

# Japan's Third Party Certification System

Class II designated by MHLW

Applicant  
(MAH)

1) Application for conformity certification



2) Application for GMP inspection



5) Certification



4) GMP site inspection



6) Follow-up audit  
(after certification.)



GMP

Manufacturer  
(Factory)

Third Party  
Certification body

3) Doc exam.

- Conformity to certification criteria
- Conformity to essential principles

4) Site inspection

Site inspection

- Conformity to New GMP standards (**ISO13485:2003** in principle)