

# **JSQA Working Group List**

## **17<sup>th</sup> Activity term**

**Japan Society of Quality Assurance**

Updated on 1st July 2025



# FY2024-2025 JSQA GCP Division Discussion Theme

Sub-committee	Working Group
Sub-committee#1 Quality Assurance	Group A: ICH E6R3 Group B: Clinical Vendor Oversight
Sub-committee#2 Digital Transformation	Group A: Decentralized Clinical Trial Group B: Remote Monitoring/Remote Audit Group C: e-Trial Master File
Sub-committee#3 Medical Device/Investigator Site	Group A: Medical Device Group B: Quality Management of Investigator Site (including Investigator Initiated-Study/Clinical Research)
Sub-committee#4 Multi International Study	Group A: US/EU Group B: ASIA
Special project groups	Group 1: PMDA Inspection – case study- Group 2: Organize-Training-Courses Group 3: Public Review Comment Group 4: Q&A for QA/QC representatives

# FY2024-2025 JSQA GLP Division Discussion Theme

Sub-committee	Working Group
Sub-committee#1	Group 1: Ordinance of Pharmaceutical GLP Group 2: Operation of Pharmaceutical GLP Group 3: Agrochemical, Chemical Substance, Medical Equipment and Regeneration Medicine GLP
Sub-committee#2	Group 1: Reliability of Chemistry, Manufacturing and Control studies Group 2: Reliability of Pharmacological and ADME studies Group 3: Training programs for "Standards of Reliability of Application Data"
Sub-committee#3	Group 1: Quality Assurance for Computerized System Group 2: Improvement of QA skills for CSV and Electronical Data
Sub-committee#4	Cross-function issues on Non-clinical studies Group 1: East Japan Group 2: West Japan
Sub-committee#5	Group 1: Reliability of Scientific research Group 2: Ensuring Reliability of Academic studies
Data integrity Working Group	Discussion of Data Integrity issue among Sub-committees

# FY2024-2025 JSQA GQP/GVP/GPSP Division Discussion Theme

Sub-committee	Working Group
Sub-committee#1 GVP	Group A: PV-QMS Group B: PV Audit Group C: Self-inspection in GVP
Sub-committee#2 GPSP	Group A: Self-inspection in GPSP Group B: PMDA inspection at Re-examination
Special project groups	Group1: GVP inspection by the local government for MAH's marketing license renewal Group2: Training of self-inspection for JSQA members Group3: Quality management in GQP/GMP Group4: Collaboration with RQA regarding Non-interventional Study

## FY2024-2025 JSQA Common Special Project Group Discussion Theme

Working Group#	Working Group Theme
Common Special Project Group#1	Quality Assurance for GMP and CMC
Common Special Project Group#2	Quality Assurance for GCLP
Common Special Project Group#3	Regenerative Medicine

# Other JSQA Common Committees and Key Activities

- **International Affairs Committee**
  - Accelerate international communication between JSQA members and Overseas QA association members
- **Events Committee**
  - Plan and Organize JSQA Official Events including Annual JSQA Conference
- **Education Committee**
  - Coordinate QA training/education matters among GLP, GCP, GQP/GVP/GPSP Divisions
- **GLP-QAP Registration Committee**
  - Provide GLP-QAP Registration Examination to JSQA GLP members