Examples of Flow of On-site GMP Compliance Inspection of Foreign Manufacturers

When Master files are not used. Applicant (Marketing authorization holder) **Application** Inspection Notification Pre-submitted Marketing Document Foreign Manufacturer authorization holder Pre-submitted Document **PMDA** On-site Inspection **Findings** Marketing authorization holder **Improvement** Reports Inspection Result Notification Inspection Result Report (copy) Inspection Result Notification (copy) Inspection Result Report (copy) Marketing authorization holder **MHLW** Prefectural Gravamens