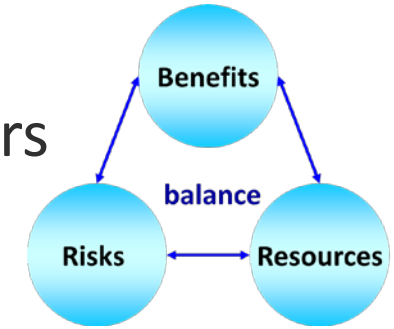
Optimize the Assessment Process of GMP Compliance

- Communication with RA of importers
  - Face-to-Face meeting with the representatives of the importers associations at least once a year
  - Conference/Seminar on GMP open for RA staffs of importers at least once a year
- Leverage of PIC/S members' resource to minimize duplication of effort
  - Simply requirements for the manufacturers located in PIC/S member countries
  - Joint GMP Inspection



Desk-top inspection on
Addition of an new dosage forms of same site

before

- Request Documentation of first submission
  - ☑Application form
  - ☑Site Master File
  - ☑Checklist of GMP Compliance & **Evidence documents [Plant Master File, PMF]**

now

Could be waived if its approval letter of GMP compliance was issued within one year

☑ Declaration Letter issued by the manufacturer that
- agree for TFDA to refer to the documentation submitted last time
- Any major change during last submission

Desk-top inspection on

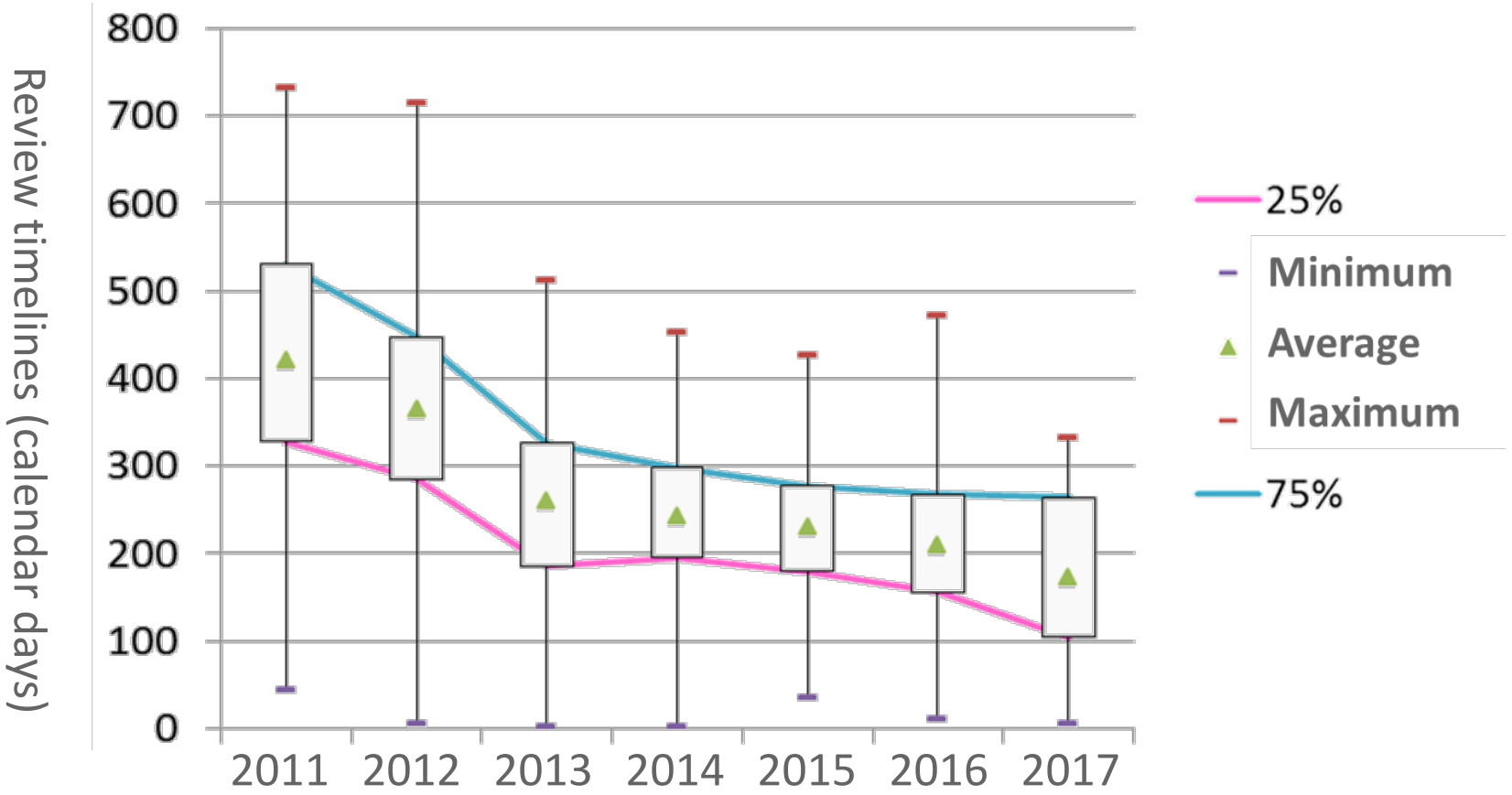
Renewal of official letter of GMP Compliance

before now

- Request Documentation
  - ☑ Application form
  - ☑ Site Master File
  - ☑ Summary reports of latest Product Quality Review
  - ☑ the most recent **inspection report** issued by its Regulatory Authority, & the CAPAs (with Chinses or English translation)
    must be applicable to the scope of the application
  - ☑ Any major changes in the past 2 years
  - ☑ The periodical evaluation result of the effectiveness for the set procedures to prevent cross-contamination

Could be replaced by **the GMP Certificate** If the manufacturing site is located in PIC/S member countries

Put effort on enhance the efficiency of GMP assessment (desk-top inspection)



Ensure a high quality and safety medicinal products be available to the patients, and Public health should not be compromised

Work Together

GMP

=

Give More **Profit**

Give More **Prestige**