Regulatory Pathways For Your Device

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Approach to medical device regulation

- Devices are regulated according to their risk around the world
- However, it remains jurisdiction by jurisdiction for the major markets; global harmonization has been developed for most pre-clinical testing
- All are becoming more strict; want more clinical data
- Quality in design, manufacturing, testing is needed no matter the risk
- Post-market is a focus everywhere; real world data, adverse events and device failures are the focus

Risk Levels in Different Jurisdictions

- Each jurisdiction (US, EU, Canada, Japan, China, Brazil, Russia) places devices in classes by the risk they perceive in their population/healthcare practice – therefore a device may be in different classes in different places

- In most locations the class determines the required data that regulators want to see either in a submission, or when they visit the manufacturing site. Inspections of sites have general approaches set by each regulatory region with small differences based on classes. Between regions there are a lot of differences.

Risk Levels For the US Regulatory Review

- Low risk = Class I, General Controls; well understood uses, well understood technologies; well understood interaction with the patient and user;
- Moderate risk=Class II, General and Special Controls; well understood uses, well understood technologies, risk management tools defined; data required for testing and submission for review defined
- High risk and unknown risk = Class III, General controls and full submission of design, testing, manufacturing methods, clinical performance and safety and efficacy of the specific device(s) going to market

Pathways

- Most jurisdictions have a standard process (dossier) for submitting products for regulatory review for permission to enter the market – each has its own name(s) for permission type and the actual process (clearance, approval, CE marking, Marketing Authorization, Medical Device License, etc).

- The higher risk products require more specific data to be submitted from testing of the specific product/model that will go to market; many require clinical data. The type and amount of clinical data differs often by device type and differs for the same device around the world. Performance and safety and efficacy are not the same standard.

- In each location, the lowest risk products are regulated, but a submission that gets reviewed by the agency prior to marketing is not required. Following all the other rules is required.

- One size, type of data, type of submission does not fit all. Its complicated.

Example: US Pathways for Devices

- Exempt from submission and review – most Class I and some Class II

- 510(k) (Premarket Notification)=premarket submission and review for finding of "substantial equivalence SE" to an already marketed Class I reserved or Class II product (and a few old Class III); clearance to market
- De Novo – Placing a new type of low or moderate risk product into Class I or II

- PMA –Pre-Market Approval -Establishment of safety and efficacy for the specific product-essentially all Class III devices – stand alone on data.

How do I know what data/pathway to submit ?

- Most regulators publish classifications of devices and data requirements for submissions on the www
- There are general documents that cover the risk level and/or the general types of devices and provide direction for submissions
- Many also have specific guidance for the types of devices that are commonly submitted and also for specific types of materials of other technologically related types of products such as active implantables.
- In vitro diagnostics are treated separately in law and guidance. Health care IT may also be regulated differently.

But…

- Guidance is good *but* real answers are often needed
- Published information is critical to understanding the approaches and how each organization works *but* its best to confirm with the specific agency about your product
- Do your homework and see what has been required for other companies with similar types of product *but* confirm with the agency before going too far

The Pathway For Your Device

- Objectively evaluate risks – to patient, to users, to the environment
- Determine if a similar device is already in the market and see what its pathway was – may be for a different use but it can still help.
- Gather all the knowledge you can from the agency's web site about devices with your risk level/technology/use – recent is best.
- Confirm with the agency before you get too far – they make the final decision and can have changed over time. You should propose what you think is correct.
- Do this early!!