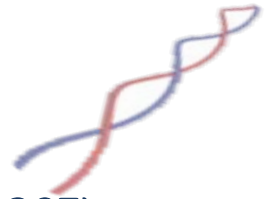


# Gene Therapy Clinical Trials Workshop

~ Focusing on *ex vivo* Gene Therapy ~



**Date** July 25, 2018 (13:00 -16:00)  
**Venue** The Jikei University School of Medicine  
Takagi Memorial Hall 2, South Auditorium  
**Sponsor** Japan Society of Gene & Cell Therapy (JSGCT)



**The fourth training course for gene therapy clinical trials in Japan!**

## Program

### **Session I** CMC and Nonclinical Safety (13:00 -14:30)

1. Points to consider on quality control strategy for *ex vivo* gene therapy products  
Takaaki Yoshida  
Pharmaceuticals and Medical Devices Agency (PMDA)
2. Quality management of gene engineered cells  
Junichi Mineno  
Takara Bio Inc.
3. Considerations on the Preclinical Assessment of Cellular and Gene Therapy Products  
Maki Kazushigei  
Pharmaceuticals and Medical Devices Agency (PMDA)

### **Session II** Clinical Development (14:45 – 16:00)

4. Clinical trial designs for gene and cell therapies  
Tomohiro Yamaguchi  
Pharmaceuticals and Medical Devices Agency (PMDA)
5. Support for clinical development of gene and cell therapies in academia  
Sumimasa Nagai  
The University of Tokyo
6. General discussion  
Akihiro Kume  
Jichi Medical University

JSGCT Clinical Trials Workshop Committee  
Chairman: Akihiro Kume

Committee Member  
Masafumi Onodera, Mai Tanaka, Hitoshi Tazawa, Eriko Uchida

Administrative Office : Support Center for Clinical Investigation, Jichi Medical University  
3311-1 Yakushiji, Shimotsuke, Tochigi 329-0498 Japan Email : kume@jjichi.ac.jp FAX : 0285-44-2575

Website : [http://jsgt.jp/CLINICAL\\_STUDY/clinical\\_study2018.html](http://jsgt.jp/CLINICAL_STUDY/clinical_study2018.html)