

## Satoshi Saeki

Quality, Innovation, and Learning Services (QuILS), Astellas Pharma Development, USA

### REPRESENTATIVE EXPERIENCE

- Approximately 20 years of experience on clinical development and operations in Astellas
- Worked in Astellas US (Chicago) as a study manager from 2010 to 2012
- From Apr. 2016, transitioned to Astellas US as an expatriate for business process improvement in clinical development
- Leading internal RBM task force activities for global implementation of RBM methodologies in Astellas
- Served as a program vice chair for DIA Japan annual meeting in 2015 and engaged in a member of program committee for DIA Japan annual meeting 2014 and 2016
- Have been serving as a member of program committee for DIA clinical operation and monitoring workshop from 2013
- Have coordinated a lot of RBM and cQMS sessions in collaboration with external stakeholders such as TCBI (TransCelerate), JPMA (Japan Pharmaceutical Manufacturers Association) and PMDA at DIA annual meetings and monitoring workshops
- Have been involved in RBM global initiative in TCBI as a representative from Astellas and engaged in health authority interactions with FDA, EMA, PMDA, CFDI, MFDS and TFDA for RBM as a representative of TCBI
- Have been working for Clinical QMS global initiatives in TCBI from Mar 2016