Are you ready to be a “manufacturer”?

Outline of FDA Medical Device Regulation Requirements

First things first…

cGMP = Quality Systems Regulation (QSR)

QSR consists of:

- Management responsibility
  - Quality Policy
    - Assure organizational structure can meet Quality objectives
    - Assess risk to patient, user, and business
  - Quality System Review
- Design Control
  - Define user requirements
  - Translate into design specifications
  - Design and develop product
  - Perform risk assessments
  - Verify and Validate product
- Document Control
  - Design History File – record of design activities
  - Device Master Record – all procedures, parts, and specifications used for the manufacturing the device
  - Design History Record – Records containing the production history of each device or lot
- Purchasing Control
  - Incoming specifications
  - Incoming quality control
- Identification and Traceability
- Production and Process Control
  - Inspect, test, verify incoming product conformance
  - Batch records must contain data that meets pre-determined specifications
  - Must conform to the Device Master Record
- Acceptance Activities
- Non-conforming Product
- Corrective and Preventive Action
  - Any allegations of deficiency related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device
- Labeling and Packaging Control
- Handling, Storage, Distribution, and Installation
- Records
- Servicing
- Statistical Techniques

All of the above must be done and be in place at the time a device is cleared or approved by FDA and may be done concurrently with the FDA review of a 510(k) or PMA submission

Premarket Notification (510k)

Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9).

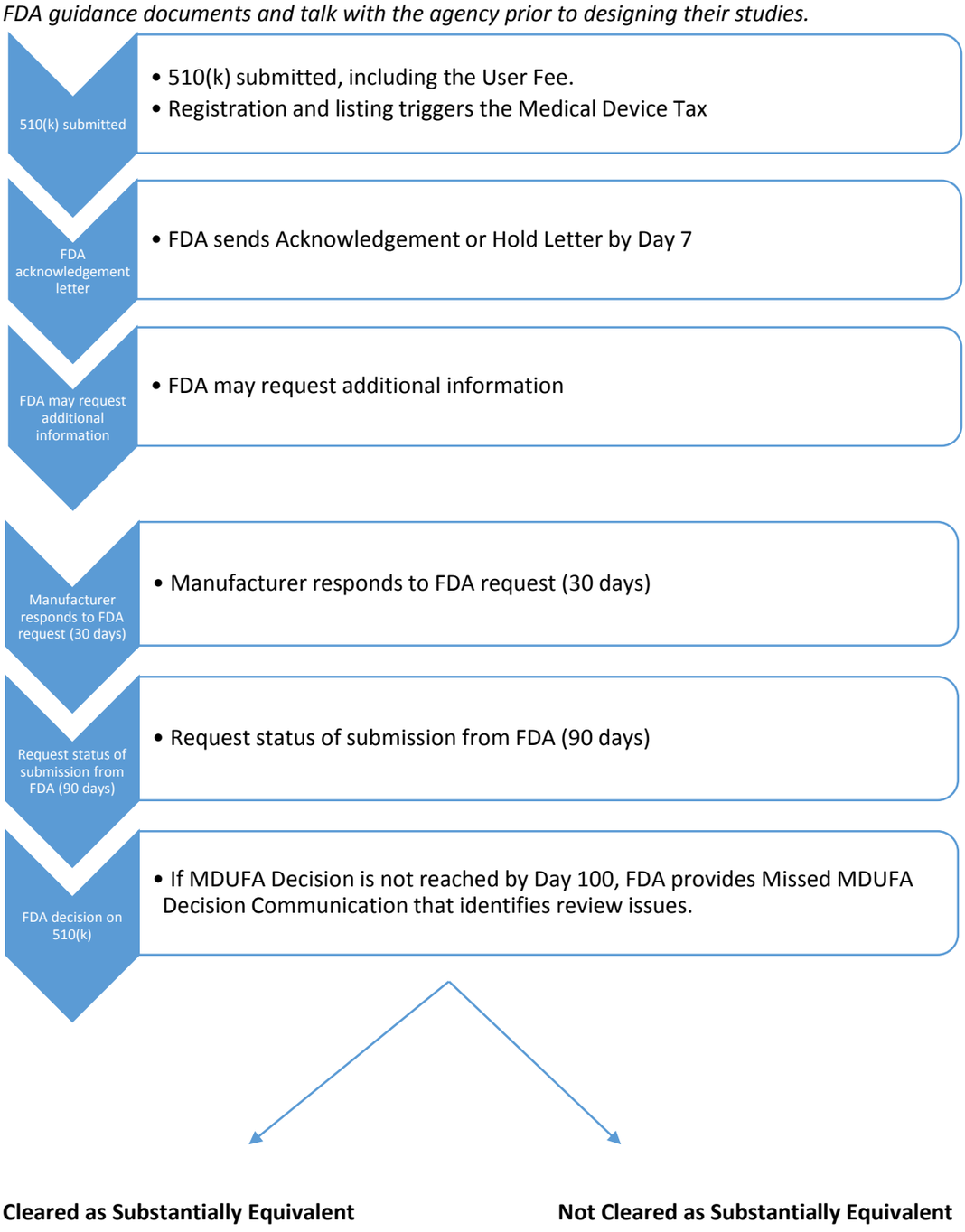
http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm

Elements of a 510(k)

- Name and address of manufacturer
- Device name and Device listing classification
- Device Description of intended use and directions for use
- Comparison to predicate device
- Truthful and accurate statement (accountability)
- Summary of safety and effectiveness
- Performance data that supports product claims
- Conformance to standards
- Labeling
- Software certification statement, if applicable
- Predicate device labeling, if available

The 510(k) Process

Population size and data required varies greatly depending on the Intended Use of the device. Applicants should consult FDA guidance documents and talk with the agency prior to designing their studies.



Cleared as Substantially Equivalent

Not Cleared as Substantially Equivalent

Premarket Notification (PMA)

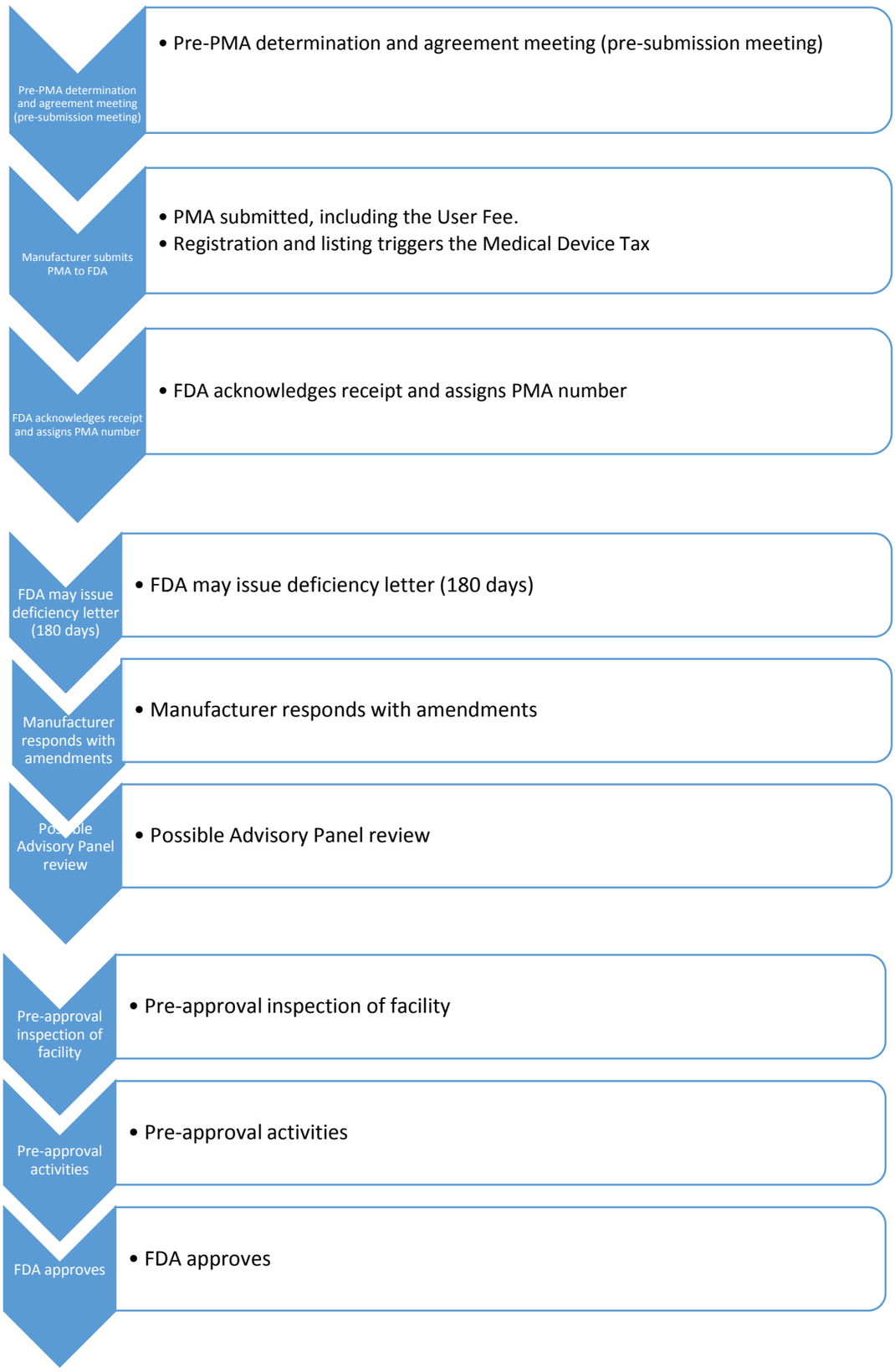
PMA requirements apply to Class III devices, the most stringent regulatory category for medical devices.
http://www.fda.gov/Medicaldevices/Deviceregulationandguidance/Howtomarketyourdevice/Premarketsubmissions/Premarketapprovalpma/Default.Htm

Elements of a PMA

- Name and address of manufacturer
- Table of contents
- Summary of safety and Effectiveness
    - Indications for use
    - Alternative practices and procedures
    - Marketing history
    - Summary of studies
    - Conclusions drawn from studies
- Complete device description
- Reference to applicable performance standards
- Results of non-clinical and clinical studies
    - Clinical studies can involve tens of thousands of samples at multiple sites
- Bibliography of all published reports
- Sample, if requested
- Labeling
- Environmental assessment (unless qualified for exclusion)
- Other FDA requests

PMA Process

Population size and data required varies greatly depending on the Intended Use of the device. Applicants should consult FDA guidance documents and talk with the agency prior to designing their studies.



Postmarket Requirements

Medical device manufacturers as well as other firms involved in the distribution of devices must follow certain requirements and regulations once devices are on the market. These include such things as tracking systems, reporting of device malfunctions, serious injuries or deaths, and registering the establishments where devices are produced or distributed. Postmarket requirements also include postmarket surveillance studies required under section 522 of the act as well as post-approval studies required at the time of approval of a premarket approval (PMA), humanitarian device exemption (HDE), or product development protocol (PDP) application.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/default.htm

Post-approval Requirements including Mandatory Medical Device Reporting (MDR)

- Continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use
- Prominent display in the labeling of a device and in the advertising of any restricted device warnings
- Maintenance of records that will enable the applicant to submit to FDA information needed to trace patients if such information is necessary to protect the public health
- Submission of periodic reports detailing publications using the device and all publicly available data on its performance related to its safety and effectiveness
- Batch testing of the device
- Device tracking
- Reports must be filed on FDA Medwatch Form 3500A or an electronic equivalent. The FDA published a final rule on Feb. 14, 2014, requiring manufacturers and importers to submit MDRs to the FDA in an electronic format that the FDA can process, review, and archive. This rule will be effective as of Aug.14, 2015.

Be informed – and submit your comments to FDA

www.FDA.gov/LDTs

AMP Association for Molecular Pathology

www.AMP.org