RISE
INTIATIVE

Regulatory science must be one step ahead to equip FDA with the necessary tools and methods to reliably assess the safety and efficacy of products derived from these new scientific developments, in order to bring the rewards of discovery safely forward to benefit patients.

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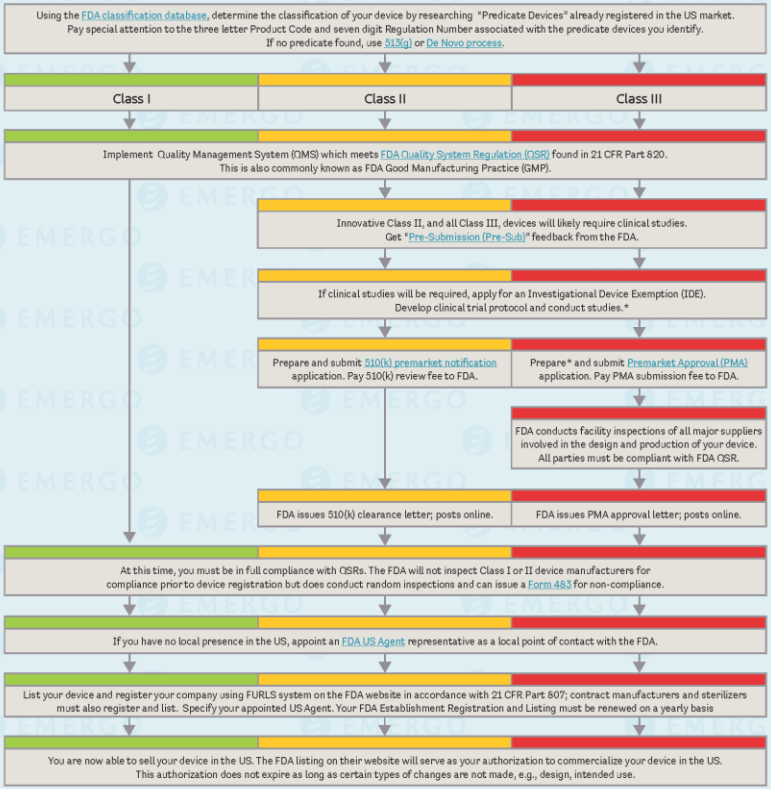
The regulatory process for medical devices

US



* The process of supplying clinical study data in support of a PMA submission is far more complex than presented in this chart. This is an extremely simplified and high level view of the FDA requirements regarding clinical study data.

This is a simplified overview of the process. The FDA may choose to audit your submission and request more documents, which will add time to your approval.

P19-0005

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FDA Priority Area for Regulatory Readiness is Broad and Taxing

OBJECTIVE

Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

Uncertainty

Timeline to approval can be a costly arduous task, and take extensive research despite being based on predicate applications

Cost

Fees from thousands to millions of dollars including the millions spent developing the science to achieve regulatory approval

Massive Scope

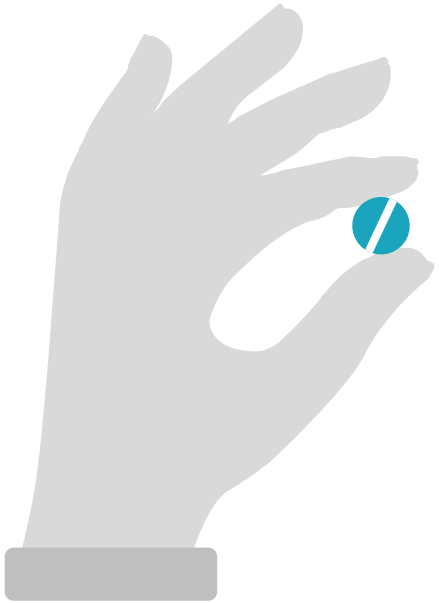
Backlogs of thousands of applications (especially new drug therapies)

Themes:

1. **Stimulate development of innovative medical products while concurrently developing novel assessment tools and methodologies**
2. Develop assessment tools for novel therapies
3. Assure safe and effective medical innovation
4. **Coordinate regulatory science for emerging technology product areas**

"Numerous innovations lay out of reach of the FDA, due to confusion amongst companies as to how to seek approvals, and the backlog of applications to sift through at the FDA. The RISE Initiative is a computer expert system, which leverages FDA data to improve the regulatory approval process."

To RISE above the fray we have introduced The RISE Initiative



All clinicaltrials.gov data processed and analyzed to give scientist the ability to determine which studies are likely to succeed and timelines for given product developments

Allow client to select an approval device or drug and be provided regulatory history of similar devices and approval pitfalls

Applications come to FDA with rating for prioritization during the approval process reducing bottlenecks – applicants get assessments of their application in the pool of other applicants

01 **Analyze**
Clinical trials, predicate approval databases

02 **Predictive Guidance**
Recommendation for approval time, needed documentation, cost reduction, and emerging trends

03 **Faster Approval/Denial**
Realtime feedback, stimulate more innovative applications, develop new approval paradigms