

FDA – Journey to Excellence and Beyond

QS Roadmap 2014-2016

2014
Plan & Improvement

2015
Build & Implement

2016
Run & Growth

Document System

- ▶ Quality Policy
- ▶ Quality Objective
- ▶ Requirements
- ▶ Quality Manual
- ▶ Documentation Review (Q, P, W, etc.)

- ▶ Continuous Quality Improvement
- ▶ Implement and Operate Requirements
- ▶ Implement and Integrate Procedure
- ▶ Continuous Process Improvement

- ▶ High Quality
- ▶ Goal to TQA, Toward HPO, Next 2 Years (2561)
- ▶ Full Implementation of the Requirements, all units
- ▶ Documentation System

Training System

- ▶ Training

- ▶ Continuous Training
- ▶ Develop Knowledge

- ▶ Continuous Training
- ▶ Develop Competency

Audit System

- ▶ Internal Audit (by Cross Check)
- ▶ Build up Internal Audit Team

- ▶ Internal Audit
- ▶ Corrective and Preventive Actions
- ▶ Register of Certificated Auditor/Lead Auditor
- ▶ Self-Assessment

- ▶ Internal Audit
- ▶ Self-Assessment
- ▶ External Audit (If...)

Assessment System

- ▶ New Certification
 - ISO 9001, One Stop Service Center
 - ISO 27001, Data and Information Center

- ▶ Surveillance Audit
 - ISO 9001, One Stop Service Center
 - ISO 27001, Data and Information Center

- ▶ Surveillance Audit
- ▶ Prepare for Re-Certification Audit, Next Year (2560)
 - ISO 9001, One Stop Service Center
 - ISO 27001, Data and Information Center
- ▶ Ready to be Assessed for Accreditation for International Standard, all units