

Summary of Self Study

Written Instructions

- SOP for review activities
- Review report template
 - General vs. Specific
- Guideline and Check list
- Regulatory information
 - Target Time for Review
- Legislation and Regulations

Quality Control

- Peer review of reports
- Management review of reports
- Certificate from outside organization-e.g. ISO
- Timeline checking point

Professional Development Activities

- Orientation program for new reviewers
- Scientific and regulatory training for all reviewers
- Mentoring
- On-line training
- Outside experts
- Qualification for the reviewers

Transparency elements

- Publication of SOP
- Publication of review decisions on specific products and/or
- Regular meetings with industry
- On-line tracking
- Publication of point to consider documents for reviewers
- Pre-submission consultation meeting

Possible Resources available

- Experienced reviewer
- Technical writer
 - Separate team to write review report
- Internal training office
- External training programs
- Industry associations
- Regulatory associations
- Professional associations
- Other organisations
 - Academia, outsourcing, 3rd party