company wishing to use it. MMC will be kept updated on progress.

# Upcoming Meetings / training

Justin McCabe reviewed upcoming MedAccred meetings and events:

* PCBA Task Group – 30 June
* Cable & Wire Harness Task Group – 01 July
* Heat Treating Task Group – 21 July
* Sterilization Task Group – 29 June
* Welding Task Group – 6 July
* MMC External Communications & Strategy – 22 June
* MMC Process Validation – 06 July

A list of all 2015 MMC meetings has also been published on the PRI Website at <http://www.p-r-i.org/2015-mmc-meeting-schedule-released/>.

# RAIL REVIEw

**ACTION: Subscribers are asked to each nominate one Sterilization supplier for audit (15-Jul-15)**

(Full RAIL is embedded in item 2.0)

**ADJOURNMENT** – 11-Jun-2015 – Meeting was adjourned at 11:30 a.m.

Minutes Prepared by: Hannah Godfrey [hgodfrey@p-r-i.org](mailto:hgodfrey@p-r-i.org) /Justin McCabe jmccabe@p-r-i.org