

## Partner Organization Report

<b>Partner Organization:</b>	ISO (TC 276, all working groups)
<b>Committee Name (if applicable):</b>	MSC Committee
<b>ISCT Representative(s):</b>	Sowmya Viswanathan
<b>Role of ISCT Representative:</b>	Formal liaison to ISO
<b>Last Committee Report Submitted on:</b>	n/a
<b>Date of Upcoming Board of Directors Meeting for Submission:</b>	June 20, 2018

### 1. How often has this committee met during the last 12 months?

The MSC committee has calls once a month. I was first included in the MSC committee monthly call in March 2017 to initiate the letter needed to elect me as a formal liaison between ISCT and ISO. The letter and approvals process through ISCT and ISO took a few months. During July and August, I had to ensure that all the MSC committee members of ISCT provided written agreement to the strict copyright rules of ISO before they could receive any ISO draft documentation. I was able to formally join the committee as a guest participant for monthly calls as of September 2017. The ISO liaison activity has been an agenda item on calls in Sept, Nov, Dec 2017 and Jan, March, April and May 2018. In total, that would be 7 committee meeting calls, after the initiation as a formal liaison.

I was also part of the Quality and Operations Organization committee for ISCT 2018 since July 2017 and have been involved in putting together a standards session at ISCT 2018. The committee met monthly from August-March 2018.

### 2. What was accomplished during the meeting(s)? (To answer this question, you may attach conference call reports or meeting minutes.)

Please see attached meeting minutes and agenda items.

- Briefly, the MSC Committee reviewed two draft documents for technical specification (biobanking) and international standard (metadata analyses) and provided feedback to the ISO working groups in time for the face-to-face meeting in Rome (Dec 2017).
- The ISO working group re-defined the scope of the two working documents and provided next round of documents for edits (Dec 2017-Jan 2018)
- The MSC committee reviewed these two working documents and the revised scope and provided further comments back to the ISO working group (March 2018).
- The MSC committee also reviewed the outcomes of a call on these two MSC standards/technical specification hosted by the Standards Coordinating Body with the US

- standards team composed of scientists from NIST and from other MSC experts in the US (including Rooster Bio from industry and Dr. Pam Robey from academia) (March 2018)
- The MSC committee also reviewed comments generated by the US mirror committee to the ISO working group and discussed them (March 2018)
  - The MSC committee received a rebuttal to their comments (March- April 2018) and chose not to respond further (May 2018) at this time.
  - Further changes to the technical specifications will be delivered from the ISO working group back to the ISCT's MSC committee

The Quality and Operations Organization committee organized a session on Standards (This was featured as a Q&O Session 1 on May 3, 2018), which I chaired. The panel featured Jiwen Zhang speaking on efforts of the Standards Coordinating Body, Jonathan Campbell speaking on the efforts of the ISO TC 276 and standards initiatives in the UK, Claudia Zylberber speaking on ISO TC 276 efforts from a vendor perspective, and Yanagita-san speaking from FIRM and ISO TC 276 perspective. The session was well attended and useful to participants based on some initial feedback.

### **3. What are the key goals and initiatives for the next 6 months to 1 year?**

I will continue to bring forward edits from the ISO working group back to the ISCT's MSC committee. The next face-to-face meeting for ISO will be in Beijing (June 2018) and should result in clarification on the two documents. There was a vote which allowed one document (biobanking) to proceed and the other document (metadata analyses) to not proceed. Based on discussions at the working group, a consensus recommendation will be taken and made available. Based on these recommendations, a new version(s) of the document will be available for further comment.

ISCT's MSC committee also suggested involvement of other Chinese academics working in the MSC area so their input could be added to the working draft documents. Currently, the working draft document is being led by a group of industry researchers in China. ISCT's MSC committee feels that having additional academic input would be valuable.

Where needed, I will coordinate efforts between ISCT's MSC committee and the Standards Coordinating Body (SCB) as well to provide two-way input on documents.

ISCT's MSC committee will provide further comments and edits if subsequent versions of the document are provided by the ISO working group. These will be conveyed through the ISO process and at the face-to-face meeting in Germany in December 2018. I will be attending this face-to-face meeting, as per the arrangement with ISCT to participate in at least one annual meeting

### **4. Are there any activities within this time period that ISCT should be aware of or take part in? Specifically, are there activities that any ISCT Committees can comment on?**

There are a number of other standards documents pertaining to bioprocessing and bioanalytics being developed at ISO TC 276 in their respective working groups pertaining to cell and gene

therapies. I am involved in these working groups at ISO TC 276 and think it would be useful once the documents are well into the draft stages to have input from ISCT's Process and Product Development Sub committee or through Lab Practices Committee. Claudia Zylberberg who is also an ISO representative from the US might be good liaison for these activities.

**5. Additional comments or feedback:**

ISCT participation in various standard development activities will be important and ISCT should ensure representation at those meetings and a way to bring the documentary standards back to relevant ISCT committees for comments and positions.

ISCT should continue to have a session devoted to standards development and progress at their annual meeting as part of the Quality and Operations track.