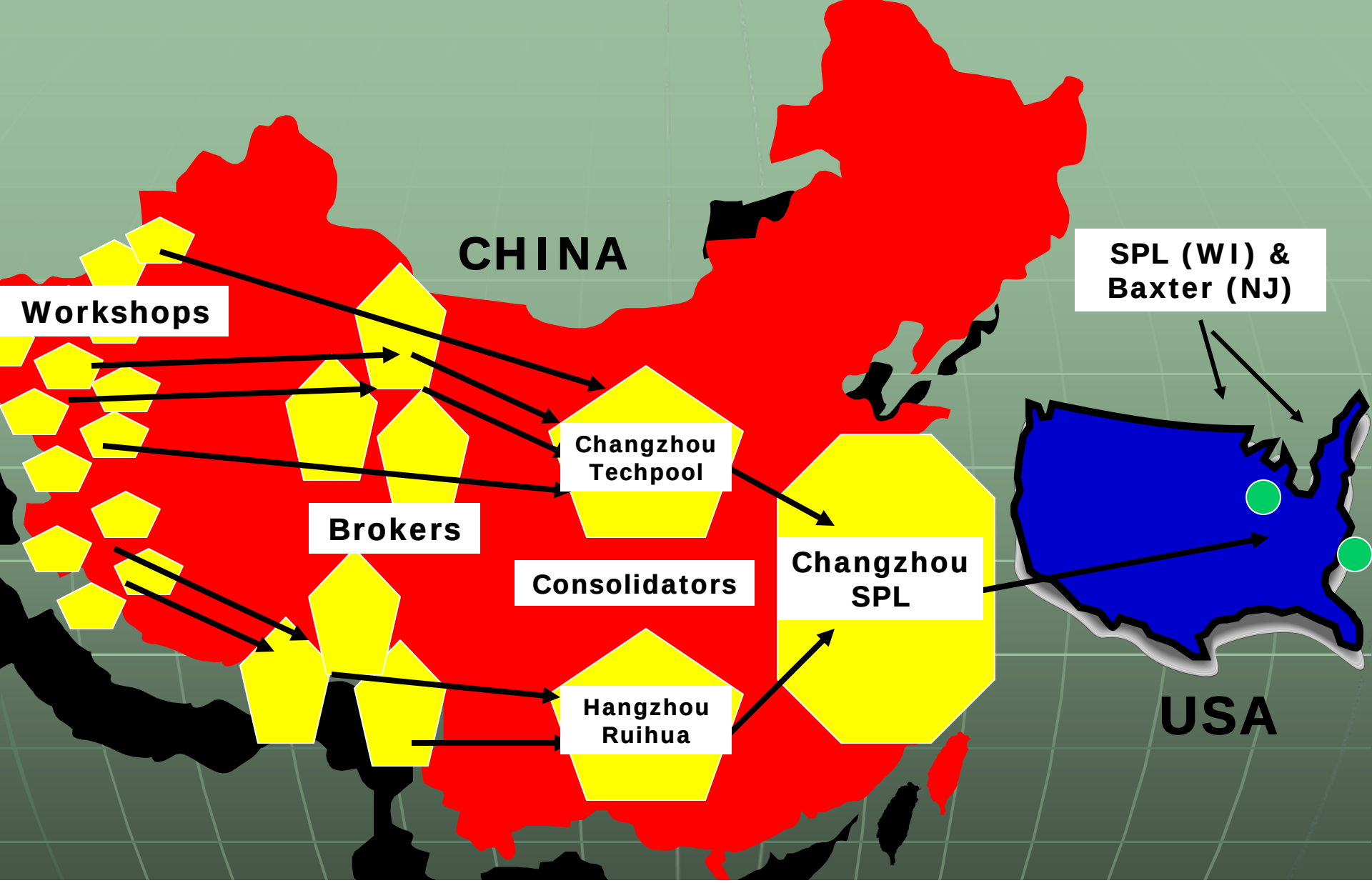
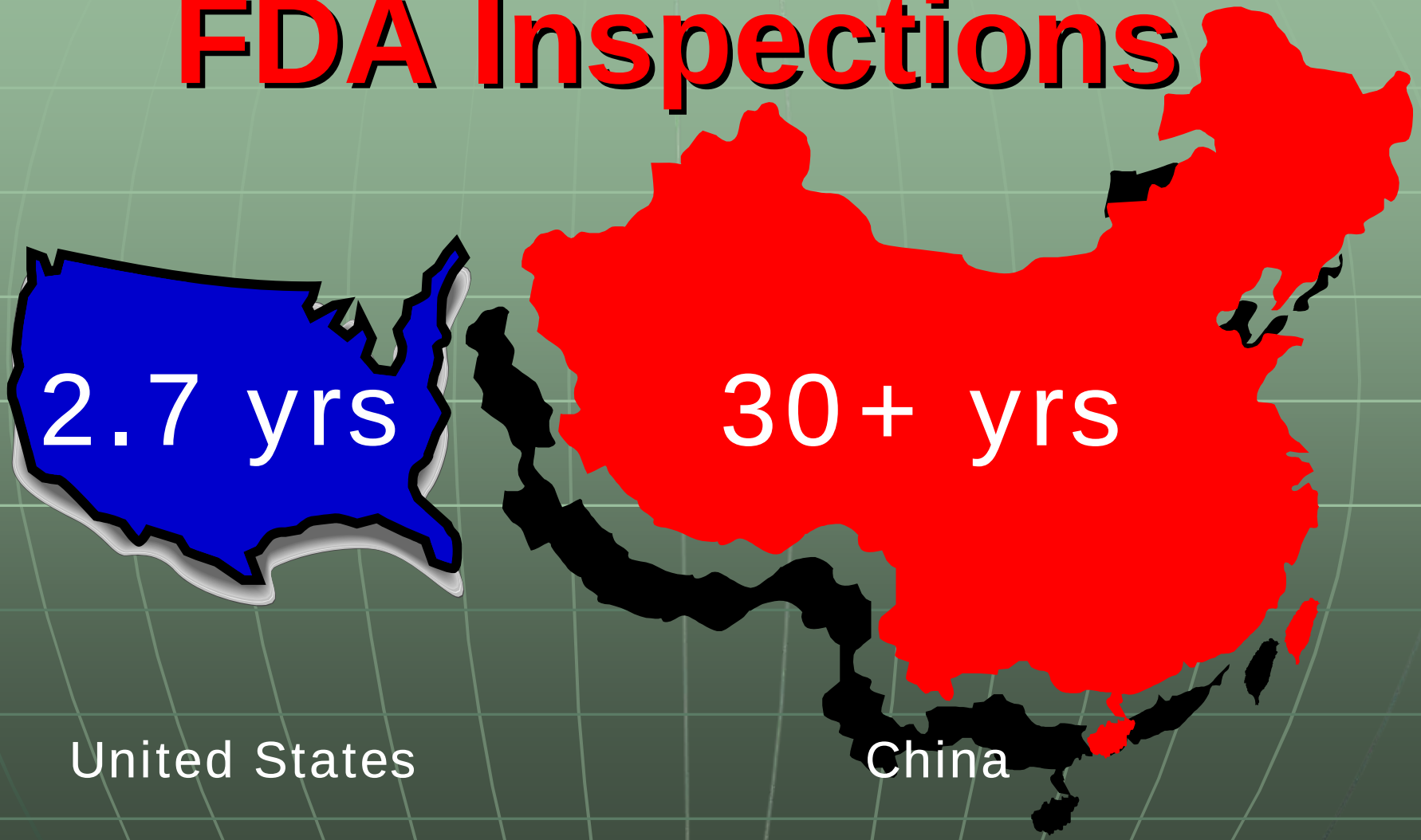



# Baxter Heparin Manufacturing Process

# Average Time Between FDA Inspections




Source: GAO/HEHS-98-21 Foreign Inspection Program

| Number of Deaths of Patients Receiving Heparin Reported to FDA, January 1, 2007 through April 13, 2008 | | |
|---|---|---|
| **Month the Medical Event(s) Occurred** | **Number of Reported Deaths*** | **Reported Deaths with One or More Allergic/Hypotensive Symptom(s)** |
| Jan-07 | 3 | 1 |
| Feb-07 | 1 | 0 |
| Mar-07 | 4 | 2 |
| Apr-07 | 4 | 2 |
| May-07 | 2 | 1 |
| Jun-07 | 3 | 2 |
| Jul-07 | 4 | 2 |
| Aug-07 | 1 | 1 |
| Sep-07 | 2 | 2 |
| Oct-07 | 7 | 4 |
| **Nov-07** | **11** | **10** |
| **Dec-07** | **20** | **13** |
| **Jan-08** | **31** | **21** |
| **Feb-08** | **28** | **18** |
| Mar-08 | 3 | 0 |
| Unknown date | 7 | 2 |
| Total | 131 | 81 |

# Preapproval Inspection Priorities

1. New molecular entities (NMEs) (includes finished drug product and the active pharmaceutical ingredient)

2. Priority NDAs

3. First application filed by an applicant

4. For-Cause inspection

5. For original applications, if the current CGMP status is unacceptable or greater than 2 years

6. For Certain pre-approval supplements, such as site change or major construction, if the CGMP status is unacceptable

7. Treatment IND inspections

8. Information is available to CDER indicating that an inspection of a clinical supplies manufacturer is warranted to protect the health of patients

Source: FDA Compliance Program Guidance Manual

# Raw Material Cost